

EXPLORING THE IMPACT OF EXERCISE IN PEOPLE EXPERIENCING SEVERE AND MULTIPLE DISADVANTAGE.

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A Thesis written in fulfilment of the requirements
for the degree of Doctor in Philosophy

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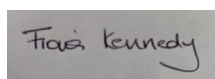
School of Medicine

2026

Declaration

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10.09.2025

Fiona Kennedy

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PREFACE

“A nation should not be judged by how it treats its highest citizens, but its lowest ones.”

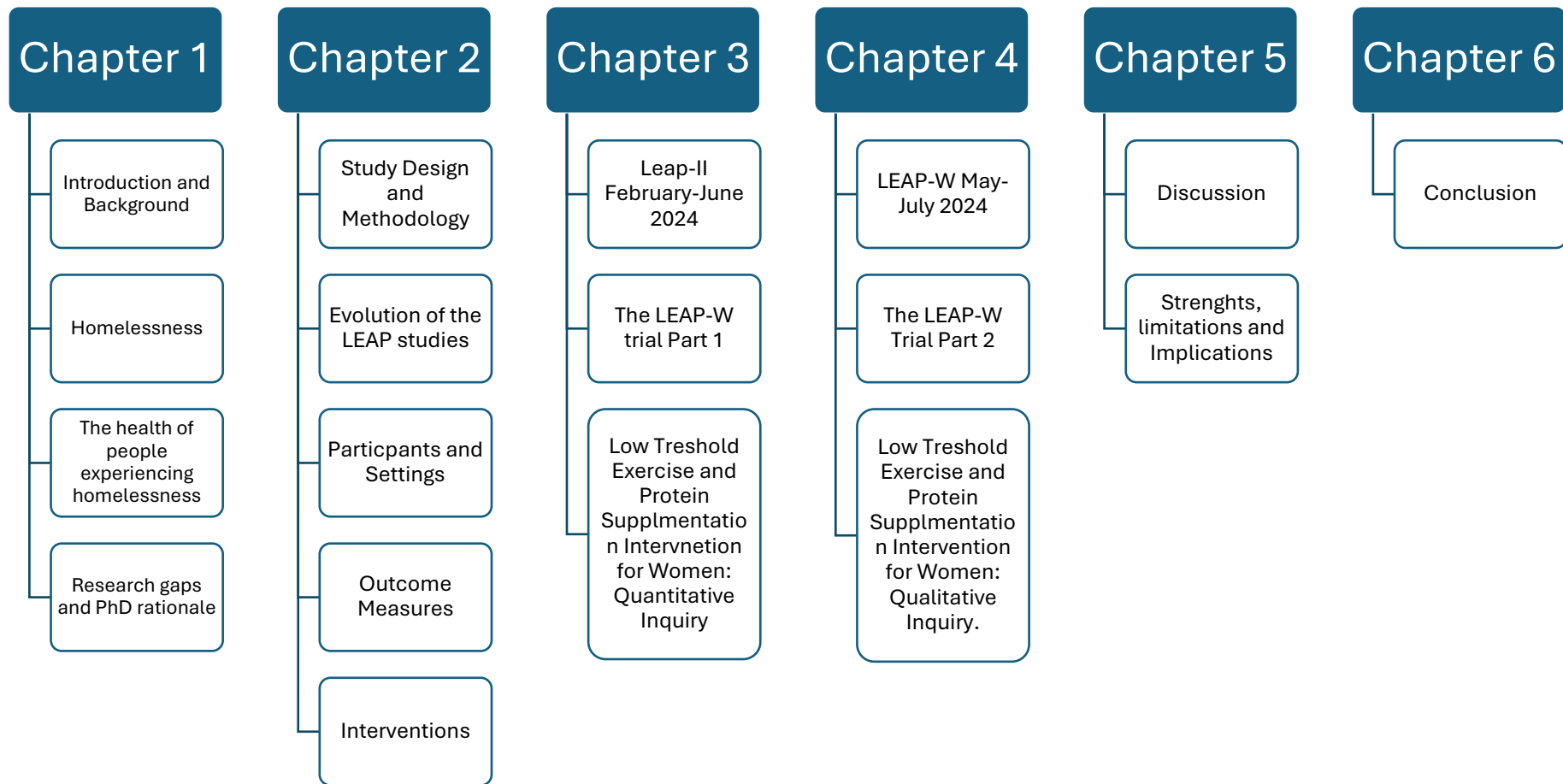
(Nelson Rolihlahla Mandela)

This is a PhD thesis and Publication. It includes work that is published as well as work that is currently under review. This work was completed during the PhD. The four published papers are presented in their entirety and unchanged from the multi-author, peer-reviewed publications as per the journal’s editing format.

Motivation

In the preliminary work which inspired this PhD journey to explore the impact of exercise as a targeted intervention for people experiencing severe and multiple disadvantage, one moment remains etched in my mind: “It’s like a free drug!” a lady declared summing up her feelings following a bout of exercise in an open-access service she was attending for support services for her homelessness, addiction and mental health challenges. This was the ‘aha’ moment, the realisation of how truly powerful this completely free and accessible intervention can be if delivered in the right way.

PhD Structure



Chapter 1: will outline provide the background and rationale for this work, through a comprehensive review of the literature as it pertains to homelessness and the health of people experiencing homelessness, addiction and mental health challenges, particularly physical health, and the physical function deficits and frailty which are evident in people who experience homelessness. It will conclude by highlighting the gaps in the evidence base and delineate the research question and the aims and objectives of this thesis.

Chapter 2: will describe the methodology in relation to the research design, the population of interest and the setting, the intervention and the data collection and analysis methodology. It will also provide an in-depth discussion on the outcome measures used in this thesis, including their validity and reliability.

Chapter 3: will discuss the results of the first PhD study, LEAP-II, a targeted pre-post intervention exercise intervention with post-intervention exit surveys delivered to a cohort of people who experienced homelessness, addiction and mental health challenges. Chapter 3 contains the following publications:

1. Kennedy F, Ní Cheallaigh C, Romero-Ortuno R, Doyle S, Broderick J. A study to explore the role of a low threshold, fitness focussed physical rehabilitation intervention with protein supplementation to target physical function and frailty in people with problematic substance use and homelessness: protocol for a single-arm pre-post intervention study. *HRB Open Res.* 2024 Oct 29;6:26.

doi:10.12688/hrbopenres.13678.2. PMID: 39569024; PMC11576564.

2. Kennedy F, Ní Cheallaigh C, Romero-Ortuno R, Murray D, Broderick J. (2025).

Acceptability and utility of a broad test battery to evaluate physical functioning and frailty in community-based settings for people experiencing homelessness and

addiction—Findings from the LEAP trials. *Physiotherapy*. 2025 Mar;126:101449. doi: 10.1016/j.physio.2024.101449. Epub 2024 Nov 7. PMID: 39626407.”

3. Kennedy F, Ní Cheallaigh C, Romero-Ortuno R, Murray D, Behan, F.P., Broderick J. An exploration of frailty in a non-geriatric population with severe and multiple disadvantage using two geriatric frailty tools. (2025). *Journal of Social Distress and Homelessness*, 1-12. <https://doi.org/10.1080/10530789.2025.2528272>.

4. Kennedy F, Ní Cheallaigh C, Romero-Ortuno R, Murray D, and Broderick J. Impact of a physiotherapy-led low threshold exercise and protein supplementation intervention to optimise physical function and target frailty in people experiencing homelessness and addiction: The LEAP-II trial. *Physiotherapy*. Pre-proof.
<https://doi.org/10.1016/j.physio.2025.101873>

Chapter 4: will discuss the results of the second study, the LEAP-W trial - a quantitative pre-post intervention study which provided a targeted exercise intervention to a cohort of women who experienced homelessness, addiction and mental health challenges.

Chapter 4 contains the following publications:

- 1. Kennedy F, Murray D, Ní Cheallaigh C, Romero-Ortuno R, Broderick J.** Evaluation of a Low-threshold Exercise And Protein supplementation intervention for Women (LEAP-W) experiencing homelessness and addiction: Protocol for a single-arm mixed methods feasibility study. *PLoS One*. 2025 Feb 6; 20(2):e0300412. Doi: 10.1371/journal.pone.0300412. PMID:39913349; PMCID: PMC11801605.
- 2. Kennedy F, Ní Cheallaigh C, Romero-Ortuno R, Murray D, Gavin, S. and Broderick J.** Exploring the impact of targeted exercise intervention for women experiencing

homelessness, addiction, and mental health challenges. A mixed-methods feasibility study. *BMJ Open* 2026;16:e103060. doi:10.1136/bmjopen-2025-103060.

Chapter 5: will discuss the results of the second part of the LEAP-W trial-the qualitative study, using semi-structured interviews and reflexive thematic analysis, which explored perspectives of 14 women who experienced homelessness, addiction and mental health challenges who participated in the targeted exercise intervention and six key stakeholders.

Chapter 6: will explore, critically reflect and interpret the overall findings of this work, including its strengths and limitations, future directions and implications for practice, policy and research. This chapter will also provide the present the concluding remarks.

Funding, publications and presentations

Funding received for this PhD

Financial support for this research was received from the following:

1. **LEAP-II-** 1252 Postgraduate Research Studentship, School of Medicine, Trinity College Dublin and the Ballyfermot Local Drug & Alcohol Task Force, Ireland.
2. **LEAP-W-** 1252 Postgraduate Research Studentship, School of Medicine Trinity College Dublin and Merchants Quay Ireland

List of Publications from the work in this PhD

1. **Kennedy F**, Ní Cheallaigh C, Romero-Ortuno R, Doyle S, Broderick J. A study to explore the role of a low threshold, fitness focussed physical rehabilitation intervention with protein supplementation to target physical function and

- frailty in people with problematic substance use and homelessness: Protocol for a single-arm pre-post intervention study. *HRB Open Res.* 2024 Oct 29;6:26. doi:10.12688/hrbopenres.13678.2. PMID: 39569024; PMC11576564.
2. **Kennedy F**, Murray D, Ní Cheallaigh C, Romero-Ortuno R, Broderick J. Evaluation of a **Low-threshold Exercise And Protein** supplementation intervention for **Women (LEAP-W)** experiencing homelessness and addiction: Protocol for a single-arm mixed methods feasibility study. *PLoS One.* 2025 Feb 6; 20(2):e0300412. Doi: 10.1371/journal.pone.0300412. PMID:39913349; PMCID: PMC11801605.
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 4. **Kennedy F**, Ní Cheallaigh C, Romero-Ortuno R, Murray D, Behan, F.P. and Broderick J. An exploration of frailty in a non-geriatric population with severe and multiple disadvantage using two geriatric frailty tools. (2025). *Journal of Social Distress and Homelessness*, 1-12. <https://doi.org/10.1080/10530789.2025.2528272>.
 5. **Kennedy F**, Ní Cheallaigh C, Romero-Ortuno R, Murray D, Gavin, S. and Broderick J. Exploring the impact of targeted exercise intervention for women experiencing homelessness, addiction, and mental health challenges. A mixed-methods feasibility study. *BMJ Open* 2026;16:e103060. doi:10.1136/bmjopen-2025-103060.

Papers in press

1. **Kennedy F**, Ní Cheallaigh C, Romero-Ortuno R, Murray D, and Broderick J.
Impact of a physiotherapy-led low threshold exercise and protein supplementation intervention to optimise physical function and target frailty in people experiencing homelessness and addiction: The LEAP-II trial.
Physiotherapy. <https://doi.org/10.1016/j.physio.2025.101873>

Presentations delivered from the work of this PhD

Oral presentations

1. **Kennedy, F.**, Romero-Ortuno, R., Ní Cheallaigh, C., Doyle, S. & Broderick, J. 'How does low threshold exercise work in practice? Feasibility of low threshold programmes for people with severe and multiple disadvantage accessing services for addiction challenges and homelessness'. Pathways from Homelessness International Conference. March 2023, **London**.
2. **Kennedy, F.**, Romero-Ortuno, R., Ní Cheallaigh, C., Murray, D. & Broderick, J. 'Evaluation of a Low threshold Exercise And Protein supplementation programme (LEAP-II) for people with severe and multiple disadvantage accessing services for addiction challenges and homelessness'. Irish Street Medicine Symposium. May 2023, **Limerick**.
3. **Kennedy, F.**, Romero-Ortuno, R., Ní Cheallaigh, C., Murray, D. & Broderick, J. 'Evaluation of a Low threshold Exercise And Protein supplementation programme (LEAP-II) for people with severe and multiple disadvantage

- accessing services for addiction challenges and homelessness'. CSP (Chartered Society of Physiotherapists) Annual Conference. November 2023, **Belfast**.
4. **Kennedy, F.**, Romero-Ortuno, R., Ní Cheallaigh, C., Murray, D. & Broderick, J.
'Impact of the LEAP-W trial: targeted exercise for women experiencing homelessness, addiction and mental health challenges. CSP (Chartered Society of Physiotherapists) Annual Conference'. October 2024, **Manchester**.
 5. **Kennedy, F.**, Romero-Ortuno, R., Ní Cheallaigh, C., Murray, D. & Broderick, J.
'Impact of the LEAP-W trial: targeted exercise for women experiencing homelessness, addiction and mental health challenges'. ISPAH (International Society of Physical Activity and Health) Congress. November 2024, **Paris**.
 6. **Kennedy, F.**, Romero-Ortuno, R., Ní Cheallaigh, C., Murray, D. & Broderick, J.
'Impact of the LEAP-W trial: targeted exercise for women experiencing homelessness, addiction and mental health challenges'. The Faculty for Homeless and Inclusion Health, International Conference. March 2025, **London**.
 7. **Kennedy, F.**, Romero-Ortuno, R., Ní Cheallaigh, C., Murray, D. & Broderick, J.
'Impact of the LEAP-W trial: targeted exercise for women experiencing homelessness, addiction and mental health challenges'. Irish Street Medicine Symposium. May 2025, **Dublin**.
 8. **Kennedy, F.**, Romero-Ortuno, R., Ní Cheallaigh, C., Murray, D. & Broderick, J.
'Impact of the LEAP trials: targeted exercise interventions for people experiencing homelessness, addiction and mental health challenges'. World Physiotherapy Congress. **Tokyo, Japan**.

Poster presentations

1. **Kennedy, F.**, Romero-Ortuno, R., Ní Cheallaigh, C., Murray, D. & Broderick, J. 'Protocol of an Intervention to Evaluate the Effects of an Optimised Exercise Programme with Protein Supplementation to Target Physical Functioning Deficits and Frailty in people Experiencing Addiction Issues and Homelessness'. National Drug Forum, October 2022, Dublin.
2. **Kennedy, F.**, Romero-Ortuno, R., Ní Cheallaigh, C., Murray, D. & Broderick, J. 'How does low threshold exercise work in practice? Feasibility of low threshold programmes for people with severe and multiple disadvantage accessing services for homelessness and addiction challenges'. Pathways from Homelessness International Conference, March 2023, London.
3. **Kennedy, F.**, Romero-Ortuno, R., Ní Cheallaigh, C., Murray, D. & Broderick, J. ' "It's like a free drug" . Impact of the LEAP trials-Low-threshold Exercise And Protein supplementation programmes to target physical function and frailty in people experiencing homeless and addiction'. HSCP (Health and Social Care Professionals) National Conference, October 2024, Croke Park, Dublin.

Online presentations

1. **Kennedy, F.** & Broderick, J. 'Evaluation of the LEAP-II trial'; presentation to stakeholders and funders, the Ballyfermot Drug and Alcohol Task force, September 2023.
2. **Kennedy, F.** 'Impact of the LEAP-W trial'; presentation to stakeholders and funders, Merchants Quay Ireland, February 2025.

3. **Kennedy, F.** Irish Society of Chartered Physiotherapists (ISCP)-'Inclusion health-providing targeted exercise interventions with a trauma informed approach to people experiencing homelessness', February 2025.
4. **Kennedy, F.** Physiotherapy department Carlow community care-'Inclusion health-providing targeted exercise interventions with a trauma informed approach to people experiencing homelessness', May 2025.

Scholarships and Awards

- Awarded the 1252 postgraduate studentship in 2022 which funded the work of this PhD.
- Winner of 3-minute PhD oral presentation in TCD Discipline of Physiotherapy, August 2024.
- TCD Travel Grant 2025.

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hope you will grow up with a wisdom that I didn't fully appreciate until I immersed myself in this important work. We are all equal, we should all be valued and we all deserve to be treated with respect, dignity, care and compassion.

Thank you.

SUMMARY

Low physical functioning and frailty are prevalent in non-geriatric at-risk populations who experience severe and multiple disadvantage such as those who are homeless. Exercise with nutritional supplementation is recommended. There is an absence of research on exercise interventions delivered to this population to target physical function and frailty specifically. It is known that people experiencing homelessness have complex health issues, yet engage poorly with healthcare services, therefore interventions require a targeted and unique approach.

The aim of this PhD was to explore the feasibility and holistic impact, of a targeted low-threshold, multi-modal exercise intervention with protein supplementation, in a non-geriatric population experiencing severe and multiple disadvantage, namely a cohort of people experiencing homelessness, addiction and mental health challenges. The secondary aim was to explore its' impact in a sub-population of women. A broad test battery was utilised to measure baseline physical function and frailty and evaluate pre-post intervention change. The primary outcome of feasibility was measured by recruitment and retention rates, adherence to the exercise and protein supplement, acceptability of the intervention and the occurrence of adverse events. Secondary outcomes were physical function, pain, frailty and nutritional status, self-reported health and perceptions of the intervention.

The first study of this PhD was LEAP-II, a 12-week exercise intervention with protein supplementation delivered to a mixed-gender cohort. Results demonstrated feasibility through high retention in sub-groups (older people and women), adherence to the exercise and protein supplementation and safety and acceptability of the programme, and also pre-post intervention improvement in a number of physical

function outcomes, namely lower limb strength [*Chair Stand Test*], gait speed [*10m Walk Test*], pain [*Numerical Pain Rating Scale*], nutritional status [*Mini-Nutritional Assessment*] and frailty [*SHARE-FI*]. An exploration of frailty demonstrated that 33% and 72% lived with some degree of frailty, by *SHARE-FI* and *Clinical Frailty Scale*, respectively. An exit survey demonstrated acceptability of the programme and highlighted possible reasons for the study's attrition as well as the need for further research to explore participant and stakeholder perspectives further.

LEAP-W followed as a 10-week intervention based on LEAP-II and was delivered to a sub-group of women. This study used quantitative and qualitative components and 20 semi-structured interviews with study participants and key stakeholders were conducted following the intervention. Quantitative results revealed study feasibility and enhanced retention in LEAP-W (38.7% [LEAP-W] v 26% [LEAP-II]) and also improved physical function evidenced by pre-post intervention change in strength [*Chair Stand Test*], balance [*Single Leg Stance Test*], pain [*Numerical Pain Rating Scale*] and quality of life/mental health [*Mental Component Summary of the Short Form-12*]. Qualitative data identified 3 main themes of 1- '*The power of exercise*' as a vehicle for enhancing physical health and other health domains; 2- '*Challenges to engagement*' which were difficult to overcome due to participants' life course, lifestyle and legacies of trauma and disadvantage, yet, required urgent intervention and care of a targeted kind given the reported health challenges; and 3- '*The LEAP approach*'- the importance of delivery of trauma informed, flexible, low threshold exercise interventions to target physical function and frailty, in order to positively engage, avoid re-traumatisation and improve health outcomes.

In conclusion, this important work adds to the knowledge base as a unique low threshold and person-centred exercise intervention which has important implications for education, clinical practice and policy and paves the way for future higher powered longitudinal research studies to further investigate effectiveness.

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LIST OF ABBREVIATIONS

ACE	Adverse childhood experiences
ADHD	Attention deficit hyperactivity disorder
ARMA	Arthritis and Musculoskeletal Alliance
BMI	Body Mass Index
CFS	Clinical Frailty Scale
COPD	Chronic obstructive pulmonary disease
CST	Chair Stand Test
DCSWP	Dublin City Sports and Wellbeing Partnership
ETHOS	European Typology of Homelessness and Housing Exclusion
EBP	Evidence Based Practice
FITT	Frequency, intensity, time and type
FFVP	Frailty Framework for Vulnerable Populations
HGS	Hand grip strength
HIV	Human immunodeficiency virus
h/o	history of
HSE	Health Service Executive
IGS	Institute of Global Homelessness
IQR	Inter-quartile range
MD	Mean difference
MQI	Merchants Quay Ireland
LEAP	Low threshold Exercise And Protein
LEAP-W	Low threshold Exercise And Protein programme for women
MCID	Minimal clinically detectable improvement
MCS	Mental component summary score (SF-12)
MNA	Mini-Nutritional Assessment
Msk	Musculoskeletal
NDTRS	National Drug Treatment Reporting System
NPRS	Numerical Pain Rating Scale
PAR-Q	Physical Activity Readiness questionnaire

PCS	Physical component summary score (SF-12)
PEH	People experiencing homelessness
PPI	Public Patient Involvement
RCT	Randomised controlled trial
RET	Resistance exercise training
RPE	Rate of perceived exertion
SCRA's	Synthetic cannabinoid receptor agonists
SD	Standard deviation
SHARE-FI	SHARE Frailty Instrument
SF-12	Short Form-12
SLS	Single Leg Stance test
SPPB	Short Physical Performance Battery
SMR	Standardised mortality rates
SUD	Substance use disorder
TIC	Trauma informed care
WHO	World Health Organisation
1RM	One repetition maximum
2-MWT	2-Minute Walk Test
10MWT	10 Meter Walk Test

LIST OF APPENDICES

Appendix I	Data collection form for the LEAP interventions
Appendix II	Physical Activity Readiness Questionnaire Borg Scale of Perceived Exertion
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Chapter 1 Introduction and background

This PhD is primarily about homelessness and health. Homelessness itself is a social disadvantage and is closely associated and intersectional with other serious and complex social disadvantages. Therefore, to be all-encompassing, the title of this work and the populations who were investigated in this research, refer to people with 'severe and multiple disadvantage' (SMD). The rationale for this will be elucidated in this chapter.

This introductory chapter will provide an overview of homelessness, its relationship with health, with a particular focus on physical health and frailty, and the unique health needs of people who are homeless. Through a comprehensive review of the literature, suitable interventions to target physical function and frailty and improve overall health outcomes in this population will be presented, the relevant gaps in the evidence base will be elucidated and the rationale for this research study will be affirmed. An overview of this chapter is presented in Table 1.1.

1.1 Literature review: search strategy

Published articles, reports, books, book chapters, doctoral dissertations and websites relevant to the research topic were identified, up to August 01, 2025, through a search online and in PubMed, Google Scholar and the Irish health repository, LENUS. Search terms included various combinations of the following: Homelessness and relevant variables-women, minority groups, social exclusion, health literacy, inclusion health, health (physical health, nutrition, mental health, substance use), healthcare use and unmet need, trauma, stigma and trauma informed care, physical function and

frailty-assessment and measurement, management, exercise and nutritional interventions. No limits were placed on date and English language only text was selected. From the search results, titles and abstracts were reviewed with relevant articles identified for thorough reading and critiquing. The reference lists of these papers were reviewed and further papers of central focus to the research question were identified and reviewed.

Table 1.1 Overview of Chapter 1

1.1 Literature review search strategy	
1.2 Homelessness	1.2.1 Definition, prevalence, aetiology and ecology 1.2.2 Homelessness in a growing sub-population: Women
1.3 The health of people experiencing homelessness	1.3.1 Substance use 1.3.2 Mental health 1.3.3 Physical health
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1.2 Homelessness

1.2.1 Definition, prevalence, aetiology and ecology

Homelessness is a complex enduring societal phenomenon of major public health concern due to its associated early and extreme levels of morbidity and mortality (Ivers et al., 2019, Fazel et al., 2014, Aldridge et al., 2018). In the US, the mortality risk for non-geriatric people experiencing homelessness has been reported as 3.5 times higher than the general population and the risk of death for a 40-year-old person in homelessness is similar to that of a housed individual almost 20 years older (Meyer et al., 2023). In the UK, more than 1,300 people died while homeless in 2022 (Fleck, 2023) and in the Irish context, the reported median age of death for people experiencing homelessness is 38 years for females and 44 years for males (Ivers et al., 2019). Official statistics on homelessness generally represent those who are visibly homeless, on the streets or in emergency accommodation and often misrepresent the true figure of those who are seen and unseen. 'Hidden homelessness' encompasses many more living environments or situations, such as overcrowded accommodation settings, staying with friends or 'sofa surfing', squatting, and more recently, due to the housing crisis, sleeping in cars or tents or even workplaces (Cunningham, 2024). This precarity highlights another dimension of homelessness which is dynamic or transitory in nature and as a result figures of homelessness invariably fluctuate. It can therefore be challenging to collaborate and compare data internationally due to the fluidity of homelessness as well as the use of varying definitions and measurement methodologies (Thomas and MacKie, 2020, Busch-Geertsema et al., 2016). In recognition of this, the Institute of Global Homelessness (IGH), informed by the European Typology of Homelessness and Housing Exclusion (ETHOS), broadly yet simply define homelessness as a state of "lacking access to minimally adequate housing", that

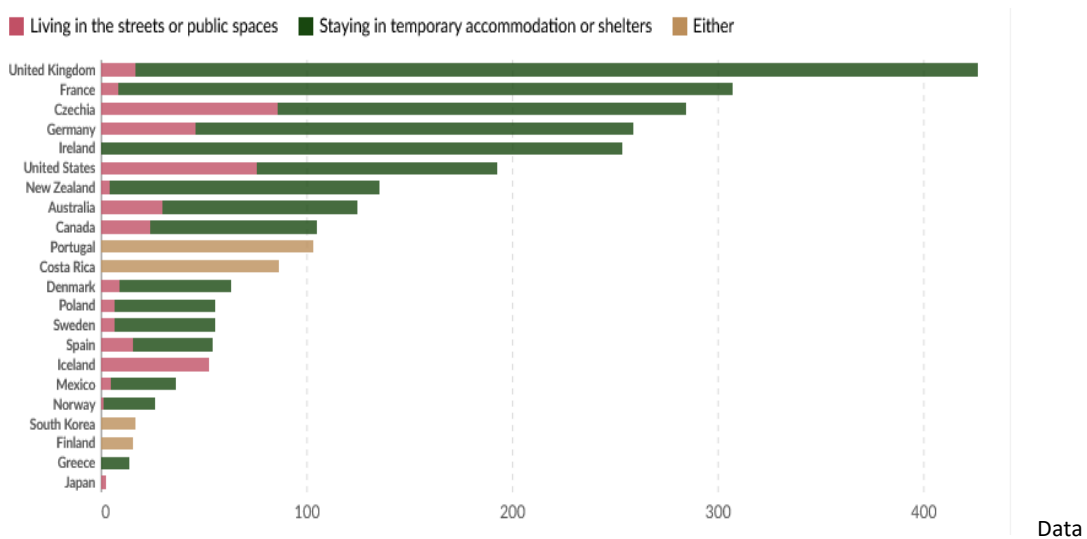
is: “rooflessness” (without any shelter/sleeping rough), “houselessness” (a temporary shelter or institution), “living in insecure housing” (insecure tenancy, threat of eviction or insecure due to domestic violence) or “living in inadequate housing” (caravans or illegal campsite, unfit housing, extreme overcrowding) (Busch-Geertsema et al., 2016, FEANTSA, 2005) . This shared language assists in driving collaborative and focussed solutions and it is posited that with the right interventions, homelessness can be successfully reduced and resolved (IGH WordPress, 2019).

It is estimated that globally 1.6 billion people live in inadequate housing, and more than 100 million people have no house at all (IGH WordPress, 2019). Poverty is closely linked to homelessness, and the vast majority of homeless people (1.1 billion) live in low income or developing countries. This homelessness is mainly attributed to the impact of climate change, war or conflict and global economic instability (Speak, 2019, IGH WordPress, 2019). Conflict and war are major drivers of homelessness due to displacement and nations including Sudan, Syria, Ukraine and Gaza are among those experiencing the highest levels of displacement (Statista, 2021, UNRWA, 2025). Nigeria has the world’s highest number of people experiencing homelessness (24.4 million) and Syria has the greatest rate of homelessness, with approximately one third (6.56 million) of the population reportedly homeless (Filipenco, 2025). Enumeration is extremely challenging, however, in low-income countries due to the diverse, transitory and cyclical nature of homelessness and the drivers of homelessness which are extremely complex (Speak, 2019).

Homelessness is escalating in high income countries. Three-quarters of a million (771, 480) people or 23 out of every 10,000 US citizens experienced homelessness in 2024, the highest ever recorded, with the highest rate in New York City, nearly twice

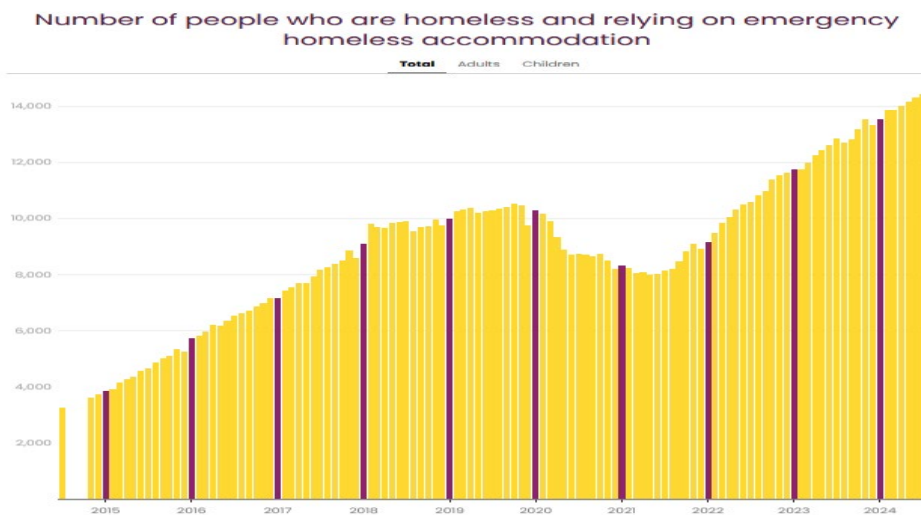
the rate of any other US city. Veterans, a group commonly represented in US homeless statistics, were the only group to decline in number in 2024, while nearly all other populations including families with children, individuals and unaccompanied youths reached record highs, and people of colour continue to be overrepresented in homeless figures (de Sousa and Henry, 2024). In comparison to other high-income countries the lifetime 'literal' homelessness rate (not including those precariously housed) in the US was among the highest at 6.2%, with the highest rate recorded in the UK at 7.7% (Toro et al., 2007).

With regard to European homelessness, key findings from the 2024 European report on homelessness revealed; (i) rising levels of homelessness, which were explained by the declining economic climate, unaffordable housing and the enduring impact of Covid-19; (ii) the presence of hidden homelessness; and (iii) rising homelessness in vulnerable populations such as migrants, women and young people (FEANSTA, 2024). These findings varied greatly among nations, with Northern and Western countries such as Finland faring better with alleviating homelessness. Ireland joins the Southern and Eastern European countries who follow the surging global trend in homelessness (FEANSTA, 2024). Moreover, Ireland has reportedly one of the highest and fastest growing levels of homelessness in Europe (Allen and Byrne, 2023). An unprecedented 15, 418 people were reported homeless in Ireland in March 2025 (The Housing Agency.ie, 2025). Of these, 10,743 were adults and 4,675 were children. See Figure 1.1 for an illustration of cross-country homelessness in OECD [Organisation for Economic Co-operation and Development] (high income) countries in 2023 and Figure 1.2 of the surging trend in numbers experiencing homelessness in Ireland.



source: OECD (2024)-People experiencing homelessness at a single point in time per 100,000 people. Data from UK considers England only.

Figure 1.1 Global Homelessness rates, 2023



Trend in data of (from the Department of Housing, Ireland) of the number of people in emergency homeless accommodation, excluding temporary accommodation, domestic violence refuges, asylum seekers, people sleeping rough, 'hidden homeless' and staying with family or friends in insecure housing

Figure 1.2 Number of people experiencing homelessness in Ireland who rely on emergency homeless accommodation

Single men are more likely to be homeless, but women in homelessness is the fastest growing demographic and, in the UK and New Zealand more women experience homelessness than men (IGH WordPress, 2019, Lewis et al., 2003). Homelessness is also growing in gender-expansive populations whose gender identity, expression or experience differs from their birth gender (Soucy et al., 2024). Furthermore,

homelessness is more prevalent in racial and ethnic minority populations than the general population (National Alliance to End Homelessness, 2020). In the US homelessness was reported as higher in non-Hispanic blacks (16.8%) or Hispanics of any race (8.1%) than for non-Hispanic whites (4.8%) (Fusaro et al., 2018). In Australia, one in five (20.4%) people experiencing homelessness were Aboriginal and/or Torres Strait Islander people in 2021, while this population represent 3.8% of the total population of Australia (Australian Bureau of Statistics, 2023). In the Irish context Irish Travellers are disproportionately represented in the homeless population (Harvey, 2021). A reported 39% of Irish Travellers are estimated to be homeless compared to 0.29% of the general population (The Housing Agency, 2021, Harvey, 2021). Yet, Irish Travellers represent less than 1% of the general Irish population (Central Statistics Office, 2023). Like other minority groups, Irish Travellers are a severely marginalised group and suffer higher mortality and morbidity than the general population due to a host of social determinants including inadequate housing, education and health literacy (AITHS, 2010, Harvey, 2021). Moreover, a scoping review of physical health conditions in Irish Travellers highlighted marked inequalities in the burden of physical health conditions experienced by this group (Kennedy et al., 2023b).

Nooe and Patterson (2010) describe the 'ecology of homelessness' as a dynamic biopsychosocial process involving the interaction of a host of individual, socioeconomic and environmental risk factors (Nooe and Patterson, 2010). In recognition of the complexity of homelessness Nooe and Patterson propose four components to homelessness in their conceptual model: (i) biopsychosocial risk factors, (ii) individual and social outcomes, (iii) temporal dimension, and (iv) housing outcomes.

- (i) *Biopsychosocial risk factors* include individual factors (including childhood development difficulties, early life adversity such as abuse, neglect and household dysfunction, race, ethnicity, health) and social factors (including education, employment, housing, culture, discrimination). Considering the imperative of the early years, it is not surprising that family conflict is cited as one of the main causes of youth homelessness (Embleton et al., 2016, Edidin et al., 2012, Milburn et al., 2024). Moreover, young people exiting institutional settings, such as foster care and justice systems are particularly at risk of homelessness (Milburn et al., 2024). In a homeless youth population (n= 641) in the US, Le et al (2023) identified at least one psychiatric diagnosis in 61.3%, vastly above the general population, and which correlated with previous suicide attempts, aggressive behaviours, traumatic experiences, tobacco use and illicit drug use (Le et al., 2023). These risk factors and social determinants are linked to poverty, an overriding risk factor and social outcome of homelessness (Nooe and Patterson, 2010).
- (ii) *Individual and social outcomes*: Individual outcomes include the detrimental effects of homelessness on the health and wellbeing of the individual, with a notable prevalence of substance misuse, mental illness, malnutrition and physical health conditions. *Social outcomes* include community dissonance, crime, violence and incarceration (Mitchell et al., 2023). A systematic review and meta-analysis revealed that incarcerated people are 20 times more likely to be homeless than the general population and higher rates of homelessness have been identified in incarcerated minority populations, those with mental health diagnoses and neurodevelopmental disorders (Bashir et al., 2021).

(iii) *Temporal dimension*: Homelessness was previously considered an entrenched condition, but with increased visibility and the emergence and growth of family homelessness, among other groups, the picture of homelessness has altered (FEANTSA, 2017a, Waldron et al., 2024). Homelessness is often defined by its temporal dimension (acute or transitional, chronic, or episodic), and both individual and social outcomes are influenced by its duration and chronicity (Nooe and Patterson, 2010, EMCDDA, 2022). Acute or transitional homelessness is characterised by brief episodes of homelessness of short duration usually occurring in a young person. Episodic homelessness is characterised by brief but more frequent episodes of homelessness, more likely in an individual with a dual diagnosis or a tri-morbidity of a physical, mental health and substance use disorder, and chronic homelessness describes a more permanent state of homelessness usually in an older individual, who is likely to have multi-morbid conditions (Kuhn and Culhane, 1998).

(iv) *Housing outcomes*: The fourth component of homelessness is related to housing and includes various living situations such as rough sleeping, emergency accommodation, shared dwelling in a friend's house, living in unfit dwellings, and prison-a highly precarious status which is known to impact on health and wellbeing (Hertzberg and Boobis, 2022, Institute of Medicine, 1988). Routhier et al (2024) demonstrated that certain classifications of homelessness, primarily unsheltered homelessness, were associated with increased emergency care attendance (Routhier et al., 2023). Undoubtedly all categories of homelessness are intricately challenging, but the 'street homeless' group are an extremely vulnerable group, and the life expectancy of a 'street sleeper' is known to be significantly shorter than that of the general population (Albert et

al., 2023). Studies have shown that the majority of rough sleepers are male, have substance use issues and mental health needs and rates of psychosis have been reported that are 50-100 times higher than the general population (Albert et al., 2023).

1.2.1.1 Social disadvantage and intersectionality

People experiencing homelessness face a host of social disadvantages. In recognition of the interconnectedness of these social disadvantages the Lankelly Chase foundation define the 'clustering of multiple and serious social harms' including homelessness, substance misuse, mental health issues and/or offending as 'severe and multiple disadvantage (SMD)' (Lankelly Chase, 2024). Severe and multiple disadvantage can lead to social exclusion and inequality (Watson et al., 2016). Social exclusion or marginalisation is defined as a process in which an individual is prevented or excluded from participating fully in economic, social, political, civic and cultural life which affects their opportunity to benefit from economic and social progress (Silver, 1994, European Commission, 2025). Poverty is closely linked to social exclusion, but social exclusion is more complex than poverty alone and is viewed as resulting from intersectionality, which describes the interconnectedness of social factors, power dynamics and human experiences and behaviours (Havinsky, 2014). The associated inequality and inequity of social exclusion (Figure 1.3) result in health disparities when compared to the general population (IGH WordPress, 2019, Fazel et al., 2014, Marmot and Bell, 2012). In pursuit of social justice Sir Michael Marmot proposed an evidence-based strategy to address social disadvantage and the social determinants to tackle social exclusion and inequality (Marmot and Bell, 2012). The Marmot principles which include and address 1) early years development, 2) employment, 3) living standards, 4) communities, 5) ill-

health prevention, 6) discrimination, and 7) environment sustainability, embody this strategy (Marmot and Bell, 2012).



Equality v Equity

Figure 1.3 Equality v Equity

Marmot proposed a range of health prevention and promotion interventions across the social gradient, including public health interventions such as drug and alcohol treatment programmes, smoking cessation and addressing chronic physical health conditions (Marmot and Bell, 2012). Ten years on from the Marmot Review, it was reported that in the UK homelessness and health inequalities had risen resulting in even poorer health for those living in the most deprived areas (Institute of Health Equity, 2020).

1.2.1.2 Functional literacy and health literacy

Functional illiteracy and numeracy problems, affecting the ability to read, write and calculate for one's development, are prevalent in people experiencing homelessness and are associated with poorer health status (Moon et al., 2015). Dumoulin and Jones (2014) demonstrated that 51% of a cohort of people who were homeless (n=139) had functional literacy challenges and 55% had functional numeracy

problems compared to the overall adult population rate of 15% (Dumoulin and Jones, 2014). Closely connected to functional literacy is health literacy. The WHO defines health literacy as representing “the personal knowledge and competencies that accumulate through daily activities, social interactions and across generations. Personal knowledge and competencies are mediated by the organizational structures and availability of resources that enable people to access, understand, appraise, and use information and services in ways that promote and maintain good health and well-being for themselves and those around them” (WHO, 2025). Health literacy therefore enables one to manage one’s health and in the case of disease, disability and ill health to manage one’s medical condition and associated needs. Where health inequity exists and healthcare resources are less available or accessible, so too is healthcare information which compounds the challenges of functional and health literacy (Marmot and Bell, 2012, Wolf et al., 2012). Health literacy has been shown to be a strong predictor of health status (Baker et al., 1997, Sentell and Halpin, 2006) and has been demonstrated in a cohort of homeless and vulnerably housed people, where higher levels of health literacy was found to be associated with higher levels of education, better housing status and lower levels of drug use (Farrell et al., 2020). Furthermore, Odoh et al (2019), in exploring health literacy and self-rated health among homeless adults, reported that the people who were health literate had better self-rated health compared to those who had poorer health literacy levels (Odoh et al., 2019). This elucidates the significance of health literacy in the health disparities of this population and the critical need to pay attention to the association of poorer health literacy with greater health burden and to provide the means to deliver health information to those who need it most.

1.2.2 Homelessness in a growing sub-population: Women

Gender is very relevant to the lived experiences of people who become homeless, resulting in pathways into homelessness as well as experiences while homeless which are frequently different for women when compared to men (Milani et al., 2016). Moreover, the health profile of women who are socially excluded is different and although mortality rates for women living in deprived areas in the UK are lower than that of men, all cause standardised mortality rates (SMRs) who are socially excluded (including women who experience homelessness) have been shown to be higher in women (11.9) than men (7.9) (Aldridge et al., 2018). Historically women's experiences of homelessness have been invisible, hidden or not acknowledged at all (Oudshoorn et al., 2018). More recently, the different experiences of women in homelessness have been explored (de Vet et al., 2019, Salem and Ma-Pham, 2015, Milaney et al., 2020, Savage, 2016). Legacies of childhood adversity have left women exposed to exploitation and abusive relationships resulting in a precarity of existence with loss of agency and 'perpetual vulnerability' (Morton et al., 2023, Li and Urada, 2020). Homelessness and substance use in women is common, and is inter-sectional, and may overlap with trauma, abuse, predation, domestic and sexual violence and exploitation (Mutatayi et al., 2022). The evidence also indicates different substance use trajectories in women with reported telescoping patterns of use exposing them to heightened risks (Mutatayi et al., 2022, Thomas and Menih, 2022).

Female domestic violence victims are disproportionately represented in the homeless populations and female single parents are disproportionately represented in homeless families (Rog et al., 2007). Of note Milani et al (2016) reported that 25% of the adult homeless population in Canada are women and they represent the majority of lone parents experiencing homelessness, which inevitability adds to the complexity

and trauma of their experiences (Milani et al., 2016). Female single parents face social and structural barriers in the struggle to work and access social supports to adequately care for and ensure the safety of their children (Li and Urada, 2020). Research also indicates that mothers with substance use issues experience barriers to accessing childcare (Morton et al., 2023). Many report fear of the loss of children to care as well as the stigma, shame and guilt experienced when their children have been removed from their care (Morton et al., 2023). Of note, it is often the mothering role which has been reported as the precursor to change their lives around and overcome homelessness. Moreover, through the anguished narrative of a mother, Lucey (2025), vividly describes the struggle of mothers who are homeless in Dublin, Ireland, mothers who struggle in their caregiving roles, and often succumb to risky behaviours and associated harms of homelessness yet remain resolute in their affective concerns and hopes for a better future for their children and family (Lucey, 2025). Milaney et al (2020), report disproportionate rates of Adverse Childhood Experiences (ACEs), mental illness and suicidal ideation in women compared to men (Milani et al., 2016). Morton et al (2023), demonstrated higher rates of intimate partner violence, sex work and coercive control in women which result in shame, stigma and a fear of seeking help therefore accessing support at breaking point and often with complex coinciding physical and mental health needs (Ní Cheallaigh et al., 2017, Department of Housing Local Government and Heritage, 2024, Morton et al., 2023).

Internationally, gender-based services for women who are experiencing homelessness and addiction are lacking and services are mostly delivered in mixed gender settings with a gender-blind lens (EMCDDA, 2022, Hurson, 2021). Ingram et al (2023) call for the provision of more women-centred services (Ingram et al., 2023b). In

prior linked research by the author of this PhD, the LEAP-I study demonstrated high retention (83% female v 42% males) with excellent engagement and feedback from its female participants, yet caution was observed around engaging in a mixed exercise programme with men (Kennedy et al., 2024). Women-specific services are advocated to increase safety, stability, wellbeing, and psychosocial functioning to respond meaningfully to the serious health and social care needs of women in this setting (Morton et al., 2023). It is evident that the needs of women are complex and unique, and gender sensitive strategies, interventions and research is warranted to fill this practice and knowledge gap.

In summary, it cannot be overstated that homelessness is a hugely complex societal challenge encompassing a myriad of interacting factors which result in a unique and arduous path for each individual experiencing it. Importantly, much of its associated extreme and premature morbidity and mortality has been shown to be preventable (Aldridge et al., 2019, NICE, 2022). Significant financial and structural resources, as well as targeted supports and interventions are required, with cohesive, collaborative and integrated engagement delivered across the whole of society (NICE, 2022). This is a matter of social justice.

1.3 The health of people experiencing homelessness

The health and wellbeing of people experiencing homelessness is gaining traction due to the unprecedented scale of the problem globally (Ivers et al., 2019, Doran et al., 2018). Due to a complex interaction of health and social issues people who are homeless are at risk of experiencing a syndemic or clustering of specific health

conditions (O'Rourke et al., 2024). Aligning with the inverse care law, the poor health of people who are homeless is perversely matched with poorer diagnosis and poorer management of health conditions and greater barriers to accessing the health and social care interventions than the general population (Hertzberg and Boobis, 2022, Hart, 1971). Compared to the population as a whole, people who are homeless are at a much higher risk for a broad range of acute and chronic physical and mental health conditions and substance use disorders, which are compounded by the exigency of being homeless (Institute of Medicine (US), 1988). This is succinctly summarised in Table 1.2 which highlights key findings from the UK health audit of people experiencing homelessness (Hertzberg and Boobis, 2022).

Table 1.2 Homeless Health: UK Health Needs Audit key findings

	People experiencing homelessness	General population
Physical Health	63% with long term illness, disability or infirmity 78% with physical health condition 80% with multi-morbidity	22% with long term illness, disability or infirmity
Mental Health	82% with mental health condition 81% with co-morbidities 72% with depression 45% self-medicated with drugs to cope with mental ill-health	10% with depression (pre-pandemic)
Substance Use	54% used drugs in previous 12 months 38% had or were recovering from drug problem 20% regularly exceeded the low-risk drinking guidelines 29% had or were recovering from alcohol problem	24% regularly exceeded the low-risk drinking guidelines
Wellbeing	76% smoked cigarettes, cigars or pipe 33% ate one meal per day 3% did not eat any meals 66% ate 1 or less portions of fruit or veg per day	13.8% were smokers

(Hertzberg and Boobis, 2022)

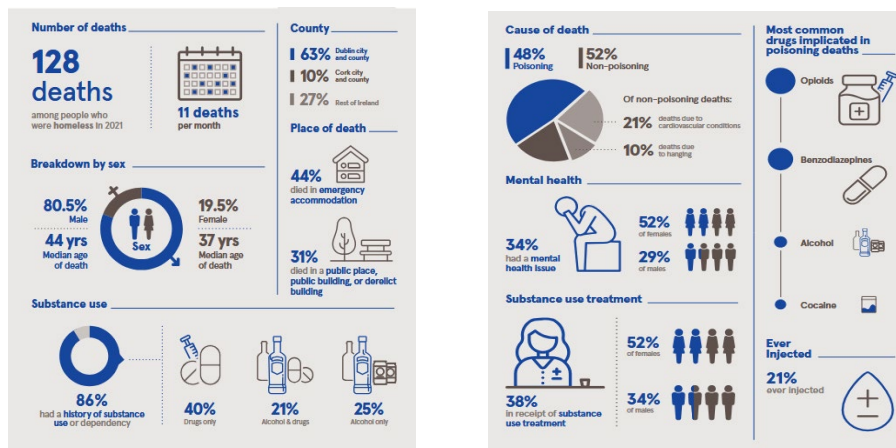
1.3.1 Substance use

Substance use disorder (SUD) or addiction is a major public health challenge due to its extensive health, economic and societal consequences (Castelpietra et al., 2022, Roth et al., 2018). Over eleven million deaths per year are reportedly due to addiction, making this condition the leading risk factor for premature death globally (Degenhardt et al., 2018). In addition to high mortality rates, addiction is associated with high morbidity with a reported global disease burden rate of more than 5% (Degenhardt et al., 2018). People with SUD often experience poor physical health and have associated comorbid conditions including accidental injuries, lung or heart disease, diabetes, stroke, cancer or other health conditions (Schulte and Hser, 2014, Hovhannisyann et al., 2018). Substance use disorder and homelessness are closely linked (Castelpietra et al., 2022).

While not all people who are homeless have substance use issues, addiction problems are very common in this population and this relationship is highly complex, intersectional and frequently cyclical (Hutson and Liddiard, 1994). Its prevalence in people who are homeless far exceeds the general population (Cox, 2000, Corr, 2003). In a study of mortality rates among homeless people, Ivers et al (2019) cited substance misuse as a behaviour which was strongly associated with homelessness and a leading cause of death (Ivers et al., 2019, Riordan et al., 2021). (see Figure 1.3). Patterns of substance use in populations who are homeless tends to vary by country and by timeframe. In a recent systematic review of substance use prevalence spanning 13 years from 2007-2020 and multiple countries, including the US, Canada and the UK, alcohol was the most commonly used substance (80%), followed by heroin (44%), cocaine (40%), cannabis (36%) and crack cocaine (24%) and synthetic cannabinoid

receptor agonists or SCRAAs (24%), and with a rise in new psychoactive substances such as SCRAAs in more recent times (Coomb's et al., 2024).

People who experience chronic or recurrent homelessness are at high risk of substance misuse (EMCDDA, 2022). Figures of 29%-64% for lifetime drug use are reported for people experiencing homelessness in Dublin and 41% of those who inject drugs commence between 15 and 19 years (O'Gorman, 2002, Corr, 2003). Furthermore, in a study of women experiencing homelessness 45% were reportedly current drug users (Smith et al., 2001).



Data from HRB Ireland 2021

Figure 1.4 Substance use related deaths in people experiencing homelessness in Ireland in 2021

Evidence has also demonstrated that substance use, and poverty is predictive of first-time homelessness (Thompson et al., 2013). Substance use, therefore, often precedes and contributes to becoming homeless, but for many it may commence during homelessness and serve as a coping mechanism to buffer the stress of being homeless (Mosel, 2024). Additionally, many substance users have claimed that their addiction was a major barrier to exiting homelessness (Cox and Lawless, 1999). It is

thus evident that there is a complex bi-directional relationship between homelessness and substance use with extreme, enduring and often life-threatening consequences. Despite this, evidenced informed policy in this area is lacking (EMCDDA, 2022).

1.3.2 **Mental health**

A dual diagnosis of co-occurring addiction and mental health disorder is commonly reported in people experiencing homelessness and the severity of mental health problem is reportedly linked to the severity of the homeless situation (Schütz et al., 2019). A range of mental health disorders occurring in this population are described including depression, anxiety, post-traumatic stress disorder, psychosis, personality disorder, eating disorder and attention deficit hyperactivity disorder (ADHD) and for many comorbid mental health conditions occur (Hertzberg and Boobis, 2022, Barry et al., 2024). In a recent systematic review and meta-analysis, Barry et al reported a current and lifetime prevalence of mental health disorders of 67% and 77%, respectively, in people experiencing homelessness. Of these, 44% were categorised as any substance use disorder, 26% antisocial personality disorder, 19% major depressive disorder, 8% bipolar disorder and 7% schizophrenia (Barry et al., 2024). Traumatic brain injuries, most commonly due to assault, are associated with a range of mental health conditions and substance use disorder and are 10 times more prevalent in homeless populations than the general population (Stubbs et al., 2020). Moreover, traumatic brain injury is associated with poor health and functioning, and higher suicidality and risk of suicide (Stubbs et al., 2020). Findings from the UK's 2022 Homeless Health Needs Audit indicated that 82% of respondents had a mental health condition, 25% had a dual diagnosis of a co-occurring substance use issue and 45% reported self-medicating to manage their condition (Hertzberg and Boobis, 2022). This audit also reported a predominance of depressive disorders in its respondents with 72% reporting

a history of depression, in comparison to a national rate of 10% (Hertzberg and Boobis, 2022). In the Irish context, a relationship between homelessness and psychiatric illness has been observed. Moloney et al (2022) identified a history of homelessness (30%) in a cohort of psychiatric in-patients (Moloney et al., 2022). In a linked research study which pre-dated this thesis, 61% of participants in an open-access day service reported mental health issues and the same rate was identified in those with substance use issues (Kennedy et al., 2024). The figures in this study may, however, under-represent the problem due to the self-report nature of the data. Qualitative research has powerfully evoked the mental toll of homelessness on health and unmet need through vivid stories of lived experience (Barror, 2014, Carolan, 2017). Poverty, adversity, instability, loss and loneliness in childhood and into adulthood were commonly reported narratives which led to mental health difficulties and homelessness (Barror, 2014, Carolan, 2017).

1.3.3 Physical health

Strong relationships have been found between mental health and physical health and an association between a tri-morbidity of a substance use disorder, a mental health condition and a physical health condition in people experiencing homelessness has also been reported (Vallesi et al., 2021, Ohrnberger et al., 2017, Surtees et al., 2008). Cancer is one of the leading causes of death in people experiencing homelessness and their risk of developing cancer is twice that of the general population, attributed to poor health literacy and access to anticipatory and preventative care (Asgary, 2024, Aldridge et al., 2019). Fazel et al (2014) report a range of physical health conditions in people experiencing homelessness, including infectious diseases, cardiovascular and metabolic diseases, and unintentional injuries (including traumatic brain injury) (Fazel et al., 2014). Furthermore, Denning and DiNenno (2010)

demonstrated that homeless populations are disproportionately affected by HIV (human immunodeficiency virus) compared to housed populations (Denning and DiNenno, 2010). Findings in a large-scale cross-sectional study of the health needs of over 51,000 homeless people who were admitted to acute care demonstrated younger and more urgent admissions compared to housed people, and while mental and behavioural admissions were more prevalent than physical conditions in people who were homeless, specific physical health conditions, such as infections, cancer, respiratory and cardiovascular diseases were more common for people experiencing homelessness than housed people (Luchenski et al., 2023). Similarly, the UK's Homeless Health Needs Audit reported a broad range of physical conditions, including 'joint aches/problems with bones and muscles' (37%), dental problems (36%) and asthma (24%) (Hertzberg and Boobis, 2022). Comorbidity was reported in 44%, and chronic illness, disability or infirmity was reported in 63% of this study's participants. In the Irish context, this finding of multi-morbidity has also been reported and in a Dublin study the most commonly occurring physical health conditions were cited as skin (55%), dental (48%), eye (31%), joint (23%) and asthma (21%) (Keogh et al., 2015). These data illuminate the health disparities in this population who are almost three times more likely to report having a longstanding illness, disability or infirmity than the general population (Hertzberg and Boobis, 2022). In another Dublin study, which examined the health of people experiencing homelessness admitted to acute care, chronic physical health conditions were also commonly reported, including hepatitis, liver disease, epilepsy/seizure disorders, chronic respiratory conditions and orthopaedic disorders (Kiernan et al., 2020). Similarly, in 2020, a follow-on study, the LEAP-I trial demonstrated high levels of physical functioning deficits and frailty in a community-based cohort of people experiencing homelessness, addiction and mental

health challenges (Kennedy et al., 2024). Furthermore, in the community setting, Primary Care GPs commonly encounter complex and chronic physical health complications of people who inject drugs (O'Donnell and Lawson, 2016). Sleep, a vital biological function, has more recently been investigated in people experiencing homelessness due to the prevalence and ill effects of sleep disturbance in this population (Huynh et al., 2024). Findings suggest that sleep is commonly reported as inadequate, and a dose-response relationship exists between sleep disturbance and poor physical and mental health (Huynh et al., 2024). Finally, considering the prevalence of a number of chronic physical health conditions (asthma, COPD [chronic obstructive pulmonary disease], epilepsy, heart problems, stroke and diabetes), Lewer et al (2019) demonstrated a sharp gradient or 'cliff' when making comparisons between a large sample of housed and homeless populations (n=1336), (see Figure 1.5) (Lewer et al., 2019). This was mirrored by the reported differences in health-related quality of life, (particularly anxiety) in this study's participants (see Figure 1.6).

The evidence portrays the poor health profile and burden of homeless populations with a high prevalence of chronic medical conditions which are often accompanied by a mental health condition and substance use disorder resulting in lower quality of life and leading to poor health outcomes

*COPD=Chronic obstructive pulmonary disease, IMD= index of multiple deprivation, CI=confidence interval

From 'Health-related quality of life and prevalence of six chronic diseases in homeless and housed people: a cross-sectional study in London and Birmingham, England'. *BMJ Open* (Lewer et al., 2019)

Figure 1.5 Prevalence of long-term conditions (top), prevalence ratios (bottom), with 95% CIs

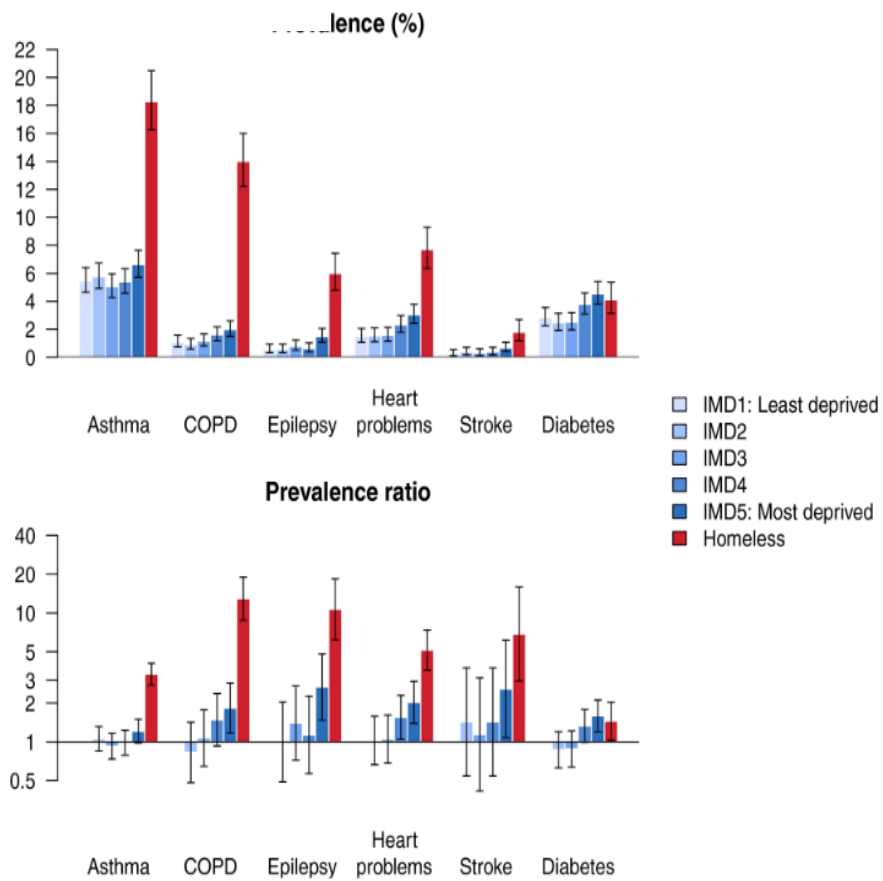
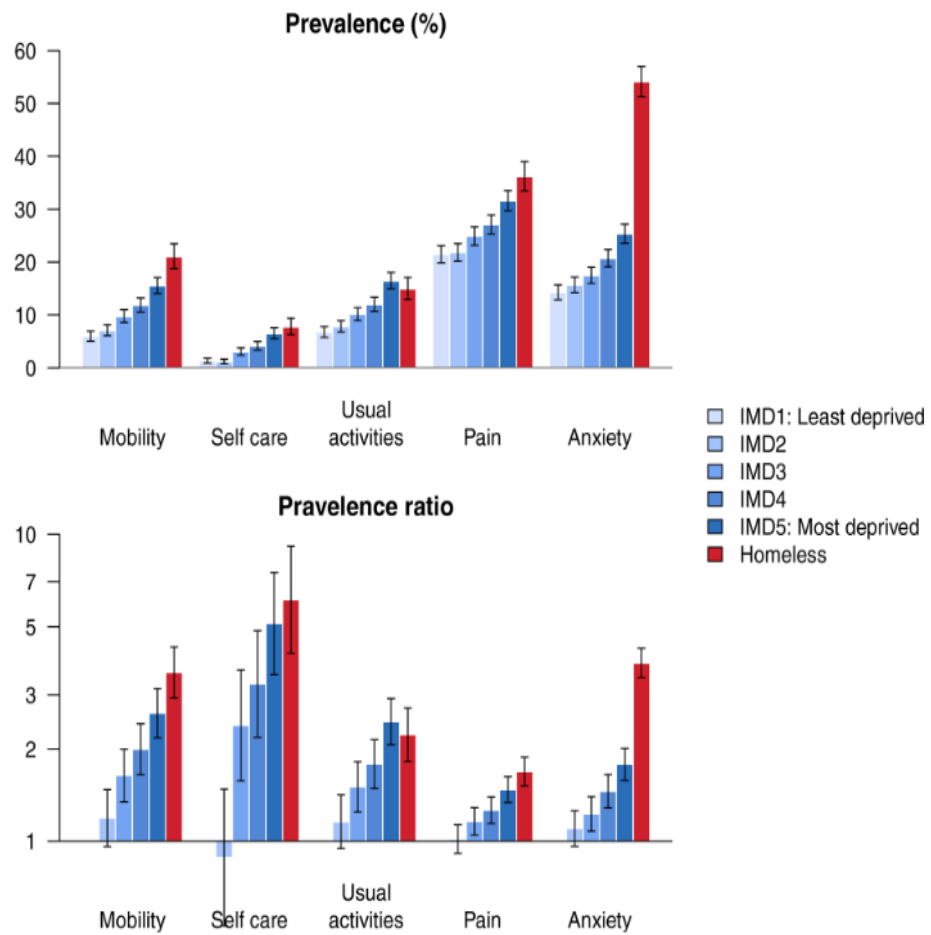


Figure 1.6 Prevalence of health-related quality of life problems (top) prevalence ratios (bottom), with 95% CIs



1.3.3.1 Physical function and frailty

This section will discuss the evidence pertaining to the prevalence and early manifestation of physical functioning deficits and frailty in people experiencing homelessness which result from the significant health burden discussed in the preceding section.

Poor physical functioning and frailty are associated with lower socioeconomic status and have been identified in populations from areas of deprivation such as people who experience homelessness (Hoogendijk et al., 2018, Kiernan et al., 2021, Rogans-Watson et al., 2020, Mantell et al., 2023, Cronin et al., 2025). Brown et al (2015) identified reduced physical functioning and common geriatric syndromes, such as difficulties with activities of daily living, falls, cognitive impairment, visual impairment and urinary incontinence, in homeless adults over 50 years (Brown et al., 2015). Salem et al (2013, 2019) identified frailty in a cohort of middle aged and older homeless adults (range 40-73 years) and in a later study, a group of formerly incarcerated homeless women who had a mean age of 39 years (Salem et al., 2013, Salem et al., 2019). Rogans-Watson et al (2020), also demonstrated a prevalence of younger frailty in a cohort of adults (range 38-74 years, mean 55.7 years) living in a homeless hostel (Rogans-Watson et al., 2020). In the Irish context, a scoping review of physical functioning limitations in people experiencing homelessness identified low physical functioning including reduced lower limb function, gait speed and grip strength, poor physical activity levels and high physical symptom burden such as joint pain, fatigue and sleep issues (Kiernan et al., 2020). Furthermore, a cross-sectional study by Kiernan et al (2021), which evaluated physical function and frailty in hospitalised people experiencing homelessness, demonstrated low physical functioning, premature ageing, and high levels of frailty (Broderick et al., 2021, Kiernan et al., 2021). In this study, 83%

of participants, who had a mean age of 47 years, had mobility limitations, over half self-reported a fall in the previous six months and only 31% were able to negotiate a flight of stairs. Seventy percent were frail or pre-frail using the Clinical Frailty Scale (CFS). Aligning with the findings of Kiernan et al (2021), a systematic review and meta-analysis demonstrated that falls were three times more prevalent in homeless individuals than housed individuals (Suh et al., 2022). More recently, preliminary research linked to this PhD study identified poor physical function and frailty in a community-based homeless population (mean age 47 years) (Kennedy et al., 2024). This finding of 'younger frailty' is evidently increasing (Loecker et al., 2021, Spiers et al., 2021) and in accordance, Dawes et al (2025), recently demonstrated, in a cross-sectional analysis of a large sample (n=2,288) of non-geriatric (aged 18-59) people experiencing homelessness, a higher prevalence of frailty (41.5%) and pre-frailty (43.8%), using a comprehensive Frailty Index, than the general age-matched population (Dawes et al., 2025a).

Linked to physical function, multimorbidity and geriatric conditions is disability (Jędrzejczyk et al., 2022). Disability described by Nagi (1976), as having two dimensions (individual and social) and relating to underlying pathology and impairment, is the 'inability or limitation in performing social roles and activities such as in relation to work, family, or to independent living' (Nagi, 1976). Disability is considered a contributory factor to entering homelessness and its prevalence in the homeless population in Ireland is almost six times higher than the general population (NDA, 2022, Stone and Wertans, 2023). Similarly in the UK 63% of participants experiencing homelessness reported having a chronic condition, disability or infirmity (Hertzberg and Boobis, 2022). Unsurprisingly, disability may exacerbate and perpetuate the experience

of homelessness creating barriers to exiting homelessness, re-illuminating the pressing need for early and targeted intervention (Stone and Wertans, 2023).

1.3.3.2 Physical health and nutrition

An important aspect of physical health, linked to physical function and frailty, is nutritional health (O'Connell et al., 2020, Bonnefoy et al., 2015). Poor nutritional health, unhealthy body mass index (BMI) and malnutrition are commonly reported in people experiencing homelessness (Huang et al., 2022, Ijaz et al., 2018). Chronic substance use, strongly associated with homelessness, affects nutritional status and body composition through decreased nutritional intake, decreased nutrient absorption, and dysregulation of hormones that alter the mechanisms of satiety and food intake (Mahboub et al., 2021). Furthermore, malnutrition severely impacts physical and psychological health and may impede recovery from substance use (Mahboub et al., 2021).

Although not uniformly experienced food poverty is another commonly cited reason for poor nutritional intake and is linked to individual experiences of homelessness, particularly when longstanding (Lee and Greif, 2008, Tong et al., 2019). In the UK Health Needs Audit one third of participants reported typically having one meal per day and two thirds ate at most one portion of fruit or veg per day. In consonance with this just under half (48%) of the participants of the LEAP-I study were at risk of malnutrition and 3% were malnourished (Kennedy et al., 2024).

1.3.3.3 Nutrition and the muscular system

Adequate physical functioning is reliant on a competent and healthy muscular system (Painter et al., 1999). Muscle health in turn is reliant on certain micro and macronutrients and as they play a role in maintaining muscle mass and performance,

they are thus critical to preventing muscle disease or sarcopenia (Ganapathy and Nieves, 2020). Good dietary intake including high consumption of fruit and vegetables akin to the Mediterranean diet is recommended (Jennings et al., 2020). A large body of evidence has explored the role of protein and resistance exercise in muscle protein synthesis (Nunes et al., 2022, van Loon, 2013, Morton et al., 2018) and while dosage remains unclear, what is agreed internationally is that 20-40g of protein ingested during or immediately following exercise, particularly resistance exercise enhances muscle protein synthesis (Jäger et al., 2017). Considering that poor nutritional health is common in people who experience homelessness and dietary protein is likely to be deficient, protein supplementation should be considered (Huang et al., 2022).

1.4 Access/use of healthcare and unmet need

As alluded to previously people experiencing homelessness face challenges accessing health and social care interventions (Dawes et al., 2017, Elwell-Sutton et al., 2017). These may be due to a combination of individual and health system factors (Siersbaek et al., 2021). Traditionally, healthcare has been delivered in rigid and structured environments involving scheduling of appointments, strict non-attendance policies and attendance being conditional to abstinence from drugs and alcohol. Conversely, research has shown that treatment for drug users is less effective or harmful in some cases where there is pressure to become drug or alcohol free (Randall and Brown, 2002). Mainstream health systems generally lack practitioners and staff with adequate training to support socially excluded populations which may lead to unconscious biases towards this population limiting access even further. Findings from Siersbaek et al (2021) demonstrated that healthcare services with professionals who have limited training and resources result in poor patient experiences and impacts on the desire to seek help when required (Siersbaek et al., 2021). As a result of traditional

practices and despite the need, attendance to primary health care settings for people experiencing homelessness is generally poor and those who do attend tend to present late for care, commonly self-discharge early, and have poor compliance with treatment (Hwang et al., 2013, O'Carroll and Wainwright, 2019, Dawes et al., 2017). Resultantly, usage of unscheduled acute care is unsurprisingly high (Ní Cheallaigh et al., 2017). Furthermore, the majority of care provided to people experiencing homelessness is provided by the charity sector and short-term funding cycles resulting in a high degree of fragmentation of care, especially when mainstream services are also required, thus creating an overly complex health system for this population (Siersbaek et al., 2021).

In Ireland and the UK higher and more frequent use of acute services in comparison to the general population has been reported in people experiencing homelessness and this has been attributed to poorer health as well as barriers in accessing primary healthcare (Hertzberg and Boobis, 2022, Ní Cheallaigh et al., 2017). The primary reason for attendance to acute care has been cited as a physical health condition. In Ireland, the rate of self-discharge from acute care for people experiencing homelessness was reported as higher than housed patients (Ní Cheallaigh et al., 2017), while in the UK Health Needs Audit, a mere 55% of participants were reportedly discharged from acute care to adequate accommodation, thus the reported high rate of readmittance to acute care in this study is not surprising (Hertzberg and Boobis, 2022).

In relation to primary and preventative care, the UK Health Needs Audit identified that vaccination rates and attendance to screening programmes were lower than the general population. This aligns with findings from Baggett et al (2015) of higher rates of colorectal, female breast and oropharyngeal cancers diagnosed at

advanced stages in people experiencing homelessness (Baggett et al., 2015). Lower attendance to primary care services such as GP, dentistry and physiotherapy services is also commonly reported in the literature (Keogh et al., 2015, Dawes et al., 2017, Hertzberg and Boobis, 2022). In an Irish study relating to healthcare use in people experiencing homelessness, increased use of GP services was noted following the establishment of Safetynet, a free primary care service for people who are homeless, and interestingly study participants declared that they would not have attended the primary healthcare services if Safety Net had not been available (Keogh et al., 2015). This makes the case for person-centred care and bespoke service design to meet the needs of this population.

In some areas of healthcare disparities have been identified in the level of support needed when compared to that which is received, particularly in relation to mental health support services (Hertzberg and Boobis, 2022). Moreover, despite complex interconnections, those with a dual diagnosis of a mental health disorder and SUD, may face barriers to accessing integrated rehabilitation services due to the existence of sequential or siloed treatments for these co-occurring conditions and in some cases recovery from substance use is a pre-condition to accessing mental health care (Selick and Wiktorowicz, 2016, Hertzberg and Boobis, 2022, Ziedonis, 2004).

It is evident that in order to enhance the health care experiences and health outcomes of people who face homelessness and multiple disadvantage and to respond appropriately to the unmet healthcare needs outlined above, the structural barriers to health care need to be removed and replaced with person-centred, low threshold, flexible, accessible and integrated services. Low threshold (with minimal barriers to entry) services have been shown to be effective in reducing drug or alcohol related

harm, often providing a bridge to further treatment and rehabilitation (Huo et al., 2023, Morton and O'Reilly, 2016). Aligned with this, a report by Miescher et al (1996), identified that accessible drug treatment programmes in familiar settings were more amenable to positive outcomes (Miescher and Galanter, 1996). Siersbaek et al, (2021) call for healthcare systems to provide stable funding, training and integration of services, led by inclusion healthcare champions and delivered through a trauma informed lens to provide accessible, anticipatory care (Siersbaek et al., 2021). The evidence is clear that a shift in service design is required to respond to the unique needs of this population and to prevent costly and sometimes ineffective admissions to acute care.

1.5 Approaches to healthcare delivery

Considering the complexities and health challenges outlined in the preceding sections it is evident that traditional practices and care delivery have limited success in making tangible differences to the health of this population and a unique and person-centred approach is required.

1.5.1 Trauma and Trauma Informed Care

Trauma affects health (SAMHSA, 2014a, Perry and Winfrey, 2021). Trauma as defined by the Substance Use and Mental Health Services Administration in the US is “an event, series of events, or set of circumstances that is experienced by an individual as physically or emotionally harmful or threatening and that has lasting adverse effects on the individual's functioning and physical, social, emotional, or spiritual well-being (SAMHSA, 2014a). People who experience SMD are more likely to have experienced trauma and adversity in their lives than the general population (Heriot-WattUniversity.,

2019). Adverse childhood experiences such as childhood abuse, neglect and household dysfunction are potentially traumatic experiences, and can lead to a host of negative outcomes including homelessness and substance use (FEANTSA, 2017b, Felitti et al., 1998). Ninety percent of people experiencing homelessness are exposed to at least one adverse childhood experience and more than 54% of people who experience homelessness have been exposed to at least four adverse childhood experiences (Koh and Montgomery, 2021). Trauma may also occur during homelessness, either due to victimisation, injury or violence, or simply due to the experience of homelessness itself (FEANTSA, 2017b). Whatever the cause, it is clear that trauma plays a key role in the persistence or the repeated experience of homelessness.

Trauma alters the basic biological regulatory systems in the brain, therefore the earlier in life that trauma occurs, the more harmful and pervasive its effects (FEANTSA, 2017b). Trauma causes uncontrollable and extreme activation of one's stress-response systems and results in adaptive behaviours which affect how an individual behaves and interacts with the world around them and can have far-reaching and harmful implications (SAMHSA, 2014a, FEANTSA, 2017b). A myriad of trauma responses may occur such as emotional dysregulation, detachment, dissociation and disengagement (SAMHSA, 2014b). While cognitive and psychological symptoms are common and often more impactful, physical health problems may present initially and may include sleep disturbance, gastrointestinal, cardiovascular, musculoskeletal, respiratory, dermatological and urological disorders (SAMHSA, 2014b). This provides further insight into the causes and contributors to the disproportionate physical health burden experienced by people who are homeless.

Stigma is commonly reported by people who are homeless and is in itself a form of trauma (Reilly et al., 2022). Healthcare provider perceived stigma has been shown to lead to health care avoidance and result in negative health outcomes. In a systematic review on stigma and the health experiences of people experiencing homelessness, participants referred to the stigma, shame, humiliation and discrimination they experienced, which resulted in perceived inadequate or inappropriate medical treatment (Reilly et al., 2022). Conversely, participants in this study placed notable value on positive interactions with healthcare providers which they perceived as ‘good care’, otherwise known as trauma informed care (Reilly et al., 2022).

Trauma informed care (TIC) is advocated to sensitively consider and appropriately engage with trauma survivors (SAMHSA, 2014a, Oregon, 2024). Trauma informed care is a comprehensive strengths-based approach which understands and acknowledges an individual’s past and present trauma, addresses the root of behaviours caused by trauma and in doing so promotes recovery while also actively attempting to avoid re-traumatisation (FEANTSA, 2017b). Principles of 1) trust, 2) transparency, 3) collaboration and mutuality, 4) voice, choice, empowerment, and 5) cultural, historical and gender consideration, embody the framework of a trauma-informed approach and it is recommended that interventions for people who have experienced trauma should be holistic and built on these principles (Oregon, 2024, Liu et al., 2021, SAMHSA, 2014a). In understanding an individual’s trauma and behaviours, Dr. Bruce Perry advocates a shift in focus from asking “What’s wrong with you” to “What happened to you” (Perry and Winfrey, 2021).



Figure 1.7 Principles of Trauma Informed Care

1.5.2 Inclusion Health

Often used interchangeably with social exclusion and at the other end of the spectrum is social inclusion, the process which provides citizens with opportunities and resources to participate and prosper in society (Eurofound, 2025). Aligned with this, Inclusion Health is an approach to practice, research and policy used to tackle the extreme health and social inequities experienced by vulnerable populations, such as people who experience homelessness. Inclusion Health applies a lens on life course epidemiology, social exclusion and intersectionality, generated by a multitude of risk factors and social harms which negatively impact on health and wellbeing (Luchenski et al., 2018). Ireland has proven to be a vanguard in Inclusion Health, establishing the world's first hospital-led Inclusion Health team in 2016 in Dublin and since then additional hospital-led inclusion health teams have been established. The overarching aim of Inclusion Health is to improve access to healthcare and provide multi-component and integrated interventions with 'active engagement' in order to address the adverse health outcomes observed in socially excluded populations (Luchenski et

al., 2018). Proposed interventions include psychosocial interventions, case management, disease prevention and harm reduction programmes (such as needle and syringe programmes, supervised injecting sites, screening in primary care and vaccination for blood-borne viruses), 'Housing First' intervention models and occupational therapy. Also recommended are physical activity or exercise interventions which have demonstrated positive outcomes for people experiencing homelessness, addiction and mental health conditions (Luchenski et al., 2018, Dawes et al., 2024, Smith and Merwin, 2021). An urgent call for further research and innovative interventions is advocated (Luchenski et al., 2018).

1.6 Health interventions to improve physical functioning deficits and frailty

To affirm, evidence indicates that healthcare interventions for people experiencing homelessness should be delivered through a trauma informed lens and led by inclusion health champion/s. This section will outline the evidence for (i) health interventions which have proven effectiveness for specifically targeting physical functioning and frailty in the older general population and (ii) exercise interventions delivered to the population of interest in this PhD to target physical and mental health. It is well known that physical functioning deficits and frailty are associated with advancing age, thus the main body of evidence for developing bespoke interventions for homeless populations is derived from geriatric medicine (Rockwood et al., 2005, Morley et al., 2013, Travers et al., 2019).

In 2017, a systematic review of interventions to manage pre-frailty in older adults demonstrated that multi-domain interventions (including physical exercise,

nutrition, medication, psychological and social supports) were superior to single interventions with observed improvements in physical functioning and frailty (Dedeyne et al., 2017). While physical exercise was identified as the key to successful outcomes, nutritional intervention was recommended for additional improvement (Dedeyne et al., 2017). Similarly, in 2019, a systematic review of interventions to manage or reverse frailty in community settings highlighted a large mix of suitable interventions (Travers et al., 2019). In this large study of 15,690 participants the most prevalent intervention was physical activity or exercise and a range of different exercise modes such as mixed exercises, strength, aerobic, balance, co-ordination, walking, tai-chi and mobility exercises was reviewed. Many interventions had mixed components, for example exercise and nutrition, or medication and comprehensive geriatric assessment. In terms of effectiveness and ease of implementation, physical activity in the form of strength training and nutritional supplementation in the form of protein supplementation, was ranked the highest, while mild-intensity mixed exercises or singular exercises such as walking, or tai-chi were moderately effective and easy to implement. More recently, a systematic review of randomised controlled trials (RCTs) aimed to specifically investigate interventions for improving physical performance outcomes and phenotypical frailty in pre-frail and frail older adults (Kidd et al., 2019). In contrast to Dedeyne et al (2017), however, this study deemed physical activity, as a single-domain intervention (with one or more physical components), the most effective intervention (Kidd et al., 2019). Nonetheless, nutritional intervention in the form of protein supplementation demonstrated a clinical improvement in physical performance and it is posited that this result should not be overlooked, especially when considering a population with poor nutritional status.

1.6.1 The role of exercise to target physical function and frailty

The terms physical activity and exercise are often used interchangeably.

Physical activity is defined as “any bodily movement produced by skeletal muscles that results in energy expenditure” and exercise is a subset of physical activity, one which is planned, structured and often prescribed (Caspersen et al., 1985). For the purpose of this research the term exercise shall be used as it was prescribed to the study participants. Exercise is known to reduce cardiovascular risk and improve longevity irrespective of age, gender and race/ethnicity (Shiroma and Lee, 2010), yet the question of prescription and dosage is frequently discussed and debated. The FITT (frequency, intensity, time and type) principle is a well-known framework for exercise prescription and was utilised in this PhD (Katsukawa, 2016). In accordance the American College of Sports Medicine outlined physical activity guidelines to aid exercise prescription in order to achieve physical fitness (Haskell, 1994). They recommend aerobic exercise 3-5 days/week, at 60-90% of maximum heart rate or 50-85% of maximum oxygen uptake; duration of training of 20-60 min per session and moderate-intensity resistance training (one set of 8-12 exercises at least twice per week). They concede that to improve health and reduce chronic disease risk such as cardiovascular disease, rather than simply increase physical fitness, exercise parameters should differ and may be achieved at lower intensities (Haskell, 1994). In accordance the World Health Organisation (WHO) physical activity guidelines propose exercise parameters to confer health benefits and offer a good starting point for an untrained individual or an untrained population. These guidelines state that to confer health benefits adults (18-65 years) should engage in a minimum of 150-300 minutes of moderate-intensity aerobic physical activity or a minimum of 75-150 minutes of vigorous-intensity aerobic physical activity per week and for additional health benefits

adults should engage in muscle strengthening activities at a moderate or greater intensity and which involve all the major muscle groups (WHO, 2020). These recommendations are based on the premise that they improve health, not physical fitness, which was an underlying objective of this PhD. Moreover, for certain populations, such as older adults or populations with chronic health conditions, who are unable to meet the recommended weekly dose of 150 minutes of exercise, it has been shown that benefits can still be derived from 15 minutes of daily exercise, which confirms the adage that some is better than none (Hupin et al., 2015).

Sport is a subset of exercise, and regardless of the frequency and intensity, the positive benefits from sports participation are manifold (Malm et al., 2019). The benefits derived from enhanced physical activity participation through sport include direct physical health benefits as well as the mental health and psychosocial benefits derived from group or team-based sports participation. Furthermore, benefits such as the development of leadership skills and the ability to set goals, which extend to wider life have also been cited (Malm et al., 2019).

Despite the benefits, adherence to physical activity guidelines is low and globally physical inactivity levels are rising, with reports that thirty-one percent of adults are not meeting WHO-recommended physical activity levels and women are less active than men (WHO, 2024). In Ireland, a mere 35% of people are physically active for at least five days per week and an even lower rate is reported for Northern Ireland at 28% (Sheehan and O'Sullivan, 2023). Looking more closely at populations of interest, Abrantes et al (2011) reported that 71% of people with SUD were not engaged in regular exercise and were completing less than 20 minutes of moderate-intensity aerobic exercise three times per week (Abrantes et al., 2011). People experiencing homelessness and addiction challenges who are known to lead chaotic lifestyles

(Hovhannisyanyan et al., 2018, O'Carroll and Wainwright, 2019), have poor health literacy (Degan et al., 2019) and engage poorly with healthcare services (O'Carroll and Wainwright, 2019, Dawes et al., 2017) are less likely than the general population to engage in health promoting physical activity interventions on a regular basis. What is noteworthy, however, is that the greatest health benefits, from increasing physical activity participation to a level of moderate intensity, appear to occur in the least active or most sedentary populations (Haskell, 1994).

A volume of evidence points to exercise prescription for maximal effects (Lee et al., 2022, Lacio et al., 2021). Peterson et al (2005) investigated dose-response for muscular strength development in three distinct populations, which included a population of untrained individuals (Peterson et al., 2005). In this group of untrained individuals, maximal strength gains are reported to be induced at 60% of one repetition maximum (1RM), three days per week and with a mean training volume of four sets per muscle group. Untrained and sedentary individuals, however, may not aspire to achieve maximal effects and low dose training parameters may be more suitable and are proposed as a pragmatic fit for the population under investigation in this research study. One could argue that the immediate short-term benefits of exercise participation such as enhancing mood and stress reduction (Peluso and Guerra de Andrade, 2005, Mikkelsen et al., 2017) are in fact critical to achieve in this population in order to facilitate medium to long-term investment in exercise to achieve and maintain the desired physical health benefits.

Regarding low-dose resistance exercise prescription, Behm et al (2024) investigated the minimal amount of resistance training required to improve physical fitness for those not meeting recommended strength training dosages (Behm et al.,

2024). This pragmatic question was answered through a narrative review which demonstrated that at least once-weekly resistance training using multi-joint exercises for at least 8-12 weeks, with at least one set of 6-15 repetitions, using loads between 30% and 80% of one-repetition max (1RM), is sufficient to produce a strengthening effect (Behm et al., 2024). This minimal dose presented a perceived achievable marker for a population who are untrained, under-resourced and have poor health literacy.

1.6.2 The role of nutritional supplementation with exercise to target physical function and frailty

Protein supplementation has been proposed following exercise to enhance muscle protein synthesis and has proven effectiveness to reverse or delay frailty in older people (Travers et al., 2019, Travers et al., 2023, Jäger et al., 2017, van Loon, 2013). Regarding the timing and amount of protein intake with exercise the evidence is mixed. What is known is that an acute exercise stimulus (particularly resistance exercise training or RET) and protein ingestion, before or after the exercise, stimulates muscle protein synthesis (Reidy and Rasmussen, 2016, Jäger et al., 2017, Morton et al., 2018). Ingestion of 20g-40g protein is recommended during and/or immediately after exercise to maximize post-exercise muscle protein synthesis rates and Jager et al (2017) posit that the effects are likely to diminish with increasing time following exercise (Jäger et al., 2017, van Loon, 2013). Reidy et al (2016), claim that the total intake of protein per day is more important than protein timing or quality but for populations with poor diet and with limited energy or protein intake, such as people who are homeless, the amount, quality and distribution pattern of protein intake may be important in enhancing muscle growth and function in response to RET (Reidy and Rasmussen, 2016). A further consideration for a population who experience food

poverty, who do not prioritise their health and experience health literacy, is to offer a protein supplement which is palatable and easily consumed.

1.6.3 Existing evidence regarding physical activity and exercise

1.6.3.1 Evidence from exercise studies in people experiencing homelessness

A recent systematic review of mixed-methods studies looked specifically at the evidence for physical activity interventions for people experiencing homelessness (Dawes et al., 2024). Dawes et al (2024) derived data from 17 studies (11 qualitative and 6 quantitative) and 554 participants and identified participation in a range of physical activity interventions which led to improvements in physical and mental health, and wider life (Dawes et al., 2024). Of note only 1 study was a randomised controlled trial which may speak to the challenges of conducting such research with this 'hard-to-reach' population. Soccer was the most common intervention (n=7) and group interventions (n= 15 including soccer) predominated, pointing to the potential draw of sport and socially connecting interventions. Results demonstrated a range of positive physical health outcomes including improved bone health and blood markers, enhanced fitness, posture and physical skills development, as well as increased physical activity levels. In terms of mental health, evidence points to improvements in confidence, mood, self-esteem, independence, resilience and empowerment and reduced stress and anxiety. Beyond this, impact was observed in the social domain with reported enhanced relationships through the social connectivity of the group and also the reported positive impact on substance use. For populations with poor health literacy and who experience social exclusion, thus have more limited opportunities to engage in physical activity, leading to sedentary behaviour and lower physical functioning, sport and group-based participation present a potential pathway to facilitating enhanced health behaviours and improving health and quality of life.

However, many of the interventions in this systematic review targeted a population who required a degree of physical fitness sufficient to enable successful participation in moderate to vigorous intensity exercise such as a running and soccer interventions and these studies did not target low physical functioning or frailty outcomes. A gap was identified for the evaluation of lower intensity exercise interventions targeting the more commonly encountered sedentary population who experience homelessness.

1.6.3.1.1 Mixed gender and men's only studies

In the aforementioned systematic review of physical activity interventions in people experiencing homelessness, Dawes et al (2024) identified mixed gender studies, men's only studies and women's only. A small number of additional studies have been delivered since this systematic review and all of these studies are outlined in Table 1.3, 1.4 and Table 1.5 which summarise the study design, physical activity intervention and main findings in each category and illuminate their differences. Two thirds of these studies were qualitative and notably the quantitative studies (n=7) had small sample sizes (ranging from 15 to 82 participants), which is unsurprising in this population. All but two of the men's studies were soccer-based, with one cycling study and the other a multi-modal physical therapy intervention. The mixed and women's-only studies had a more diverse range of interventions, some of which demanded higher intensity activity and energy expenditure such as soccer - which predominated in the men's studies - in contrast to a lower level of intensity required from activities such as gardening.

1.6.3.1.2 Women's-only studies

A number of studies which have explored physical activity interventions in homeless populations are gendered and to date six studies (seven reports) have been identified which were specifically for women only (Grabbe et al., 2013, Shors et al., 2014, Randers et al., 2018, Dawes et al., 2019, Norton et al., 2020, Miller et al., 2025)

[see Table 1.5]. These interventions involving 158 women (82 of whom were in one study; with a reported available age range of 18-63 years) were group-based and involved gardening (Grabbe et al., 2013); meditation followed by walking and dance (Shors et al., 2014); soccer (Randers et al., 2018); running (Dawes et al., 2019); archery, geocaching, rock climbing and hiking (Norton et al., 2020) and indoor physical activity (Miller et al., 2025). Physical health outcomes included improved aerobic fitness (oxygen consumption) (Shors et al., 2014), increased heart rate and moderate perceived exertion (Randers et al., 2018). Mental health outcomes included reported reduction in depression and anxiety (Shors et al., 2014), a reduction in stress and positive perceptions of empowerment and escapism (Grabbe et al., 2013, Miller et al., 2025). Further improvements in mental health and wellbeing were also demonstrated by a reported sense of belonging and renewed sense of self as well as perceptions of inclusion derived from the cohesion of the group (Grabbe et al., 2013).

The importance of the group was also affirmed by Dawes et al (2019) (Dawes et al., 2019). Interestingly, those who attended more frequently were seen to demonstrate larger improvements (Norton et al., 2020). This abundance of qualitative data, which is supportive of the quantitative findings, provides rich insight into tailoring interventions to the needs of this population

Table 1.3 Mixed-gender physical activity intervention studies in people experiencing homelessness

Study Title	Author & Year	Study Design	Physical Activity Intervention	Relevant results
“It Gives Me Purpose”: The Use of Dance with People Experiencing Homelessness.”	(Knestaut et al., 2010)	Qualitative (n=11)	Dance (group-based)	Improvement in psychosocial impact of homelessness.
“A kick in the right direction: longitudinal outcomes of the Australian Community Street Soccer Program.”	(Sherry and Strybosch, 2012)	Qualitative (n=165 players, 11 coaches, 10 support workers)	Soccer (group-based)	Improvement in social capital and strengthening of social inclusion.
“Street Soccer USA Cup: Preliminary Findings of a Sport-for-Homeless Intervention.”	(Peachey et al., 2013)	Qualitative (focus groups) (n=17)	Soccer (Street soccer USA Group-based)	Positive perceived impact on wellbeing and personal development
“Evaluation of a Shelter-Based Diet and Physical Activity Intervention for Homeless Adults.”	(Kendzor et al., 2017)	RCT (n=32)	Pedometer, educational newsletter, fruit & veg snacks	Increased accelerometer-measured physical activity.
“A theory-based evaluation of an intervention to promote positive health behaviours and reduce social isolation in people experiencing homelessness.”	(Malden et al., 2019)	Qualitative (interviews) (n=10)	Indoor multi-modal group-based exercise	Improvement in health and wellbeing.

“Improving outcomes in young people experiencing homelessness with My Strengths Training for Life™ (MST4Life™): A qualitative realist evaluation.”	(Parry et al., 2021a)	Qualitative (n=30)	Group-based outdoor activities such as canoeing, hiking, high ropes & raft building.	Psychosocial health benefits.
“Promoting Personal Growth in Young People Experiencing Homelessness Through an Outdoors-Based Program.”	(Parry et al., 2021b)	Qualitative (n=54)	Outdoor Adventure Education-based group programme	Improvements observed in personal growth and wellbeing benefits.
“Physical therapy interventions in people experiencing homelessness to improve pain and self-perceived health.”	(Jiménez-Sánchez et al., 2024)	Pre-post intervention Study (n=64)	Indoor multi-modal exercise therapy with health education and physiotherapy	Improvement in pain and self-perceived health.

Table 1.4 Men's-only physical activity intervention studies in people experiencing homelessness

Study Title	Author & Year	Study Design	Physical Activity Intervention	Relevant results
Positive performance and health effects of a football training program over 12 weeks can be maintained over a 1-year period with reduced training frequency.”	(Randers et al., 2010)	Non-RCT (n=15)	Soccer (group training)	Improvements in cardiovascular fitness.
(Re)engaging marginalized groups through sport: The Homeless World Cup.”	(Sherry, 2010b)	Qualitative (n=8)	Soccer (group training)	Improvements in social inclusion and social connectedness and wellbeing.
“Football’s coming home: A critical evaluation of the Homeless World Cup as an intervention to combat social exclusion.”	(Magee and Jeanes, 2011)	Qualitative (interviews) (n=6)	Soccer (group training)	Limited and short term social and psychological benefits which highlighted the need for more sustainable interventions and support beyond the intervention.

<p>“Short-term street soccer improves fitness and cardiovascular health status of homeless men.”</p>	<p>(Randers et al., 2012)</p>	<p>Quasi-experimental (non-RCT) (n=32)</p>	<p>Soccer (group)</p>	<p>Improved physical fitness markers (VO2 max ↓, cycle test performance improved, fat percentage and LDL ↑)</p>
<p>“Street football is a feasible health-enhancing activity for homeless men: Biochemical bone marker profile and balance improved.”</p>	<p>(Helge et al., 2014)</p>	<p>Quasi-experimental -non-randomised intervention (n=32)</p>	<p>Soccer (group)</p>	<p>Musculoskeletal health benefits demonstrated, including improved postural control.</p>
<p>“Perspectives on an earn-a-bike intervention on transportation, health and self-esteem among men experiencing homelessness.”</p>	<p>(Grimes and Smirnova, 2020)</p>	<p>Qualitative (interviews) (n=16)</p>	<p>Provision of bike and cycle safely training</p>	<p>Improvements in health and social and psychological domains.</p>

Table 1.5 Women's-only physical activity intervention studies in people experiencing homelessness

Study Title	Author & Year	Study Design	Physical Activity Intervention	Relevant results
“Gardening for the mental well-being of homeless women.”	(Grabbe et al., 2013)	Qualitative (interviews) (n=8)	Gardening (group based)	Gardening demonstrated a positive impact on mental health.
“Mental and Physical (MAP) Training: a neurogenesis-inspired intervention that enhances health in humans.”	(Shors et al., 2014)	Quasi-experimental (intervention study) (n=8)	Combined meditation training and aerobic training (group based)	Improved mental (anxiety and depression) and physical health outcomes (aerobic fitness through enhanced O2 consumption).
“Heart rate and movement pattern in street soccer for homeless women.”	(Randers et al., 2018)	Analytical cross-sectional (intervention study) (n=15)	Street soccer (tournament participation-Homeless World Cup)	Street soccer for homeless women elicits high HR and a movement pattern comparable and for some parameters even higher than street soccer and recreational football for homeless and untrained men.
“ “A Mile in Her Shoes”: A qualitative exploration of the perceived benefits of volunteer led running groups for homeless women.”	(Dawes et al., 2019)	Qualitative (interviews) (n=11)	Outdoor running (group based)	Positive impact on physical and mental health and importance of social support of the group.
“Utilizing outdoor adventure therapy to increase hope and well-	(Norton et al., 2020)	Quasi-experimental (non-equivalent	Outdoor adventures (group based)	Improvements in social and interpersonal well-being.

being among women at a homeless shelter.”		groups longitudinal design) (n=32)		
“Empower: An exploratory study of physical activity educational programming for women experiencing homelessness.”	(Miller et al., 2025).	Qualitative exploratory study (n=27)	Indoor group exercise education & focus group	Improvement in perceptions of health status and mental health.

1.6.3.2 Evidence from exercise studies in substance use disorder

In relation to exercise and its impact on substance use, there is a growing body of evidence. While primary treatments to manage SUD are pharmacological and psychological, interventions such as exercise may be beneficial and have been proposed as an adjunctive, low cost, safe and accessible therapy (Linke and Ussher, 2015, Ye and Liu, 2023, Smith and Lynch, 2012, Wang et al., 2014). Much of the research on exercise in substance use disorder (SUD) has focused on substance use-related outcomes (abstinence, reduced cravings and rate of relapse) and a range of mental health outcomes (stress, anxiety, depression, mood) (Wang et al., 2014, Colledge et al., 2018). Regarding health outcomes, the evidence base has demonstrated the positive impact of exercise through reduced cravings and increased abstinence, enhanced mood, reduced anxiety and depression and in some studies improved cardiorespiratory markers, physical activity levels and strength (Giesen et al., 2015, Wang et al., 2014, Linke and Ussher, 2015).

In summary, despite the known poor physical health of people who experience homelessness and addiction issues (Kiernan et al., 2021, Broderick et al., 2021, Kennedy et al., 2024) there is a dearth of evidence on exercise targeting physical functioning deficits and frailty in this population (Ye and Liu, 2023, Colledge et al., 2018, Giesen et al., 2015, Dawes et al., 2024).

1.6.3.3 Evidence from participation in sport

Sport is well recognised for its ability to unite and include, build social connections and resilience and these attributes have been fostered through the establishment and

continued success of the Homeless World Cup (Sherry, 2010a, Magee and Jeanes, 2011, Peachey et al., 2013). This tournament organised by the Homeless World Cup Foundation, and with its 70 member countries, has taken place all over the world, with this year's 20th anniversary tournament taking place in Oslo, Norway. Its purpose is to use the shared language of football to 'support and inspire people who are homeless to change their own lives' and also to 'change perceptions and attitudes towards people who are experiencing homelessness' (Homeless World Cup Foundation, 2025). Figure 1.8 highlights its positive and transformative impact. It must be noted that the threshold requirement for soccer as a physical activity intervention is high requiring a moderate to high level of physical fitness and may therefore exclude those with lower levels of physical function, frailty and disability.



(Homeless World Cup Foundation, 2025)

Figure 1.8 Impact of the annual Homeless World Cup tournament

The effects of exercise and nutritional supplementation to target physical health and frailty in people experiencing homelessness and addiction issues has been recently explored in a linked study, the LEAP-I trial (Kennedy et al., 2024). While feasibility of a once-weekly exercise intervention with protein supplementation was demonstrated, pre-post intervention change was not demonstrated and recommendations for an

optimised intervention with additional exercise opportunities to enhance engagement, retention and physical function and frailty outcomes were made (Kennedy et al., 2024). The holistic impact of an enhanced exercise intervention of low-moderate intensity delivered to a non-geriatric population with similar characteristics to this population of interest is not yet known.

1.6.4 Considerations for Inclusion Health interventions

This penultimate section will discuss the perceived nuances of delivering health interventions for this unique population. Upon reflection of the evidence base and in advance of study design, certain factors and considerations to the delivery of safe and effective exercise interventions to this population were deemed important:

- Delivery of interventions with an inclusion health and trauma informed lens to align with the ethos of social inclusion and health equity. In consideration of trauma and exercise specifically, evidence has shown that the stress-response activation system is regulated by patterned, repetitive and rhythmic movement, the basis of exercise and sport in general, and particularly in the simple action of walking (Mullane, 2019). It has been found that it is especially regulating to walk in nature (Berman et al., 2012, Grassini, 2022).
- Consideration of the characteristics of the population under investigation and their ability to engage and participate; characteristics attained from exposure to severe and multiple disadvantage (Lankelly Chase, 2024). For example, acute or chronic medical conditions, mental health difficulties such as anxiety and chronic depression, fluctuating motivation levels, chaotic living and sleep issues due to insecure accommodation, lack of or loss of mobile phone, active addiction issues and poor health literacy.

- Consideration of the impact of substance use on exercise participation which may be varied and unpredictable.
- Consideration of the FITT principle or the exercise intervention components. Physical activity interventions to date delivered to people experiencing homelessness specifically appears to be moderate-high intensity, aerobic and mixed (Dawes et al., 2024), while the majority of the evidence in substance use disorders recommends aerobic exercise, with emerging evidence of strength training (Wang et al., 2014, Colledge et al., 2018). There is limited evidence of for light to moderate exercise intensity (Abrantes et al., 2011), and evidence is lacking on the frequency and duration of an exercise session in this population.
- Consideration of the likelihood of study attrition. In clinical trials for SUD, recruitment and retention challenges were commonly reported (Lappan et al., 2020, Northrup et al., 2017). Study attrition is anticipated in exercise trials for people experiencing homelessness, addiction and mental health issues and may be compounded by the presence of poor physical functioning and low physical activity levels (Kiernan et al., 2021, Abrantes et al., 2011, Marmot and Bell, 2012). Moreover, in a linked study, the LEAP-I trial experienced recruitment challenges and low retention in certain subgroups such as those with unstable addiction and insecure accommodation (Kennedy et al., 2024). Participant preference and choice have been cited as strategies to increase enjoyment, participation, and adherence in exercise trials involving people with substance use disorder (Abrantes et al., 2011, Abrantes and Blevins, 2019, Weinstock et al., 2017). This may have a positive ripple effect on accessible interventions.

1.7 Rationale for PhD

Homelessness is escalating and its impact is pervasive. Further research is critical to unravel many unanswered questions to resolving this public health crisis. While people experiencing homelessness, particularly women, are a relatively under-researched population, evidence of the physical health burden and its negative impact in this group is very apparent. There remains a paucity of research on physical activity or exercise interventions in people experiencing homelessness who have a significant physical health burden and who demonstrate concerning levels of low physical functioning, premature ageing and frailty—a construct traditionally researched in the general older adult population. Given the “early manifestation of non-communicable diseases and poor general physical health” and the prevalence of frailty in this population, “specifically focused lower threshold physical activity interventions should be considered” in order to enhance health outcomes in this population (Dawes et al., 2024). Furthermore, little is known of appropriate outcomes measures to assess and monitor physical function and frailty outcomes in this non-geriatric population in the community setting. To the authors knowledge, no published research intervention, beyond the work of LEAP-I (a preliminary low-frequency, low-threshold exercise intervention with protein supplementation) which preceded and inspired this PhD (Kennedy et al., 2024), has specifically investigated the impact of a more intense intervention involving exercise with nutritional supplementation to target physical functioning deficits and frailty in this population. The frequency of the LEAP-I trial was viewed as inadequate to effect changes in physical function and frailty outcomes and an enhanced programme was proposed (Kennedy et al., 2024).

1.8 Research question, study aims and objectives

1.8.1 Research question

The complexity of categorising the population under investigation in this PhD needs to be recognised. As homelessness rarely occurs in isolation and is usually accompanied by a number of social disadvantages, including addiction and mental health challenges, consensus was reached that in order to be fully inclusive in each study and also comprehensively and accurately describe the population under investigation, the population would be described as people with severe and multiple disadvantage (SMD) (Lankelly Chase, 2024), and the primary research question for this PhD was:

“Is a frequently delivered targeted exercise with nutritional supplementation intervention in a non-geriatric cohort of people experiencing severe and multiple disadvantage, feasible and what is its impact”?

1.8.2 Study aims

The overarching aim of this PhD was to build upon the findings of the LEAP-I trial and explore the feasibility and holistic impact of an enhanced, low-threshold, multi-modal exercise intervention with protein supplementation delivered to a non-geriatric cohort of people with severe and multiple disadvantage (Lankelly Chase, 2024). The secondary aim was to evaluate whether a gender-specific, women’s-only intervention enhanced retention/adherence and impact for women.

1.8.3 Objectives

The objectives were:

To investigate the differences in feasibility and impact of the programme between mixed-gender and women only groups, by evaluating and comparing:

- (i)
 - recruitment and retention rates,
 - adherence to a) the exercise and b) the nutritional supplementation,
 - safety of the interventions,
 - acceptability of the interventions,
 - challenges associated with the interventions,
 - programme effectiveness through objective assessment of pre- and post-intervention changes in physical function and frailty outcomes,
 - perspectives of study participants and key stakeholders, of their health and their unmet physical health needs, of their challenges with engaging in healthcare interventions and the
 - impact of the targeted exercise intervention on their overall health and wellbeing.
- (ii) the utility of the previously defined broad test battery for this community-based population.
- (iii) The prevalence of pre-frailty and frailty, and its drivers, and the agreement and points of divergence between two frailty tools utilised in these studies.

Chapter 2 STUDY DESIGN AND DEVELOPMENT OF STUDY METHODOLOGY

2.1 Introduction

This chapter will provide (i) an overview of the study design of the LEAP interventions which evolved from the overarching research question, and study aims and objectives discussed in Chapter 1, and (ii) an in-depth development of the methodologies of the studies in this PhD, which shared important features (see Table 2.1). Important study design features, such as the setting and the unique low threshold approach, which contributed to successful implementation of each intervention will also be discussed. The homogeneity of study outcomes, tools and the intervention framework will then be more extensively described and justified. This chapter will conclude with a summary analysis plan.

Table 2.1 Overview of Chapter 2

2.1 Introduction
2.2 Evolution of the LEAP studies
2.3 Design
2.4 The unique approach of the LEAP studies
2.5 Setting
2.6 Sampling method and sample size
2.7 Primary outcome of LEAP-II and LEAP-W
2.8 Secondary outcomes of LEAP-II and LEAP-W
2.9 Exercise screening tool used in this thesis
2.10 Safety monitoring in the intervention
2.11 The LEAP Interventions
2.12 Analysis Plan

2.2 Evolution of the LEAP studies

The LEAP acronym stands for the *Low Threshold Exercise And Protein* supplementation interventions. These were delivered, as experimental interventions, to a population who experienced severe and multiple disadvantage (SMD), defined as

people who have experienced serious and complex social disadvantages, including homelessness, addiction, mental health challenges and incarceration (Lankelly Chase, 2024) (see Chapter 1, section 1.2.1.1).

The studies described in this PhD evolved from the LEAP-I trial, which was a preliminary feasibility study, conducted prior to this PhD (Kennedy et al., 2024). LEAP-I was conducted to ascertain how a low threshold, flexible, exercise intervention, which deviated from the traditional and rigid structure and timing of standard and routine exercise interventions and included protein supplementation, would work in a real-world setting for people experiencing homelessness and addiction. The results of LEAP-I demonstrated proof of concept, based on the feasibility markers utilised, where high retention was observed in subgroups (older people and women), and safety and acceptability of the intervention was demonstrated. However, as no changes in physical function and frailty outcomes were observed and participant perspectives about the programme were not collected, the requirement for future studies to further explore the LEAP approach was evident.

The knowledge gained from LEAP-I inspired and informed the design of the LEAP-II trial. Following LEAP-II, a women's only LEAP intervention, LEAP-W, was designed and conducted in a sub-population of women. The overarching features of the LEAP trials are outlined below and presented in Table 2.2.

- **LEAP-I** was a once weekly exercise intervention with protein supplementation, which took place in 2022, prior to this PhD.
- **LEAP-II**, the focus of this chapter was the optimisation of the LEAP-I study and consisted of a three-times per week exercise intervention with protein

supplementation, which took place in from October 2022 to March 2023. Exit surveys followed the intervention.

- **LEAP-W**, also described in this chapter which followed LEAP-II, was a further derivation of LEAP-I and was a three-times per week exercise intervention with protein supplementation, delivered for women only and thus, had a gendered focus. It took place from February 2024-July 2024. Exit interviews followed the intervention.

Table 2.2 Distinguishing features of the LEAP trials

	Year /study duration	Setting	Exercise class Frequency/ type	Protein Supplementation	Park Walk	Exit Survey	Exit Interview
LEAP-I	2022 16 weeks	Open access centre for PEH* and addiction, mixed gender	Once weekly Multi-modal**	<input checked="" type="checkbox"/>	X		
LEAP-II	2022/2023 12 weeks	Centre for people with chronic addiction issues and homelessness, mixed gender	Twice weekly on 2 days Multi-modal**	<input checked="" type="checkbox"/>	Once weekly on 1 day	<input checked="" type="checkbox"/>	
LEAP-W	2024 10 weeks	Centre for PEH and addiction, women only	Twice weekly on 4 days Multi-modal** Women's health exercises^	<input checked="" type="checkbox"/>	Once weekly on 4 days		<input checked="" type="checkbox"/>

*PEH=people experiencing homelessness **= primarily aerobic and strength-based exercises, ^=core stability and pelvic floor exercises

All of the LEAP trials were feasibility studies. A feasibility study is ‘a piece of research done before a main study in order to answer the question “Can this study be done?”. They are used to estimate important parameters that are needed to design the main study. (Eldridge et al., 2016).

A pilot study is a smaller version of a main study, used to test whether parts of the main study will work and is recognised as a subset of a feasibility study. It must be noted that the LEAP trials were feasibility studies, not pilot studies and were designed to examine feasibility parameters, with a view to optimising design features to employ a future powered randomised controlled study to extensively evaluate effectiveness.

Feasibility parameters evaluated in the LEAP trials were:

- (i) the number of eligible participants and the willingness of participants to enrol (recruitment),
- (ii) the follow-up rates (retention),
- (iii) adherence/compliance (to the exercise and protein supplement),
- (iv) the characteristics of the outcome measures and their suitability for the population of interest and
- (v) safety
- (vi) acceptability of the intervention.

Based on the outcomes of the LEAP-I trial, the LEAP trials in this PhD employed quantitative and qualitative methods in order to more comprehensively understand the perspectives of the participants and stakeholders and to more holistically inform the potential value and design of future studies. Quantitative research is a method of collecting numerical data from a sample of the population to describe

characteristics of the population, find correlations and evaluate effectiveness of an intervention (Watson, 2015). Quantitative methods were utilised to evaluate feasibility and pre-post intervention change in each study. Qualitative research, a form of social inquiry, focuses on the interpretation of the experiences of a population in the context of the world in which they live (Ahmad et al., 2019) and this methodology was utilised to explore perspectives of participants and stakeholders following the (LEAP-W) intervention.

2.3 Design

2.3.1 LEAP-II Design

Due to the nascency of this research topic, LEAP-II took the form of a single-arm feasibility study with a pre-post intervention evaluation design to explore the feasibility and impact of an optimised and targeted exercise intervention in people with SMD (Lankelly Chase, 2024).

A randomised controlled trial (RCT) is the gold standard and most common trial design for measuring effectiveness of an intervention or treatment (Hariton and Locascio, 2018). With successful randomization of participants, pre-post intervention changes detected may be accredited to the study intervention (Hariton and Locascio, 2018). Cognisant of this study standard, further consideration was made to a) the scope of this research in terms of cost, resources and anticipated sample size, and b) the opportunistic nature of the study for the population of interest who were willing to engage and participate at the programme commencement date, but were unlikely to act as a control group or a cross-over group and wait for a period of time before engaging in the intervention. In accordance with this sentiment, Chapter 1 alludes to a

systematic review of physical activity interventions in people experiencing homelessness, which identified only one study (5%) that took the form of a RCT (Dawes et al., 2024). This speaks to the challenges of undertaking this type of research design with this population, who are often described as 'hard-to-reach'. Nonetheless findings in smaller uncontrolled studies provide important insights for future research especially in under-studied populations. Therefore, for the purpose of this PhD, a pragmatic decision was made to utilise a non-randomised, pre-post intervention study design and conduct a prospective study, which would include all eligible and interested participants. Accordingly, changes detected in outcomes before and after the intervention cannot be fully attributed to the intervention. LEAP-II also utilised an exit survey to collect data from the study participants following the intervention. Further detail of the distinctive features of LEAP-II including the exit survey will be discussed in Chapter 3.

2.3.2 LEAP-W Design

LEAP-W utilised quantitative and qualitative components.

to more comprehensively answer the overarching research question of the impact of targeted exercise in this population of interest - women who experience homelessness, addiction and mental health challenges. The author felt that this form of triangulation would provide completeness and would address a range of questions which were not deemed possible to answer by quantitative methods alone. For example, what was the impact of the intervention beyond physical health? How did the study's impact translate to the health and wellbeing status of participants and what were the wider life implications of this, if any? What were the challenges of the intervention and how could these be addressed in future studies?

LEAP-W had two main aims:

(a) firstly, to evaluate the feasibility and pre-post intervention effect of a targeted exercise intervention in a real-world setting and

(b) secondly to assess the implementation effect. In this way implementation barriers and facilitators could be identified, and outcomes of feasibility, acceptability, and sustainability of targeted interventions such as the LEAP trials could be more rigorously evaluated than by quantitative methods alone (Palinkas et al., 2019).

Resultantly, LEAP-W had two separate and sequential components: (i) a quantitative study and (ii) a qualitative inquiry, where data was collected and analysed sequentially to provide:

- 1) depth and further exploration and explanation of the quantitative findings in this setting,
- 2) to examine the extent to which the qualitative data supported and validated the quantitative results and
- 3) to explore further factors in the qualitative data, which were not addressed by the quantitative method (such as the mental health benefits, social benefits, extension to real world, retention issues, the approach used)

2.3.2.1 Rigour

To ensure rigour of the qualitative process in LEAP-W the following criteria were adhered to:

Credibility: This criterion is essential to the trustworthiness of research. This was firstly demonstrated by (i) in-depth planning, (ii) a clear exposition of the research topic, question, aims and objectives, (iii) the application of robust procedures to the data

collection and analysis stages, (iv) purpose sampling to ensure the attainment of extensive knowledge from participants to the point of data saturation, (v) the use of triangulation with multiple sources of data from study participant and stakeholder views, (vi) informed consent ensuring participation was voluntary, (vii) regular debriefing with supervisor, (viii) the practice of reflexivity, (ix) audio-recording and verbatim transcribing of interview data and use of external validator to validate codes, themes and subthemes and finally (x) validating respondents data through member checking.

Dependability: This refers to the study's reliability and reproducibility, which was achieved by the audit trail described in this chapter and subsequent chapters (Chapter 4 and Chapter 5) demonstrating that the results of LEAP-W represent the entire data set.

Confirmability: This criterion was met by the researcher's recognition of her own influence and bias on the research process. The researcher had prior experience of working with this population and conducting qualitative research. Reflexivity was utilised throughout the data collection and analysis stages, and field notes captured the researchers' thoughts and feelings following interviews in an effort to maintain neutrality throughout each interview and the interpretation of the data. Peer debriefing with the Principal Investigator/PhD supervisor also supported the reflexive process.

Transferability: In relation to the applicability of the findings of LEAP-W, this was firstly demonstrated by a thick description of the research phenomenon, the setting in which the LEAP-W study took place and the population of interest-women who had SMD, women who experienced homelessness, addiction and mental health challenges

(Lankelly Chase, 2024). Purposive sampling ensured the data represented the views of the women who attended Jane's Place and key stakeholders involved in the provision of care to women who attend Jane's Place, MQI, the setting where LEAP-W took place.

2.3.3 Public Patient Involvement

Public Patient Involvement (PPI) was utilised in the LEAP trials to provide meaningful involvement of potential participants to shape the design of the interventions in this under-researched area- an area where existing evidence demonstrates a lack of engagement and participation of this population in healthcare practice and research, resulting in recruitment and retention challenges. It is considered imperative to use PPI especially when the target population is challenging to engage. Through this process of PPI and consultation, it was anticipated that a real world understanding of this complex phenomenon would be learned. It is known that PPI can enhance research and make a tangible impact if carefully conducted and participants are acknowledged and valued for their contribution to the process (THIS, 2019). An informal stakeholder engagement session was held in-person in the Ballyfermot Advance centre prior to programme commencement with potential participants and key stakeholders, who included service users and people who worked in the centre, where they were invited to express their views of how the LEAP-II programme could meet their needs and wishes. Similarly, two sessions were held in Jane's Place. Based on learning from LEAP-II, these two sessions involved a brief interactive discussion with slides and visual information to provide general knowledge and practical advice regarding physical activity and nutrition, as well plans for the LEAP-W programme, which were subsequently informed by the participants. The aim of

these sessions was to enhance health literacy, to encourage participation and promote inclusion in order to maximise enrolment in the programme.

As a result of the PPI process, the interventions were participant centred and co-designed with consideration of lived experiences and preferences for exercise participation. Participants were thanked for their input and assured that post-programme feedback would be provided to acknowledge their valuable contribution to the research process.

2.4 The unique approach of the LEAP studies

Emanating from the comprehensive review of the literature pertaining to access and use of services for people experiencing homelessness, as delineated in Chapter 1, and confirmed by the PPI engagements prior to LEAP-II and LEAP-W, was the need to provide a unique person-centred intervention which followed the low threshold design of services which this population attend for their health and support services. In light of this, flexibility was embedded into programme design. The recruitment period was phased, with flexibility provided in the programme commencement and completion dates. Flexibility in the days and times of attendances, as well as flexibility within the exercise classes were incorporated into each LEAP intervention. These features will be further elaborated in each respective chapter.

2.5 Setting

The setting of the LEAP-II and W studies was central to the unique design of this PhD. A low threshold consideration to place minimal barriers on the population of interest was to meet people where they were at and provide them with an accessible programme by bringing it to them. Therefore, LEAP-II and LEAP-W were set in real-

world locations which were convenient and familiar, a place where this low resource population would frequent to access services and support for their day-to-day needs. The setting for LEAP-II was a drop-in day service centre, The Advance Ballyfermot Project, in Dublin 10, a centre for people with chronic addiction issues. The setting for LEAP-W was also drop-in day centre called 'Jane's Place', situated in Dublin 2, a bespoke women's only service in the city centre in close proximity of homeless accommodation centres, for women who experience homelessness, addiction and mental health challenges. Further detail on the setting of each study is provided in each respective chapter.

2.6 Sampling method and sample size

2.6.1 Sampling method

LEAP-II employed a non-probability convenience-based sampling method where the sample was sourced from all the service users of the Ballyfermot Advance Project, day service centre. Participants were recruited through a gatekeeper in the centre. Gatekeepers provided potential participants with a Participant Information Leaflet (Appendix V) and flyers in plain English (Appendix V) were displayed in the centre.

Like LEAP-II, LEAP-W also employed a convenience-based sampling method, where the sample size was determined from all the service users of Jane's Place, day service centre. Participants were recruited through a gatekeeper in Jane's Place, Merchants Quay Ireland. Gatekeepers provided potential participants with a Participant Information Leaflet (Appendix VI) and flyers in plain English (Appendix VI) were displayed in the centre. A purposive sampling strategy was used for the LEAP-W qualitative inquiry. where participants who had taken part in the LEAP-W exercise intervention trial, were selected. In this way they were able to discuss the impact of the

intervention and its challenges, based on their lived experience and depth of understanding and to provide rich data on the phenomenon of interest. Stakeholders from MQI were also included in the qualitative inquiry.

Further detail specific to each study will be provided in subsequent chapters.

2.6.2 Sample size

As this is a nascent field of research, sample size calculations were challenging. A sample size of at least 24 participants has been recommended for feasibility studies (Sim and Lewis, 2012, Julious, 2005). Due to the novelty of this study, the challenges of recruitment in a population who engage poorly with services, and the feasibility focus of this study, a minimum of 30 participants was sought for each study to allow for a drop-out rate of 20% in order to achieve a minimum of 24 participants.

2.7 Primary outcome of LEAP-II and LEAP-W

Considering the LEAP intervention trials have been the first exercise intervention of their kind to utilise an exercise intervention with nutritional supplementation to target physical function and frailty in this population, feasibility was the primary outcome for LEAP-II and LEAP-W.

As mentioned in the initial section, feasibility was measured by evaluating recruitment numbers, the retention rate, the adherence to the exercise programme and the protein supplement, the occurrence of adverse events, indicating safety of the intervention and the acceptability of the programme. See Table 2.3 for details.

Table 2.3 Feasibility LEAP-II and LEAP-W

Feasibility	Method of reporting
Recruitment Numbers	Number of eligible consenting participants who completed the initial assessment
Retention rate	Number of return visits and the frequency of attendance

Sub-group retention rate	<ul style="list-style-type: none"> - <i>regular attender: attended at least once/week for > 50% of the duration of the programme*</i>. - <i>sporadic attender: attended at least once/week for < 50% of the duration of the programme.</i> - <i>non-attender: did not return following initial assessment.</i> <ul style="list-style-type: none"> -Attendance by gender -Attendance by age
Adherence rate (exercise)	Number of sessions adhered to/number of sessions attended by participants
Adherence rate (protein supplement)	Percentage of participants who consumed the protein supplement drink
Adverse events or safety of the intervention	An unfavourable and unintended sign, symptom, or disease having been absent at baseline, or, if present at baseline, appears to worsen and is temporally associated with medical treatment or procedure, regardless of the attribution (Grimes et al., 2005).
Programme Acceptability	<p>LEAP-II: Participant feedback provided by Exit Survey: analysed by frequency of responses, observing patterns and themes in the data collected.</p> <p>LEAP-W: Participant and stakeholder perspectives provided in the qualitative interviews.</p>

***LEAP-II: 12 weeks duration, LEAP-W: 10 weeks duration**

2.8 Secondary Outcomes of LEAP-II and LEAP-W

The cornerstone of this PhD was targeting physical function and frailty in this defined population. These constructs will firstly be delineated by their definitions and methods of measurement, whereafter the rationale for the selection of specific physical function and frailty outcome measures for this research will be expounded.

2.8.1 Physical function

Physical function is a tangible construct closely related to health and defined as the performance of physical movements and activities and must be of adequate level to live independently (Painter et al., 1999). These activities include basic activities of daily living and higher-level instrumental activities of daily living, both requiring

different levels of physical functioning. An individual's physical functioning level thus determines their ability to perform social, vocational and recreational activities and is associated with quality of life. Determinants of physical functioning are manifold and include a range of physical, sensory, environmental and behavioural factors. Often referred to as the 'sixth vital sign' (Fritz and Lusardi, 2009), physical functioning is an indicator of health status (Dong et al., 2014), early signs of disability, future health and social care needs (Guralnik et al., 1996) and death risk (Brown et al., 2017, Penninx et al., 2000), elucidating the value of its measurement.

There is a close relationship between physical health and physical function (Ryan et al., 2018). Greater functional decline has been demonstrated in patients with poor physical health or multi-morbidity, with greater decline evident in those with a higher number of health conditions and greater disease severity (Ryan et al., 2015). Chronic poor health and multimorbidity is more prevalent in people with socioeconomic deprivation such as people experiencing homelessness (Barnett et al., 2012). Furthermore, a dose-response relationship has been identified between physical function and multimorbidity and, reduced gait speed and grip strength, measures of physical function, have been associated with the development of and exacerbation of existing multimorbidity in older adults (Ryan et al., 2018). Thus, where extreme health disparities exist the need for targeted interventions to improve physical function is warranted.

2.8.2 Frailty

Frailty is related to physical function but is more complex in nature, as evidenced by the absence of a singular definition for this construct. Expert consensus posits that frailty is a multi-dimensional state or clinical syndrome characterised by

cumulative decline and vulnerability to stressors, and adverse health outcomes (Morley et al., 2013). Pre-frailty is considered its prodromal stage (Sezgin et al., 2022).

Dimensions of frailty include physical, medical, cognitive, psychological and social.

Therefore, interventions to manage frailty should be multi-component or targeted to address the specific domains which are affected. Frailty is strongly associated with age (Morley et al., 2013). Nonetheless, evidence demonstrates that frailty is more closely related to biological age than chronological age (Romero-Ortuno and O'Shea, 2013), therefore, age alone should therefore not be used to allocate health and social care, and frailty screening is recommended to identify those at higher risk and in need of intervention. Considering chronic illness, multimorbidity and physical decline are all associated with people experiencing homelessness it is not surprising that accelerated ageing and frailty are also prevalent in this 'young' population (Kiernan et al., 2021, Salem et al., 2019, Salem et al., 2014, Rogans-Watson et al., 2020).

2.8.3 Measuring physical function and frailty

With the limited availability of healthcare resources globally screening for physical function deficits and frailty seems prudent to enable healthcare providers to prioritise care and inform future planning and resource use (Brown et al., 2015). Early prodromal symptoms may be detected, and appropriate timely physical rehabilitation and frailty interventions can be implemented early, thus, avoiding the more costly care of chronic disease, functional decline and frailty (Walston et al., 2018, Kiernan et al., 2020).

Measuring physical functioning can be complex, with the availability of a vast selection of self-report, performance-based and vigorous laboratory measures such as treadmill testing or strength testing (Painter et al., 1999). In clinical practice, measures

should be psychometrically sound, easy to administer and appropriate for the target population. Therefore, brief performance-based measures are useful, such as lower limb strength, balance, stair climbing and not least the widely used gait speed and grip strength (Bortone et al., 2021, Lee et al., 2017, Vaishya et al., 2024, Painter et al., 1999) measurements. While there is evidence of reliability of self-report assessments of physical function, their validity may be in question, and a dual trait measure may be prudent (Painter et al., 1999).

Similarly, a vast range of frailty instruments exist, useful for different purposes depending on the population and the setting (Martin and Brighton, 2008). Most instruments are based on the two dominant frailty paradigms, the Frailty Phenotype and the Frailty Index. The Frailty Phenotype, developed by Fried assumes a physical measurement of five physical markers; weight loss, exhaustion, grip strength, physical activity, and speed (Fried et al., 2001). Similarly, the SHARE-Frailty Instrument (SHARE-FI), designed more recently for use in Primary Care also measures these five constructs, but is more easily administered in practice (Romero-Ortuno et al., 2010). Phenotypical measures have a specific yet limited scope as they omit cognitive frailty and the psychosocial dimensions of frailty. The Frailty Index assumes a multi-dimensional view of the many domains of frailty, but in practice is more challenging to administer (Rockwood and Mitnitski, 2007). Rockwood's Clinical Frailty Scale (CFS), which has evolved over time and is now widely used due to its brevity and ease of use, yet it provides a multidimensional view of the frailty status of the patient beyond the physical domain (Rockwood et al., 2005).

As discussed in Chapter 1, physical functioning and frailty have been evaluated in hospitalised people experiencing homelessness (Broderick et al., 2021). However,

validated outcome measures for this population are lacking and therefore need to be carefully selected. Due to the prevalence of premature ageing (Brown et al., 2015), manifesting as falls, poor balance, frailty, and poor mobility (Brown et al., 2017, Brown et al., 2012), outcomes commonly used to assess people who are homeless are often extrapolated from the geriatric setting (Broderick et al., 2021, Kiernan et al., 2021). With a much lower mean age in people who experience homelessness (Aldridge et al., 2018), the usefulness of these measures is not fully known. Due to the high disease acuity in hospital-based settings, the application of measures used in these settings may differ in the community setting. Establishing the usefulness of a physical functioning and frailty test battery in community-based settings is important as people experiencing homelessness should have access to Primary Care services to meet their unmet healthcare needs before they consider hospital-based care (Thorndike et al., 2022).

2.8.4 The test battery for LEAP-II and LEAP-W

Secondary outcomes for this PhD were measured and monitored using a broad test battery based on the outlined descriptions of physical function and frailty. A core outcome set, to evaluate the constructs of physical function and frailty in people experiencing homelessness and enhance their relevance and applicability, is not currently available and no frailty instruments have been validated for younger adults under the age of 50 years who are at risk of premature ageing and frailty (Kiernan et al., 2020, Kirkham et al., 2016, Clarke, 2007). The bespoke test battery utilised for this PhD was devised from consensus of clinical and academic experts in physical functioning, frailty, and inclusion health. The merits of each tool were considered in terms of their clinical utility in evaluating aspects of physical function and frailty in a

real-world setting for this target population, their ease and brevity of administration, practical issues such as cost, equipment and space required and to ensure rigour in evaluation, their psychometric properties (validity and reliability). A further consideration was the use of combined self-report and performance-based measures. Self-report measures, shown to be associated with clinical outcomes, may provide information about specific characteristics of a population which impacts on function, which are not captured in a performance-based test, whereas an objective test-based measure may clarify if a patient has the capacity to perform an activity (Painter et al., 1999). Moreover, a number of the outcome measures were informed by the aforementioned preliminary research which evaluated physical functioning limitations and frailty in hospitalised people experiencing homelessness (Kiernan et al., 2021). The measures used in this hospital-based study were limb strength (handgrip dynamometry) and circumference, the Short Physical Performance Battery (SPPB) and the Clinical Frailty Scale (CFS).

However, in the LEAP-I trial, which followed the hospital-based study, a ceiling effect in the SPPB was demonstrated in participants with high levels of physical functioning (Kennedy et al., 2024). More challenging measures were considered appropriate for community settings and for the LEAP-II and LEAP-W trials, the SPPB was replaced by a number of appropriate measures: the Single Leg Stance Test (SLST) (Springer et al., 2007), the Chair Stand Test (CST) (Lein et al., 2022), the 10m-Walk Test (10mWT) (Bohannon, 1997), the 2-Minute Walk Test (2MWT) (Bohannon, 2017). These selected measures and the justification for their inclusion will be outlined in detail in the following section (2.8.5-2.8.11).

As pain was cited a common reason for non-completion of physical functioning tests in people experiencing homelessness (Kiernan et al., 2021), pain evaluation was included. Similarly, as nutritional status can influence physical functioning (Lin et al., 2012) and is a driver of frailty (Ni Lochlainn et al., 2021), the Mini-Nutritional Assessment (MNA) was included. The SHARE-FI was introduced as a rapid measure of physical frailty for use in community settings (Romero-Ortuno et al., 2010). Finally, the SF-12 was introduced as a quality-of-life measure to encompass a multi-dimensional view of health beyond the physical domain. The test battery is summarised in Table 2.4.

Table 2.4 Test Battery LEAP-II and LEAP-W

Construct Measured	Outcome Measure
1. Strength & Muscular mass	Grip strength Limb circumference
2. Physical performance & lower extremity function	10m Walk Test 2 Minute Walk Test Chair Stand Test Single Leg Stance Test
3. Pain	Numerical Pain Rating Scale
4. Frailty	Clinical Frailty Scale Share-FI
5. Nutritional status	Mini Nutritional Assessment
6. Self-rated Health/Quality of Life	SF-12

2.8.4.1 Merits of the outcome measures

The psychometric properties of each of the secondary outcomes used in this PhD were considered to determine their merit and suitability and will be discussed in this section. Reliability refers to how much the outcome measure or instrument in question controls for error and how credible the data collected is and it is based on the stability or test-retest reliability of the measure, the internal consistency, and the inter-rater reliability (Kimberlin and Winterstein, 2008). Validity refers to the degree to

which an instrument measures what it claims to measure, how well it measures it and how responsive the measure is to change over time. Clinically useful measures should be both valid and reliable (Kimberlin and Winterstein, 2008). The reliability and validity of measures are only applicable if they are used for the purposes they were designed, for example if they are used for the population they were designed for and therefore, modifications made to measures may require future validation (Kimberlin and Winterstein, 2008).

The practical utility of these measures was also deemed as critically important considering the population of interest, who are known to engage poorly with healthcare services. When conducting research with a hard-to-reach population, the respondent burden (time taken to administer the tests and the ease of administration) and the relevance of the measures to the participants needed strong consideration.

2.8.5 Measuring Strength and Muscular Mass

2.8.5.1 Grip strength

(i) Description

Hand grip strength (HGS) is a basic metric, commonly used to assess muscle function and is associated with frailty, sarcopenia, morbidity and all-cause mortality (Roberts et al., 2011, Leong et al., 2015, Syddall et al., 2003, Vaishya et al., 2024). It is a brief and easy to administer test-based measure which takes 1-2 minutes as a rest period is required between tests.

(ii) Psychometric properties

Not only does it mark upper limb strength, but HGS has been shown to correlate to knee extension, thereby it is reflective of overall limb muscle strength

(Bohannon, 2012). More recently, Jiang et al (2022) made a notable finding of an association between grip strength, brain structure and cognitive function (Jiang et al., 2022). Unsurprisingly, it had been proposed as a new vital sign of health. It can be easily and reliably measured using a digital hand dynamometer and the Jamar dynamometer utilised in this study is regarded as the gold standard device for research with proven reliability and validity in young and middle-aged adults (Hamilton et al., 1992, Trampisch et al., 2012).

(iii) Measurement and interpretation

There are different ways to measure HGS but what's important is consistency. Vargas-Pinilla et al (2021) determined that various positions including sitting and supine, with elbow flexed and extended, provided reliable results as long as standardisation was used (Vargas-Pinilla and Rodríguez-Grande, 2021). Based on this, dynamometry testing was conducted in a seated position with the shoulder adducted, the elbow positioned at 90° flexion, the forearm in the mid-prone position, the wrist supported in a neutral position and the hand free and unsupported. Each participant was instructed to obtain a comfortable grasp and to squeeze the dynamometer as hard as possible to achieve maximal grip strength (see Figure 2.1). The Jamar Hand Dynamometer offers five positions and position two was used as per recommendations (Trampisch et al., 2012). While three trials are recommended, in the interest of time, two trials were conducted for each limb with a rest period of at least one minute provided between trials. Grip strength was used as a solitary measure of limb strength but also as part of the frailty evaluation, as it formed one of five domains of the SHARE-Frailty Instrument measure, which will be discussed (Romero-Ortuno et al., 2010). Results measured in kg were compared to normative values (Steiber, 2016).



Figure 2.1 *Jamar Digital Dynamometer*

2.8.5.2 Limb circumference

(i) Description

Girth measurement, an easily administered, brief and relatively reliable test, was taken at two standard anatomical sites, mid-calf and mid-arm, to measure body composition and change over time (LEAP-II) (PT Direct, 2025, Wood, 2008). The two test sites were chosen as mid-arm testing has been recommended for use in physical testing of people experiencing homelessness due to the high prevalence of injuries and disorders of the skin and blood vessels in this population leading to lower limb swelling, cellulitis and skin conditions (Chen et al., 2014, To et al., 2016, Institute of Medicine (US), 1988).

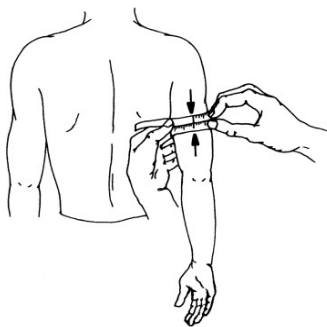
(ii) Psychometric properties

Calf circumference was recorded due to evidence from a large study (n=1458) which demonstrated its correlation with appendicular skeletal muscle mass and proposed it as a potential marker of physical function (Rolland et al., 2003). Mid-arm muscle circumference is known to reflect muscle mass and protein energy status,

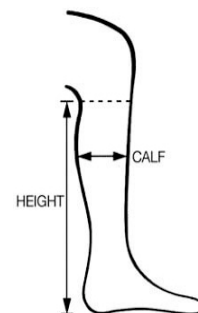
thereby signifying muscle wasting and/or malnutrition (Cano et al., 2009). Lower limb manual circumference is a proven reliable measurement method and upper limb volumes calculated from anatomic landmarks (as per this study's method) also have proven reliability and validity (Bakar et al., 2017, Taylor et al., 2006).

(iii) Measurement and interpretation

In this study, circumferential measures were taken using a flexible tape measure, flat and horizontal on the skin, where possible, at the level of the largest circumference of the calf and mid upper arm. The reliability of girth measurement is dependent on the tester, the tension on the tape and the correct landmarking, and in this study was carried out by the same researcher (FK). Reduced reliability was anticipated for some measurements due to the trauma informed design of the LEAP programmes, where participants were invited, but not required, to undress adequately to ensure the tape was in direct contact with the skin. Limb measurements (in centimetres) were compared to global cut-off measurements (Tang et al., 2020, Gonzalez et al., 2021).



Upper Arm circumference



Calf circumference

Figure 2.2 Limb Circumference measurement

2.8.6 Measuring physical function

All of the physical function tests in this research were test-based measures and assessed gait, functional mobility, strength and balance. The LEAP-I trial which preceded LEAP-II and LEAP-W utilised the SPPB (Kennedy et al., 2024). This 3-part test which also included measures of gait, functional mobility, strength and balance and was recommended from preliminary research of hospitalised people experiencing homelessness (Broderick et al., 2021). The SPPB presented as a brief and easy to administer test and demonstrated high feasibility. However, for participants in the LEAP-I trial, who were community-based and not acutely unwell, and many younger individuals had high physical functioning levels, a ceiling effect was noted in the SPPB. As a result, careful consideration was placed on selecting the following physical function tests.

2.8.6.1 10 Metre Walk Test (10mWT)

(i) Description

The 10mWT measures walking speed and functional mobility. It is a brief test-based measure and is recorded in metres per second (m/s) (Bohannon, 1997).

(ii) Validity and reliability

This test has excellent reported reliability and validity in many populations including healthy adults, orthopaedic patients and those with neurological conditions (Bohannon, 1997, Hollman et al., 2008, Steffen and Seney, 2008, van Loo et al., 2004, Wolf et al., 1999, van Hedel et al., 2005).

(iii) Measurement and interpretation

There are many variations of the 10mWT, and it can be conducted over different distances. For the purpose of this study, a 10m total walkway was used, marked with tape at each half metre point. The participant's time was calculated over 6m, from the 2m point to the 8m point, and gait speed was calculated as total distance/time. A mobility aid was permitted if required. Participants were measured at their maximal gait speed and while two trials are recommended, for the purpose of this research and the population of interest, one trial only was performed.



Figure 2.3 10m Walk Test

2.8.6.2 2-Minute Walk Test

(i) Description

The 2-Minute Walk Test (2-MWT) is an easily administered, test-based measure of self-paced walking ability, functional capacity and endurance and takes two minutes to complete.

(ii) Validity and reliability

It's reliability and validity has been established in many populations such as those with neuromuscular disorder, cardiac and respiratory disease, amputees and older patients (Brooks et al., 2007, van Hedel et al., 2005, Connelly et al., 2009, Witherspoon et al., 2019, Resnik and Borgia, 2011, Leung et al., 2006). It has

demonstrated positive correlation with the 6-Minute Walk Test and is recommended for those who may not manage the longer distance or where brevity of testing is important, which was an important consideration for this study's population (Witherspoon et al., 2019, Gacto-Sánchez et al., 2023).

(iii) Measurement and interpretation

The 2-MWT assesses a participants' ability to walk unassisted over a 15m distance, as fast and as safely as possible, for two minutes. A mobility device and rest breaks are permitted, and the distance covered in the two minutes is measured. In this study the 15m distance was marked by tape at each half metre point and the beginning and end of the walkway was marked with a cone. Practice walks are recommended but for the purpose of this research one trial only was performed and recorded. Results were compared to normative reference values (Bohannon, 2017).

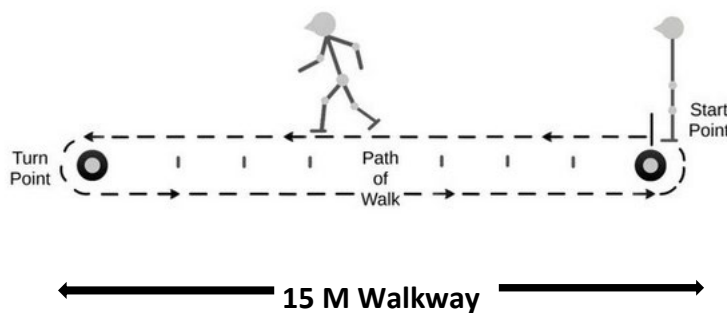


Figure 2.4 2-Minute Walk Test

2.8.6.3 Chair Stand Test (CST)

(ii) Description

The Chair Stand Test (CST) or often called the 30-Second Chair Stand Test is an indicator of lower limb strength and endurance (Lein et al., 2022). It is a brief (taking 30-seconds) and easy to administer test-based measure.

(ii) Validity and reliability

The CST has strong psychometric properties, and its validity and reliability have been demonstrated in osteoarthritic individuals and community dwelling older adults and young adults, and it has been proposed as a physical performance test for athletes (Gill and McBurney, 2008, Lein et al., 2022, Rikli and Jones, 2013, Wright et al., 2011).

(iii) Measurement and interpretation

The CST measures the total number of full sit-to-stand repetitions a participant can perform in 30 seconds. It is more challenging than the five times sit to stand test of the SPPB therefore has better utility in younger individuals with higher physical capacity. In this study each participant was evaluated performing the CST using the same chair which was placed against a wall. Participants were advised to sit up straight, with their feet shoulder width apart and placed at an angle slightly back from their knees, in preparation for standing and with their arms placed across their chest. They were instructed to perform full stands, and this was demonstrated initially by the researcher. The total number of full and correct stands performed in 30 seconds was recorded. Results were compared to normative values for young (mean + SD age, age 25.1 (\pm 3.4) years) healthy individuals. No other comparative values are available.

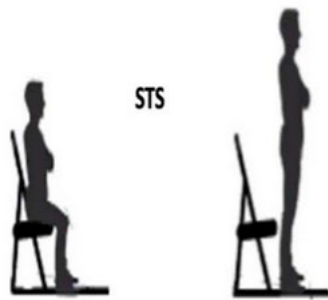


Figure 2.5 Chair Stand Test

2.8.6.4 Single Leg Stance (SLS) test

(i) Description

The Single Leg Stance test, a measure of static balance, is widely used in clinical settings as a brief, easily administered, test-based measure to monitor neurological and musculoskeletal conditions and has been proven as a predictor of falls and mortality (Springer et al., 2007, Vellas et al., 1997, Araujo et al., 2022).

(ii) Validity and reliability

Its validity and reliability have been proven in patients with osteoarthritis, however, it has less absolute reliability in detecting change in older adults (aged 60-89 years) (Sarac et al., 2022, Choi et al., 2014, Goldberg et al., 2011).

(iii) Measurement and interpretation

For comparative purposes, the SLS test is evaluated on each leg. In this research, the participant was timed standing unassisted on one leg, without the free leg touching the standing leg, with eyes open and hands placed on the hips (Springer et al., 2007). In many studies, at least one practice trial has been permitted on each leg (El-Kashlan et al., 1998, Sarac et al., 2022). In this study, to keep the test duration to a minimum, a second trial was permitted if desired or if the individual lost balance within

the initial five seconds. Variability in SLS was expected between limbs due to the known existence of physical health conditions in this population, therefore, the lowest value was used as a measure of overall function in participants. Results recorded in seconds were compared to normative values determined by Springer et al (2007) (Springer et al., 2007).

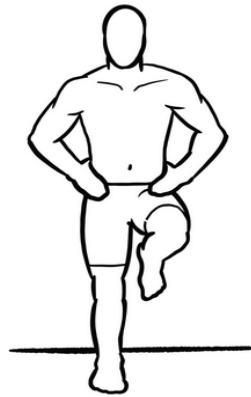


Figure 2.6 Single Leg Stance Test

2.8.7 Measuring frailty

A myriad of frailty tools exist which need careful consideration when evaluating a population with unique and varied needs such as people who are homeless. Different frailty tools are advocated for different purposes due to the multi-dimensional nature of frailty, the differing settings, different populations and the age of those who are screened (Martin and Brighton, 2008). It is well known that frailty is closely linked to advancing age but there is growing evidence of frailty in non-geriatric populations (Martin and Brighton, 2008, Spiers et al., 2021, Loecker et al., 2021). Findings from The Irish Longitudinal Study of Ageing (TILDA) demonstrated, in 4,961 people, that a combination of self-report and test-based measures provided the most accurate results to measure frailty (Theou et al., 2015). The use of combined frailty measures was firstly considered important in the context of this study given the prevalence of cognitive

impairment and the potential for recall or even trust issues which are commonly reported in people experiencing homelessness (Spence et al., 2004, Reilly et al., 2022, Ennis et al., 2015). For the purpose of this PhD, the selected frailty measures were a combination of test-based and self-report instruments.

Secondly, as targeting physical functioning deficits was an objective of this PhD, frailty was assessed using a tool which examined the physical domain of frailty. As frailty is multi-factorial and the population of interest is extremely heterogenous, a second frailty tool which focussed on the multi-dimensional aspects of frailty was chosen. The Survey of Health, Ageing and Retirement in Europe-Frailty Instrument (SHARE-FI) (Romero-Ortuno et al., 2010) and the Clinical Frailty Scale (CFS) (Rockwood et al., 2005) were the chosen frailty instruments for the LEAP-II and LEAP-W trials.

2.8.7.1 SHARE-Frailty Instrument

(i) Description

The Share-Frailty Instrument (FI) is a brief, easily administered, mixed self-report and test-based frailty tool. It measures the physical dimension of frailty.

(ii) Psychometric properties

The SHARE-FI is validated (in 20,547 Europeans) for screening and monitoring frailty in community settings. It offers a simpler way of identifying frailty than one of the dominant models of frailty, the Frailty Phenotype. While Fried's frailty phenotype has been validated for people over 65 years (Fried et al., 2001), the SHARE-FI is validated and recommended for younger people (over 50 years) (Romero-Ortuno et al., 2010). Reliability of the SHARE FI has also been demonstrated (Muszalik et al., 2018).

(iii) Measurement and interpretation

The SHARE-FI consists of four brief questions relating to: (i) exhaustion, (ii) loss of appetite, (iii) walking difficulties and (iv) low physical activity as well as (v) one objective measure of grip strength (Appendix I). Results can be calculated quickly. Answers are entered into a freely available web calculator and a frailty continuous score, as well as a frailty category (non-frail, pre-frail and frail) is generated.



EXHAUSTION
In the last month, have you had too little energy to do the things you wanted to do?

- No
- Yes

LOSS OF APPETITE
What has your appetite been like?

- Diminution in desire for food and/or eating less than usual
- No change in desire for food and/or eating the same as usual
- Increase in desire for food and/or eating more than usual

WEAKNESS
Maximum grip strength in Kilograms:

- Right hand attempt 1
- Right hand attempt 2
- Left hand attempt 1
- Left hand attempt 2

WALKING DIFFICULTIES
Because of a health or physical problem, do you have any difficulty doing any of the following everyday activities? (Exclude any difficulties that you expect to last less than three months)

Walking 100 metres:

- Yes
- No

Climbing one flight of stairs without resting:

- Yes
- No

LOW PHYSICAL ACTIVITY
How often do you engage in activities that require a low or moderate level of energy such as gardening, cleaning the car, or doing a walk?

- More than once a week
- Once a week
- One to three times a month
- Hardly ever, or never

Figure 2.7 SHARE-FI

2.8.7.2 Clinical Frailty Scale

(i) Description

The Clinical Frailty Scale is a judgement-based scale, which encompasses multiple frailty domains. Its content and scoring are based on self-report responses, collateral information and good clinical reasoning.

(ii) Psychometric properties

The CFS is validated for older adults (over 65 years) and is traditionally rated following a comprehensive geriatric assessment (Rockwood et al., 2005). Of note, it has more recently been used as a brief screening tool in acute and emergency settings (Church et al., 2020). The CFS also has proven reliability in a number of settings and once trained in its use it is easily measured (Hörlin et al., 2022, Kaeppli et al., 2020).

(iii) Measurement and interpretation

The CFS is assessed and scored by the tester uses a 9-point scale which correlates with an image and a description of frailty to aid the tester in classifying frailty from 1 (very fit) to 9 (terminally ill) (see Appendix I). Higher scores indicate higher levels of frailty.

Frailty results from the SHARE-FI and CFS (for LEAP-II and LEAP-W), were compared to frailty ratings in older populations and studies with younger homeless populations which also utilised frailty measures (Romero-Ortuno et al., 2010, O'Halloran et al., 2021, Rogans-Watson et al., 2020).

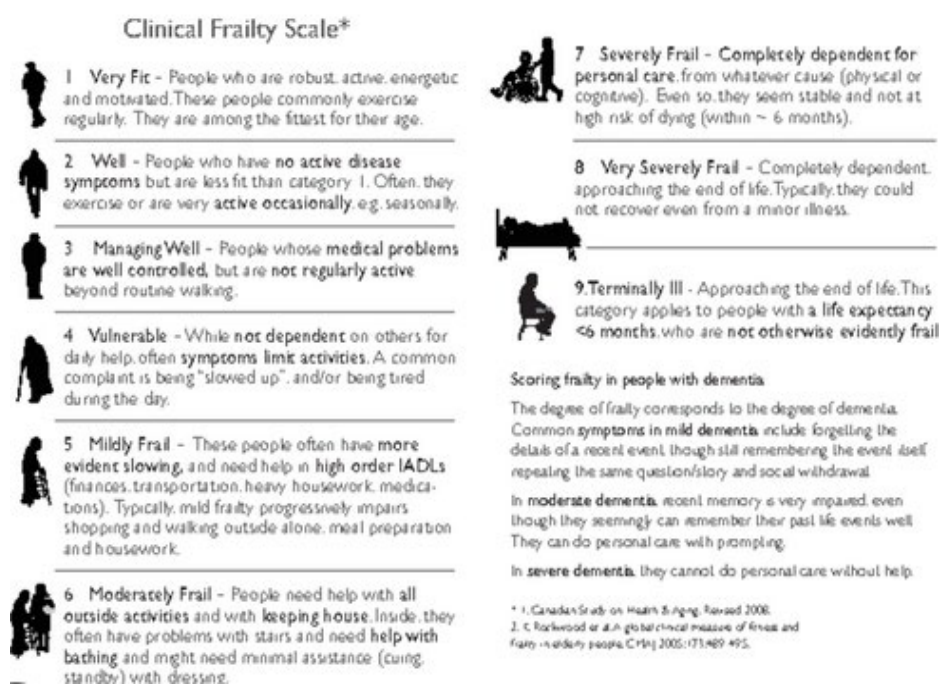


Figure 2.8 The Clinical Frailty Scale

2.8.8 Measuring pain

As high rates of pain are commonly reported in people experiencing homelessness and preliminary research which evaluated physical function in this population cited pain as the primary reason for the non-completion (n=24%) of a number of physical function tests, it was therefore considered an important construct to explore (Broderick et al., 2021, Anastas et al., 2023).

2.8.8.1 Numerical Pain Rating Scale

(i) Description

Participants were asked (i) if they experienced pain, (ii) where it was located and (iii) if it was present for more than three months. Pain severity was assessed using a simple self-report measure, the Numerical Pain Rating Scale (NPRS).

(ii) Psychometric properties

The NPRS scale has proven reliability and has been validated over diverse populations (Alghadir et al., 2018).

(iii) Measurement and interpretation

The NPRS is a uni-dimensional measure of pain intensity scored from 0-10, with 0 being zero pain and 10 the worst pain imaginable (Scott and Huskisson, 1976). The SF-36 health questionnaire is commonly used to evaluate pain in people experiencing homelessness and, in this research, pain was also explored using the SF-12, its shorter version, and this tool will be discussed in a subsequent section (Anastas et al., 2023). Results from the NPRS were compared across time points in LEAP-II and LEAP-W.



Figure 2.9 Numerical Pain Rating Scale

2.8.9 Measuring nutritional status

2.8.9.1 Mini-Nutritional Assessment

(i) Description

Nutritional status was assessed using the Mini-nutritional assessment (MNA) score (Guigoz et al., 1996). The MNA assessed the risk of malnutrition, deemed an important construct to evaluate considering food poverty is common in people experiencing homelessness and is closely linked to frailty. The short form of the MNA (MNA-SF) was selected for the purpose of this research. It is a brief mainly self-report test with one test-based measure of body mass index (BMI). It is easily administered and takes 2-3 minutes.

(ii) Psychometric properties

The MNA is a well validated tool with high sensitivity, specificity and reliability (Kaiser et al., 2009, Bleda et al., 2002, Vellas et al., 2006).

(iii) Measurement and interpretation

The MNA consists of six questions relating to (i) food intake, (ii) weight loss, (iii) mobility, (iv) psychological stress, or acute disease, (v) the presence of dementia or depression, and (vi) BMI (Kaiser et al., 2009). These questions were read to each participant and scored by the researcher. An MNA score of greater than or equal to 12 (12-14) identifies good nutritional status, while scores between eight and 11 identified those at risk of malnutrition and scores lower than eight indicate malnutrition.

Suitability of two sections of the MNA was questioned for the purposes of the study population and setting, and consensus was reached with the supervisory team to modify its terminology, regarding acuity of illness and the presence of a neuropsychological problem. Results were compared to the above cut-off and measures across time points (see Figure 2.10).

Last name:		First name:		
Sex:	Age:	Weight, kg:	Height, cm:	Date:

Complete the screen by filling in the boxes with the appropriate numbers. Add the numbers for the screen. If score is 11 or less, continue with the assessment to gain a Malnutrition Indicator Score.

Screening		J How many full meals does the patient eat daily?	
A Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?	<input type="checkbox"/>	0 = 1 meal	<input type="checkbox"/>
0 = severe decrease in food intake		1 = 2 meals	
1 = moderate decrease in food intake		2 = 3 meals	
2 = no decrease in food intake			
B Weight loss during the last 3 months	<input type="checkbox"/>	K Selected consumption markers for protein intake	
0 = weight loss greater than 3kg (6.6lbs)		• At least one serving of dairy products (milk, cheese, yoghurt) per day	yes <input type="checkbox"/> no <input type="checkbox"/>
1 = does not know		• Two or more servings of legumes or eggs per week	yes <input type="checkbox"/> no <input type="checkbox"/>
2 = weight loss between 1 and 3kg (2.2 and 6.6 lbs)		• Meat, fish or poultry every day	yes <input type="checkbox"/> no <input type="checkbox"/>
3 = no weight loss		0.0 = if 0 or 1 yes	<input type="checkbox"/>
		0.5 = if 2 yes	<input type="checkbox"/>
		1.0 = if 3 yes	<input type="checkbox"/>
C Mobility	<input type="checkbox"/>	L Consumes two or more servings of fruit or vegetables per day?	
0 = bed or chair bound		0 = no	<input type="checkbox"/>
1 = able to get out of bed / chair but does not go out		1 = yes	<input type="checkbox"/>
2 = goes out			
D Has suffered psychological stress or acute disease in the past 3 months?	<input type="checkbox"/>	M How much fluid (water, juice, coffee, tea, milk...) is consumed per day?	
0 = yes	<input type="checkbox"/>	0.0 = less than 3 cups	<input type="checkbox"/>
2 = no	<input type="checkbox"/>	0.5 = 3 to 5 cups	<input type="checkbox"/>
		1.0 = more than 5 cups	<input type="checkbox"/>
E Neuropsychological problems	<input type="checkbox"/>	N Mode of feeding	
0 = severe dementia or depression		0 = unable to eat without assistance	<input type="checkbox"/>
1 = mild dementia		1 = self-fed with some difficulty	
2 = no psychological problems		2 = self-fed without any problem	<input type="checkbox"/>
F Body Mass Index (BMI) (weight in kg) / (height in m²)	<input type="checkbox"/>	O Self view of nutritional status	
0 = BMI less than 19		0 = views self as being malnourished	<input type="checkbox"/>
1 = BMI 19 to less than 21		1 = is uncertain of nutritional state	
2 = BMI 21 to less than 23		2 = views self as having no nutritional problem	<input type="checkbox"/>
3 = BMI 23 or greater			
Screening score (subtotal max. 14 points)	<input type="checkbox"/>	P In comparison with other people of the same age, how does the patient consider his / her health status?	
12-14 points: Normal nutritional status	<input type="checkbox"/>	0.0 = not as good	<input type="checkbox"/>
8-11 points: At risk of malnutrition	<input type="checkbox"/>	0.5 = does not know	<input type="checkbox"/>
0-7 points: Malnourished	<input type="checkbox"/>	1.0 = as good	<input type="checkbox"/>
		2.0 = better	<input type="checkbox"/>
For a more in-depth assessment, continue with questions G-R		Q Mid-arm circumference (MAC) in cm	
		0.0 = MAC less than 21	<input type="checkbox"/>
		0.5 = MAC 21 to 22	<input type="checkbox"/>
		1.0 = MAC 22 or greater	<input type="checkbox"/>
Assessment		R Calf circumference (CC) in cm	
G Lives independently (not in nursing home or hospital)	<input type="checkbox"/>	0 = CC less than 31	<input type="checkbox"/>
1 = yes		1 = CC 31 or greater	<input type="checkbox"/>
0 = no			
H Takes more than 3 prescription drugs per day	<input type="checkbox"/>	Assessment (max. 16 points)	
0 = yes	<input type="checkbox"/>	Screening score	<input type="checkbox"/>
1 = no		Total Assessment (max. 30 points)	<input type="checkbox"/>
I Pressure sores or skin ulcers	<input type="checkbox"/>		
0 = yes	<input type="checkbox"/>		
1 = no			

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For more information: www.mna-elderly.com

Malnutrition Indicator Score	
24 to 30 points	<input type="checkbox"/> Normal nutritional status
17 to 23.5 points	<input type="checkbox"/> At risk of malnutrition
Less than 17 points	<input type="checkbox"/> Malnourished

Modification: As the MNA test has not been validated for people experiencing homelessness, the terminology of two of its questions, 1) question D regarding acuity of illness and 2) question E, regarding the presence of a neuropsychological problem were slightly modified for the purposes of this study, that is:

- D: "Have you recently been sick or in hospital?" 0=yes, 2=no
- E: "Have you problems with concentration or memory?" 0=yes, 1= a little, 2=no

Figure 2.10 Mini-Nutritional Assessment

2.8.10 Measuring quality of life/self-reported health status

2.8.10.1 Short Form-12 (SF-12)

(i) Description

The SF-12 is a quality-of-life outcome which measures overall health status. It is a shortened version of the widely used measure of health status, the SF-36 whose psychometric properties have been well established in the general population (Ware et al., 1993). The SF-12 is 12-item self-report measurement tool and like the SF-36

encompasses eight domains including: physical and social activities, pain, mental health, emotional health, vitality and general health perceptions (Ware et al., 1996). It yields two scores, a Physical Component Summary (PCS) and a Mental Component Summary (MCS) thus, providing rich data on overall health, beyond the physical domain.

(ii) Psychometric properties

Correlation between the SF-12 and SF-36 has been demonstrated (Gandek et al., 1998). Validity and reliability of the SF-12 has been confirmed, and it has been shown to reflect change over time (Ware et al., 1996, Jenkinson et al., 1997). The SF-12 has been recommended for use in people experiencing homelessness (Larson, 2002). It represents the only outcome measure in this study which has been validated for people experiencing homelessness specifically.

(iii) Measurement and interpretation

The SF-12 was read to each participant, and results were entered into software licenced for this study by Quality Metric consulting services (<https://www.qualitymetric.com/scientific-consulting/>). This software enabled the data to be aggregated and analysed in terms of a physical component and mental component summary score (Quality Metric, 2025). Normative values for the SF-12 are available for comparison purposes with a mean score of 50 and standard deviation of 10 reported in the general population and scores above 50 indicate better than average health related quality of life (Ware et al., 1996). An online algorithm and calculator are available to score the SF-12. In consultation with the research supervisory panel, a minor change was made to the terminology of one question,

Question 2 of the SF-12, (where moderate activities were described as “moving a table, pushing a vacuum cleaner, bowling, or playing golf”) to ensure real world relevance for participants who were sleeping rough, in temporary accommodation or in other crisis situations. Rather moderate activities were compared to “moving a table or carrying a bag or walking up to 30 minutes”. (See Figure 2.11).

In addition to measuring physical and mental health status, the author considered measuring pain important to facilitate a comprehensive understanding of the experience of pain and its impact on function and wider life in this population, thus was viewed as offering complementarity to the NPRS where those with lower functional literacy may view numerical pain rating as a challenge (Kennedy et al., 2024, Kennedy et al., 2025).

SF-12 Health Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. **Answer each question by choosing just one answer.** If you are unsure how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

Excellent Very good Good Fair Poor

The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	YES, limited a lot	YES, limited a little	NO, not limited at all
2. Moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Climbing several flights of stairs.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	YES	NO
4. Accomplished less than you would like.	<input type="radio"/>	<input type="radio"/>
5. Were limited in the kind of work or other activities.	<input type="radio"/>	<input type="radio"/>

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	YES	NO
6. Accomplished less than you would like.	<input type="radio"/>	<input type="radio"/>
7. Did work or activities less carefully than usual.	<input type="radio"/>	<input type="radio"/>

8. During the **past 4 weeks**, how much **did pain interfere** with your normal work (including work outside the home and housework)?

Not at all A little bit Moderately Quite a bit Extremely

These questions are about how you have been feeling during the **past 4 weeks**.

For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm & peaceful?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Did you have a lot of energy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Have you felt down-hearted and blue?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

12. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time Most of the time Some of the time A little of the time None of the time

Patient name:

Date:

PCS:

MCS:

Figure 2.11 Short Form-12

Of note, all but one outcome measure from the test battery for LEAP-II and LEAP-W have not been validated for use in people experiencing homelessness. For the purpose of this research, all physical function and frailty outcomes were compared to normative data. Data for each study was collected on a bespoke data collection form (see Appendix I).

2.9 Exercise screening tool used in this thesis

In each intervention study participants were initially screened to ensure safety in participation. The Physical Activity Readiness Questionnaire (PAR-Q) was used. The PAR-Q is a brief and easy to administer 7-item survey which screens a person's ability to safely participate in a physical activity programme (Adams, 1999) (See Appendix). The questions, which relate to medical history, current symptoms and risk factors, require dichotomous responses. For this study seven 'no' responses were required to enable immediate enrolment in the programme. One or more 'yes' responses prompted a letter to each participant's GP or to one of the study collaborators, who is a consultant physician, to confirm a medical diagnosis and seek consent for the participant to partake in the programme. Results from the questionnaire also assisted the researcher to tailor the exercise intervention to each participant's unique needs.

2.10 Safety monitoring in the intervention

As a safety measure, pre- and post-intervention blood pressure and heart rate monitoring was conducted and recorded for each exercise class. As GP approval was provided in advance of programme commencement and a number of participants had an elevated baseline BP measurement but were stable on anti-hypertensive

medication, some leeway was permitted beyond standard BP measurements (that is between 90/60 and 120/80 mmHg). An absolute cut-off of 170 mmHg diastolic and 60 mmHg systolic was utilised, but caution was exercised for any participant with measurements between 150-160 mmHg diastolic at the upper end and 60 mmHg systolic at the lower end. These participants were advised to wait and relax before commencing for a short period after arrival, were closely monitored and advised to rest frequently.

Borg's Rate of Perceived Exertion (RPE) Scale was used to gauge exercise exertion and enable safe progression with the exercise programme (Borg, 1982), (see Appendix II). Exercise intensity commenced at low to moderate, where participants were advised to exercise between 11 and 13 on the RPE scale, a subjective level of 'fairly light' to 'somewhat hard'. Later in the programme, they were advised to progress to a level of 13–15, a level perceived as 'somewhat hard to hard', if they felt they were no longer being challenged by the exercise intensity (Borg, 1982).

2.11 The LEAP Interventions

Bearing in mind the known challenges and anticipated needs of the population of interest the intervention in LEAP-II and LEAP-W was designed with the following features in mind:

- Trauma informed sensitivity: A trauma informed approach was utilised with consideration of past and present trauma at all times (FEANTSA, 2017b). Attempts to promote engagement and inclusiveness, provide transparency, offer choice and aid empowerment, and also to avoid re-traumatisation were actively made.

- **Low threshold:** Low threshold refers to the accessibility of the intervention and was the approach adopted due to its successful implementation in drug rehabilitation settings and recommendations in settings with trauma survivors, as discussed in Chapter 1 (Huo et al., 2023, Morton and O'Reilly, 2016). Minimal barriers to entry were imposed and engagement and participation was encouraged, as per the location and open-access nature of the settings. Participants were informed of the schedule of the exercise sessions and the Park Walk and were provided with flexibility in their attendance. Abstinence from drugs or alcohol was not a requirement to entry. The researcher used judgement and clinical reasoning to ascertain safety for all participants in the exercise room.
- **Flexibility:** Multiple classes were delivered each day the programme was delivered (see Chapter 3, Table 3.3 and Chapter 4, Table 4.4 for programme schedules for each study). One-to-one, group and gendered classes were delivered, based on participant preference. The exercise circuit framework (see Chapter 3, Table 3.4 and Chapter 4, Table 4.4 for LEAP-II and LEAP-W, respectively) guided the exercise session but consideration to the physical and mental health needs of each participant was given, bearing in mind that fluctuating presentations were expected if participants were using substances on a given day. Therefore, exercises were tailored for each participant as appropriate.
- **Multi-modal:** The intervention was multi-modal and focussed on strength and general fitness with a view to improving physical function and frailty status. An emphasis was placed on strength training due to the evidence of its

effectiveness in frailty management and its ease of implementation (Travers et al., 2019). A twice-weekly strength-based exercise circuit-class was available to all participants. Music was an important feature of the classes, and the music was often selected by participants. Each session commenced with a warm-up and ended with a cool-down and stretch of all the major muscles. The exercises were progressed at a low-moderate intensity, with 2-3 sets of 10-15 repetitions completed at each session and beyond that, low resistance weights (1.1kg-4.5kg), theraband resistance bands or increased step height and other variations were introduced to achieve a strengthening effect. Exercise intensity and frequency was built incrementally and was based on the baseline status of participants, previous attendances and presentation on the day. Aerobic exercise was built into the programme in the circuit and specifically in the 'Park Walk' which took place in a local green space facility. Specifics of the exercise circuit of LEAP-W, which placed a focussed lens on women's health and wellbeing is provided in Chapter 4.

- Group-based: LEAP-II and LEAP-W were primarily group-based- however, individual sessions were facilitated if requested. In LEAP-II (i) men's-only, (ii) women's-only and (iii) mixed classes were facilitated to cater for the needs of all participants. Additionally, a class was facilitated for a group of Irish Traveller women who attended the Ballyfermot Advance Project who were provided with transport to the centre on a once weekly basis to attend the programme. This class was protected for their attendance only.

With the aforementioned considerations in mind, the intervention for the LEAP-II and LEAP-W trials sought attendance to three exercise sessions per week, (i) an

exercise circuit delivered for participants to attend twice per week and (ii) a Park Walk delivered for a once-weekly aerobic activity. (see Chapter 3, Table 3.3 and Chapter 4, Table 4.3 for the intervention schedule for each unique study). The Park Walk was a self-paced 20-to-30-minute walk which took place in a nearby recreational green space. Participants were instructed to walk at a comfortable pace and to increase the distance or the pace as they wished over the course of the programme. The Park Walk took the form of a group walk but one-to-one walks were also delivered depending on attendance and participant preference. The walk often stimulated conversations about health and wellbeing and presented as an opportunity to relax and enjoy the surroundings or to educate participants about the multiple benefits of exercise.

Each exercise circuit session incorporated brief interventions to target health literacy. Topics of physical activity and exercise were broadly discussed in relation to its benefits and protective effects and ideas of how physical activity could be easily incorporated into daily life outside of the intervention. The role of nutrition on muscle health and general health was also discussed. These brief interludes were delivered ad lib with the intent to stimulate interest, encourage active engagement and to confer relevance to the group. Further detail of the intervention pertinent to the respective studies are discussed in the relevant chapters.

LEAP-W utilised a qualitative interview process, using one-to-one semi-structured interviews with participants of the exercise intervention and stakeholders from the two sites of Merchants Quay Ireland from where participants were recruited. See Appendix IV for the exit interview schedule for programme participants and stakeholders.

2.12 Analysis Plan

In each study, descriptive statistics were performed to summarise participant characteristics and generate a demographic profile. Quantitative data were tested for normality using the Kolmogorov–Smirnov test. Pre- and post-intervention data were then compared and analysed using paired t-tests or Wilcoxon signed-rank tests if normally distributed or non-normally distributed, respectively. A complete case analysis was performed due to the feasibility focus of LEAP-II and LEAP-W.

The outcome measure feasibility rate was assessed for each measure of the test battery. The frailty prevalence was presented as frequencies and percentages. Linear regression was used to identify associations between frailty and variables of interest and to examine the influence of these variables on the variance in frailty using the SHARE-FI and the CFS. Where associations were demonstrated binary logistic regression modelling was utilised to establish odds ratios. Cohen’s Weighted Kappa statistical test was used to determine agreement between the frailty instruments.

Pre-post intervention data were analysed using IBM SPSS V28 and a *p*-value with statistical significance was set at $p < 0.05$. Baseline frailty data and exploration analysis was conducted using Stata 18. The qualitative data was analysed using Braun and Clarke’s reflexive thematic analysis (Braun and Clarke, 2006, Braun and Clarke, 2024). Further detail is provided in each respective chapter.

PROTOCOL AND PUBLISHED PAPERS LINKED TO CHAPTER 3



STUDY PROTOCOL

REVISED A study to explore the role of a low threshold, fitness focussed physical rehabilitation intervention with protein supplementation to target physical function and frailty in people with problematic substance use and homelessness: protocol for a single-arm pre-post intervention study.

[version 2; peer review: 2 approved]

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Abstract

Background

People who are homeless are more likely to experience poor mental health and addiction as well as suffering from non-communicable diseases. There is evidence of frailty and accelerated physical ageing among people experiencing homelessness. Appropriate physical rehabilitation and nutritional supplementation strategies can stabilise or reverse frailty and general physical decline, but it is not known how this type of intervention would work in practice in this population.



Aim

To evaluate the feasibility and pre-post intervention impact of a low threshold physical rehabilitation intervention with protein supplementation to target physical functioning and frailty in people with problematic substance use who are experiencing homelessness.

Open Peer Review

Approval Status  

	1	2
version 2 (revision) 29 Oct 2024	 view	 view
version 1 25 Apr 2023	  view	  view

1. **JUAN TORTOSA-MARTÍNEZ** , University of Alicante, Alicante, Spain
2. **Catriona Connell** , University of Stirling, Stirling, UK

Any reports and responses or comments on the article can be found at the end of the article.

Methods

The intervention will consist of a 12-week low threshold rehabilitation programme with protein supplementation. Participants will be service users of the Ballyfermot Advance Project, a day services centre for people with addiction issues and experiencing homelessness. Primary outcomes will be feasibility including numbers recruited, retention of participants and adherence to the exercise intervention and protein supplement. Any adverse events will be recorded. Secondary outcomes will be strength and muscular mass, physical performance and lower extremity physical function, pain, frailty and nutritional status.

Discussion

An immediate impact may be simply a distraction from difficult circumstances and potentially an improvement of physical health of participants, which can be a conduit for the emergence of other positive behaviours and recovery. Longer term, this study will generate preliminary data on which to inform the design of a definitive randomised controlled trial of physical rehabilitation and protein supplementation, if indicated.

Ethics and dissemination

Ethical approval was granted by the Faculty of Health Sciences Research Ethics Committee in TCD. Study findings will be disseminated through publication into an international peer-reviewed journal and presented at national and international conferences.

Keywords

Inclusion health, addiction, homelessness, exercise, nutritional supplementation

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REVISED Amendments from Version 1

This revised manuscript is intended to provide more clarity to the protocol presented. In response to the reviewer comments we have made a minor amendment to the title and aims. We have provided additional background in the introduction. The main amendment is to the methodology section which provides greater detail of the intervention and the outcome measures utilised and there is a minor revision in the analysis section. We have addressed the small number of grammar and punctuation issues. It is hoped that this version has provided the reader with more clarity and enhanced the quality of this manuscript.

Any further responses from the reviewers can be found at the end of the article

Introduction

Inclusion health is an approach which aims to prevent and address health and social inequalities of vulnerable people such as those who are homeless¹. The collision of disease risk factors with poverty, constant stressors and social exclusion in people experiencing homelessness has demonstrated a markedly elevated rate of non-communicable diseases². Related to non-communicable diseases and a complex interaction of other factors such as addiction and accidental death, socially excluded populations have a mortality rate that is almost eight times higher than the average for men, and nearly 12 times higher for women³. The median age of death among people experiencing homelessness⁴ in Dublin, Ireland is staggeringly low among females at 38 years and 44 years among men⁵.

Accelerated ageing and earlier geriatric conditions such as falls, poor strength and mobility problems are common in people experiencing homelessness^{6,7}. A single centre, cross-sectional study, which applied a broad test battery of physical functioning tests to people experiencing homelessness who were admitted for inpatient care, demonstrated that despite a low median age of 45 years, 83% of participants had mobility problems and 70% were frail or pre-frail⁸.

As frailty, a complex multidimensional state of physiological vulnerability⁸ and pre-frailty, its prodromal stage⁹, is normally a concept associated with ageing¹⁰ - the concept of frailty in younger populations can be contentious. Nonetheless, frailty has been identified in younger populations across a number of settings^{11,12} and it is recognised that those living in areas of greater deprivation experience the earlier onset of illness and associated disability^{13,14}. A high prevalence of frailty has been identified in people experiencing homelessness^{6,15-20}. Poorer physical health and frailty means people experiencing homelessness have fewer options for moving to independent housing due to accessibility issues which reinforces the cycle of entrenched homelessness, rough sleeping and dependence on long-term hostel accommodation²¹. The challenge is to bridge the implementation gap and provide innovative solutions to key challenges faced by people in long term homelessness. Improvements in physical health will not solve all complex challenges, it is nonetheless a sensible solution focussed target

which can be a positive focus from which there can be a ripple effect in terms of outcomes.

Key drivers of physical frailty are poor nutritional intake²² and sedentary behaviour. Food insecurity is extremely prevalent among people experiencing homelessness²³ and may contribute to frailty. It is possible that protein supplementation after exercise may optimise protein synthesis rates²⁴ and help stabilise frailty and physical de-conditioning²⁵. This has been successfully demonstrated in frail older people²⁶. Furthermore, in illicit drug users, exercise can increase the abstinence rate and can reduce withdrawal and anxiety symptoms²⁷.

There is a dearth of research exploring physical activity and nutritional interventions in this population. Kendzor *et al.*, 2017 investigated the effects of a diet and exercise intervention in homeless adults²⁸, in a randomised controlled trial. This study, however, did not provide a structured, supervised exercise programme. The intervention involved the provision of educational newsletters, healthy snacks and pedometers with advice on physical activity. This study is the first of its kind which will provide a structured exercise and nutritional intervention in this population.

Aim and objectives

The overall aim of this study is to test the feasibility and pre-post intervention impact of a low threshold physical rehabilitation programme with dietary supplementation to target frailty and poor physical functioning in people who are homeless.

Objectives:

1. To evaluate recruitment, retention and adherence to the physical rehabilitation and protein supplementation programme.
2. To examine baseline and pre-post intervention change in measures of physical, nutritional and frailty status, and self-reported pain.
3. To ascertain perceptions of unmet physical health needs, exercise habits and how an exercise intervention should ideally be designed to meet the needs of this cohort with lived experience of homelessness and active addiction issues.

Methods

Design and study setting

This single arm feasibility study is taking place in a suburban area of Dublin with high levels of deprivation. The study will commence in October 2022 and will finish in March 2023. The Ballyfermot Advance Project provides a five-day a week meal service, as well as drug and alcohol related services for people with active addiction issues, the majority of whom experience homelessness. A dedicated exercise room in a nearby community centre has been allocated for the duration of the intervention period. This study has received

ethical approval from the Faculty of Health Sciences REC at Trinity College Dublin (Ethical Approval Reference Number: 211202).

Sample selection, recruitment and eligibility screen

A gatekeeper in Ballyfermot Advance has been appointed as the study liaison. The gatekeeper will distribute the Participation Information Leaflet (PIL) and consent form in advance of the study. Staff members with a knowledge of eligible clients who access services in Ballyfermot Advance will inform them of the study and supply them with study related information. Study information leaflets in plain English will be available throughout the centre. Once referred, and the potential participants present to the exercise room, the dedicated research physiotherapist, FK, will do an initial eligibility screen at the point of enrolment to ensure potential participants meet the eligibility criteria.

Obtaining consent

All potential participants will be provided with a PIL and an exercise information leaflet detailing the purpose of the data collection, the exercise intervention, potential risks and benefits and data protection rights. Due to the expected high levels of functional illiteracy, the research physiotherapist will read the study related information where applicable and will be available to answer any study related queries. Where possible there will be a seven-day gap between receipt of the PIL and obtaining consent to allow potential participants time to consider participation. Due to the anticipated fluctuation in interest levels however, and other competing priorities related to mood, motivation and active addiction issues, flexibility has been built into the consent process. This means that clients who express an interest in the programme and willingness to participate the same day as first receiving the study information can be consented and commence the programme at a time suited to them. This method was successfully employed previously in a cross-sectional study conducted with patients experiencing homelessness in St. James's Hospital⁶.

Once the research physiotherapist is satisfied that the potential participant has read (or has been read to) and fully understands the PIL, they will proceed to obtain written informed consent. Obtaining consent will take place at the first interaction with the participant prior to commencement of testing. The written consent informs participants that they are permitted to withdraw from the study at any time. Participants are given their own copy of this consent form and PIL, signed by themselves and the research physiotherapist. The research physiotherapist will be accompanied by a second research assistant.

Inclusion and exclusion criteria

The aim of the study is to be as pragmatic and low threshold as possible. This means that minimal constraints are put in place to access the intervention. In order to be as pragmatic as possible in terms of inclusion criteria, all clients (>18 years) accessing services in Ballyfermot Advance who consent to study participation can be included in this study.

Only participants with problematic behavioural issues, including confusion or extreme agitation, or have major physical problems, (medical or orthopaedic) which would preclude ability to safely participate in the exercise class will be excluded from study participation. Participants with a confirmed pregnancy will also be excluded as physical functioning/performance tests scores in advanced stages of pregnancy may vary from baseline values²⁹.

In the design of this study, we were cognisant of the likely complex needs of many participants as complex childhood trauma has been commonly experienced by people who experience homelessness and substance misuse problems. Using a Trauma Informed approach to care³⁰ and based on experience from a previous Inclusion Health undergraduate clinical placement³¹, the following were incorporated in the approach to assessment and follow up with participants; (i) empathy, (ii) consistency, (iii) understanding, and (iv) flexibility.

Intervention

The intervention will consist of three exercise opportunities, including a twice weekly, 12-week exercise programme with nutritional supplementation. The intervention will be fully supervised and delivered by two research physiotherapists. Group exercise classes or one-to one sessions will be delivered depending on participant preference. Participants will be advised of a schedule of class times, including gender specific classes and will be allocated to a specific class based on their preference. An alternate class will be offered if participants cannot attend at their scheduled time. A 'Park Walk' will also be scheduled one day per week. This will be a 30-minute self-paced walk of low intensity led by the research assistant involved in this programme. This is to build up exercise frequency during the week and is building in a habit which it is hoped can be continued by participants beyond the life cycle of the project. Flexibility in programme commencement and completion dates will be provided to enable the 12-week intervention to be completed within a 15-week period of time.

The PAR-Q³², a pre-screening questionnaire, will be conducted with participants prior to commencement of the exercise classes. The research physiotherapist will, with permission, write to the participants General Practitioner (GP) to advise them of their intention to take part in the programme and to clarify that it is safe for them to proceed with the exercise intervention. If the individual does not have a GP, the research physiotherapist will discuss this individual case with a specialist consultant in Inclusion Health based in St. James's Hospital, Dublin. The case will be outlined in broad terms, without revealing any personal details of the participant, solely as a sounding board as to whether it would be suitable for the participant to attend or not.

The exercise intervention will focus on general fitness and will include resistance, aerobic and functional exercises, with in-built flexibility based on individual participants' needs. The exercise component will be based on 'core' exercises (Table 1)

Table 1. Exercise Circuit.

Core exercise	Initial Intensity	Progression/Adaptations*
Sit to stand/squats/lunges	2 sets 10-15 reps	3 sets of 15 reps use of weights/ball
Elbow Bends	2 sets 10-15 reps	3 sets of 15 reps weights
Step-ups	2 sets 10-15 reps	3 sets of 15 reps height of step; weights
Arm elevations	2 sets 10-15 reps	3 sets of 15 reps weights
'Penguin waddle'-hip abduction	2 sets 10-15 reps	3 sets of 15 reps With additional upper limb abduction and elevation; movement with 360° turns
Scapular retractions	2 sets 10-15 reps	3 sets of 15 reps weights
Aerobic activity	2 mins	3 mins ladders, hurdles, skipping ropes, jumping jacks dance, game with cones/balls
Balance	4-5 mins	5 mins Tandem; single leg stance, upper limb and trunk movements; weights and ball work

*Adaptations: exercises individualised and progressed for each participant by research physiotherapist

which will be adjusted to increase or decrease difficulty based on the results of the initial assessment and ability of participants, as judged by the research physiotherapist. Each session, of approximately 20 minutes duration, will commence with a warm-up and stretch of the major muscles and will end with cool-down and stretch.

A low-specification pedometer will be supplied to encourage increasing daily step count and goal setting will be discussed with participants. This is to build a scientifically sound psychological framework into the intervention to encourage motivation to partake in physical activity.

The intensity of the workout will be managed by using the Borg Perceived Rate of Exertion (RPE) scale³³ where participants will be advised to exercise at a rate of between 11 and 13 on the PRE scale, i.e. where they find the exercise somewhere between 'fairly light' to 'somewhat hard', where they find it hard to have a conversation but can comfortably continue to exercise.

To promote post-exercise muscle protein synthesis³⁴, a nutritional supplement (200ml pre-prepared 'protein shake' Fresubin, <https://www.fresubin.com/>) which consists of 20g of protein will be offered to all participants immediately post exercise in the exercise room.

In an attempt to build sustainability beyond the life cycle of the project, participants will also be educated about exercise and available local resources where possible. Participants will

be invited and encouraged to return three times weekly to continue with the exercise intervention.

Adherence

The service provided will be low threshold to facilitate adherence and compliance. The research physiotherapists will make every effort to be flexible and accommodating to participants in terms of their attendances to the exercise classes and the Park Walk. Adherence to the programme will be measured by the uptake, compliance and number of repeat visits to the drop-in programme. Demographic information will include biological sex and current homeless status.

Demographic details collected

Demographic details, including age, and named GP of participants will be collected. A letter will be sent to each GP to inform them of study participation. Questions around current addiction status will be guided by Section 1 of the Treatment Outcome Profile²⁷. As the research physiotherapist will not have access to participant medical/social records, senior staff of Ballyfermot Advance Project will provide pertinent medical/addiction/social information relating to the participants if required.

Outcomes

Primary outcomes

The following feasibility outcomes will be recorded; numbers recruited, retention of participants including number of repeat visits and adherence. Any adverse events will also be threshold to facilitate its feasibility.

Recruitment and retention

The numbers recruited and frequency of attendances will be recorded. Participants will be encouraged to attend all sessions if possible. Drop out will also be recorded.

Adherence

The research physiotherapists will make every effort to be flexible and accommodating to participants in terms of their attendances and adherence to the programme. Adherence will be measured by the adherence to the exercise programme and the protein supplement.

e recorded. The service provided will be low threshold to facilitate its feasibility

Secondary outcomes

1. Strength and muscular mass: Muscular strength will be estimated^{34,35} by using a Digital Hand Dynamometer in a sitting position while the hand is unsupported with the elbow at 90° flexion and the underarm and wrist in neutral. Two measurements will be inputted as part of the SHARE-FI frailty instrument³⁶ and values will also be compared to normative reference values established by Steiber³⁷.

Mid-calf circumference girth will be evaluated as this measure correlates with appendicular muscular mass³⁸. This will be measured using a flexible tape measure at the level of the largest circumference of the calf. Higher scores indicate higher levels of muscular mass. The cut-off value for moderately and severely low calf circumference is 34 cm and 32 cm in males, and 33 cm and 31 cm in females³⁹.

Mid-arm muscle circumference reflects both muscle mass and caloric and protein adequacy, and may be used to signify malnutrition or wasting⁴⁰. This test has been recommended for use in physical testing of those experiencing homelessness⁴¹ due to the high prevalence of lower limb swelling⁴². The maximum upper arm muscular mass will be measured using a flexible tape measure. Results will be compared to global reference values⁴³.

2. Physical performance and lower extremity physical function:

This will be measured using the following physical performance measures:

(i) The 10m Walk Test (10MWT). This test measures walking speed and functional mobility and is recorded in m/s. Gait speed is calculated as total distance/time⁴⁴.

(ii) The 2minute Walk Test (2MWT). This test of self-paced walking ability and functional capacity assesses a participants' ability to walk unassisted over a 15m distance, as fast as possible, for two minutes. Rest breaks are permitted and the distance covered is measured⁴⁵.

(iii) The Chair Stand Test (CST). This test of lower limb strength and endurance measures the total number of sit to stand repetitions a participant can perform in 30 seconds⁴⁶.

(iv) The Single Leg Stance Test (SLS). This test of balance is performed on each leg. The participant is timed standing unassisted on one leg, with eyes open and hands placed on the hips⁴⁷.

3. Pain: Each participant will be questioned whether they are experiencing any pain and will be questioned about its location and duration. Severity of pain will be assessed using the Numerical Rating Scale (NRS). The NRS is a unidimensional measure of pain intensity from 0–10, with 0 being zero pain and 10 the worst pain imaginable⁴⁸.

4. Frailty: This will be assessed in two ways; using the Clinical Frailty Scale (CFS)⁴⁹ and the SHARE-FI³⁶. This scale is assessed by the tester and each point on the scale is correlated with a description of frailty along with a visual chart to aid the tester in classifying frailty from 1 (very fit) to 9 (terminally ill). Higher scores indicate higher levels of frailty. The SHARE-FI is a valid tool to measure the level of frailty in individuals aged ≥50 years³⁶. It consists of quick questions related to the following variables; exhaustion, loss of appetite, walking difficulties and low physical activity. Answers are entered into a freely available web calculator to generate a frailty score and a frailty category of non-frail, pre-frail and frail is generated.

5. Nutritional status will be assessed by using the Mini-nutritional assessment (MNA) score⁵⁰. The MNA assesses the risk for malnutrition. In particular, the short form of the MNA (MNA-SF)⁵¹ is a screening tool consisting of six questions on food intake, weight loss, mobility, psychological stress, or acute disease, the presence of dementia or depression, and body mass index (BMI). The maximum score for this part is equal to 14. A score equal to or higher than 12 indicates that the subject under study has an acceptable nutritional status thus excluding malnutrition and/or malnutrition risk, meanwhile, a score ≤ 11 implicates to proceed with the complete version of the MNA (MNA-LF)⁵¹. As this test has not been validated for this population, the terminology of two of the questions of the MNA (regarding acuity of illness and psychological stress) have been slightly modified for the purposes of this study, ie "Have you recently been sick or in hospital?" and "Have you problems with concentration or memory?"

6. Body Mass Index (BMI). Height and weight will be measured and the following formula will be applied to generate BMI; kg/m².

7. Self-report:

Short-Form 12 (SF-12)⁵². The SF-12 is a self-report measure of health used across age, disease and treatment groups. It uses eight domains including physical and social activities, pain, mental health, emotional health, vitality and general health perceptions to measure health. The participant completes a 12 question survey which is scored by the researcher. The minimum possible score is 12 and the maximum possible score is 48. Lower scores indicate better health. To ascertain perceptions of unmet physical health needs & rehabilitation/exercise preferences, open-ended questions will be used regarding

(i) concerns with current physical health, (ii) exercise history (iii) current concerns/priorities of the participant and (iv) the final questions asks “do you have someone who looks out for you?”. This information will be transcribed by the research physiotherapist and repeated back to the participant to verify accuracy. It will not be audio-recorded.

*Reliability and validity of secondary outcomes measures have been confirmed (see *Extended data*, Supplementary Figure).

Data collection and management

Data will be collected pre- and post-intervention for those who complete the programme, by the research physiotherapist.

Analytic plan

Our study is very much feasibility focussed and not hypothesis driven so formal power calculations are not directly applicable. Prospectively, potential participants that meet the study eligibility criteria will be invited to participate. Descriptive statistics will summarise participant demographics and feasibility measures such as attendance rates. Nominal or ordinal variables will be reported as frequencies and percentages. Continuous variables will be summarised as mean and standard deviation if normally distributed and median and inter-quartile range if non-normally distributed. Results will be compared to evaluate change over time from initial to final intervention. Normally distributed data will be compared from initial to final recorded time-points using paired t-tests and non-normally distributed data via the Wilcoxin-sign rank test. As participants will be heterogeneous, data will be sub-stratified and participants will be grouped meaningfully. Free text responses from subjective questions will be reported and organised into topic areas.

Funding

This has been funded by Trinity College Dublin and the Ballyfermot Advance Project.

Dissemination plans

Conference presentations and publications in peer-reviewed journals will be one method of dissemination. Results will also be presented to the key stakeholders including people with lived experience and the funders of this study.

Study status

Recruitment and data collection will commence on October 3rd 2022 and will be completed by March 2023.

Discussion

This protocol describes a novel and pragmatic, low threshold intervention which aims to address the known poor physical health condition of people experiencing homelessness and problematic substance use. Given this is such a novel area there is no comparator group. This study will nevertheless increase knowledge, understanding and awareness of the physical health needs of this population and facilitate a better understanding of unmet need, thus assisting in shaping future physical rehabilitation services to suit these complex and transient needs. It is hoped that this study will provide preliminary data to optimise the intervention and inform the design of a definitive randomised controlled trial, where applicable. An immediate impact may be an improvement in physical health of participants, which can be a conduit for the emergence of other positive behaviours and recovery. Overall, this research will address an intractable global societal challenge, have wide impact and improve the quality of life, health and well-being of some of our most vulnerable citizens.

Data availability

Data from this study will be available in open access form.

Underlying data

No data are associated with this article.

Extended data

OSF: A study to explore the role of a low threshold, fitness focussed physical rehabilitation intervention with protein supplementation to target physical function and frailty in people who experience homelessness and addiction: protocol for a single-arm feasibility pre-post intervention study. <https://doi.org/10.17605/OSF.IO/3AG9B>⁵³.

The project contains the following extended data:

- Supplementary Figure.docx

Data are available under the terms of the [Creative Commons Zero “No rights reserved” data waiver](#) (CC0 1.0 Public domain dedication).

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Acceptability and utility of a broad test battery to evaluate physical functioning and frailty in community-based settings for people experiencing homelessness and addiction—Findings from the LEAP trials

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Abstract

Background Physical function deficits and frailty are commonly reported in people experiencing homelessness and addiction. Typically, geriatric, or general physical performance measures are employed to evaluate these constructs.

Objectives and setting We aimed to investigate the feasibility of a broad test battery to evaluate physical functioning and frailty in a non-geriatric community-based population of people experiencing homelessness and addiction.

Design and methods Physical function and the presence of frailty was evaluated using combined data from two linked low-threshold exercise pre-post intervention studies (LEAP-I and II).

Participants Seventy-four participants attending an open-access day-service centre (18 to 65 years) were evaluated. Participants with acute confusion or behavioural issues, or major medical conditions precluding safe participation were excluded.

Intervention A broad test battery was performed which evaluated physical functioning and frailty.

Main outcome measures Outcome measures included were the Short Physical Performance Battery, Single Leg Stance, Chair Stand Test, 10mWT and 2 Minute Walk Tests, limb circumference, dynamometry, Clinical Frailty Scale, SHARE-Frailty Instrument, Numerical Pain Rating Scale and Short Form-12.

Results Test completion was 100% for all outcomes except pain rating (81% and 79% for LEAP-I and II, respectively), and balance and walking tests (95% and 93% in LEAP-II). A ceiling effect was detected for the Short Physical Performance Battery.

Conclusion High feasibility of the test batteries was demonstrated. An optimised test battery was proposed based on findings. This has important implications for clinicians working in inclusion health settings.

Clinical Trial Registration Number Clinical Trials.gov: [NCT05700305](https://clinicaltrials.gov/ct2/show/study/NCT05700305).

Contribution of the Paper

- This paper proposes a suitable test battery to enable clinicians to evaluate physical functioning and frailty in people experiencing homelessness and addiction challenges in community settings.
- There is a paucity of research evaluating outcome measures for this population and no core outcome set has been reported.
- This test battery would allow the effect of treatment and targeted interventions to be evaluated in this marginalised population.

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Introduction

People experiencing homelessness (PEH) and addiction often have disproportionately poor health [1] which can lead to the earlier manifestation of physical functioning limitations, accelerated ageing and geriatric syndromes such as falls, mobility deficits and frailty [2]. Physical functioning determines one's ability to live independently [3]. It is an indicator of health status [4], early signs of disability, future health and social care needs [5], and death risk [6]. Frailty, a complex multi-dimensional construct, which has been shown to correlate with physical function and independence [7], also predicts adverse outcomes [8]. It is recommended that clinicians screen PEH and addiction for physical functional deficits and frailty syndromes such as mobility impairments and falls to initiate appropriate rehabilitation interventions and inform future planning and resource use [9].

A high prevalence of chronic conditions, including pain, infectious diseases, respiratory, cognitive, and mental health conditions have been identified among PEH and addiction [10] and the co-existence of two or more chronic conditions has been reported in 100% of PEH in a London-based study [11]. Therefore, the evaluation of physical functioning may be challenging, and disease specific outcomes may not be suitable. There is a paucity of research evaluating outcome measures for this population and no core outcome set has been reported [12]. Due to the prevalence of premature ageing in this population, outcomes commonly used to assess PEH are often extrapolated from the geriatric setting [2,13]. With a lower mean age [14], and high level of functional literacy in PEH [15], the usefulness of these measures is not fully known. Physical functioning and frailty tests therefore need to be carefully selected.

Physical functioning and frailty have been evaluated in PEH in a Dublin hospital [13]. Due to high disease acuity in hospital-based settings, the application of the measures used in the community setting may differ. Establishing the usefulness of a physical functioning and frailty test battery in community-based settings is important as this population should have access to Primary Care services to meet their unmet healthcare needs [16] before they consider hospital-based care.

The aim of the study was to evaluate the feasibility of a broad battery of physical functioning and frailty tests in PEH and addiction in the community setting.

The study objectives were to:

- explore the acceptability of the test battery in terms of the (i) ease of administration (ii) administration time, and (iii) practicalities (cost, resources) involved.
- consider the utility of these measures in terms of their (i) value and (ii) application to community settings.

Methods

Setting and target population

This study evaluated the utility of a test battery from two linked pre-post intervention studies (*Low-threshold Exercise And Protein* supplementation interventions: LEAP-I and II trials) involving PEH and addiction. The recruitment sites for these studies were day-service centres for PEH and addiction in Dublin. All participants received an information leaflet and provided full written informed consent.

Study design and procedure

LEAP-I and II were single-arm pre-post intervention cohort trials which involved the delivery of an exercise intervention with protein supplementation to target poor physical functioning and frailty in PEH and addiction in 2022 and 2023, respectively. Both trials evaluated feasibility and effectiveness of the interventions which are reported elsewhere [17,18] (Table 3). In both trials, the intervention was preceded by an evaluation, conducted by the lead researcher (FK), of baseline physical function and frailty status using a broad test battery (Table 1) which will be discussed in this paper. The baseline scores from each trial were used to ascertain the acceptability and utility of each outcome measure.

Considerations for the test battery

The test battery was devised by consensus from clinical and academic experts in physical functioning, frailty, and inclusion health. The merits of each tool were considered, which included psychometric properties, ease of administration, clinical utility, and practical issues such as cost, equipment, space and administration burden. A number of the outcome measures (handgrip dynamometry, limb

circumference, the Short Physical Performance Battery (SPPB) and the Clinical Frailty Scale (CFS)) were selected based on a recommended brief test battery which evaluated physical functioning limitations and frailty in hospitalised PEH [2]. As pain was cited as a common reason for non-completion of physical functioning tests in hospitalised PEH [2], pain evaluation was included in the LEAP studies and as nutritional status can influence physical functioning and drive frailty [19] the Mini-nutritional assessment (MNA) was included [20]. The SHARE-Frailty Instrument (FI) was introduced as a rapid measure of physical frailty [21]. A number of outcomes replaced the SPPB in the LEAP-II trial. These were the Single Leg Stance Test (SLST) [22], the Chair Stand Test (CST) [23], 10 Metre Walk Test (10mWT) [24] and the 2 minute Walk Test (2MWT) [25]. Finally, the Short Form-12 (SF-12) [26] was introduced to the LEAP-II trial as a quality-of-life measure to encompass a multi-dimensional view of health beyond the physical domain.

Description of test battery (Table 1)

Strength and muscular mass

Muscle strength was measured [27] using a digital hand dynamometer. This was conducted in sitting, with the elbow positioned at 90° flexion, the forearm mid-prone, the wrist supported in neutral and the hand free. Mid-calf circumference was measured as it correlates with appendicular muscular mass [28]. Mid-arm muscle circumference reflects both muscle mass and caloric and protein adequacy and may also be used to signify malnutrition or wasting [29]. This test is recommended for use in physical testing of PEH due to the high prevalence of lower limb swelling [30]. Circumferential measurements were taken using a flexible tape measure at the largest circumferential level of the calf and upper arm.

Physical performance and lower extremity physical function

LEAP-I utilised: The Short Physical Performance Battery [31]. This performance-based test consists of: (i) a balance task (ii) 5 timed-chair stands, (iii) a short timed-walk (4 m). The scores range from 0 (worst) to 12 (best performance). The cumulative score of the three timed tests was recorded.

LEAP-II utilised: (i) The 10mWT: a measure of gait speed, recorded in m/s [24]; (ii) the 2MWT: a measure of walking ability and functional capacity, assessed the ability to walk unassisted over a 15 m course, as fast as possible for two minutes, with rest breaks permitted and distance covered was recorded [25]; (iii) the CST: a measure of lower limb strength and endurance, recording the number of sit-to-stand repetitions performed in 30 seconds [23] and (iv) the SLST: a timed unassisted measure of unipedal balance, recorded on each leg with eyes open and hands placed on the hips [22]. To keep the test duration to a

minimum, a second attempt was permitted if balance was lost within the initial five seconds. These 4 brief measures replaced the SPPB utilised in LEAP-I.

Pain

Participants were asked (i) if they experienced pain, (ii) the site of the pain and (iii) its' chronicity. Pain severity was assessed using the Numerical Pain Rating Scale (NPRS), a uni-dimensional measure of pain intensity scored from 0 to 10, with 0 being zero pain and 10 the worst pain imaginable [32].

Frailty

Frailty was assessed using the Clinical Frailty Scale (CFS) [33] and the SHARE-Frailty Instrument (SHARE-FI) [21]. The CFS, scored by the tester, uses a 9-point scale, each point accompanied by an image and description of frailty to aid classification from 1 (very fit) to 9 (terminally ill). The SHARE-FI, a measure of physical frailty [21], consists of four brief questions relating to; (i) exhaustion, (ii) loss of appetite, (iii) walking difficulties and (iv) low physical activity and (v) one objective measure of grip strength. A minor change was made to language of the physical activity question to make it relevant to the population of interest. Answers were entered into a freely available web calculator and a frailty score, and category was generated.

Nutritional status

The Mini Nutritional Assessment short-form (MNA-SF) [20] screening tool was used to assess the risk of malnutrition. It consists of six questions relating to (i) food intake, (ii) weight loss, (iii) mobility, (iv) psychological stress, or acute disease, (v) the presence of dementia or depression, and (vi) body mass index (BMI). Terminology of two questions in the MNA (regarding acuity of illness and the presence of a neuropsychological problem) was also modified for the purposes of the study population.

Quality of life

The Short Form-12 (SF-12) was used. This is a self-report measure of health status which encompasses physical and social activities, pain, mental health, emotional health, vitality and general health perceptions [34]. Normative values are available for comparison purposes [26].

The evaluation of physical function and frailty, using the aforementioned test batteries, was conducted using trauma informed care, a distinct approach advocated to appropriately and sensitively address the complex needs of this population [35].

Data analysis

The plan was to recruit at least 29 participants in each study, which is based on minimum recommendations of 24 for feasibility studies [36] and allowing for a 20% drop out.

Descriptive analysis was performed, and the test feasibility rate was assessed for each measure. This was calculated from the number of participants who were able to complete the tests divided by the total number of participants in the study. The feasibility rates were interpreted using pre-specified feasibility rates identified by Wouters *et al.* [37] (< 50% not feasible, 20% to 70% quite feasible, > 70% feasible) [37].

Results

Seventy-four participants completed the evaluation. The evaluations took between 20 to 23 and 25 to 29 minutes to complete for the LEAP-I and LEAP-II trials, respectively (Table 2).

Table 1
Test battery for LEAP-I and LEAP-II trials.

Measures	LEAP-I	LEAP-II
1. Strength	Grip strength	Grip strength
Muscular mass	Limb circumference	Limb circumference
2. Physical performance & lower extremity function	Short Physical Performance Battery	10 m Walk Test 2 Minute Walk Test Chair Stand Test Single Leg Stance Test
3. Pain	Numerical Pain Rating Scale	Numerical Pain Rating Scale
4. Frailty	Clinical Frailty Scale Share-FI	Clinical Frailty Scale SHARE-FI
5. Nutritional status	Mini-Nutritional Assessment	Mini Nutritional Assessment
6. Quality of Life	Not tested	SF-12

Table 2
Completion rates/times of LEAP-I and LEAP-II trials.

Test	LEAP-I Completion Rate N (%)	LEAP-I Completion Time	LEAP-II Completion Rate N (%)	LEAP-II Completion Time
Strength & Muscle Mass				
Limb circumference	31(100)	1 to 2 minutes	43(100)	1 to 2 minutes
Grip	31(100)	1 minute	43(100)	1 minute
Physical Performance & Lower Limb function				
SPPB	31(100)	5 minutes		
10 m Walk Test			43(100)	1 minute
2 Minute Walk Test			40(93)	2.5 minutes
Single Leg Stance			41(95)	2.5 minutes
Chair Stand Test			43 (100)	1 minute
Pain	25 (81)	1 to 2 minutes	34 (79)	1 to 2 minutes
Frailty				
CFS/SHARE-FI	31 (100)	10 minutes	43(100)	10 minutes
Nutritional Status				
MNA	31 (100)	2 to 3 minutes	43(100)	2 to 3 minutes
Quality of Life				
SF-12			43(100)	3 to 4 minutes
Total		20 to 23 minutes		25 to 29-minutes

Strength and muscular mass

There was a 100% compliance with dynamometry testing. All participants ($n = 74, 100\%$) completed both limb circumference tests. Using trauma informed care, participants who had the testing limb covered by clothing were not required to remove this to minimise potential feelings of discomfort. However, if willingness was indicated, participants were encouraged to remove a layer of clothing to maximise the accuracy of data collection.

Physical performance and lower extremity physical function

LEAP-I: All participants ($n = 31, 100\%$) completed the SPPB in under five minutes. A ceiling effect was observed in the reporting of results, where higher functioning participants ($n = 16, 52\%$) scored the maximum score of 12.

LEAP-II: All participants ($n = 43, 100\%$), completed the 10mWT and CST. There was a marginally lower completion

Table 3
Detail of LEAP-I and II trials.

Trial	Intervention		
	1. Exercise Class*	2. Protein Supplement**	3. Park Walk
LEAP-I	Once weekly	Once weekly	
LEAP-II	Twice weekly	Twice weekly	Once weekly

* Multi-modal exercises, focus on strength.

** Protein Supplement offered immediately post exercise class.

rate for the 2MWT ($n = 40$, 93%) and the SLST ($n = 41$, 95%). The reasons for non-completion were cited as pain, fatigue, and alcohol intoxication.

Pain

There was 81% ($n = 25$) and 79% ($n = 34$) compliance with the NPRS for LEAP-I and LEAP-II, respectively. The NPRS was challenging to score for many. Often, despite clear verbal instruction participants failed to provide a numerical score to rate their pain, opting to use descriptive terms to explain their pain.

Frailty

There was a 100% completion rate for the CFS and SHARE-FI. The CFS took longer to complete (approximately 10 minutes) due to the necessity to probe for relevant information and occasionally seek collateral information from the medical team in the centre. The SHARE-FI was brief and simple to administer.

Nutritional status

The MNA assessed by the researcher had a 100% completion rate. It involved five brief questions, each based on a Likert scale, followed by BMI measurement, and took approximately two minutes to complete.

Quality of life (SF-12)

To ensure full understanding and completion of this survey the researcher read the SF-12 survey to each participant. This assessment took approximately four minutes to complete with 100% completion rate.

Discussion

Appropriate measures are needed to evaluate physical functioning and frailty in community-based settings for PEH and addiction to manage primary healthcare conditions locally and avoid the common pathway to emergency care and hospitalisation [38]. For the first time, these studies evaluated the acceptability and utility of a physical functioning and frailty test battery for this population in the community setting. Overall, the results demonstrated

feasibility with a completion rate in excess of 70% for all outcome measures used. However, a number of measures, namely the SPPB and the NPRS, may not be suitable for people with higher physical functioning and those with lower functional literacy.

In terms of acceptability, the test batteries were time and resource efficient, and simple to conduct in both settings. The duration of the performance-based measures (dynamometry, the SPPB, 10mWT, 2MWT, CST and SLS tests) was brief, taking between 6 and 8 minutes in LEAP-I and II, respectively. The self-report tests took longer to complete, however, the researcher considered that trauma informed care, involving active listening and understanding, superseded the need to curtail discussions, particularly relating to addiction, homelessness, previous trauma, and healthcare needs.

Mixed results were found regarding the utility of the outcome measures employed in this study. Firstly, in terms of value, these measures were deemed relevant to the target population known to experience a high burden of physical health deficits and frailty syndromes. The frailty tools, the CFS and SHARE-FI, were useful in identifying a notable level frailty and pre-frailty in this non-geriatric population. In utilising two frailty measures, multiple domains of frailty could be explored, (physical, cognitive, psychological, and social functioning) which are particularly relevant to socially excluded populations.

Considering the measurement of physical function in a young, heterogeneous population, some community dwelling PEH are likely to have high physical functioning scores. This was evident in the number of participants who completed the SPPB with ease and scored the maximum score in the LEAP-I trial. Thus, modifications to the test battery were made for the LEAP-II study (Table 2) to avoid the ceiling effects observed in LEAP-I. This concurs with the evidence base where the SPPB has been shown to have ceiling effects in high functioning adults [39]. Resultantly, the SPPB was replaced for LEAP-II by four single tests, namely the 10mWT, 2MWT, CST and the SLST which also measured lower limb functional mobility and strength.

The modified test battery used in LEAP-II is considered more useful for research and clinical practice to evaluate physical functioning and frailty in a broad spectrum of community-based PEH and addiction. It is hoped that this test battery will be useful in primary care settings where rehabilitation interventions can be more accessible if delivered in closer proximity to this population.

In terms of application of the test battery to the community setting a number of noteworthy considerations arose. The finding of lower completion rates for the 2MWT and the SLST provides important insights into low physical functioning and the physical health burden which this young population experiences. Numerical pain rating was sometimes problematic. Considering this and the known functional literacy levels in PEH [16], the utility of a uni-dimensional outcome such as a pain rating scale alone is limited. An additional measure of pain was proposed for the LEAP-II trial to support pain rating, in order to understand this commonly reported symptom and contributor to physical decline. The SF-12 was selected, as it captured multiple dimensions of health including pain, and it has been validated in PEH [34]. Considering the known lower levels of functional literacy in this population, the researcher read the questionnaire to the participant to facilitate accurate interpretation. Finally, minor modifications to the terminology of the MNA-SF and SHARE-FI were made to ensure relevance and applicability of these measures to this population with unique needs and to the context and setting of these studies.

Although the outcome measures in the recommended set were selected based on expert opinion and available clinimetric evidence, none fulfil all desirable criteria, limiting the ability for a definitive core set of measures to be defined [40]. The outcome measures described in this proposed set require clinimetric evidence and some require minor modifications to their terminology to enable more meaningful score interpretations. While this study broadly indicated feasibility, acceptability and utility of the test battery, evidence of the validity and reliability of these outcomes in this population is lacking and needs to be explored in future studies.

Strengths, limitations, and implications

Considering the high usage of unscheduled care in PEH and addiction, the timely surveillance of physical functioning deficits and frailty in community settings for this population is important in identifying those with lower functioning and higher frailty.

The primary strength of this study lies in its high feasibility rate (>70%), the acceptability of the test battery, as well as its relevance, safety, and usefulness to evaluate physical function and health in this population of interest. Another strength is the multiple review methods and consultation to identify the 'best' assessment tools in a representative population, albeit small, before conducting it in a community setting. It must be acknowledged that many of the tools used in this study were primarily geriatric tools which have been validated for use in older populations only. Nonetheless, it is known that geriatric syndromes commonly present in PEH and the concept of frailty in younger populations is gaining more attention and

investigation [41]. The Share-FI is validated in community-dwelling Europeans aged 50 years and over and this age cut-off is lower than the generally reported cut-off of 65+ for frailty instruments. However, a suite of specific measures for this population are not yet available. Another limitation of this study is the small sample size, and the authors acknowledge that generalizability of its findings may be limited. For LEAP-I a post-hoc sample size calculation was conducted using the statistical package R. This was based on an expected adherence of 60%, a minimal acceptable adherence of 45% and a power of 80% [18]. This generated a required sample size of 68, suggesting these studies were potentially underpowered. However, when making this judgement it is important to also acknowledge the challenges of recruitment and retention in this 'hard to reach' population, many with acute addiction and mental issues as well as the sample size numbers proposed by Sim and Lewis [36].

Yet, this paper offers clinicians and researchers working in this emerging area a framework to guide and enhance future physical activity interventions with improved health outcomes.

Conclusion

These outcome measures provide meaningful data on the physical functioning and frailty status of PEH and addiction to assist in targeting and evaluating appropriate community-based interventions to mitigate the impact of the physical health burden experienced by this marginalised population. The modified test battery utilised in LEAP-II is proposed for use in evaluating physical functioning and frailty in community dwelling PEH and addiction challenges. Future research into the psychometric properties of such measures is warranted.

Ethical approval: Faculty of Health Sciences Research Ethics Committee, Trinity College Dublin (ethical approval reference no.: 211202).

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Data availability

Full study data cannot be made publicly available due to the sensitive nature of the data, agreements and procedures governing usage and sharing of the collected dataset

established by Trinity College Dublin and the Research Ethics Board (ref: 211202).

Conflict of Interest

The authors have no conflicting interests to declare.

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An exploration of frailty in a non-geriatric population with severe and multiple disadvantage using two geriatric frailty tools

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ABSTRACT

Frailty is linked to age acceleration and results in adverse outcomes. While traditionally explored in geriatric populations, certain non-geriatric populations also experience frailty. This study's aim was to explore frailty in a cohort of non-geriatric people experiencing homelessness and addiction using two frailty instruments. The SHARE-Frailty Instrument and Clinical Frailty Scale were utilized. Results indicated earlier onset and higher prevalence of frailty compared to geriatric populations. Both tools identified a frailty prevalence of 11.6%. Pre-frailty was threefold higher using the Clinical Frailty Scale. Linear regression identified associations between frailty and nutritional status, addiction status and gait speed. Binary logistic regression indicated poor nutritional status increased frailty odds fivefold (OR 5.49, $p = 0.015$) using the Clinical Frailty Scale, while increased gait speed decreased frailty odds (OR 0.05, $p = 0.021$) using the SHARE-Frailty Instrument. Fair inter-scale agreement [$k_w = 0.317$, $p = 0.001$] was identified. Utility of both scales was demonstrated. This unique exploration of these frailty tools identified distinct dimensions of frailty, endorsing their use and complementarity to highlight the need for intervention. Identifying frailty and the pre-frailty syndrome, and factors which drive frailty critically elucidate the need for early targeted interventions such as exercise and nutrition to mitigate its affect in this population.

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Introduction

Frailty, a consequence of population ageing, is a public health priority and creates immense challenges for healthcare systems globally (Kojima et al., 2019). There are many perspectives on frailty, and as a concept it continues to evolve (Morley et al., 2013). Widely accepted is that frailty is an age-associated syndrome and dynamic state of vulnerability to adverse outcomes and is due to an accumulation of deficits across multiple domains (Morley et al., 2013; Rockwood & Mitnitski, 2007). It is known, however, that frailty is more closely linked to biological age than chronological age (Elliott et al., 2021; Romero-Ortuno & O'Shea, 2013) and there is mounting evidence of the presence of frailty in non-geriatric populations, for example in people with chronic conditions such as COPD and MS (Hanlon et al., 2018; Loecker et al., 2021; Spiers et al., 2021). Frailty in

younger populations is however less well explored and understood.

Identifying frailty in clinical practice is important in order that healthcare resources can be allocated equitably and considering the disproportionate burden of poor health in distinct populations the need for responsive and targeted intervention is apparent (Aldridge et al., 2018). A large number of frailty identification instruments exist, which have been designed and validated for geriatric populations, and are sometimes extrapolated to younger populations (Loecker et al., 2021). There are yet no bespoke frailty tools for younger vulnerable populations whose characteristics and risk factors are likely to differ to older adults. Little is known about how frailty tools extrapolated from the geriatric setting work in practice for younger populations.

Evidence is emerging of the increased propensity to premature ageing and frailty in certain younger and

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vulnerable sub-populations including people with severe and multiple disadvantage, such as those experiencing homelessness and addiction, a population who face social inequality, extreme health disparities and socioeconomic deprivation (Ayrygnac et al., 2021; Dugravot et al., 2020; Rogans-Watson et al., 2020). Chronic disease and multiple prolonged stressors is common in people experiencing homelessness and addiction (Kiernan et al., 2021; Schulte & Hser, 2014), therefore it is unsurprising that accelerated ageing and frailty occurs which can lead to a host of adverse outcomes including disability, hospitalization and death (Hanlon et al., 2018; Salem, Nyamathi, et al., 2014). Previous research identified physical functioning deficits and frailty in this population using the Clinical Frailty Scale and the SHARE-Frailty Instrument which were then proposed for a follow-up intervention study (Broderick et al., 2021; Kennedy et al., 2024).

There is a gap in the evidence base around the evaluation of frailty in people experiencing homelessness and addiction, the drivers of frailty and the practical utility of frailty tools currently used. Identifying suitable tools and factors influencing frailty in this population will assist in delivering targeted interventions to delay or mitigate frailty as well as address unmet needs faced by this population who experience exclusion and multiple disadvantage.

This study evaluates and explores frailty in this distinct non-geriatric sub-population using two widely used geriatric frailty tools.

Secondary objectives, using these frailty tools was to explore attributes and drivers of frailty as well as the practical utility of and agreement between the selected frailty tools.

Materials and methods

Design, setting

This research was part of a pre-post intervention study which measured the feasibility and impact of a 12-week *Low threshold Exercise And Protein (LEAP-II)* supplementation programme in a non-geriatric at-risk population (Kennedy et al., 2023). A broad test battery was utilized in this study to evaluate physical function and frailty (including pain, nutritional status and self-reported health status) and the measures used are reported elsewhere (Kennedy et al., 2025). Pre-intervention (baseline) and post-intervention results were evaluated by the lead researcher, however, for the purpose of this paper, baseline frailty measures only were considered.

The programme took place from October 2022 until March 2023 in a day center for people with

chronic drug and alcohol addiction issues in Dublin, Ireland. All service users had addiction issues. Participants came from one of the highest areas of deprivation nationally (Pobal, 2024), had chronic addiction issues and had mixed levels of stability in accommodation with many (51%) experiencing homelessness. Furthermore, there was a reported history of homelessness in 86% of the cohort.

Inclusion criteria were all clients (18–65 years) accessing services in the day-service center who consented to participate.

Exclusion criteria were participants with

- (i) problematic behavior, confusion or major physical impairments which precluded ability to safely participate in the programme. Problematic behavior was defined as a perceived threat to the researcher or other participants or behavior which was deemed sufficiently challenging to impede the efficient running of the class. Problematic behavior and confusion were established informally by expert clinical judgement.
- (ii) confirmed pregnancy.

Frailty Instruments

The selection of frailty instruments was informed by previous research (Broderick et al., 2021; Kennedy et al., 2024). Due to the known prevalence of physical health conditions in this population of interest (Kiernan et al., 2020; Kiernan et al., 2021), physical frailty was assessed using the SHARE-Frailty Instrument (FI) for primary care. For a multi-dimensional view of frailty, the Clinical Frailty Scale (CFS) was selected. Brevity of tests was also an important consideration. Frailty levels were categorized meaningfully as non-frail, pre-frail and frail for comparison purposes, as shown in Table 1.

SHARE-frailty instrument (FI)

The SHARE-FI has been validated for screening and monitoring frailty in community settings and offers

Table 1. Corresponding frailty categories in the CFS and the SHARE-FI.

Frailty category	Frailty score	CFS	SHARE-FI
Non-frail	1	CFS 1 – Very fit CFS 2 – Well CFS 3 – Managing well	Non-frail
Pre-frail	2	CFS 4 – Very mildly frail	Pre-frail
Frail	3	CFS 5 – Mildly frail CFS 6 – Moderately frail CFS 7 – Severely frail CFS 8 – Very severely frail CFS 9 – Terminally ill	Frail

a simpler way of identifying frailty than one of the dominant models of frailty, the Frailty Phenotype (Fried et al., 2001; Romero-Ortuno et al., 2010) and is recommended for people over 50 years (Fried et al., 2001; Romero-Ortuno et al., 2010). Reliability of the SHARE-FI has also been demonstrated (Muszalik et al., 2018; Yont et al., 2023). A minor modification was applied to the terminology of the SHARE-FI in the final question relating to physical activity participation to make it relevant and reflect the real-life experience of this population.

Clinical frailty scale

The Clinical Frailty Scale (CFS), is validated for older adults (over 65 years), and is traditionally rated following a comprehensive assessment (Rockwood et al., 2005). Of note, it has more recently been used as a brief screening tool in acute and emergency settings (Church et al., 2020). The CFS also has proven reliability in a number of settings (Hörlin et al., 2022; Kaeppli et al., 2020). No modifications were made to the CFS. Collateral information was sometimes sought to corroborate or supplement clinical evaluation findings. For consistency, the same rater (FK) assessed frailty.

Attributes and predictors of frailty

Frailty attributes and predictors were evaluated by observing demographics of the frail participants and relationships between frailty (using the SHARE-FI and the CFS) and selected independent variables (age, gender, addiction status, nutritional status and gait speed). Advancing chronological age and female gender are associated with frailty (Rockwood et al., 2004) and as this novel research was delivered to a non-geriatric mixed population these attributes merited exploration. Moreover, the study setting, a center for people with problematic drug and alcohol use, expounds the exploration of association between frailty and addiction. Finally, considering exercise with nutritional supplementation was the cornerstone of the LEAP-II trial, gait speed (measured by the 10-Metre Walk test) (Bohannon, 1997) and nutritional status (measured by the Mini-Nutritional Assessment tool) (Kaiser et al., 2009) were included as variables of interest.

Practical utility of and agreement between frailty instruments

The practical utility of the tools was determined by the relevance and application of each tool to the population of interest. This included the language and terminology of the tools, the administration burden and any

modifications which were made to improve their acceptability. Agreement between frailty instruments was investigated using the Cohen Weighted Kappa test where a score of 0.01–0.20 indicated no or slight agreement, 0.21–0.40 fair agreement, 0.41–0.60 moderate agreement, 0.61–0.8 substantial agreement and 0.81–1 almost perfect agreement (McHugh, 2012). Points of divergence were identified by observing the rate of frailty and the characteristics of the frail, pre-frail and non-frail participants identified by each instrument.

Statistical analysis

Demographic data of the study participants and the rate of frailty were presented as frequencies and percentages. Linear regression was used to identify associations between frailty and selected independent variables of interest and to examine the influence of these explanatory variables on the variance of frailty using the SHARE-FI and the CFS. Where associations were demonstrated binary logistic regression modeling was utilized to establish odds ratios. Cohen's Weighted Kappa statistical test was used to determine agreement between the frailty instruments. All analyses were conducted using Stata 18. A p value <0.05 was considered statistically significant.

Results

In this study, 43 people complied with the eligibility criteria and consented to participate. Baseline characteristics of the participants are presented in Table 2. The mean (SD) age of the cohort was 45.6 (9.5) years. Just over half (53.5%, $n = 23$) were female. The majority of the participants were single ($n = 17$, 39.5%) and unemployed ($n = 39$, 90.7%). Almost three-quarters (74.4%, $n = 32$) were white Irish and 25.6% ($n = 11$) were Irish Travellers. Half (51.1%) of the participants ($n = 22$) were homeless (in line with the European Typology of Homelessness and Housing definition (FEANTSA, 2025)) at the time of the LEAP-II trial, while 86% had a current or past experience of homelessness. 81.4% of participants ($n = 35$) experienced problematic drug and/or alcohol use. All participants (100%) had self-reported mental health problems and a range of physical health conditions were reported, with some participants reporting comorbidities.

Attributes and predictors of frailty

Summary baseline frailty scores for all participants are presented in Table 3. Frailty was identified in 11.6% (n

Table 2. Participant demographics.

Demographic item	n (%)
Age mean (std dev)	45.6 (9.5)
Sex (n and %)	
Female	23 (53.5)
Male	20 (46.5)
Marital status (n and %)	
Single	17 (39.5)
Married/partnership	10 (23.3)
Separated/divorced	8 (18.6)
Widowed	7 (16.3)
*Data unavailable	1 (2.3)
Race (n and %)	
White Irish	32 (74.4)
Irish Traveler	11 (25.6)
Employment status	
Full-time employment	1 (2.3)
Part-time employment	3 (7)
Unemployed	39 (90.7)
Housing environment	
House/apartment	21 (48.9)
Hotel/hostel/staying with friend/family/other	8 (18.6)
Halting site	9 (20.9)
Rough sleeper	5 (11.6)
Living Arrangement	
Alone	18 (41.9)
With spouse/partner	5 (11.6)
Other	20 (46.5)
History of Addiction	
Dependency	27 (62.8)
Harmful to hazardous use	4 (9.3)
Stable/in recovery	4 (9.3)
No addiction issues	8 (18.6)
Physical health conditions	
Musculoskeletal	18 (41.9)
Respiratory	13 (30.2)
Cardiovascular	11 (25.5)
Seizures	6 (13.9)
Hepatitis	6 (13.9)
Liver disease	5 (11.6)
Diabetes	4 (9.3)
Cancer	3 (6.9)
HIV	2 (4.6)
Other	7 (16.3)

*Some participants had >1 physical health condition.

= 5) using the SHARE-FI and the CFS, while pre-frailty was identified in 20.9% ($n = 9$) and 60.5% ($n = 26$) using the SHARE-FI and the CFS, respectively. The median (IQR) frailty scores were 1 (1-2) and 2 (1-2) using the SHARE FI and the CFS respectively.

The age of the frail participants ranged from 44 to 56 years. Three out of five (60%) frail participants (by SHARE-FI) were male, while four out of five (80%) frail participants (by CFS) were male. Of those who were frail by SHARE-FI or CFS ($n = 6$), 66% ($n = 4$)

had inadequate housing, 83% ($n = 5$) had previously been incarcerated, 83% ($n = 5$) had drug dependency, all had co-morbidities and 50% ($n = 3$) used a mobility aid.

Tables 4 and 5 outline the results obtained from the regression modelling tests performed. Simple linear regression revealed that 31% of the variance of frailty (by the CFS) was explained by nutritional status while 12% of the variance of frailty (by the CFS) was explained by addiction status. Using the SHARE-FI, 23% of frailty was explained by nutritional status while 1% of frailty was explained by addiction status. In terms of gait speed, 15% of frailty (by the SHARE-FI) was explained by the gait speed (using the 10 m Walk Test). No associations (<10%) between frailty and independent variables of age and gender were found using the two frailty scales.

Binary logistic regression modelling was conducted by categorizing frailty into frail (frail/pre-frail) and non-frail categories. Results demonstrated that poor nutritional status increased the odds of frailty fivefold using the CFS and threefold using the SHARE-FI. Increased gait speed (10m Walk Test) reduced the odds of frailty by 0.5 using the SHARE-FI.

Practical utility of and agreement between frailty instruments

The SHARE-FI presented as a brief and easy to administer tool. In the final question of the SHARE-FI the exemplar of low physical activity, was deemed unfitting for the target population, and was rephrased to reflect the real-life experiences of the population under investigation (Romero-Ortuno et al., 2010). The CFS was scored using clinical judgement following comprehensive history taking and an assessment of physical function, a pre-requisite to participation in the exercise intervention in the LEAP-II trial. Collateral information was sought from management of the day service in some cases where reliability of responses was in doubt due to the perceived level of substance intake at the time of evaluation. In terms of administration time the SHARE-FI demonstrated a lower respondent burden than the CFS (duration

Table 3. Baseline summary statistics for frailty measures.

Frailty category	Clinical Frailty Scale			SHARE-FI		
	n (%)	Female n (%)	Male n (%)	n (%)	Female n (%)	Male n (%)
Non-frail	12 (27.9)	8 (18.6)	4 (9.3)	29 (67.4)	15 (33.9)	14 (32.5)
Pre-frail	26 (60.5)	14 (32.5)	12 (27.9)	9 (20.9)	6 (14)	3 (6.9)
Frail	5 (11.6)	1 (2.3)	4 (9.3)	5 (11.6)	2 (4.7)	3 (6.9)
Total	43	23	20	43	23	20

Table 4. Linear regression analysis.

Response variable	Explanatory variable	R ² *	p-Value	Response variable	Explanatory variable	R ² *	p-Value
Frailty: SHARE-FI	Age	0.086	0.056	Frailty: CFS	Age	0.097	0.042
	Sex	0.000	0.944		Sex	0.063	0.106
	Addiction Status	0.001	0.534		Addiction Status	0.119	0.023
	Nutritional Status	0.227	0.001		Nutritional Status	0.306	0.000
	Gait Speed	0.154	0.009		Gait Speed	0.062	0.107

*R² = square of the correlation coefficient.

Table 5. Binary logistic regression analysis.

Response variable	Explanatory variable	AOR ^a	p-Value	95% CI
Frailty: SHARE-FI	Addiction status	0.85	0.849	0.15–4.75
Frailty: SHARE-FI	Nutritional status	2.99	0.044	1.03–8.73
Frailty: SHARE-FI	Gait speed	0.05	0.021	0.00–0.65
Frailty: CFS	Addiction status	3.19	0.159	0.64–15.94
Frailty: CFS	Nutritional status	5.49	0.015	1.39–21.77
Frailty: CFS	Gait speed	0.47	0.52	0.04–4.95

^aAdjusted Odds Ratio.

of SHARE-FI: approximately 3 mins, duration of CFS: up to 10 mins), with its four brief questions (three binary) and one brief objective test of grip strength.

Fair agreement was detected between the two frailty instruments using three frailty categories (frail, pre-frail and non-frail); [$k_w = 0.317$ (95% CI: 0.226 to 0.431), $p = 0.001$]. Four participants were frail using the SHARE-FI and the CFS. One participant, who identified as frail using the SHARE-FI, was found to be pre-frail using the CFS and conversely, one participant, who identified as frail using the CFS, was found to be pre-frail using the SHARE-FI. Greater divergence was detected between the instruments in the pre-frail and non-frail categories, with almost two-thirds (60.5%, $n = 26$) pre-frail using the CFS while only 20.9% ($n = 9$) were pre-frail using the SHARE-FI. Correspondingly, 27.9% ($n = 12$) and 64.7% ($n = 29$) were found to be non-frail using the CFS and the SHARE-FI, respectively.

Discussion

The main findings of this study detected a high level and early onset of frailty (frailty and pre-frailty) in this non-geriatric population who experienced severe and multiple disadvantage using two frailty instruments. While both instruments identified a similar prevalence of frailty, uniquely the CFS identified a prevalence of pre-frailty which was three times that of the SHARE-FI. Nutritional status and addiction status were predictive of frailty using the CFS while gait speed was predictive of frailty using the SHARE-FI. Fair agreement was detected between these tools. Utility of the tools was also demonstrated with only a minor modification to the terminology of the

SHARE-FI to reflect the real-world experiences of this population. Therefore, the early identification of frailty and the application of these two instruments to this population is considered relevant and useful.

Firstly, the prevalence of frailty (11.6%) in this population (age range of frail: 44–56 years) is considered relatively high when viewed alongside studies investigating frailty in older populations (aged over 50 and 65 years respectively) (O'Halloran et al., 2021; Romero-Ortuno et al., 2010). Despite advancing age and a progressive accumulation of health challenges and chronic medical conditions, older people from the general population are unlikely to *also* have been exposed to the co-existence of chronic and extreme social disadvantages (homelessness, addiction, mental health challenges, unemployment, food poverty) and adverse lifestyle behaviors associated with this population under investigation, factors which are likely to contribute to frailty. In younger populations, a frailty prevalence of 3.9% to 63% has been reported (Loecker et al., 2021), but without a standard definition of frailty or comparable study design, it can be challenging to compare the proportion of frailty across studies with similar populations which expounds the case for exploring factors beyond chronological age which contribute to frailty in this non-geriatric population. For example, in a London-based study which investigated frailty in people experiencing homelessness a higher prevalence of frailty (48%) was reported using the CFS (Rogans-Watson et al., 2020). However, in this study the population was older (mean (SD) age of 55.7 (Aygnac et al., 2021) years) and the setting differed (hostel-based setting for people with high needs) (Rogans-Watson et al., 2020). Dawes et al. (2025) discuss the disparities in frailty prevalence across studies of people experiencing homelessness due to varying settings, populations and frailty tools (Dawes et al., 2025). A recent systematic review reported a pooled frailty prevalence between 16% and 70% and pre-frailty prevalence between 18 and 60% in people experiencing homelessness, explained by the heterogeneity of studies particularly variability in the use of frailty measurement tools as mentioned previously (Cronin et al., 2025).

Nonetheless, frailty levels in this current study are considered high and it is thought that an accumulation of multiple factors, including the presence of chronic stressors, adversity, deprivation and chronic illness (Aldridge et al., 2018) played a critical role in this finding.

Secondly, regarding attributes of frailty in this population, the SHARE-FI identified physical frailty in 11.6% ($n = 5$), while a significant degree of vulnerability (pre-frailty) beyond the physical domain was highlighted by the CFS (60.5%, $n = 26$). This disparity mirrors the low agreement found between the two frailty instruments. In participants identified with phenotypical frailty by SHARE-FI a level of frailty by CFS was also detected in 80% ($n = 4$), explained by medical (chronic conditions), psychosocial (living situation and environment) and behavioral factors (addiction and poor nutritional health). Addressing the physical health burden in this population, for example, through physical rehabilitation interventions, may have a ripple effect in addressing other domains of frailty detected by the CFS and may mitigate the broader frailty sequelae. Additionally, many participants with higher physical functioning by SHARE-FI (i.e. non-frail), demonstrated a vulnerability and using the CFS, a level of pre-frailty was identified in almost two-thirds of this cohort. Dual diagnosis and tri-morbidity are commonly reported in this population (Vallesi et al., 2021), therefore extreme psychosocial and behavioral factors are likely to play a key role in the manifestation of negative changes in function and frailty. In contrast, Loecker et al. (2021) reported the presence of fewer psychological factors driving frailty in the younger populations investigated (Loecker et al., 2021). This is not surprising given that the exploration of frailty in this population is less well researched.

Thirdly, regarding factors which drive frailty, this study identified a number of important findings. Firstly, considering that frailty is more closely linked to biological age than chronological age and higher levels of frailty are known to exist in *older* females, it is unsurprising that no association was detected between age and gender in this sample. However, nutritional status and addiction status appear to be predictive of frailty. This concurs with previous research findings of an association between substance use, nutrition, and adverse health outcomes, where protein-energy malnutrition can further complicate alcohol-related conditions and survival outcomes (Kamran et al., 2020). Furthermore, an increased odds of frailty was found in people with poor nutritional status using both frailty tools, also concurring

with the existing evidence base (Dorner et al., 2014; Lionetti et al., 2024). Food poverty is commonly reported in this population (Salem et al., 2013; Tong et al., 2019) and associated with frailty (Pérez-Zepeda et al., 2016), therefore, nutritional intervention is proposed as an important consideration for care providers when targeting interventions to mitigate frailty and adverse outcomes in this population. This finding also endorses the provision of post-exercise protein supplementation and basic nutritional advice, an intervention utilized in the LEAP-II trial to enhance muscle protein synthesis and health literacy. Another interesting finding is the predictive ability of gait speed (10m Walk Test) using the SHARE-FI frailty instrument. This finding concurs with the findings of Danilovich et al. (2018) where the SHARE-FI continuous scores were found to predict gait speed (Danilovich et al., 2018). It must be acknowledged that despite the apparent predictive ability of these frailty tools, interpretations must be cautiously considered due to the wide confidence intervals observed and larger samples are required to confirm these findings.

Larger scale studies have identified numerous correlates of frailty in similar populations. Salem et al. (2013) identified significant relationships between frailty and age [mean age 52.4 (40–73) years], gender [male: female: 50:50], healthcare utilization, nutrition and resilience (Salem et al., 2013). Interestingly, while it was reported that over two-thirds of this study's participants had addiction issues no correlation between frailty and substance use was determined (Salem et al., 2013). However, in a more recent study of 130 formerly incarcerated homeless women, higher drug dependency was significantly associated with higher levels of frailty (Salem et al., 2019). Of note in this current study 83% of participants frail by SHARE-FI or CFS reported former incarceration.

The Frailty Framework for Vulnerable Populations (FFVP), developed in 2014 through research and expert opinion, describes a framework underpinning frailty in this population of interest (Salem, Phillips, et al., 2014). Guided by this framework, the authors in this study have identified a number of potential drivers of frailty in addition to those discussed earlier; (i) housing situation and recent incarceration (Situational Factors), (ii) chronic medical conditions, nutritional status, mobility status and mental health conditions (Health-related Factors), (iii) addiction (Behavioral factors) and (iv) a subjective feeling of frailty (Resilience factors). In relation to resilience, in this study, those who felt frail were frail (Table 6).

Table 6. Profile of the participants who met the criteria for frailty as measured by the SHARE-FI and the CFS.

UIN	Age CATEGORY	Gender	SHARE-FI	CFS	Perceived frailty	Nutritional status ^a	Homeless	Drug dependency	Hx of incarceration	Medical conditions	Mobility
P2	55-60	F	Frail	Frail	Yes	6 (malnourished)	No	Yes	Yes	Cardiac, HIV, hyperthyroidism, Ca	Independent
P3	50-55	M	Pre-frail	Frail	Yes	11 (at-risk of malnutrition)	Yes ^b	Yes	Yes	Bowel condition, msk, lung condition	Stuck
P24	40-45	M	Frail	Frail	Yes	4 (malnourished)	Yes ^b	Yes	Yes	Suicidality, msk	Independent
P37	50-55	M	Frail	Frail	Yes	5 (malnourished)	Yes ^b	Yes	Yes	msk, depression	Caught
P40	45-50	F	Frail	Pre-frail	Yes	7 (malnourished)	Yes ^b	No	No	COPD, Ca, depression	Independent
P47	50-55	M	Frail	Frail	Yes	4 (malnourished)	No	Yes	Yes	COPD, OA, HIV	Stuck

^aMini-nutritional assessment scoring.

^bETHOS definition of homelessness.

^cMusculoskeletal condition.

However, larger scale research is required to further explore these factors.

Finally, regarding practical utility both instruments performed well. The SHARE-FI required a minor terminology change to better exemplify low physical activity to the target population. Otherwise, it presented as a brief and simple tool for use in community settings to identify the presence of physical frailty in this population. The CFS, being a judgement-based tool, required collateral information in some instances where substance misuse and recall may have impacted on the credibility of self-report responses. Similarly, Thorpe et al. (2022) identified that fundamental to screening for frailty in acutely unwell hospitalized patients is the collation of data from sources aside from self-report (Thorpe et al., 2022). The SHARE-FI was therefore superior in terms of lower respondent burden, an important consideration for this population where low threshold services are recommended (Morton & O'Reilly, 2016). Dual trait frailty measures have been recommended (Theou et al., 2015) and this feature highlights another advantage of the SHARE-FI with its combined test-based and self-report construct. Nonetheless, a comprehensive appraisal of frailty is required especially when evaluating a heterogenous population such as people experiencing homelessness and addiction. This is where the CFS triumphed and is most useful to identify a comprehensive view of this construct. Frailty is a multi-dimensional construct, therefore despite fair agreement between the frailty tools, selecting different yet complementary tools is important (Martin & Brighton, 2008). Moreover, proactive detection of pre-frailty, by CFS, through screening programmes in younger cohorts may provide insight into preventative care strategies and frailty mitigation. Additionally, it is known that higher levels of frailty are associated with higher health and social care needs and use of resources, and the CFS has been advocated in community settings to inform and improve the allocation of resources (O'Halloran et al., 2021; Roe et al., 2017). This is another important consideration for addressing health disparities and inequities and highlights the suitability of this frailty instrument. These findings highlight a research gap where a single, multi-dimensional tool is warranted, one that is designed for this population, reflecting the real-life experience of homelessness and captures the aforementioned psychosocial challenges as well as the physical health challenges which contribute to frailty. In conclusion, while no frailty tool is available for use in homeless populations specifically, both tools utilized in this study were considered relevant and practical for use in people experiencing homelessness

and addiction challenges and when used in harmony they have potential to be beneficial if they identify distinct needs and result in the delivery of targeted interventions.

Strengths, limitations and clinical implications

A strength of this study was the use of two easy to administer measures to identify distinct dimensions and degrees of frailty in addition to frailty drivers. This study adds knowledge to the social issues of this population which are linked to health outcomes. The convenience sampling method utilized in this study may have inadvertently introduced selection bias by the nature of the chronicity of the participants substance use issues and therefore has limited its generalizability to the wider population of people experiencing homelessness and addiction. The small sample size ($n = 43$) made it difficult to extensively explore relationships between frailty and other variables of interest, such as housing, history of incarceration and unemployment, and make inferences about effect size. Higher powered research would enable further exploration of additional risk factors in order to proactively implement strategies to mitigate frailty and its associated adverse outcomes. Data on the duration of homelessness and addiction, a factor which may also impact on frailty, was not investigated. This is a limitation and should be explored in future research. However, this speaks to the requirement of balancing the depth of information sought from participants with pragmatically ensuring the length of the evaluation was not excessively onerous or triggering. This study's findings are useful to inform public health strategies. For example, for clinicians working with this population, these findings provide guidance in selecting appropriate tools to efficiently and accurately screen for frailty, identify those at risk and plan practical and targeted interventions, such as exercise and nutritional supplementation interventions, factors which have been shown to be associated with frailty, factors known to mitigate frailty and which were the targeted interventions in this research (Travers et al., 2019). An important consideration for policy makers is to advocate case-finding for pre-frailty to mitigate against the more costly economic and societal implications of the frailty syndrome. This study illuminates the need for integrated and cross-sectoral care to address these complex health and social issues which contribute to costly adverse outcomes. Additionally, identification of frailty in unhoused participants in this study may assist in influencing housing policy to improve housing allocation for those

most in need. In a recent study on frailty prevalence in the UK, Dawes et al. (2025) demonstrated that those identified with the greatest levels of frailty were recently housed participants, perhaps reflective of a responsiveness to need with the prioritization of housing for the most vulnerable and frail presentations, where those who were too frail to live safely in homelessness were accommodated. This indicates the urgent need for earlier preventative intervention and a Housing First approach (Dawes et al., 2025). For researchers it highlights the need to further investigate drivers of frailty and to develop a bespoke frailty tool for people experiencing severe and multiple disadvantage.

Conclusion

In light of the poor health of young people experiencing homelessness and addiction challenges it seems prudent to identify tools to accurately screen for frailty and identify the factors driving frailty in this population and address them in a timely manner. Identifying frailty is increasingly relevant to narrow health disparities and provide equitable care to this multiply excluded and marginalized population. The two frailty instruments utilized in this study exhibit complementarity through their distinct findings. This study has uniquely highlighted a concerning level of pre-frailty in this chronologically younger population, an unmet need which warrants urgent attention and a proactive response to delay or avert the more costly consequences of the ensuing frailty syndrome (Salem et al., 2019). Further research through a higher-powered study is needed to explore and better understand the drivers of pre-frailty and frailty in this population.

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Data availability

The data underlying this article cannot be shared publicly for the privacy of individuals that participated in this study. The data will be shared on reasonable request to the corresponding author.

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Impact of a physiotherapy-led low threshold exercise and protein supplementation intervention to optimise physical function and target frailty in people experiencing homelessness and addiction: The LEAP-II trial

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Impact of a physiotherapy-led low threshold exercise and protein supplementation intervention to optimise physical function and target frailty in people experiencing homelessness and addiction: The LEAP-II trial.

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ABSTRACT

Objectives: Frailty is an age-associated state of physiological vulnerability due to loss of biological reserves and is associated with adverse outcomes such as falls, disability and hospitalisation. People who are homeless and in addiction experience health inequities and have a higher burden of poor physical function and frailty than the general population.

Design: Pre-post intervention study.

Setting: Day service centre for people with chronic addiction issues and homelessness.

Participants: People experiencing homelessness and addiction.

Intervention: A physiotherapy-led low threshold three-times weekly exercise intervention with protein supplementation was flexibly delivered over 12 weeks.

Main Outcome Measures: The primary outcome of feasibility was measured by recruitment, retention, adherence, acceptability and adverse events. Secondary outcomes were physical function, pain, frailty and nutritional status, and self-reported health.

Results: Forty-three participants enrolled. Overall retention was 70%, with higher retention observed in subgroups (women and older adults). Programme adherence and acceptability was reported in 93% and 100% of participants, respectively. No adverse events occurred. At baseline, sub-normative values were demonstrated for limb strength and balance; pain was prevalent in 35%; 70% had poor nutritional health and between 33% and 72% lived with some degree of frailty. Significant improvements were demonstrated for lower limb strength, gait speed, pain, nutritional status and frailty, ($p < 0.05$).

Conclusions: This novel and pragmatic intervention delivered to this **commonly overlooked** population was shown to be feasible and impactful, indicating proof of concept.

229 words

Trial registration number: Clinical Trials.gov: NCT05700305

Contribution of the Paper:

- This study addresses a gap in the evidence base on physiotherapy-led frailty-focussed physical activity interventions in people with severe and multiple disadvantage.
- It proposes a novel and targeted physical activity intervention to mitigate the physical health burden and frailty in this population.
- This small-scale intervention paves the way for larger studies of this kind which are considered critical to engagement and participation of a population who do not prioritise their health.

Keywords Addiction, homelessness, physical functioning, frailty, exercise, protein supplementation.

Introduction

Frailty is a complex state of cumulative decline **across multiple physiological systems** which renders a person vulnerable to adverse health outcomes [1]. Frailty is associated with lower socioeconomic status and has been identified in populations with socioeconomic inequalities and multiple disadvantage [2,3]. Moreover, poor physical functioning and frailty have been reported in people experiencing homelessness (PEH) and association between a tri-

morbidity of addiction, mental and physical health conditions and PEH is commonly reported [3,4].

People experiencing homelessness and addiction face challenges accessing healthcare, which is mostly delivered in highly structured environments [5,6]. Low-threshold, trauma informed interventions are advocated to address the complex needs identified and are shown to be effective in reducing substance use-related harm [7,8]. Exercise has been proposed as an adjunctive therapy for addiction or Substance Use Disorder (SUD) [9,10]. Much of the research in this area, however, has focused on substance use-related outcomes and a range of mental health outcomes [9,10]. Despite the known poor physical health of PEH and addiction issues [3,11] there is a dearth of evidence on exercise interventions targeting physical functioning deficits and frailty in this population [11,12,13].

Poor nutritional intake has been identified as a key driver of frailty and **consistent with this, a lower risk of frailty has been associated with higher intake of nutrients and higher quality dietary patterns [14, 15] The evidence points to food insecurity in PEH, although research on drivers of frailty in this population is lacking [16].** Protein supplementation, in addition to exercise, has proven effectiveness in reversing or delaying frailty [17]. **The impact of exercise with protein supplementation to target frailty in PEH was explored in the LEAP-I (Low threshold Exercise And Protein supplementation) trial, a linked preliminary feasibility study [11]. While feasibility of this once-weekly intervention was demonstrated, recommendations for further exercise opportunities were made [11].**

The aim of this study was to measure the feasibility and the impact of an enhanced low-threshold exercise intervention with multiple exercise opportunities each week with protein supplementation to target physical function and frailty in PEH and addiction.

Methods

Study design.

This was a pre-post intervention study measuring the impact of a 12-week exercise programme with protein supplementation. **It took place in a day centre for people with chronic addiction issues, many of whom experienced homelessness.** Recruitment commenced on October 3rd, 2022, and follow-up continued until March 3rd, 2023. The full trial protocol is available [18].

Stakeholder engagement, in the form of a focus group, took place in advance of the intervention, to build in a co-design approach with people with lived experience of addiction and homelessness, who discussed their exercise preferences and challenges due to poor health and their desire for a fun and flexible programme. This helped to shape the design of the intervention which was tailored to their needs. Participant information leaflets were distributed via a gatekeeper in the centre. Eligibility screening, written informed consent and baseline assessment was initially conducted, and GPs were notified of participants involvement.

Any person (18-65 years) accessing services in the centre who consented to participate was included. Participants with problematic behavioural issues, major physical or cognitive impairments which precluded ability to safely participate or with a confirmed pregnancy were excluded.

Outcomes.

The primary outcome was feasibility measured by recruitment, retention, adherence, adverse events, and programme acceptability (Supplementary File,S1).

Secondary outcomes, **measuring pre-post intervention change**, were physical function and pain, frailty and nutritional status and self-reported health status, recorded at baseline and end of programme (Supplementary File,S2).

Further detail of the broad test battery utilised in this study which was informed by the LEAP-I trial is reported in a linked paper [19].

Intervention

The 12-week intervention was designed to be low-threshold, flexible and participant-centred. Group, individual, and gender-based exercise classes were flexibly delivered twice weekly by two research physiotherapists (FK and MM) over 15 weeks to facilitate maximum inclusion and participation. For consistency FK conducted the pre- and post-intervention evaluation. The exercise classes were multi-modal with a primary focus on strength and were adapted and progressed based on the physical ability of the participants, and their often-fluctuating presentations and motivation (Table 1). Blood pressure and heart rate was monitored as a safety indicator and exercise intensity was set at low to moderate and was modulated using Borg's Perceived Rate of Exertion (RPE) scale, where participants were advised to exercise between 11 and 13 on the RPE scale [20]. To promote post-exercise muscle protein synthesis, 20g of protein supplement (Fresubin, <https://www.fresubin.com/>) was offered to participants. Participants were educated about physical activity and provided with basic nutritional advice. They were encouraged to exercise three times weekly, for two exercise classes and a weekly 'Park Walk'. Motivational phone calls were made to remind participants of the classes and address barriers to adherence. **A brief, 5-minute exit survey was**

utilised following the intervention to explore the study's attrition.

Data analysis

Descriptive statistics were performed to summarise participant characteristics. Data were analysed using IBM SPSS V28 and a p -value with statistical significance was set at $p < 0.05$. Data were tested for normality using the Kolmogorov–Smirnov test. Pre- and post-intervention data were then compared using paired t-tests or Wilcoxon signed-rank tests if normally distributed or non-normally distributed, respectively. Exit survey data were analysed by (i) observing frequencies of responses, (ii) exploring data for themes using a low level of interpretation and (iii) illustrating themes through verbatim comments, while bearing in mind that this survey **was designed as purely exploratory and was designed during the programme in response to the study's attrition. Thus, the data wasn't sufficiently rich enough for full qualitative analysis and rather** represents 'quasi-qualitative data', not in-depth analysis addressed by qualitative study methodology [21]. (Exit survey: Supplementary File, S3)

Sample size

Determination of sample size was influenced by a power calculation performed on the statistical package R which recommended a sample size of 68. However, considering this '**commonly overlooked**' population and sample sizes of at least 24 participants have been proposed for feasibility studies, the minimum target for this study was 24 [22,23].

Results

Feasibility

Recruitment

Forty-seven people were initially recruited. Forty-three participants progressed to study enrolment, 30 returned for the intervention and 20 completed the final evaluation (Figure 1).

The mean (SD) age was 45.6 (9.5) years. Just over half (54%, n=23) were female. Most were single (40%, n= 17) and unemployed (91%, n=39). Three-quarters (74%, n=32) were white Irish and 26% (n=11) were Irish Travellers. The majority (81%, n=35) experienced problematic substance use. Half (51%, n=22) of the participants were homeless. All participants had a self-reported mental health condition and were on prescribed medication for this. A range of physical health conditions were reported. Reminder phone calls of classes yielded a 0% return rate. Baseline data of participants including physical function and frailty, are presented in Table 2 and 3.

Retention.

The overall retention rate showed that two thirds (70%, n=30) attended at least one session. One quarter (26%, n=11) were *regular attenders*, under half (44%, n=19) were *sporadic attenders* and just under one third (30%, n=13) did not return following initial assessment (*non-attenders*)*. Greater attendance was observed in the older participants with 73% (n=8/11) of the regular attenders over the median age (48 years), while 42% (8/19) of the sporadic attenders were over the median age. Greater female attendance was observed. Over one third (35% (n=8/23)) of females (regular attenders) versus 15% (n=3/20) of males attended regularly.

*Supplementary file, S1 contains details of retention categories.

Adherence.

Adherence to the exercises and protein supplement was 93% and 90%, respectively. Pain (n=7, 23%), assault or accidental injury (n=2, 7%), external stresses (n=3, 10%), time (n=2, 7%), personal preference and lack of motivation (n=4, 13%) were the reported reasons for the inability to complete the prescribed exercises and taste was the cited reason for declining the protein drink.

Adverse Events.

No adverse events occurred during the entire programme.

Acceptability.

The exit survey was completed by 20(47%) participants. Three themes emerged:

Barriers to retention: This theme was highlighted by:

"I should have kept going but I was in such a bad place that I didn't want to feel happy." (P1)

"I was more interested in the drink". (P5)

"... just things in my addiction". (P12)

"There was a lot going on for me." (P16)

Psychological benefits: The exercise classes were reported to be fun, inclusive and sociable.

Music was important and enjoyed particularly by the female participants.

"It was an enjoyable kind of exercise." (P29)

"I felt alive, I walked out tall, and I didn't walk in like that ... gave me something to look forward to." (P1)

"I felt great after it, I often feel down in the dumps, and it brings me back up ... I've often a lot going on at home. I feel I leave it all behind me when I come ... getting out mixing with people is great. (P40)

"I got pain relief, friendship, energy, positivity" (P12).

The Park Walk was considered more feasible for some who felt unable for the exercise class.

"The Park Walk was just great, just doing the walk and the having the chat with the girls was good." (P4)

Reduced substance use: Another important finding was the reported reduction in substance use for some (n=8, 40%). Participants reported that it helped to postpone the use of substances until later in the day.

"I don't smoke as much weed ... I don't smoke as much cigarettes" (P2)

"It was keeping me away from the weed" (P15)

"it was another thing stopping me from using" (P47)

Baseline measures

Eleven percent (n=5) of females and 11% (n=5) of males had **below normative values** for lower limb (LL) circumference measures, while 9% (n=4) of females and 14% (n=6) of males had **below normative values** for upper limb (UL) circumference [24,25]. Eighty-eight percent (n=38) of participants scored below the mean normative values for grip strength [26]. Just over half (55% and 53%) scored below the normative and average values for the 2-Minute Walk Test (2MWT) and the Single Leg Stance test (SLST), respectively [27,28]. Pain was prevalent in 35% (n=15). Twenty-three percent (n=10) were malnourished and a further 47% (n=20) were at risk of malnutrition. The proportion of living with some degree of frailty was 33% and 72% using the SHARE-Frailty Instrument (FI) (pre-frail or frail) and Clinical Frailty Scale (CFS) (4+), respectively. The Short-Form-12 (SF-12) highlighted below average scores [mean (SD)=50(10)] for physical and mental component scores (PCS/MCS) for the

collective group when compared to 1998 normative values [29]. More than half (58%, n=25) scored below the mean PCS value, while 81%, (n=35) scored below the mean MCS value.

Impact

Impact was measured by observing pre-post intervention changes in the 20 participants who completed the final evaluation. Overall improvements were demonstrated in the Chair Stand Test (CST) (95% CI: 0.57 to 3.43, $t(19)=2.922$, $p=0.009$) the 10m Walk Test (10mWT) (95% CI: 0.02 to 0.47, $t(19) =2.328$, $p=0.031$) and Mini-Nutritional Assessment (MNA) ($Z=-2.18$, $p=0.029$) (Table 4). Data were stratified into regular and sporadic attenders. In the *regular attenders* (Table 5) improvements were observed in the 10mWT (95% CI: 0.1 to 0.75, $t(10) = 2.943$, $p=0.015$), MNA (95% CI: 0.30 to 3.97, $t(10) =2.262$, $p=0.047$) and in pain levels ($Z= -2.214$, $p=0.027$). Additionally, an improvement was detected in the CFS ($Z=-2.121$, $p=0.034$) and SHARE-FI continuous score (95% CI: -2.81 to -0.73, $t(10)= 2.042$, $p=0.041$). Evidence was lacking for effectiveness in all outcomes for the *sporadic attenders*.

Discussion

Key findings in this study indicate feasibility, demonstrated by safety, acceptability, adherence, and retention in certain sub-groups. Impact was demonstrated in the regular attenders in pre- to post-intervention changes for a number of outcomes indicating proof of concept.

Unsurprisingly this study had a notable attrition level, with survey feedback indicating participants chronic addiction challenges as the primary reason. Furthermore, those with unstable or inadequate accommodation attended less. The participants in this study lived in

one of the highest areas of deprivation nationally within Ireland [30]. These findings were also demonstrated in the LEAP-1 trial, where stability in housing and addiction, appeared to drive better retention [11]. Furthermore, often observed was the presence of a tri-morbidity of substance misuse, a mental health disorder and a physical health condition. Many participants alluded to prior trauma, and it is suggested that adverse experiences, known to impact the life course likely influenced participants' ability to engage. It is clear that the co-existence of these complex social factors contributed to attrition.

In this study, health literacy appeared to be low in terms of realising the impact of risky lifestyle behaviours. Many participants smoked prior to and immediately following exercise. Others declined to exercise due to reported health conditions and they viewed exercise as a futile activity rather than an opportunity to improve health. Concurring with these findings, Hovhannisyan et al (2019) reported over 90% of patients in receipt of addiction services with unhealthy lifestyle behaviours [31]. Moreover, lower health literacy levels in this population have been linked to poorer quality of life and mental health [32]. These barriers combined with poor exercise histories were considered to negatively influence motivation. Health promoting and awareness programmes preceding health interventions are proposed to enhance health literacy and retention.

Numerous strategies and behavioural change techniques have been proposed to enhance adherence and outcomes in physical activity interventions, many of which were utilised in this study [33,34]. Among these are: exploring barriers and facilitators; improved participant knowledge and expectations, enjoyment and social support; goal setting and self-efficacy, and multi-disciplinary involvement [33,34]. **Brief interventions on relevant health topics such as physical activity and nutrition are recommended to enhance health literacy and**

improve retention in future studies. Finally, stakeholder involvement, also a feature in this study, particularly of those with lived experience is advocated in the planning stages of trials [35].

Findings of higher retention in older and female participants in LEAP-II similarly emerged from the LEAP-I trial [11]. This may be due to a greater physical health need associated with ageing as well as the benefits of social engagement observed in the females. Another distinct group who engaged well were the female Travellers in this study. Factors influencing retention in this group were enjoyment and psychosocial support that the group offered, a cited distraction from difficult and often stressful living conditions. Irish Travellers, an indigenous Irish ethnic group, are known to suffer a disproportionate burden of physical health conditions compared to the general Irish population and their inclusion and engagement in this programme is considered important [36]. Furthermore, women experiencing homelessness and addiction have unique needs and this gendered dimension to the programme highlights a need for gender-sensitive services [37].

The 'Park Walk' offered an alternative mode of exercise for some. Some preferred the "walk and talk" and enjoyed the "chat with the girls". There is growing evidence of the restorative powers of exercising in open green spaces, improving cardiovascular markers as well as mental health outcomes [38,39]. Finally, other positive indicators in this study were high adherence to the exercises and the protein supplement as well as the absence of adverse events.

This study, in harmony with linked studies [3,11] highlighted sub-normative physical functioning and frailty scores, validating the need for a targeted intervention. In terms of

impact, sub-group analysis demonstrated that improvements were observed in those who attended regularly. Movement components of the CST and walking featured in the programme and were reportedly practiced outside of the programme and may have influenced improvements observed. Nutritional levels also improved. The post-exercise consumption of protein supplement regularly stimulated discussion around healthy eating and healthy behaviours which may have contributed to the enhanced nutritional scores detected. Baseline levels of frailty in this study were relatively high (11% SHARE-FI and CFS) when compared to studies of older populations [40,41]. These outcomes evince the manifestation of accelerated ageing in this population and need for early intervention. Interestingly, the prevalence of living with some degree of frailty was much higher by CFS (73% ≥ 4) than the phenotypical SHARE-FI (33% pre-frail/frail), indicative of other drivers of frailty in this non-geriatric population. Effectiveness of exercise interventions with nutritional supplementation to mitigate frailty in older adults has been demonstrated [17]. In this study, an improvement was observed in the regular attenders using the CFS and in the continuous scores of the SHARE-FI. Nonetheless, post-intervention frailty (frail/pre-frail) using both measures was lower, and it is posited that even the postponement of decline, particularly in extremely vulnerable non-geriatric populations, is a positive outcome and such markers need to be acknowledged.

This study has addressed a research gap regarding frailty-focussed interventions in this population. It appears that this study, in harmony with the LEAP-1 trial, is one of the first to provide a physiotherapy-led structured exercise intervention to target frailty in this population. Its strengths are its pragmatic, low-threshold and flexible design, coupled with its' co-design methodology. The exit survey highlighted important issues regarding retention and the impact exercise may have on **substance use** and psychological wellbeing. Anecdotal feedback from stakeholders indicated that positive behaviours persisted beyond the lifecycle

of the programme where a number of participants (n=6) continued the Park Walk and completed the Women's 10km Mini Marathon two months later and others went on to engage in drug rehabilitation programmes. This concurs with the evidence where physical activity interventions translate into positive effects on wider life and addiction [13]. Mainstream services are unlikely to reach this population, and low-threshold services are initially key to the delivery of interventions and may work as a bridge to mainstream services and more positive health behaviours.

Limitations

Limitations of this study were the small sample size and absence of a control group. Furthermore, multiple testing was not conducted due to the feasibility focus of the study. As this was a feasibility study, findings should be regarded as preliminary and subject to future testing in a larger population [42]. This was a frailty-focussed study which aimed to explore the impact of exercise and protein supplementation collectively due to recommendations of its effectiveness in managing frailty [17] and therefore, the effect of these variables individually is unknown. Generalizability of this study findings may be limited in general populations but may have important application to marginalised groups with addiction and homelessness challenges.

Conclusion

This pragmatic study offers a valuable contribution to an expanding area of research and highlights the benefit of interventions to enhance physical health and delay the premature onset of frailty syndromes in this non-geriatric population who experience extreme health inequities. Greater consideration of the complex presentations of this population who face

immense challenges to accessing and participating in health interventions is warranted. Study attrition should thus be expected and novel research such as this with its pragmatic and accessible design features should be welcomed and viewed with optimism. Further higher-powered research to evaluate effectiveness of exercise interventions and identify retention-enhancing strategies is warranted, particularly in sub-groups where better adherence and impact was observed. Nonetheless, where possible, all potential participants regardless of addiction issues and other challenges should be offered the opportunity to participate in exercise and physical rehabilitation programmes due to the breath of potential impacts demonstrated in this study and possibility of translation of these benefits to wider life. This research may be useful to drive policy in this area and guide physiotherapists to deliver appropriate and flexible person-centred interventions for this '**commonly overlooked**' population.

Tables

Table 1 Exercise Circuit

Table 2 Participant Demographics

Table 3 Baseline Physical Function and Frailty scores

Table 4 Secondary Outcomes at 12-week follow-up

Table 5 Secondary Outcomes at 12-week follow-up (Regular Attenders)

Figures

Figure 1 CONSORT Flow Diagram

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Table 1 Exercise Circuit

Core exercise	Initial Intensity	Progression/Adaptations*
Sit to stand or squats	2 sets 10-15 reps	3 sets of 15 repetitions. lunges, inner range quads; use of weights/ball
Elbow Bends	2 sets 10-15 reps	3 sets of 15 repetitions. use of weights
Step-ups	2 sets 10-15 reps	3 sets of 15 repetitions. alter height of step; use of weights
Arm elevations	2 sets 10-15 reps	3 sets of 15 repetitions. use of weights
Hip abductions	2 sets 10-15 reps	3 sets of 15 repetitions. with additional upper limb abduction and elevation; movement with 360° turns
Scapular retractions	2 sets 10-15 reps	3 sets of 15 repetitions. use of weights
Aerobic activity	2 mins	3-5 mins use of ladders, hurdles, skipping ropes, jumping jacks. dance, game with cones/balls
Balance	4-5 mins	5 mins tandem; single leg stance, upper limb, and trunk movements; weights and ball work

Commenced with warm-up and ended with cool-down. * Adaptations: exercises were individualised and progressed for each participant by the research physiotherapist Progression: 2-3 sets of 10-15 repetitions completed at each session; beyond that, low resistance weights (1.1kg-4.5kg), theraband or increased step height was introduced to achieve a strengthening effect.

Exercise equipment: therabands, dumbbells, steps, ladders, hurdles, skipping ropes and balls.

Table 2. Participant Demographics

Demographic item	n (%)^
Age mean (std dev) (range)	45.6 (9.5) (26-62) years

Female	23 (54)
Male	20 (47)
Marital status	
Single	17 (40)
Married/partnership	10 (23)
Separated/divorced	8 (19)
Widowed	7 (16)
*Data unavailable	1 (2)
Ethnicity	
White Irish	32 (74)
Irish Traveller	11 (26)
Employment status	
Full-time employment	1 (2)
Part-time employment	3 (7)
Unemployed	39 (91)
*Housing environment	
House/apartment	21 (49)
Hotel/hostel/staying with friend/family/other	8 (19)
Halting site	9 (21)
Rough sleeper	5 (12)
Living Arrangement	
Alone	18 (42)
With spouse/partner	5 (12)
Other	20 (47)
History of Addiction	
Dependency	27 (63)
Harmful to hazardous use	4 (9)
Stable/in recovery	4 (9)
No addiction issues	8 (19)
Physical health conditions	
Musculoskeletal	18 (42)
Respiratory	13 (30)
Cardiovascular	11 (26)
Seizures	6 (14)
Hepatitis	6 (14)
Liver disease	5 (12)
Diabetes	4 (9)
Cancer	3 (7)
HIV	2 (5)
Other	7 (16)

some participants had >1 physical health condition

* except for age *Homelessness status: aligned with the European Typology for Homelessness and Housing (ETHOS)

Table 3. Baseline Physical Function and Frailty scores (n=43)

	Mean (SD)	Median (IQR)	n (%)
Limb circumference			

Upper Limb (cm)	27.86 (3.69)	43 (100)
Lower Limb (cm)	35.94 (4.30)	43 (100)
Physical Performance		
10m Walk Test (m/sec)	1.7 (0.34)	43 (100)
2 Min Walk Test (m)	180 (158-193)	43 (100)
Grip Strength		
Male (kg)	42 (8)	20 (46.5)
Female (kg)	28 (6)	23 (53.4)
Chair Stand Test (n)		
	13 (2)	43 (100)
Single Leg Stance (s)		
	8 (3-23)	43 (100)
Short Form-12 (SF-12) (score)		
Physical Component Summary	46 (11)	43 (100)
Mental Component Summary	36 (14)	43 (100)
Pain prevalence		
		15 (35)
Clinical Frailty Scale (CFS)		
CFS 3 (managing well)		12 (28)
CFS 4 (vulnerable)		26 (61)
CFS 5 (mildly frail)		5 (12)
SHARE-Frailty Index		
	Continuous scores	Categorical result
Non-frail	-0.172 (0.726)	29 (67)
Pre-frail	1.287 (0.774)	9 (21)
Frail	3.614 (0.840)	5 (12)
Mini Nutritional Assessment		
0-7 (malnourished)		10 (23)
8-11 (at risk of malnutrition)		20 (47)
12-14 (normal nutritional status)		13 (30)

Table 4. Secondary Outcomes at 12-week follow-up (n=20)

	Pre-intervention		Post Intervention		Difference	
	n	n	n	n	Mean/median difference (95% CI)	P
Chair stand test mean (SD)	13 (2) (n)	20	15 (4) (n)	20	2.00 (0.57 to 3.43) (n)	*0.009 a
Grip strength mean (SD)	39 (9) (kg)	20	33 (12) (kg)	20	0.78 (-1.34 to 2.91) (kg)	0.452 a
10m Walk Test mean (SD)	1.6 (0.32) (m/sec)	20	1.9 (0.5) (m/sec)	20	0.30 (0.02 to 0.47) (m/sec)	*0.031 a
2min Walk Test median (IQR)	1.80 (1.66-1.89) (m)	19	1.94 (1.50-2.20) (m)	19	0.14 (0.13 to 0.61) (m)	0.387 b
Single leg stance median (IQR)	8 (4-33) (sec)	19	14 (6-36) (sec)	19	10.6 (2.80 to 23.50) (sec)	0.355 b
UL circumference mean (SD)	28 (4) (cm)	20	28 (4) (cm)	20	0.43 (-0.24 to 1.09) (cm)	0.201 a
LL circumference mean (SD)	36 (4) (cm)	20	37 (4) (cm)	20	0.38 (-0.25 to 1.01) (cm)	0.218 a
Mini Nutritional Assessment median (IQR)	10 (6-12)	20	12 (9-12)	20	3 (0.00 to 4.00)	*0.029 b
Pain (NPRS) median (IQR)	3 (0-6.5)	13	0 (0-5)	13	0 (0.00 to 7.00)	0.240 b

SF12

PCS median (IQR)	45 (35-55)	17	49 (45-54)	17	10.7 (1.51 to 17.46)	0.381 b
MCS	39 (12)	17	37 (12)	17	1.26 (-7.89 to 10.42)	0.774 a
Frailty						
<i>Clinical Frailty Scale</i>		20		20	0(0.00 to 0.00)	0.096 b
CFS 3 (Managing well)		5		9		
CFS 4 (Vulnerable)		13		10		
CFS 5 (Mildly frail)		2		1		
<i>SHARE-FI</i>		20		20	0(0.00 -0.00)	0.248 b
Non-frail		11		14		
Pre-frail		6		5		
Frail		3		1		
<i>SHARE-FI continuous scores Mean (SD)</i>	0.968 (1.602)	20	0.372 (1.365)	20	-0.595 (2.224)	0.246 a

a-paired samples t-test comparing pre- to post- intervention, b-Wilcoxon signed-rank test, * = significant result; Pain NPRS= Numerical Pain Rating Scale; SF-12 PCS = Physical Component Score, MCS = Mental Component Score

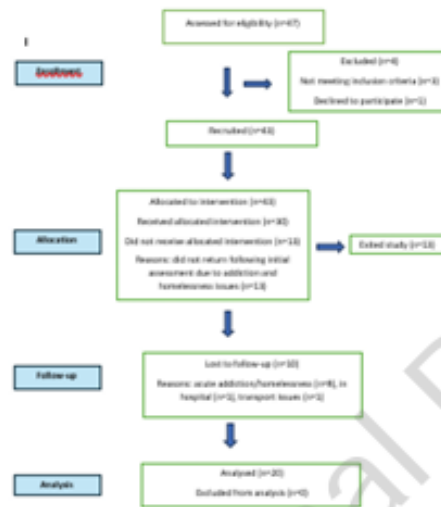
Table 5: Secondary Outcomes at 12-week follow-up (Regular Attenders)

	Pre-intervention		Post Intervention		Difference	P
		Number (%)		Number (%)		
Chair stand test mean (SD)	13 (2) (n)	11(55)	15(3) (n)	11(55)	2.18 (-0.19 to 4.56) (n)	0.068 a
Grip strength mean (SD)	29 (8) (kg)	11(55)	30 (10) (kg)	11(55)	0.51 (-2.17 to 3.19)) (kg)	0.682 a
10m Walk Test mean (SD)	1.7 (0.3) (m/sec)	11(55)	2.1 (0.4) (m/sec)	11(55)	0.48 (0.10 to 0.75) (m/sec)	*0.015 a
2min Walk Test mean (SD)	1.81 (0.2) (m)	11(55)	1.93 (0.3) (m)	11(55)	0.12 (-0.09 to 0.34) (m)	0.226 a
Single leg stance mean (SD)	21 (15) (sec)	11(55)	26 (22) (sec)	11(55)	4.63 (-7.2 to 16.46) (sec)	0.404 a
UL circumference mean (SD)	28 (5) (cm)	11(55)	28 (5) (cm)	11(55)	0.55 (-0.48 to 1.58) (cm)	0.267 a
LL circumference mean (SD)	36 (5) (cm)	11(55)	36 (5) (cm)	11(55)	0.25 (-0.47 to 0.96) (cm)	0.464 a
MNA mean (SD)	9 (3)	11(55)	11 (2)	11(55)	2.00 (0.29 to 3.97)	*0.047 a
Pain (NPRS) median (IQR)	5 (0-6.5)	9(45)	0 (0-4)	9(45)	0 (0.00 to 0.00)	*0.027b
SF12						
PCS	42 (10)	11 (55)	49 (7)	11(55)	-3.7 (-2.81 to 16.99)	0.142
MCS	37 (14)	11 (55)	40 (13)	11(55)	2.49 (-10.7 to 15.75)	0.684
Frailty						
<i>Clinical Frailty Scale</i>		11(55)		11(55)	0(0.00 to 00.00)	*0.034b
CFS 3 (Managing well)		4(36.4)		8(72.7)		
CFS 4 (Vulnerable)		5(45.5)		3(27.3)		
CFS 5 (Mildly frail)		2(18.2)		0(0)		
<i>SHARE-FI</i>		11(55)		11(55)	0(0.00 to 0.00))	0.063 b
Non-frail		6(54.5)		9(81.8)		

Pre-frail		2(18.2)		2(18.2)	
Frail		3(27.3)		9(0)	
<i>SHARE-FI continuous score</i>	1.235 (1.904)	11(55)	-0.204 (0.755)	11(55)	-1.439 (2.033) *0.041 a

a=paired samples t-test comparing pre- to post- intervention, b=Wilcoxon signed-rank test, * = significant result; Pain NPRS= Numerical Pain Rating Scale; SF12 PCS = Physical Component Score, MCS = Mental Component Score

Figure 1. CONSORT Flow Diagram of participants through the study.



Chapter 3 The LEAP-II Trial

3.1 Introduction

Chapter 3 will present the first study of this PhD, the LEAP-II trial. It will expand on detail of the study's design and methodology discussed in Chapter 2, which was pertinent to this study only and following this, relay the results and findings with an in-depth evaluation and discussion. An overview of the content of this chapter is displayed in Table 3.1.

Table 3.1 Overview of Chapter 3

3.1 Introduction	
3.2 Methods	3.2.1 Study setting 3.2.2 Study participants 3.2.3 Study procedure 3.2.4 Ethics 3.2.5 Data analysis
3.3 Results	3.3.1 Baseline results 3.3.2 Feasibility 3.3.3 Pre-post Intervention results 3.3.4 Test battery evaluation 3.3.5 Exploration of frailty
3.4 Discussion	3.4.1 Feasibility 3.4.2 Impact 3.4.3 Test battery utility 3.4.4 Frailty exploration

The LEAP-II trial was the Low threshold Exercise And Protein supplementation intervention which was delivered to a population from Dublin, who experienced severe and multiple disadvantage (SMD) (Lankelly Chase, 2024). This study followed the LEAP-I trial, which took place in 2022, prior to this PhD. LEAP-I primarily tested the feasibility of delivering low threshold exercise to people experiencing homelessness in a real world setting where they attended for support and services for their homelessness

related challenges (Kennedy et al., 2024). The results of the LEAP-I trial, indicated that while the intervention was feasible, the once-weekly delivery was not sufficient to effect changes in secondary outcomes and further exercise opportunities were required.

The overall aim of LEAP-II was to test the feasibility and pre-post intervention impact of an optimised 12-week exercise intervention, with nutritional supplementation by advancing the exercise parameters utilised in LEAP-I in order to drive physiological change and improve physical function and frailty outcomes.

The objectives of this study were:

1. To evaluate recruitment, retention and adherence to the intervention, as well as its safety and acceptability.
2. To examine baseline and pre-post intervention change in physical, nutritional and frailty status, self-reported pain and overall health status.
3. To ascertain perceptions of unmet physical health needs and how interventions should be designed to meet the needs of this population.
4. To evaluate the feasibility of the test battery in terms of its acceptability and utility.
5. To explore attributes and drivers of frailty in this population, as well as the practical utility of and, agreement between the selected frailty tools.

3.2 Methods

3.2.1 Study setting

The study took place in the Ballyfermot Advance Project, a day-service centre located in a West Dublin suburban area (Dublin 10), from October 2022-March 2023. Ethical approval was granted by the Faculty of Health Sciences Research Ethics Committee at Trinity College Dublin and written informed consent was provided by all study participants (Appendix V).

The Ballyfermot Advance Project (Figure 3.1) was established in 2003 to support people (individuals and their families) in the community affected by substance misuse (Ballyfermot Advance Project, 2025). It is funded by the Ballyfermot Local Drug and Alcohol Task Force, who funded this study, and the Health Service Executive (HSE). It provides a five-day per week, low threshold, drop-in service, including meals, drug and alcohol related services, counselling, family support services and wellbeing services for people who have addiction issues, homelessness and mental health problems. It also provides needle and syringe exchange and an outreach service to the Dublin 10 area in West County Dulin. The service is 'low threshold' (with minimal constraints or barriers to access) and open to all people residing in Dublin 10. This area is one of the highest areas of deprivation nationally with a population of over 33,000 people (Pobal, 2023). The Ballyfermot Advance Project also provides services to members of the Travelling community who reside in a local halting site 'Labre Park'. A dedicated room in an adjacent community centre was utilised for the exercise classes and a local abutting green space, 'Le Fanu Park', was used for the once weekly 'Park Walk', for the duration of the study intervention.



Figure 3.1 Ballyfermot Advance Project

3.2.2 Study participants

Considering the frailty focus of this PhD was on accelerated ageing and ‘younger frailty’, the eligibility criteria narrowed those who were recruited as study participants, however, to be inclusive, all service users were invited to participate and benefit from the programme.

The eligibility criteria were as follows:

Inclusion Criterion

- (i) Service users (18-65 years) of the Ballyfermot Advance Project who consented to participate.

Exclusion criteria

- (i) Any participant with perceived problematic behaviour or confusion, or with significant physical or cognitive impairments which precluded ability to safely participate in the programme. Problematic behaviour was defined as a perceived

threat to the researcher or other participants, or behaviour which was deemed sufficiently challenging to impede the efficient running of the class. Problematic behaviour and confusion were established informally by expert clinical judgement.

- (ii) Any participant with a confirmed pregnancy, as physical functioning/performance test scores in advanced stages of pregnancy may vary from baseline values (Wowdzia and Davenport, 2021).

3.2.3 Study procedure

3.2.3.1 Initial Evaluation

Using a bespoke data collection form (Appendix I), an initial evaluation was undertaken to gather

- (i) demographic data to establish a profile of the study participants. This enabled the researcher to identify any safety issues or medical concerns which needed to be addressed prior to the intervention and to tailor the exercise intervention to the needs of the participants

and

- (ii) baseline physical functioning and frailty status measurements.

3.2.3.2 Study Measures

Primary outcome measures of this study's feasibility were discussed in Chapter 2 and recorded recruitment numbers, retention and adherence rates to the exercise and nutritional supplement, the occurrence of adverse events and the acceptability of the programme (Chapter 2, Table 2.2). Participant feedback indicating acceptability was captured in the exit survey (Appendix III), which was completed (with written informed consent) when the programme ended, or when participants dropped out.

Secondary outcome measures of physical function and frailty status were recorded using a broad test battery of physical performance measures, frailty assessment, nutritional assessment, pain rating and self-reported health status (Chapter 2, Table 2.5). Table 3.2 provides a brief summary of the test battery.

Table 3.2 Test Battery (secondary outcomes LEAP-II)

Construct	Measures
1.Strength & muscular mass	Grip strength Limb circumference
2.Physical performance & lower extremity function	10m Walk Test 2 Minute Walk Test Chair Stand Test Single Leg Stance Test
3.Pain	Numerical Pain Rating Scale
4.Frailty	Clinical Frailty Scale Share-FI
5.Nutritional status	Mini Nutritional Assessment
6.Quality of Life	SF-12

These measures were recorded at baseline (T1) and at the completion of the programme (T2) to measure pre-post intervention change and have been discussed in detail in Chapter 2. The feasibility of this test battery was also evaluated.

In brief, upper limb strength was measured by using a digital hand dynamometer (Leong et al., 2015, Roberts et al., 2011) and the Chair Stand Test (Lein et al., 2022) evaluated lower limb strength. Mid-calf and mid arm circumference girth was measured to demonstrate appendicular muscle mass (Gonzalez et al., 2021). The 10m Walk Test (10m WT) (Bohannon, 1997) measured walking speed and functional mobility; the 2-Minute Walk Test (2-MWT) (Brooks et al., 2007) measured self-paced walking ability and functional capacity, and the Single Leg Stance (SLS) test (Springer et

al., 2007) measured balance and falls risk. Results were compared to normative reference values. Each participant was asked if they experienced pain and were questioned about its severity, location and duration. Severity of pain was assessed using the Numerical Pain Rating Scale (NPRS) (Hawker et al., 2011). Frailty was assessed using the Clinical Frailty Scale (CFS) (Rockwood et al., 2005) and the SHARE-FI (Romero-Ortuno et al., 2010). Nutritional status was assessed by using the Mini-nutritional assessment (MNA) score (Guigoz et al., 1996, Kaiser et al., 2009). Finally, the Short-Form 12 was used as a global self-report evaluation of health and quality of life (Ware et al., 1996).

A number of the brief and easy to administer outcomes (grip strength, CST, 10mWT) were re-assessed once weekly prior to the exercise class to monitor progress and motivate participants.

3.2.3.3 Practical utility and agreement between frailty measures

The practical utility of and agreement between frailty instruments was also explored. The practical utility of the tools was determined by their relevance and their application to the population of interest. This included the language and terminology of the tools, the administration burden and any modifications which were made to improve their acceptability. Agreement between frailty instruments was investigated using the Cohen Weighted Kappa test. Points of divergence were identified by observing the rate of frailty and the characteristics of the frail, pre-frail and non-frail participants identified by each instrument.

3.2.3.4 Measuring frailty correlates

The attributes and predictors of frailty were evaluated in this study by observing the demographics of the frail participants and the relationships between frailty (using

the SHARE-FI and the CFS) and selected independent variables (age, gender, addiction status, nutritional status and gait speed). Advancing chronological age and female gender are associated with frailty (Rockwood et al., 2004) and since this novel research was delivered to a non-geriatric, mixed gender population these attributes merited exploration. Moreover, the study setting, a centre for people with problematic drug and alcohol use, expounds the exploration of association between frailty and addiction. Finally, considering exercise with nutritional supplementation was the cornerstone of the LEAP-II trial, gait speed (measured by the 10-Metre Walk test) (Bohannon, 1997) and nutritional status (measured by the Mini-Nutritional Assessment tool) (Kaiser et al., 2009) were included as variables of interest.

3.2.3.5 Intervention

The 12-week intervention was designed to be low-threshold and participant-centred to maximise retention and outcomes. It involved a target attendance to three exercise sessions per week - two exercise classes and one Park Walk. This was facilitated by running multiple classes over two days per week at times of convenience for participants. The Park Walk was run on a Friday morning each week. Supervised group, individual and gender-based classes (one women's only class and one men's only class) and the Park Walk were facilitated for 15 weeks to enable flexibility in commencement of the programme, and to ensure the opportunity to complete as many sessions of the 12-week programme, was available for the maximum number of participants as possible. A separate class was also delivered one day per week for a cohort of women from the Traveller community, a group who communicated in advance, their preference to stay together, and separate, from the other study

participants. The intervention was delivered by two research physiotherapists (FK and MM).

The exercise circuit focused on general fitness, with an emphasis on strength training in the twice weekly exercise circuit (to target frailty), with in-built flexibility, balance and core exercises based on participant preference and individual need. Blood pressure and heart rate monitoring was used as a safety indicator and took place before and following the exercise class. Each session commenced with a warm-up and ended with a cool-down and stretch. The cool down and stretches were sometimes led by participants who were familiarised with the routine. The circuit comprised of six to eight core exercises which were adapted and progressed based on the diverse and fluctuating presentations of participants (see Table 3.4). Music, as requested in the stakeholder-engagement session, was an important feature of the programme, and was selected by the study participants. 'Dance like no-one's watching' was the theme when the exercise circuit ended, and a 5-minute aerobic 'dance' was performed in the women's group due to the observed enjoyment of the movement to music. The men preferred a structured fun game or competition as an alternative end of session activity. Exercises were progressed at a low to moderate intensity, with 2 to 3 sets, of 10 to 15 repetitions completed at each session, and beyond that, low resistance weights (1.1kg-4.5kg), theraband or increased step height was introduced to achieve a strengthening effect. This was progressed incrementally and was based on baseline participant status and previous attendances. The intensity of the workout was modulated using the Borg Perceived Rate of Exertion (RPE) scale, where participants were advised to exercise between 11 and 13 on the RPE scale (Appendix II), that is, where they found the exercise somewhere between 'fairly light' to 'somewhat hard'

(Borg, 1982). To promote post-exercise muscle protein synthesis, a nutritional supplement (200ml pre-prepared 'protein shake' Fresubin, <https://www.fresubin.com/>) which consists of 20g of protein was offered to all participants following the exercise class.

Participants were encouraged to avail of the three exercise opportunities each week- the twice weekly exercise class and the once weekly 'Park Walk'. The Park Walk was a self-paced 20–30-minute walk which took place in a nearby recreational green space, 'Le Fanu Park'. A number of individual or group walks took place one morning each week to offer choice and flexibility to service users. In keeping with the flexible, low-threshold approach, the Park Walk was included as an additional, as well as an alternative mode of exercise, to enhance physical activity participation and to strive to make physiological changes and improve physical outcomes.

To build sustainability beyond the lifecycle of the programme, study participants were provided with basic nutritional advice and educated about the benefits of physical activity and informed of local resources which were available to them in order to engage in meaningful physical activity. A low-specification pedometer was supplied to participants midway through the programme to enhance motivation and encourage continued unsupervised physical activity. Motivational phone calls were employed (up to week 8) to remind participants, who had not yet attended, of the ongoing intervention and to address barriers to adherence to maximise retention to the study. When the programme was completed, each participant was provided with a certificate of attendance/completion and those who attended regularly were provided with a low specification fitness watch to motivate them to continue exercising and also to track their progress.

Table 3.3 Schedule of a typical week in the LEAP-II intervention

Class times	Mon	Tues	Wed	Thurs	Fri
10am	Men's class	X	X	Mixed class	Park Walk
11am	Women's class	X	X	Class for Traveller group	Park Walk
12pm	Mixed class	X	X	Mixed class	Park Walk
2pm	Mixed class	X	X		
3pm	Mixed class	X	X		

3.2.3.6 Exit survey

An exit survey was conducted following the intervention to primarily investigate the reasons for the study's attrition but also to capture data on participants reflections on the intervention, and to ascertain unmet physical health needs (see Appendix III for Exit survey).

Table 3.4 Exercise Circuit LEAP-II

Core exercise	Initial Intensity	Progression/Adaptations*
Sit to stand/squats/lunges	2 sets 10-15 reps	3 sets of 15 repetitions. use of weights/ball
Elbow Bends	2 sets 10-15 reps	3 sets of 15 repetitions. weights
Step-ups	2 sets 10-15 reps	3 sets of 15 repetitions. height of step; weights
Arm elevations	2 sets 10-15 reps	3 sets of 15 repetitions. weights
'Penguin waddle'-hip abduction	2 sets 10-15 reps	3 sets of 15 repetitions. With additional upper limb abduction and elevation; movement with 360° turns
Scapular retractions	2 sets 10-15 reps	3 sets of 15 repetitions. weights
Aerobic activity	2 mins	3 mins ladders, hurdles, skipping ropes, jumping jacks. dance, game with cones/balls
Balance	4-5 mins	5 mins Tandem; single leg stance, upper limb and trunk movements; weights and ball work

Adaptations: exercises individualised and progressed for each participant by research physiotherapist

Progression: 2-3 sets of 10-15 repetitions completed at each session; beyond that, low resistance weights (1.1kg-4.5kg), theraband or increased step height was introduced to achieve a strengthening effect.
Exercise equipment: therabands, dumbbells, steps, ladders, hurdles, skipping ropes and balls.

3.2.4 Ethics

This study received ethical approval from the Faculty of Health Sciences, Trinity College Dublin (Ethical Approval Reference Number: 211202). Further approval was sought and granted mid-way through the study when a notable drop-off in numbers occurred. All participants who completed the initial assessment were eligible to participate. The exit survey and the ethics documentation relevant to the exit survey, are available in Appendix III and Appendix V, respectively.



Figure 3.2 The LEAP-II Intervention

3.2.5 Data analysis

Descriptive statistics were performed to summarise participant characteristics. Data were tested for normality using the Kolmogorov–Smirnov test. Pre- and post-intervention data were then compared using paired t-tests or Wilcoxon signed-rank tests if normally distributed or non-normally distributed, respectively. A complete case analysis was performed due to the feasibility focus of the work. Exit survey data were analysed by (i) observing frequencies of responses, (ii) exploring data for themes using a low level of interpretation and (iii) illustrating themes through verbatim comments, while bearing in mind that this represents ‘quasi-qualitative data’, not in-depth analysis addressed by qualitative study methodology (O' Cathain et al., 2008).

The test feasibility rate was assessed for each outcome measure of the test battery. This was calculated from the number of participants who were able to complete the tests divided by the total number of participants in the study. The feasibility rates were interpreted using pre-specified feasibility rates identified by Wouters et al (2017), [<50% not feasible, 20-70% quite feasible, >70% feasible] (Wouters et al., 2017).

The rate of frailty was presented as frequencies and percentages. To explore associations between frailty and selected covariates univariable linear regression models were fitted to examine unadjusted associations between frailty (CFS and SHARE-FI) and each explanatory variable. Due to sample size constraints, models were univariable and interpreted descriptively. Binary logistic regression was used to estimate odds of frailty for each explanatory variable.

Cohen's Weighted Kappa statistical test was used to determine agreement between the frailty instruments, where a score of 0.01-0.20 indicated no or slight

agreement, 0.21-0.40 fair agreement, 0.41-0.60 moderate agreement, 0.61-0.8 substantial agreement and 0.81-1 almost perfect agreement (McHugh, 2012).

Pre-post intervention data were analysed using IBM SPSS V28 and a *p*-value with statistical significance was set at $p < 0.05$. Baseline frailty data and exploration analysis was conducted using Stata 18.

3.3 Results

3.3.1 Baseline results

In this section the study participants and the results of their baseline evaluation will be described. Forty-seven people consented to participate and were assessed. Of these 47, three did not meet the eligibility criteria (two were over 65 years and one was not a service user of the Ballyfermot Advance Project) and one declined to fully complete the initial assessment. Therefore, forty-three people met the eligibility criteria and 30 returned for follow up, following the initial assessment to participate in the exercise intervention. Twenty participants completed the end of programme assessment (see Prisma, Figure 3.3).

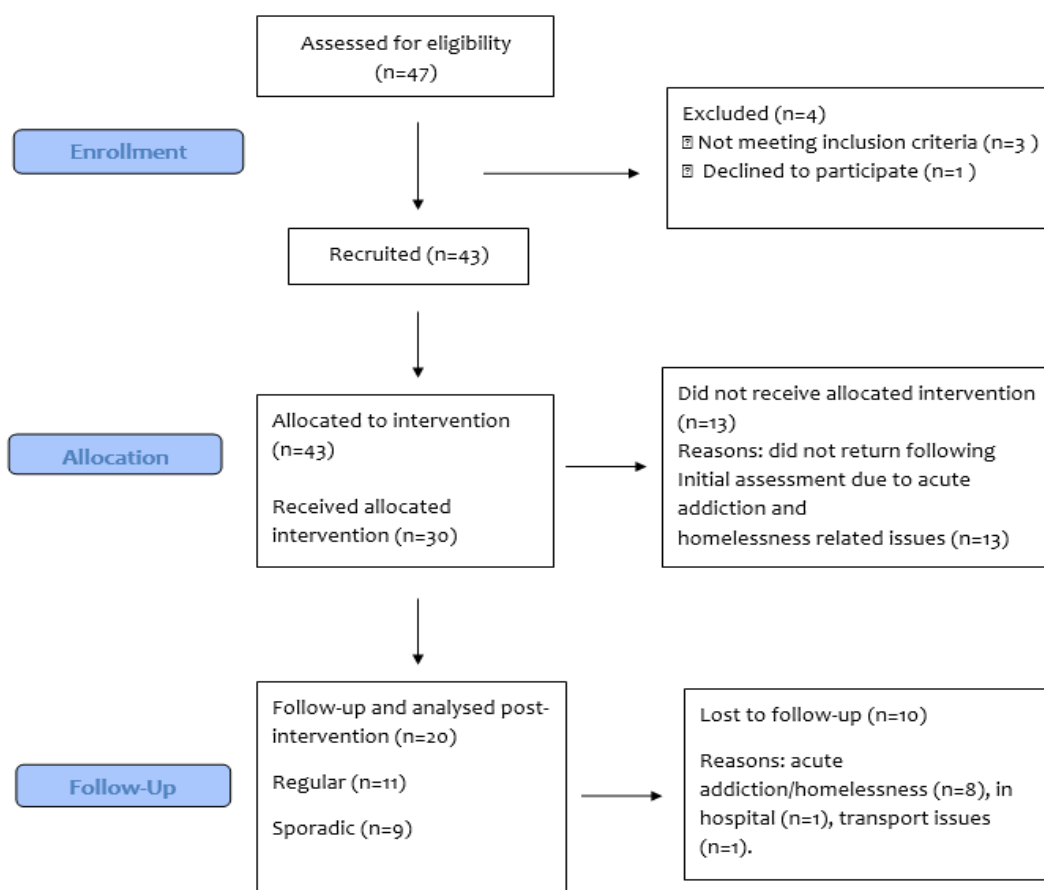


Figure 3.3 PRISMA flow diagram of participants through LEAP-II

3.3.1.2 Participant demographics

The mean (SD) age of the participants was 45.6 (9.5) years. Just over half (53.5%, n=23) were female and 46.5% (n=20) were male. The majority of participants were single (n= 17, 39.5%) and unemployed, (n=39, 90.7%). Almost three-quarters (74.4%, n=32) were white Irish and 25.6% (n=11) were Irish Travellers. Most of the study participants (n=35, 81.4%) experienced problematic drug or alcohol use. Aligned to the National Drug Treatment Reporting System (NDTRS) definitions, 62.8% of participants had drug or alcohol dependency, 9.3% experienced harmful to hazardous use and 9.3% were in recovery and stable in their addiction journey (52). Of note, eight female study participants from the Travelling community reported no addiction issues. Baseline characteristics of the participants are presented in Table 3.5.

While half (51.1%, n=22) of the participants were homeless at the time of the initial evaluation [aligning with the European Typology for Homelessness and Housing Exclusion (ETHOS)] many had dynamic housing biographies and self-reported past experiences of homelessness (86%) (FEANTSA, 2005). With respect to health, all participants had a self-reported mental health condition and were on prescribed medication for this. A range of physical health conditions were also reported, the most common conditions including musculoskeletal conditions (n=18, 41.9%), respiratory conditions (n= 13, 30.2%) cardiovascular conditions (n=11, 25.5%), seizures (n= 6, 13.9%), hepatitis (n=6, 13.9%) and liver disease (n=5, 11.6%).

Table 3.5 Participant demographics (n=43)

Demographic item	
Age mean (std dev) (range)	45.6 (9.5) (26-62) years
Sex n (%)	
Female	23 (53.5)
Male	20 (46.5)
Marital status n (%)	
Single	17 (39.5)
Married/partnership	10 (23.3)
Separated/divorced	8 (18.6)
Widowed	7 (16.3)
*Data unavailable	1 (2.3)
Race n (%)	
White Irish	32 (74.4)
Irish Traveller	11 (25.6)
Employment status n (%)	
Full-time employment	1 (2.3)
Part-time employment	3 (7)
Unemployed	39 (90.7)
Housing environment n (%)	
House/apartment	21 (48.9)
Hotel/hostel/staying with friend/family/other	8 (18.6)
Halting site	9 (20.9)
Rough sleeper	5 (11.6)
Living Arrangement n (%)	
Alone	18 (41.9)
With spouse/partner	5 (11.6)
Other	20 (46.5)

History of Addiction n (%)	
Dependency	27 (62.8)
Harmful to hazardous use	4 (9.3)
Stable/in recovery	4 (9.3)
No addiction issues	8 (18.6)
Physical health conditions n (%)	
Musculoskeletal	18 (41.9)
Respiratory	13 (30.2)
Cardiovascular	11 (25.5)
Seizures	6 (13.9)
Hepatitis	6 (13.9)
Liver disease	5 (11.6)
Diabetes	4 (9.3)
Cancer	3 (6.9)
HIV	2 (4.6)
Other	7 (16.3)

**some participants had >1 physical health condition*

3.3.1.3 Baseline outcome measure results

When compared to standardised values, limb circumference scores demonstrated that five (11%) females and five (11%) males had ‘moderately low’ or ‘severely low’ lower limb circumference measures, while four (9%) females and six (13.9%) males were below the cut-off values for upper limb circumference (Gonzalez et al., 2021, Tang et al., 2020). Baseline grip strength scores demonstrated that 38 participants (88%) scored below the mean normative values (Steiber, 2016). The CST scores ranged from nine to 19 stands, below the normative values (33 stands) for healthy young (18-35 years) adults [mean (SD) 25 (\pm 3.4) years] (Lein et al., 2022). Five participants (12%) scored below normative values for the 10mWT (Bohannon, 2017). Just over half (n=25, 55%) of the participants scored below normative values for the 2MWT (Bohannon, 2017). Similarly, just over half (n=23, 53.4%) had lower than average scores for the SLS test (El-Kashlan et al., 1998). Pain was prevalent in over one third (34.8%) and almost one quarter (23.3%) were malnourished, while a further 45.6% were at risk of malnutrition. Baseline, pre-intervention levels of frailty were identified using the SHARE-FI with 11.6% and 20.9% frail and pre-frail, respectively; and

the CFS with 11.6% and 60.5%, frail and pre-frail, respectively. The SF-12 highlighted below average scores [mean (SD) 50 (10)] for both physical and mental component summary scores for the collective group, when compared to 1998 normative values (Larson, 2002). More than half (58%, n=25) of the group scored below the mean for the physical component summary (PCS) and more than three quarters (81%, n=35) scored below the mean for the mental component summary (MCS) (see Table 3.6 for baseline outcome measure results).

Table 3.6 Baseline physical function and frailty scores (n=43)

	Mean (SD)	Median (IQR)	n (%)
Limb circumference			
Upper Limb (cm)	27.86 (3.69)	27.5 (25-30)	43 (100)
Lower Limb (cm)	35.94 (4.30)	36 (32.5-38)	43 (100)
Physical Performance			
10m Walk Test (m/s) (maximal)	1.7 (0.34)	1.75 (1.46-1.94)	43 (100)
2 Min Walk Test (m)	170 (37.64)	180 (158-193)	43 (100)
Grip Strength			
Male (kg)	41.5 (8.09)	42.5 (34.8-48.9)	20 (46.5)
Female (kg)	27.9 (5.5)	27.8 (24.1-32.6)	23 (53.4)
Chair Stand Test (n)	12.83 (2.26)	13 (11-14)	43 (100)
Single Leg Stance (s)	15.06 (14.65)	8.08 (3.3-22.9)	43 (100)
SF12 (score)			
PCS	46.36 (10.65)	47.73 (38.63-	43 (100)
MCS	35.49 (14.27)	54.55) 36.29 (23.3-49.18)	43 (100)
Pain n (%)			15 (34.8)
Frailty			
CFS n (%)			
CFS 3 (managing well)			12 (27.9)
CFS 4 (vulnerable)			26 (60.5)
CFS 5 (mildly frail)			5 (11.6)
SHARE-FI categories			
Non-frail	-0.172 (0.726)		29 (67.4)
Pre-frail	1.287 (0.774)		9 (20.9)
Frail	3.614 (0.840)		5 (11.6)
Nutrition			
MNA categories			

n (%)	
0-7 (malnourished)	10 (23.3)
8-11 (at risk of malnutrition)	20 (46.5)
12-14 (normal nutritional status)	13 (30.2)

*PCS=physical component summary score, MCS=mental component summary score

3.3.2 Feasibility

3.3.2.1 Recruitment

Recruitment commenced on Mon October 3rd, 2022. The majority of participants were recruited in October (n=31, 72%) prior to commencement of the programme on Mon November 7th, 2022. Twelve participants (28%) were recruited in November and early December 2022, when final participant was recruited.

3.3.2.2 Retention

The overall retention rate was 69.8% with over two thirds (n=30) of the cohort returning for at least once session (exercise class or Park Walk) following the initial evaluation. A quarter (25.6%, n=11) came at least once per week for more than 50% of the duration of the programme (*regular attenders*). Near half (44.2%, n=19) came at least once/week for less than 50% of the duration of the programme (*sporadic attenders*) and just under one third (n=13, 30.2%) did not return following their initial evaluation (*non-attenders*).

Regarding the motivational phone calls, which were utilised to remind participants to attend, a total of 54 calls to 20 (46.5%) participants (who owned a phone at the time of recruitment) were made over the course of the initial eight weeks. There was a 0% return rate to the programme as a direct consequence of these calls. Consequently, a decision was made to cease this initiative.

Table 3.7 Summary of retention

	Total attendance (n=30) (100%)	Older (> 48 years) (n=19)	Female (n= 23)	Male (n= 20)
Regular attenders	11 (25.6%)	8 (72.7%)	8 (34.7%)	3 (15%)
Sporadic attenders	19 (44.2%)	11 (42.1%)		
Did not attend	13 (30.2%)			

3.3.2.2.1 Retention to Exercise Class v Park Walk

Of those who returned following initial evaluation (n=30, 70%) only one participant attended each week for 12 consecutive weeks. Nine (9/30, 30%) participants attended $\geq 50\%$ of the exercise class sessions. Five participants (16.6%) attended more than 50% of the Park Walks. Eighteen (18/30, 60%) participants completed at least one Park Walk, 1 person (1/30; 3.3%) walked every week and 11 who returned (36.6%) did not partake in any of the Park Walk sessions. Of note, participants from the Traveller community (n=10, 23%) were unable to attend the Park Walk on the designated day due to other commitments or transport issues.

3.3.2.2.2 Retention in sub-groups

Older participants: Greater attendance was observed in the older participants with 72.7% (n=8/11) of the regular attenders over the median age of 48 years, while 42.1% (8/19) of the sporadic attenders were over the median age of 48 years.

Female participants: Female attendance was more than double the rate for men. Over one third of (34.7%, n=8/23) of the females attended regularly (>50% of the sessions) while 15% (n=3/20) males were regular attenders.

3.3.2.3 Adherence-exercise/nutritional supplementation

Regarding adherence to the exercise class component of the intervention (expressed as the number of sessions adhered to relative to the number of sessions (or contacts in the sessions) attended, 93% adherence was observed, with completion of 208 of the total of 224 sessions delivered to the participants. Among the multiple reasons cited for non-completion or non-adherence were pre-existing and ongoing musculoskeletal pain (n=7), recent assault or accidental injury (n=2), stress or emotional dysregulation due to external factors (n=3), time pressures (n=2), personal preference and lack of motivation (n=4). High adherence to the protein supplement was observed, with a minority (n= 3, 10%) who declined the protein supplement following the exercise intervention due to its perceived unpleasant taste. For the most part it was acceptable and enjoyable.

Table 3.8 Summary of adherence

Intervention	Adherence rate
Exercise	93% (208/224)
Protein supplement	90% (27/30)

3.3.2.4 Adverse Events

For the purpose of this study an adverse event was defined as an unfavourable experience during the exercise intervention which caused the participant to cease exercising and seek medical attention (31). No adverse events occurred during the 15 weeks of the programme, which included 30 Exercise Class sessions and 15 Park Walks.

3.3.2.5 Acceptability

Acceptability was demonstrated through the feedback provided from the exit surveys. The exit survey was researcher-administered and completed by 20 (47%) participants. It was brief and took five to ten minutes to complete. Overall, the feedback received from all participants who attended the programme was positive.

Three main themes of ‘barriers to retention’, ‘psychological benefits’ and ‘abstinence’ emerged.

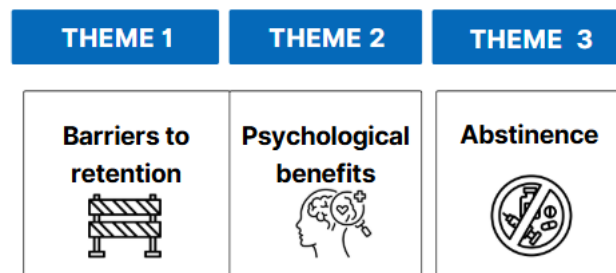


Figure 3.4 Exit survey themes

3.3.2.5.1 Barriers to retention

Among the reasons cited for low retention and study attrition were:

“I should have kept going but I was in such a bad place that I didn’t want to feel happy. (P1)

“I was more interested in the drink”. (P5)

“Just life, just things in my addiction”. (P12)

3.3.2.5.2 Abstinence

Another important finding reported in the exit survey was the reported reduction in substance use for some (n=8, 40%). Those participants who attended the morning exercise sessions reported that it helped to postpone the use of substances until later in the day, where in the past it was part of their morning ritual.

“I don’t smoke as much weed ... and I don’t smoke as much cigarettes.” (P2)

"It was keeping me away from the weed anyway." (P15)

"It was another thing stopping me from using." (P47)

"There was a lot going on for me at the time and it was on my mind." (P16)

3.3.2.5.3 Psychological benefits

The exercise classes were reported to be fun, inclusive and sociable. Music was cited as an important feature and the female participants particularly enjoyed dancing at the end of the exercise circuit.

"It was an enjoyable kind of exercise, no point in doing it if you're not enjoying it." (P29)

"I felt alive, I walked out tall, and I didn't walk in like that ... It gave me something to look forward to." (P1)

"I felt great after it, I often feel down in the dumps, and it brings me back up ... I've often a lot going on at home. I feel I leave it all behind me when I come ... getting out mixing with people is great. (P40)

"I got pain relief, friendship, energy, positivity." (P12)

The option of the Park Walk was important for some who did not feel able for the exercise class. The walk was considered as a more suitable, feasible and accessible mode of exercise.

"The Park Walk was just great, just doing the walk and the having the chat with the girls was good." (P4)

P2, the only participant who completed all 12 weeks of the programme, said “I doubt myself, I needed the push... I feel proud.”

3.3.3 Pre-post intervention results

Impact of the intervention on physical function and frailty status was evaluated by comparing pre-intervention (T1/week 1) and post-intervention (T2/end of programme/12 weeks) results which were obtained from 20 (46.5%) participants upon study completion (Table 3.9).

In terms of physical function outcomes in the collective group (n=20), improvements were shown in the Chair Stand Test (CST) from pre- to post-intervention; from 12.65 ± 2.23 stands (T1) to 14.65 ± 3.54 (T2) stands, (95% CI: 0.568 to 3.432, $t(19)=2.922$, $p=0.009$), an improvement of 2 ± 3.06 stands (CST). Improvements were also demonstrated in the 10m Walk Test (10mWT); [from 1.6 ± 0.32 m/s (T1) to 1.85 ± 0.50 m/s (T2), (95% CI: 0.025 to 0.47, $t(19)= 2.328$, $p=0.031$), an improvement of 0.25 ± 0.48 m/s (10mWT)] and in the Mini Nutritional Assessment ($Z=-2.181$, $p=0.029$). No changes were observed from T1 to T2 for; limb circumference (Upper Limb: from 27.57 ± 3.88 cm to 28 ± 4.07 cm, a mean difference of 0.43 ± 1.44 cm, (95% CI: (-2.46 to 1.09); $t(19)=-1.324$, $p=0.20$; Lower Limb: from 36.14 ± 4.35 cm to 36.52 ± 4.1 cm, a mean difference of -0.39 ± 1.34 cm, 95% CI: (-2.46 to 1.01); $t(19)=-1.275$, $p=0.218$); hand grip strength (HGS) (from 31.8 ± 8.99 kg to 32.58 ± 11.86 kg, a mean difference of -0.078 ± 4.54 kg, 95% CI: (-1.34 to 2.91); $t(19) =0.767$, $p=0.452$), the 2 Minute Walk Test ($Z=-8.66$, $p=0.387$), the Single Leg Stance Test ($Z= -0.926$, $p=0.355$) or pain ($Z=-1.174$, $p=0.240$). See Table 3.9.

In terms of frailty in the collective group (n=20), no changes were observed in the Clinical Frailty Scale ($Z=-1.667$, $p=0.096$) or the SHARE-FI categories ($Z=-1.155$,

$p=0.248$) and continuous scores [95% CI(-1.63 to 0.445), $t(-1.197)$, $p=0.246$]. See Table 3.9.

In terms of percentage change, the range of improvement in the CST was 5.8% to 109%. Similarly, the percentage change in the 10mWT and the MNA ranged from 4% to 73% and from 7.6% to 150%, respectively. The largest improvements were seen in the regular attenders to the intervention. No changes were detected in the SF-12 with $p = 0.381$ and $p = 0.774$ for the PCS and MCS, respectively.

Table 3.9 Secondary outcomes at 12-week follow-up (n=20)

	Pre-intervention		Post Intervention		Difference	p-value
		Number (%)		Number (%)	Mean/median difference (95% CI)	
Chair stand test mean (SD)	12.65 (2.23) stands	20 (100)	14.65 (3.54) stands	20 (100)	2.00(0.57 to 3.43) stands	*0.009 a
Grip strength mean (SD)	31.8 (8.99) kg	20(100)	32.58 (11.86) kg	20 (100)	0.78 (-1.34 to 2.91) kg	0.452 a
10m Walk Test mean (SD)	1.60 (0.32) m/s	20 (100)	1.85 (0.5) m/s	20 (100)	0.25 (0.02 to 0.47) m/s	*0.031 a
2min Walk Test median (IQR)	180 (166-189) cm	19(95)	194 (150-220) cm	19 (95)	34(13 to 61) cm	0.387 b
Single leg stance median (IQR)	8.2 (4-33) secs	19(95)	14 (6-36) secs	19 (95)	10.6 (2.80 to 23.50) secs	0.355 b
UL circumference mean (SD)	27.57 (3.88) cm	20 (100)	28 (4.07) cm	20 (100)	0.43 (-0.24 to 1.09) cm	0.201 a
LL circumference mean (SD)	36.14 (4.35) cm	20 (100)	36.52 (4.1) cm	20 (100)	0.38 (-0.25 to 1.01) cm	0.218 a
MNA median (IQR)	9.5 (6.25-12)	20 (100)	12 (9-12)	20 (100)	3 (0.00 to 4.00)	*0.029 b
Pain median (IQR)	3 (0-6.5)	13 (65)	0 (0-5)	13 (65)	0 (0.00 to 7.00)	0.240 b
SF12						
PCS median (IQR)	44.7 (35.1-55.4)	17 (85)	48.9 (45.4-53.84)	17 (85)	10.7 (1.51 to 17.46)	0.381 b
MCS mean (SD)	38.61 (12.15)	17(85)	37.35 (12.44)	17 (85)	1.26 (-7.89 to 10.42)	0.774 a

	Pre-intervention	N (%)	Post-intervention	N (%)	Difference	p-value
Frailty						
<i>Clinical Frailty Scale</i>		20(100)		20(100)	0(0.00 to 0.00)	0.096 b
CFS 3 (Managing well)		5 (25)		9 (45)		
CFS 4 (Vulnerable)		13 (65)		10 (50)		
CFS 5 (Mildly frail)		2 (10)		1 (5)		
<i>SHARE-FI</i>		20(100)		20(100)	0(0.00 -0.00)	0.248 b
Non-frail		11 (55)		14 (70)		
Pre-frail		6 (30)		5 (25)		
Frail		3 (15)		1 (5)		
<i>SHARE-FI continuous scores</i> Mean (SD)	0.968 (1.602)	20 (100)	0.372 (1.365)	20 (100)	-0.595 (2.224)	0.246 a

a=paired samples t-test comparing pre- to post-intervention, b=Wilcoxon signed-rank test, *= significant result; SF12 PCS =Physical Component Summary, MCS = Mental Component Summary

3.3.3.1 Subgroup analysis

Regular attenders (Table 3.10). In this group (n=11), improvements were observed in the 10mWT (from 1.65m/s \pm 0.29 to 2.07m/s \pm 0.44, an improvement of 0.428m/s \pm 0.48, 95% CI: 0.10 to 0.75; $t(10)=2.943$, $p=0.015$), the MNA (from 8.7 \pm 3.13 to 10.7 \pm 2.32, an improvement of 2.00 \pm 2.93, 95% CI: 0.299 to 3.97; $t(10) = 2.262$, $p=0.047$) and in pain levels ($Z=-2.214$, $p=0.027$). Additionally, an improvement was detected in the CFS ($Z= -2.121$, $p= 0.034$) and SHARE-FI continuous score [95% CI(-2.805 to -0.73, $p=0.041$)]. However, no change was detected from T1 to T2 in the CST (from 13.27 \pm 2.19 to 15.45 \pm 3.29, a mean difference of 2.18 \pm 3.54, (95% CI: 4.56 to -0.19); $t(10)=2.042$, $p=0.068$). The line graphs (Figure 3.5a-c) illustrate individual improvements in this group for the 10MWT, the MNA and the CFS.

In the *sporadic attenders* (Table 3.11), evidence is lacking for effectiveness in all outcome measures. In this group, no significant changes were observed in any of the physical functioning or frailty measures.

Line Graphs of individual change scores from T1 to T2 for regular attenders

(n=11)

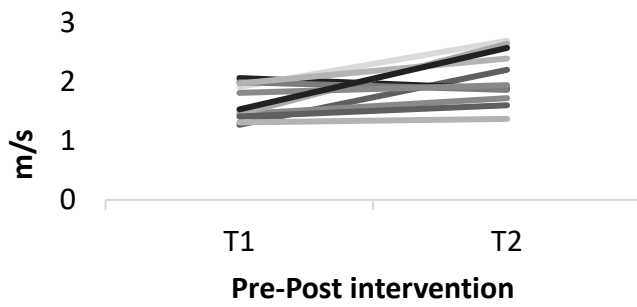


Figure 3.5 A Individual change scores for the 10mWT

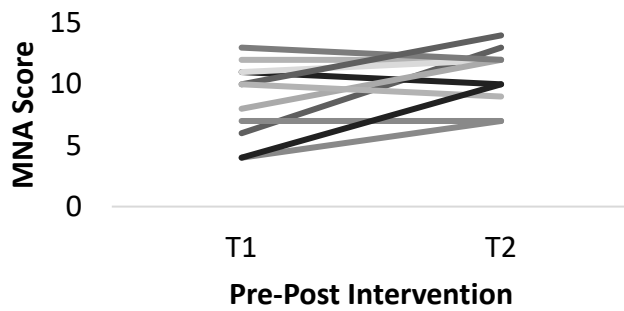
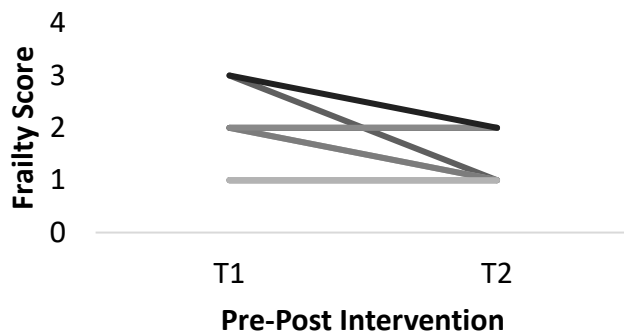


Figure 3.5 B Individual change scores for the MNA



*CFS 1=managing well, CFS 2=vulnerable and CFS 3=frail

Figure 3.5 C Individual change scores for the CFS

Table 3.10 Secondary outcomes at 12-week follow-up (Regular Attenders, n=11)

	Pre-intervention		Post Intervention		Difference	
		N (%)		N (%)	Mean/median difference (95% CI)	p-value
Chair stand test mean (SD)	13.27 (2.19) stands	11(55)	15.45(3.29) stands	11(55)	2.18(-0.19 to 4.56) stands	0.068 a
Grip strength mean (SD)	29.07 (7.96) kg	11(55)	29.58 (10.09) kg	11(55)	0.51(-2.17 to 3.19)) kg	0.682 a
10m Walk Test mean (SD)	1.65 (0.29) m/s	11(55)	2.07 (0.44) m/s	11(55)	0.48 (0.10 to 0.75) m/s	*0.015 a
2min Walk Test mean (SD)	180.90 (18) cm	11(55)	193.36 (32.1) cm	11(55)	12.45(-9.05 to 33.96) cm	0.226 a
Single leg stance mean (SD)	20.9 (15.30) secs	11(55)	25.56 (21.64) secs	11(55)	4.63(-7.2 to 16.46) secs	0.404 a
UL circumference mean (SD)	27.90 (4.64) cm	11(55)	28.45 (4.62) cm	11(55)	0.55(-0.48 to 1.58) cm	0.267 a
LL circumference mean (SD)	36.20 (4.7) cm	11(55)	36.45 (4.57) cm	11(55)	0.25(-0.47 to 0.96)) cm	0.464 a
MNA mean (SD)	8.7 (3.13)	11(55)	10.7 (2.32)	11(55)	2.00(0.29 to 3.97)	*0.047 a
Pain median (IQR)	5 (0-6.5)	9(45)	0 (0-4)	9(45)	0 (0.00 to 0.00)	*0.027b
SF12 mean (SD)						
PCS	42.3 (10.4)	11 (55)	49.4 (6.8)	11(55)	7.08 (-2.81 to 16.99)	0.142
MCS	37.0 (13.5)	11 (55)	39.5 (13.2)	11(55)	2.49 (-10.7 to 15.75)	0.684

Frailty	Pre Intervention	N (%)	Post Intervention	N (%)	Difference	p-value
<i>Clinical Frailty Scale</i>		11(55)		11(55)	0(0.00 to 00.00)	*0.034b
CFS 3 (Managing well)		4(36.4)		8(72.7)		
CFS 4 (Vulnerable)		5(45.5)		3(27.3)		
CFS 5 (Mildly frail)		2(18.2)		0(0)		
<i>SHARE-FI</i>		11(55)		11(55)	0(0.00 to 0.00))	0.063 b
Non-frail		6(54.5)		9(81.8)		
Pre-frail		2(18.2)		2(18.2)		
Frail		3(27.3)		9(0)		
<i>SHARE-FI continuous score</i>	1.235 (1.904)	11(55)	-0.204 (0.755)	11(55)	-1.439 (2.033)	*0.041 a

a=paired samples t-test comparing pre- to post-intervention, b=Wilcoxon signed-rank test, * = significant result; SF12 PCS= Physical Component Summary, MCS= Mental Component Summary

Table 3.11 Secondary outcomes at 12-week follow-up (Sporadic attenders, n=9)

	Pre-intervention		Post-intervention		Difference	
		Number (%)		Number (%)	Mean/median difference (95% CI)	p-value
Chair stand test mean (SD)	11.88 (2.14) stands	9(45)	13.66 (3.77) stands	9(45)	1.77(-0.17 to 3.73) stands	0.069 a
Grip strength mean (SD)	35.13 (9.5) kg	9(45)	36.2 (13.39) kg	9(45)	1.11(-3.01 to 5.24) kg	0.552 a
10m Walk Test mean (SD)	1.54 (0.35) m/s	9(45)	1.57 (0.44) m/s	9(45)	0.03(-0.27 to 0.34) m/s	0.809 a
2min Walk Test median (IRQ)	178 (156.75-193) cm	8(40)	159.5 (130-210.5) cm	8(40)	34(5 to 61) cm	0.889 b
Single leg stance median (IQR)	5.25 (2.58-28.26) secs	8(40)	12.65 (2.28-29.61) secs	8(40)	10.6(1.69 to 47.67) secs	0.889 b
UL circumference mean (SD)	27.16 (2.9) cm	9(45)	27.44 (3.4) cm	9(45)	0.27(-0.77 to 1.33) cm	0.560 a
LL circumference mean (SD)	36.05 (4.1) cm	9(45)	36.61 (3.71) cm	9(45)	0.55(-0.73 to 1.85) cm	0.352 a
MNA mean (SD)	9.77 (3.27)	9(45)	10.55 (2.65)	9(45)	0.77(-0.79 to 2.35)	0.288 a
Pain mean (SD)	2.25 (3.30)	4(20)	4.25 (2.98)	4(20)	2.00(-5.46 to 9.46)	0.456 a
SF12 mean (SD)						
PCS	50.1 (13.5)	6(30)	46.4 (14.3)	6(30)	-3.7 (-10.57 to 3.14)	0.222 a
MCS	37.9 (10.4)	6(30)	36.9 (11.9)	6(30)	-0.996 (-16.81 to 14.82)	0.878 a

Frailty	Pre-intervention	N (%)	Post-intervention	N (%)	Difference	p-value
<i>Clinical Frailty Scale</i>		9(45)		9(45)	0 (0.00-0.00)	0.317 b
CFS 3 (Managing well)		1(11.1)		1(11.1)		
CFS 4 (Vulnerable)		8(88.9)		1(77.8)		
CFS 5 (Mildly frail)		0(0)		1(11.1)		
<i>SHARE-FI</i>				9(45)	0 (0.00 to 2.00)	0.705 b
Non-frail		5(55.6)		5(55.6)		
Pre-frail		4(44.4)		3(33.3)		
Frail		0(0)		1(11.1)		
<i>SHARE-FI continuous score</i>	0.641 (1.161)	9(45)	1.076 (1.64)	9(45)	0.435 (2.099)	0.551 a

a=paired samples t-test comparing pre- to post- intervention, b=Wilcoxon signed-rank test, SF12 PCS = Physical Component Summary, MCS = Mental Component Summary

3.3.4 Test battery evaluation

Pre-intervention evaluations took between 25-29 minutes to complete for LEAP-II. Table 3.12 below outlines the feasibility results.

Table 3.12 Completion rates/times for LEAP-II trial

Test	Completion Rate n (%)	Completion Time (mins)
Strength & Muscle Mass		
Dynamometry	43(100)	1 min
Limb circumference	43(100)	1-2 mins
Physical Performance & Lower Limb function		
10m Walk Test	43(100)	1 min
2-Minute Walk Test	40(93)	2.5 mins
Single Leg Stance Test	41(95)	2.5 mins
Chair Stand Test (30 sec)	43 (100)	1 min
Pain	34 (79)	1-2 mins
Frailty		
CFS/SHARE-FI	43(100)	10 mins
Nutritional Status		
MNA	43(100)	2-3 mins
Quality of Life		
SF-12	43(100)	3-4 mins
Total		25-29-mins

3.3.4.1 Strength and muscular mass

There was a 100 per cent compliance/feasibility rate detected with hand grip dynamometry, with no issues identified when taking this measure. All study participants (n=43, 100%) also completed both limb circumference tests. Using a trauma informed approach, participants who had the testing limb covered by clothing were not required to remove this to minimise potential feelings of discomfort. However, if willingness was indicated, participants were encouraged to remove a layer of clothing to maximise the accuracy of data collection.

3.3.4.2 Physical performance and lower limb physical function

The community hall adjacent to the Ballyfermot Advance Project utilised for this study comfortably facilitated the 15m+ distance required for the walking tests. All

participants (n=43, 100 per cent) completed the 10mWT and the CST. There was a marginally lower completion rate for the 2MWT (n=40, 93 per cent) and the SLS test (n=41, 95 per cent) and the reasons for non-completion were cited as pain, fatigue, and alcohol intoxication.

3.3.4.3 Pain

There was 79 per cent (n=34) compliance with the NPRS at baseline. The numerical rating scale was noted as challenging for some participants. Despite clear instruction, participants were unable to provide a numerical score to rate their pain and instead used descriptive terms to explain their pain or discomfort.

3.3.4.4 Frailty

There was a 100 per cent completion rate for the CFS and SHARE-FI. As the CFS is based on clinical judgement following a comprehensive assessment, this part of the evaluation was often protracted due to the necessity to probe for relevant information and also to allow participants to talk freely about their history. Occasionally the researchers sought collateral information from the team in the centre to corroborate and confirm findings. This scale took approximately 10 minutes to rate. The SHARE-FI was brief and simpler to administer.

3.3.4.5 Nutritional Status

The MNA assessed by the researcher had a 100 per cent completion rate. It involved five brief questions which were read aloud by the tester and the test was completed with body mass index measurement. The MNA took approximately two minutes to complete.

3.3.4.6 Quality of Life

To ensure full understanding and completion of this survey, the researcher read aloud and scored the SF-12 survey with each participant. This assessment took approximately four minutes to complete and had 100 per cent completion rate.

3.3.5 Exploration of frailty

3.3.5.1 Attributes and predictors of frailty

Summary baseline frailty scores for all participants are presented in Table 3.6. Frailty was identified in 11.6% (n=5) using the SHARE-FI and the CFS, while pre-frailty was identified in 20.9% (n=9) and 60.5% (n=26) using the SHARE-FI and the CFS, respectively. The median (IQR) frailty scores were 1 (1-2) and 2 (1-2) using the SHARE FI and the CFS, respectively.

3.3.5.1.1 Profile of the frail

The age of the frail participants ranged from 44 to 56 years. Three out of five (60%) frail participants (by SHARE-FI) were male, while four out of five (80%) frail participants (by CFS) were male. Of those who were frail by SHARE-FI or CFS (n=6), 66% (n=4) of participants lived in inadequate accommodation conditions, 83% (n=5) had previously been incarcerated, 83% (n=5) had drug dependency, all had co-morbidities and 50% (n=3) used a mobility aid. (Table 3.13).

Table 3.14 and Table 3.15 outline the results obtained from the regression modelling tests performed. Simple linear regression revealed that 31% of the variance of frailty (by the CFS) was explained by nutritional status while 12% of the variance of frailty (by the CFS) was explained by addiction status. Using the SHARE-FI, 23% of frailty was explained by nutritional status while 1% of frailty was explained by addiction status. In terms of gait speed, 15% of frailty (by the SHARE-FI) was explained by the gait

speed (using the 10m Walk Test). No associations (<10%) between frailty and independent variables of age and gender were found using the two frailty scales.

Table 3.13 Profile of the study cohort who were identified as frail/pre-frail (n=6)

UIN	Age category	Gender	SHARE-FI	CFS	Perceived frailty	Nutritional status*	Homeless	Drug dependency	Hx of incarceration	Medical conditions	Mobility
P2	55-60	F	Frail	Frail	Yes	6 (malnourished)	No	Yes	Yes	cardiac, HIV, hyperthyroidism, Ca	independent
P3	50-55	M	Pre-frail	Frail	Yes	11 (at-risk of malnutrition)	Yes**	Yes	Yes	bowel condition, msk***, lung condition	stick
P24	40-45	M	Frail	Frail	Yes	4 (malnourished)	Yes**	Yes	Yes	Suicidality, msk	independent
P37	50-55	M	Frail	Frail	Yes	5 (malnourished)	Yes**	Yes	Yes	msk, depression	crutch
P40	45-50	F	Frail	Pre-frail	Yes	7 (malnourished)	Yes**	No	No	COPD, Ca, depression	independent
P47	50-55	M	Frail	Frail	Yes	4 (malnourished)	No	Yes	Yes	COPD, OA, HIV	stick

*Mini-nutritional assessment scoring **ETHOS definition of homelessness ***musculoskeletal condition

Table 3.14 Linear regression analysis (n=43)

Response Variable	Explanatory Variable	R ² *	p-Value	Response Variable	Explanatory Variable	R ² *	p-Value
Frailty: SHARE-FI				Frailty: CFS			
	Age	0.086	0.056		Age	0.097	0.042
	Sex	0.000	0.944		Sex	0.063	0.106
	Addiction Status	0.001	0.534		Addiction Status	0.119	0.023
	Nutritional Status	0.227	0.001		Nutritional Status	0.306	0.000
	Gait Speed	0.154	0.009		Gait Speed	0.062	0.107

*R²=square of the correlation coefficient

Binary logistic regression modelling was conducted by categorising frailty into frail (frail/pre-frail) and non-frail categories. Results demonstrated that poor nutritional status was associated with higher odds of frailty using the CFS and threefold using the SHARE-FI. Increased gait speed (10m Walk Test) was associated with substantially reduced odds of frailty, estimated using the SHARE-FI.

Table 3.15 Binary logistic regression analysis (response variable: non-frail v pre-frail or frail; n=43)

Response Variable	Explanatory Variable	AOR*	p-Value	95% CI	
Frailty: SHARE-FI	Addiction status	0.85	0.849	0.15	4.75
Frailty: SHARE-FI	Nutritional status	2.99	0.044	1.03	8.73
Frailty: SHARE-FI	Gait speed	0.05	0.021	0.00	0.65
Frailty: CFS	Addiction status	3.19	0.159	0.64	15.94
Frailty: CFS	Nutritional status	5.49	0.015	1.39	21.77
Frailty: CFS	Gait speed	0.47	0.52	0.04	4.95

*Adjusted Odds Ratio

3.3.5.2 Practical Utility of and agreement between frailty instruments

The SHARE-FI presented as a brief and easy to administer tool (Chapter 2, Figure 2.7). In the final question of the SHARE-FI, the exemplar of low physical activity was deemed unfitting for the target population and was rephrased to reflect the real-life experiences of the population under investigation (Romero-Ortuno et al., 2010). The CFS was scored using clinical judgement following comprehensive history taking and assessment of physical functioning. Collateral information was sought from management of the day service in some cases where reliability of responses was in doubt due to the perceived level of substance intake at the time of evaluation. In terms

of administration time the SHARE-FI demonstrated a lower respondent burden than the CFS (duration of SHARE-FI: approximately 3 mins, duration of CFS: up to 10 mins), with its four brief questions (three binary) and one brief objective test of grip strength.

Fair agreement was detected between the two frailty instruments using three frailty categories (frail, pre-frail and non-frail); [$k\omega=0.317$ (95% CI: 0.226 to 0.431), $p=0.001$]. Four participants were frail using the SHARE-FI and the CFS. One participant, who identified as frail using the SHARE-FI, was found to be pre-frail using the CFS and conversely, one participant, who identified as frail using the CFS, was found to be pre-frail using the SHARE-FI. Greater divergence was detected between the instruments in the pre-frail and non-frail categories, with almost two-thirds (60.5%, $n=26$) pre-frail using the CFS while only 20.9% ($n=9$) were pre-frail using the SHARE-FI.

Correspondingly, 27.9% ($n=12$) and 64.7% ($n=29$) were found to be non-frail using the CFS and the SHARE-FI, respectively.

3.4 Discussion

Key findings in the LEAP-II trial indicate feasibility of the intervention evidenced by safety, acceptability and adherence, and retention in certain sub-groups. Pre-post intervention impact was demonstrated by improvements in a number of physical functioning outcomes, specifically lower limb strength and gait, pain, nutritional status and frailty. Results also demonstrated feasibility of the test battery with a completion rate of over 70 per cent for all the outcome measures used (Wouters et al., 2017). Of note, when exploring frailty, a high level and an early onset of frailty was detected using the two frailty instruments, the CFS and the SHARE-FI, however, the CFS identified a prevalence of pre-frailty which was three times that of the SHARE-FI. Nutritional status and addiction status were predictive of frailty using the CFS, while gait speed was

predictive of frailty using the SHARE-FI. Therefore, the identification of frailty is important.

3.4.1 Feasibility

In terms of recruitment, anecdotally the majority of the service users of the Ballyfermot Advance Project were enrolled in the programme. However, to place a sharper lens on retention, thirteen participants (30.2%) did not attend any of the exercise sessions following their initial evaluation and of those who attended, 44.2% (n=19) came infrequently. It must be acknowledged that, in defining a regular attender as one who partook in a minimum of one session per week for >50% of the duration of the programme, a low threshold was set, however, considering the target population who are known to engage poorly with healthcare services (Elwell-Sutton et al., 2017), it was deemed a realistic and achievable marker. It is posited that there are many complex reasons for the low attendance and this study's attrition. Firstly, those with acute housing issues (sleeping rough, staying in temporary and/or remote accommodation) were among those who did not return following the initial evaluation, although they expressed a desire to attend. Furthermore, feedback from those who completed the exit survey (n=20) indicated that the primary reason for poor retention was substance use, with chronic, longstanding addiction issues in the majority. This finding was also demonstrated in the linked LEAP-I trial, where stability in addiction, as well as stability in housing, appeared to drive better retention (Kennedy et al., 2024). It must also be noted that both medical history and addiction history recorded for this study were self-reported, therefore it is plausible to assume these figures are underestimated. Although the retention profile in these linked studies is comparable, some differences have been noted. In LEAP-II, the majority of the participants lived in

an area which has the highest level of deprivation nationally (Pobal, 2023). They had chronic addiction issues (92%), but greater stability in accommodation (51%), (that is, not roofless or houseless (FEANTSA, 2005), when compared to the LEAP-I trial. In LEAP-I, 64% of participants reported current addiction issues and 71% had a more unstable housing status (roofless or houseless). Nonetheless it is apparent that the existence, or co-existence of these complex social factors contributed to the retention issues observed in both studies.

In this study, health literacy appeared to be low, firstly in terms of the nescience of the impact of risky lifestyle behaviours on health status and future outcomes; for example, many participants regularly engaged in cigarette smoking prior to and immediately following the exercise intervention. In conversations regarding nutrition, participants expressed limited knowledge and there appeared to be limited interest in healthy eating. This is not surprising considering food insecurity in this population (Kendzor et al., 2017, Tong et al., 2019). Moreover, the UK Health Needs Audit reported that two thirds of people experiencing homelessness ate at most one portion of fruit or veg per day (Hertzberg and Boobis, 2022). Some participants, who declined to attend the intervention due to a reported musculoskeletal disorder, discussed their distrust of the medical advice previously provided to them disbelieving that exercise could have a beneficial effect on their condition. The poor physical health that they experienced was viewed as a barrier to exercise rather than a valued opportunity to improve health. This, combined with reported poor exercise histories and low baseline levels of physical activity reduced their motivation. Aligning with these findings, the literature has shown that over 90% of patients in receipt of addiction services demonstrate unhealthy lifestyle behaviours (Hovhannisyan et al., 2018). Many participants described their

reluctance or inability to engage effectively with primary healthcare services; some had problems registering with a GP in their community and for others, apart from receiving their weekly prescribed medication, getting an appointment with their own GP was extremely difficult and attributed to healthcare provider perceived stigma (Reilly et al., 2022). This low level of engagement with health care in this population is a common finding (Elwell-Sutton et al., 2017). Participants alluded to the stigma and shame attached to attending for healthcare services, a barrier often experienced by this population and known to impact on health and wellbeing (Reilly et al., 2022). Moreover, lower health literacy levels in people with SUD have been linked to poorer quality of life and mental health (Degan et al., 2019). These factors undoubtedly contributed to the evident unmet physical health needs of this cohort and this population in general. Health promoting and awareness programmes preceding physical health interventions such as in this study are thus proposed as strategies to enhance health literacy and retention to exercise trials as well as adopt healthy lifestyles to improve health outcomes, thereby taking an active role in addressing the social determinants of health.

Other barriers to participation that were encountered were mental health issues, reported by all of the study participants, and these were heightened at critical times, for example, at Christmas time or anniversaries of loved ones. Comorbid depression, which can be extremely prevalent among people with SUD, is known to challenge the responsiveness to treatment and negatively affect prognosis and cannot be managed in isolation (Tirado Muñoz et al., 2018). Inclement weather and the provision of supplementary state social welfare payments which occurred over the course of the programme and coincided with the exercise schedule reportedly

influenced footfall to the centre. In other instances, conflict occurred between some participants, resulting in a number of withdrawals from the programme. Additionally, many participants alluded to adverse life events, and it is suggested that these traumatic legacies, known to impact the life course are likely to have influenced the participants' ability to engage and commit (SAMHSA, 2014b). A further important finding in this study and commonly reported in the evidence base was the presence of tri-morbidity (Vallesi et al., 2021) in this cohort. It is proposed that this myriad of intrinsic and extrinsic stressors outlined in this section that affected participation requires targeted, multi-disciplinary input rather than siloed single-model interventions to address the various dimensions of health and well-being which are so complexly intertwined.

Changing behaviour is undoubtedly complex and dependent on a myriad of interacting factors. Thal et al (2022) propose a number of behavioural change techniques including behavioural practice, social support, goal setting, self-monitoring and problem solving to improve outcomes in physical activity interventions in people with SUD (Thal et al., 2023). Considerable work has been conducted by Michie in the field of behavioural change (Michie et al., 2013). Of 26 behavioural change techniques utilised in intervention studies to promote physical activity and healthy eating specifically, Michie et al (2009), in a meta-analysis, identified 'self-monitoring' with at least one other technique as the most effective to promote change in behaviour (Michie et al., 2009). In addition to these recommendations, numerous strategies have also been proposed to enhance adherence in exercise trials, many of which were utilised in this study (Collado-Mateo et al., 2021). Among these are characteristics of the exercise programme, multi-disciplinary involvement, exploration of barriers and

facilitators, improved participant knowledge and education, management of expectations, enjoyment, social support, communication (including phone calls) and feedback, self-efficacy and goal setting (Collado-Mateo et al., 2021, Robiner, 2005). It is clear that many complex and interacting factors are involved in behavioural change. Motivational phone calls were not effective in increasing retention in this study. Many participants did not own a phone, phone calls were mostly unanswered, or phones were not operational during the period that this initiative was employed. Of note, is that phone calls were made by the researcher without caller identification and may have deterred participants from answering calls. Another strategy, utilised in this study, and advocated in the planning stages of trials to positively influence recruitment and retention, is stakeholder involvement, particularly of those with lived experience of the condition under investigation (Crocker et al., 2018). However, its impact is not fully known. Finally, the effect of substances on behaviour and participation during exercise classes was noted to be varied and unpredictable in this study. Awareness of participants characteristics and their motivation to participate warrants attention and indubitably influenced the retention rate in this 'hard-to-reach' group (Chaudhari et al., 2020).

Findings of higher retention in the older and female participants in this study, similarly, emerged from the LEAP-I trial where higher rates were observed in participants over 50 years and in the female participants. Greater physical health need associated with advancing age and social engagement are likely reasons for this finding. Another distinct group in this study who demonstrated higher retention rates and acceptability was a cohort of women from the Traveller community. Four women came regularly from a nearby halting site and the feedback from this small, unique group was

overwhelmingly positive. Factors influencing retention in this group were the enjoyment and psychosocial support the group offered, a cited distraction from a difficult and often stressful living environment. It is known that the Irish Traveller population suffer a disproportionate burden of physical health conditions compared to the general Irish population and their inclusion and engagement in this programme is important (Kennedy et al., 2023b). Furthermore, women experiencing homelessness and substance use have unique needs and this gendered dimension to the programme highlights a need for adopting bespoke women-only interventions (Morton et al., 2023).

Considering other factors which positively influenced retention, the exit survey highlighted a degree of empowerment derived from having choice, to engage in the Park Walk and/or participate in the exercise class. Some participants preferred the “walk and talk” and enjoyed the “chat with the girls”. There is growing evidence of the restorative powers of green space for physical and mental health. Lower cortisol levels and cardiovascular markers (heart rate and blood pressure) as well as reduced stress, anxiety and depression have been linked to exposure to and exercise close to nature, fresh air and open space (Ribeiro et al., 2021, Park et al., 2010) Additionally, evidence points to improved cognitive function and memory from walking in nature (Berman et al., 2012). Regardless of inclement weather conditions, a minority in this study enjoyed the Park Walk. It was viewed as a familiar and often easier option when motivation levels were low and thus is recommended for inclusion in future studies. A final positive indicator was the high adherence to the exercise and the protein supplement as well as the absence of adverse events thereby supporting the feasibility of this study and indicating proof of concept.

3.4.2 Impact

Regarding baseline physical function and frailty measures, this study, like previous linked studies (Kennedy et al., 2022, Kiernan et al., 2021) highlighted sub-normative values for physical functioning outcomes, accelerated ageing and high levels of frailty, validating the need for early intervention. In terms of the impact of the intervention, a number of positive changes to the outcome measures were observed in this study. Significant improvements were demonstrated in lower limb strength, gait speed, pain intensity and the nutritional status of the twenty participants who completed the final assessment.

3.4.2.1 Sub-group analysis

Sub-group analysis demonstrated that improvements were observed in the regular attenders, for gait speed (10mWT), pain levels and nutritional status (MNA), but not for lower limb strength (CST), which may be due to this subgroup being underpowered (n=11). A number of these outcome measures, which were brief and easy to administer, were recorded once weekly when participants returned to the programme, the CST the, 10mWT and pain. The minimal clinically important difference (MCID) for the CST in older people is one stand and importantly in this study the mean difference was two stands (McAllister and Palombaro, 2020). Furthermore, the MCID for the 10mWT in older people is 0.05m/s and in this study the mean difference in gait speed was 0.25m/s (Perera et al., 2006). Movement components of the CST featured in two of the stations included in the exercise circuit (sit-to-stand/squatting and step-ups) and some participants alluded to performing this simple exercise at home between attendances to the programme. This may have contributed to the observed improvements. The 10mWT was also measured weekly and as walking at incremental

speeds was a feature of the warm-up session and the end of session group activities, this may have influenced the improvement observed in this measure.

As walking was the main mode of daily transport for the majority of participants in this study, it is unsurprising that the post-intervention result for the 2-MWT outcome was unchanged. Despite this, baseline levels were lower than normal values in 55% of the study participants, perhaps explained by reported baseline physical health conditions and multi-morbidity.

3.4.2.2 Nutritional results

Nutritional levels in this study improved, yet it must be acknowledged that the direct effect of the nutritional (protein) supplement utilised in this study was not measured. Of note, the period following the exercise session was used for rest, safety monitoring and taking the protein supplement. It was also a time for opportunistic discussions around nutrition and healthy eating, and these strategies may have in some way influenced the enhanced MNA scores observed in the regular attenders. Limb circumference (a potential indicator of malnutrition) scores did not change from T1 to T2 (Cano et al., 2009). It is suggested that this measure served only to highlight muscle mass deficits and was a useful indicator of baseline physical health status, however, an intervention of longer duration would be required to impact on significant changes to muscle mass.

3.4.2.3 Muscle test results

Muscle strength and muscle performance testing including hand grip dynamometry and the chair stand test which were used in this study are more sensitive measures and better indicators of muscle disease for shorter interventions. Therefore, limb circumference measures are useful solely as baseline indicators in this context and

were not proposed for the follow-up study for monitoring change over time. Baseline grip strength scores were low, and no significant improvements were demonstrated post-intervention. Of note, the tester observed that despite clear instructions for all performance-based measures, participants found it challenging to remain focused on all the physical tests, especially in exerting maximal effort for dynamometry testing.

3.4.2.4 Balance test results

The SLS test identified balance deficits at baseline assessment. As many participants (n=33, 76.7%) achieved below the normative values for unipedal stance and were unable to stand on one leg for greater than 30 seconds at baseline, the lowest score was recorded for analysis as this was considered to contribute to the observed gait and mobility deficits, highlighting a truer measure of physical function and performance (Springer et al., 2007). Given that notable differences between limbs existed in SLS testing and potentially resulting from a pre-existing condition, it is not surprising that changes were not detected following the intervention.

A final point to note regarding impact of an intervention of this kind is the importance of considering the characteristics of the population as well as the impact of substance use on participation. As a result, willingness, and ability, to exert sufficient effort required to gain a strengthening effect varied considerably between participants and between sessions.

3.4.2.4.1 Comparisons to the evidence base

A number of comparable studies investigated the effect of exercise on physical function in this population. Most exercise and nutritional studies targeting people experiencing homelessness have employed multi-modal interventions (Dawes et al., 2024). One randomised controlled trial (RCT) investigated the effects of a diet and exercise intervention in homeless adults (Kendzor et al., 2017). However, this RCT did

not provide structured, planned, and supervised exercises like the LEAP-II trial, rather the provision of educational newsletters on physical activity, pedometers and healthy snacks. It appears that the LEAP-II trial, in harmony with the LEAP-I trial, is one of the first to provide a structured exercise and nutritional intervention in this population. The LEAP-I study, which evaluated the impact of a once weekly multi-modal exercise intervention in people experiencing homelessness and addiction issues, did not demonstrate pre-post intervention improvement in physical function or frailty scores (Kennedy et al., 2024). This was not surprising given its pragmatic and low threshold design, delivering a less-intense once-weekly rolling exercise programme. Nonetheless, its findings informed this current optimised study.

A systematic review of 27 studies, investigating the effects of exercise in a population with SUD, demonstrated significant improvements in grip strength [MD=1.21, 95% CI (0.34, 2.08), $p=0.007$] and balance [MD=9.95, 95% CI(6.29, 13.62, $p<0.000001$], outcome measures also utilised in this study (Ye and Liu, 2023). However, this review focussed on aerobic exercise only and the balance outcome measured balance with eyes closed, which differed to the methodology used in this study. Giesen et al (2015), proposed the potential benefits of multi-modal exercise interventions in people with alcohol use disorder, however, the physical functioning outcomes (cardiorespiratory) used in these studies differed to this study, so no meaningful comparisons could be made (Giesen et al., 2015). Common to the latter study by Giesen et al (2015), the present study also employed multi-modal exercises, with a primary focus of anaerobic strength training in the exercise class, but with additional aerobic only exercise session in the once-weekly 'Park Walk'. Considering that the literature is inconclusive regarding exercise type and the general recommendations to

incorporate both modes of exercise into physical activity participation, a multi-modal intervention seems prudent. Furthermore, it presented participants with choice, a strategy known to assist in retention in SUD trials and an important component of trauma-informed practice (Abrantes et al., 2011, SAMHSA, 2014b).

3.4.3 Test battery utility

As discussed in Chapter 1 and 2, appropriate outcomes measures are needed to evaluate physical functioning and frailty in community-based settings for people who are homeless to manage their associated primary healthcare conditions locally and avoid the common pathway to emergency care and hospitalisation (Ní Cheallaigh et al., 2017). For the first time, this study along with its sister study, the LEAP-I trial, evaluated the feasibility of a physical functioning and frailty test battery for this non-geriatric population (with unique healthcare needs) in the community setting and the results demonstrated feasibility (Wouters et al., 2017, Kennedy et al., 2025).

Firstly, and critically, the test battery was deemed relevant to the target population. It was time efficient, inexpensive and simple to conduct in the setting and required minimal equipment to conduct the full evaluation. The duration of the performance-based outcome measures (hand-grip dynamometry, the 10MWT, the 2MWT, the CST and SLS tests) was short. The self-report tests (pain rating, frailty, nutritional status and quality of life) took longer to complete, but the researcher considered that use of a trauma informed approach superseded the need to curtail discussions, in particular conversations relating to addiction history, homeless status, previous trauma and healthcare needs (SAMHSA, 2014c).

Regarding the utility of the test battery, firstly the confirmed validity of limb circumferential testing in this population is lacking, where measurements were taken

through clothing for a number of participants in this study. Furthermore, a small number of participants had difficulty completing the 2-MWT (n=3, 6.9 per cent) and the SLS test (n=2, 4.6 per cent) due to pain, lack of energy or motivation and alcohol intoxication. However, this finding is not considered a flaw in the test battery, rather it provides insight into the challenges faced by this population. Pain rating was sometimes inconsistent and considering the known functional literacy levels in people experiencing homelessness (Wolf et al., 2012), the credibility of the pain rating scale in some cases may be questioned. The SF-12, a measure which has been validated in people who are homeless (Gordon et al., 2019), provided this additional detail in this study. Despite validation of the SF-12 in this population, the terminology of one of the questions was deemed unsuitable in terms of the real world experienced by some participants in this study who did not live in a situation or an environment where housework or leisure activities were conducted. Considering this and the known lower levels of functional literacy in this population, the researcher read aloud the questionnaire to the participant and made a minor modification to its language to better contextualize one question and facilitate accurate interpretation and completion of the test as well as providing data which represented this population. Terminology of a portion of the MNA was also modified to make this measure relevant and applicable to this setting, (see Chapter 2, section 2.8.11.1 and 2.8.10.1, for SF-12 and MNA description, respectively).

Regarding the frailty tools used in this study, the CFS and the SHARE-FI were useful to identify frailty and pre-frailty in this young, vulnerable population. Danilovich et al (2018) demonstrated that the SHARE-FI predicted certain physical functioning scores, some of which were also utilised in this study, namely, the Timed Up and Go

test, gait speed, the Short Physical Performance Battery and inability to complete the Chair Stand Test (Danilovich et al., 2018). This is an important finding as these two constructs, physical function and frailty, are closely linked, as discussed in Chapter 2 (sections 2.8.1, 2.8.2 and 2.8.3). This Chicago-based study acknowledged that, like the LEAP-II study, these findings could not be generalised and that the SHARE-FI, while correlating to physical function, identified physical frailty only and failed to look at other important frailty domains. This present study in utilising a second frailty measure, the CFS, enabled other dimensions of frailty to be explored, (cognitive, psychological and social functioning) which are particularly relevant to people experiencing homelessness, as well as other socially excluded populations. Frailty itself will be explored further in the next section in this chapter.

The test battery utilised in LEAP-II is considered useful for research and clinical practice to evaluate physical functioning and frailty in a broad spectrum of people experiencing homelessness and addiction and this test battery was proposed and utilised in the follow-up study, the LEAP-W trial. It is hoped that this test battery will be useful in primary care settings where rehabilitation interventions may be more accessible and effective if delivered earlier and in closer proximity to this population.

In this study, higher test completion rates were found when compared to a linked study which was conducted in acute care, where only 31% could attempt the Stair Climb Test (which involves climbing one standard flight of stairs) and only 38% could attempt the 6-Minute Walk Test (which involves walking a 30m course for six minutes) (Broderick et al., 2021). Reasons cited for non-completion in the hospital-based tests were acuity of illness, pain, footwear and safety which is unsurprising when

considering the setting and context. Moreover, the brevity of 2-Minute Walk Test is likely to have led to higher completion rate in this current study.

Although the outcome measures in this test battery were selected based on available clinimetric evidence and expert consensus, they fail to fulfil the criteria to create a core outcome set (Williamson et al., 2012). In particular only one measure the SF-12 has been validated for people experiencing homelessness (Larson, 2002). This points to the relative novelty of this research and a population who are generally less researched. The outcome measures described in this proposed set thus require clinimetric evidence and some require modifications to their terminology to enable more meaningful score interpretations. While this study broadly indicated feasibility and utility of the test battery, evidence of the validity and reliability of these outcomes in this population is lacking and needs to be addressed in future studies.

Finally, a number of considerations are proposed when applying this test battery and other assessment tools to evaluate this unique population who experience a plethora of complexities. These are outlined in Table 3.16.

Table 2.5 Table 3.16 Clinical implications of test battery in this population

Implications	Recommendations
<i>Literacy issues</i>	<ul style="list-style-type: none"> • Check terminology of measures, ensure plain text, ensure real world relevance (living/social situation) • Effective communication, use simple language, avoid distractions • Provision of verbal/visual information • Read surveys to participants • Encourage questions/teach-back technique
<i>Addiction issues - fluctuating mood and behaviours</i>	<ul style="list-style-type: none"> • Flexibility in approach: <ul style="list-style-type: none"> ○ Alternate between test-based and self-report measures – may tire or get distracted ○ Brief tests – may lose interest ○ Give additional time if needed or do assessment in parts if preferred
<i>Adverse Childhood Experiences</i>	<ul style="list-style-type: none"> • Trauma informed approach: <ul style="list-style-type: none"> ○ Watch for triggering in line of questioning, effective communication critical - sensitivity required ○ Undressing not a pre-requisite for limb circumferential measurements ○ Show empathy and kindness
<i>Setting</i>	<ul style="list-style-type: none"> • ‘We will come to you’ – arrange in an appropriate and convenient setting • Low threshold - ‘Come as you are’
<i>Health status – may fluctuate</i>	<ul style="list-style-type: none"> • Pre-screening (eg PAR-Q*), continuous/vigilant monitoring (CV monitoring)

*PAR-Q (Adams, 1999)

3.4.4 Frailty exploration

Firstly, regarding frailty prevalence, the baseline level of frailty in this study is considered relatively high (SHARE:11.6% frail; CFS:11.6% frail) especially when viewed alongside studies investigating frailty in older populations (Romero-Ortuno et al., 2010, O'Halloran et al., 2021). For example, in Wave 1 of The Irish Longitudinal Study of Ageing (TILDA), using Fried’s Phenotype (upon which the SHARE-FI is founded), a frailty prevalence of 8% was demonstrated in a population of older adults (mean age 74 years) (Roe et al., 2017). Furthermore, the Survey of Health, Ageing and Retirement in Europe

(SHARE) study, demonstrated a frailty prevalence of 7.3% using the SHARE-FI (Romero-Ortuno et al., 2010). The mean age in this SHARE study (63.8 years) was also higher than in this current study, the LEAP-II trial. Interestingly, levels of frailty in participants of the third wave of TILDA were similar to this study, with 11% presenting as frail by CFS, however their mean age (74.5 years) was 28.9 years older than participants of the LEAP-II trial (45.6 years) (O'Halloran et al., 2021). Exposure to extreme, chronic stressors and social harms, including homelessness, addiction, mental health challenges and food poverty, is likely to lead to an increased propensity to acquire frailty syndromes at an early age. These findings demonstrate clear evidence of the early manifestation of accelerated ageing in this study's participants who had a chronological age of at least 20 years younger and points to a critical need for early intervention (O'Halloran et al., 2021).

In younger (under 65 years) generic populations, a frailty prevalence of 3.9% to 63% has been reported (Loecker et al., 2021) , and more recently in a systematic review of the prevalence of frailty in people experiencing homelessness specifically, a frailty prevalence of 18-60% was cited (Cronin et al., 2025). It is therefore challenging to compare proportions of frailty across studies even with similar populations. For example, in a London-based study which investigated frailty in a homeless population a much higher prevalence of frailty (48%) than this study was reported using the CFS (Rogans-Watson et al., 2020). However, in this study the population was older (mean (SD) age of 55.7 (10) years) and the setting in particular was notably different (a hostel for people with high and complex needs) (Rogans-Watson et al., 2020). Nonetheless, frailty levels in this current study, the LEAP-II trial are considered high and it is thought that an accumulation of multiple factors, including the presence of chronic stressors,

adversity, deprivation and chronic illness played an important role in this finding (Aldridge et al., 2018).

Secondly, regarding attributes of frailty in this population, the SHARE-FI identified physical frailty in 11.6 % (n=5) and pre-frailty in 20.9 % (n=9), while a significantly higher degree of vulnerability (pre-frailty: 60.5%, n=26), which encompassed more than the physical domain, was highlighted by the CFS which measures multiple dimensions of frailty. This was also recently observed in the LEAP-I trial where higher levels of frailty were observed using the CFS, indicative of other drivers of frailty in this chronologically young population (Kennedy et al., 2023a). This disparity also mirrors the low agreement found between the two frailty instruments. In participants identified with phenotypical frailty by SHARE-FI, a level of frailty by CFS was also detected in 80% (n=4), explained by reported medical (chronic conditions), psychosocial (living situation and environment) and behavioural factors (addiction and poor nutritional health). Addressing the physical health burden in this population, for example, through physical rehabilitation interventions, may have a ripple effect in addressing these other domains of frailty detected by the CFS and may aid in mitigating the broader frailty sequelae. Additionally, many participants with higher physical functioning by SHARE-FI (ie. the non-frail), demonstrated a vulnerability and using the CFS, a level of pre-frailty was identified in almost two-thirds of this sub-group. Dual diagnosis and tri-morbidity are commonly reported in this population (Vallesi et al., 2021), therefore extreme psychosocial and behavioural factors are likely to play a key role in the manifestation of the observed negative presentations in function and frailty. In contrast, Loecker et al (2021) reported the presence of fewer psychological factors

driving frailty in the younger populations investigated (Loecker et al., 2021). This is not surprising given that the exploration of frailty in this population is less well researched.

When more closely exploring the factors which drive frailty, this study identified a number of important findings. Considering that frailty is more closely linked to biological age than chronological age and higher levels of frailty are known to exist in *older* females, it is unsurprising that no association was detected between age and gender in this sample. However, nutritional status and addiction status appear to be predictive of frailty. This concurs with previous research findings of an association between substance use, nutrition, and adverse health outcomes (Kamran et al., 2020). Furthermore, an increased odds of frailty was found in people with poor nutritional status using both frailty tools, also concurring with the existing evidence base (Lionetti et al., 2024, Dorner et al., 2014). Food poverty is commonly reported in this population (Salem et al., 2013, Tong et al., 2019) and associated with frailty (Pérez-Zepeda et al., 2016), therefore, nutritional intervention is proposed as an important consideration for care providers when targeting interventions to mitigate frailty and adverse outcomes in this population. This finding also endorses the provision of post-exercise protein supplementation and basic nutritional advice, an intervention utilised in the LEAP-II trial to enhance muscle protein synthesis and improve health literacy. Another interesting finding is the predictive ability of gait speed (10m Walk Test) using the SHARE-FI frailty instrument. This finding concurs with the findings of Danilovich et al where the SHARE-FI continuous scores were found to predict gait speed (Danilovich et al., 2018). It must be acknowledged that despite the apparent predictive ability of these frailty tools, interpretations must be cautiously considered due to the wide confidence intervals observed and larger samples are required to confirm these findings.

Larger scale studies have identified numerous correlates of frailty in similar populations. Salem et al (2013) identified significant relationships between frailty and age [mean age 52.4 (40-73) years], gender [male: female: 50:50], healthcare utilisation, nutrition and resilience (Salem et al., 2013). Interestingly, while it was reported that over two-thirds of the study's participants had addiction issues no correlation between frailty and substance use was determined (Salem et al., 2013). However, in a more recent study of 130 formerly incarcerated homeless women, higher drug dependency was significantly associated with higher levels of frailty (Salem et al., 2019). Of note in LEAP-II, 83% of participants frail by SHARE-FI or CFS, reported former incarceration.

The Frailty Framework for Vulnerable Populations (FFVP), developed in 2014 through research and expert opinion, describes a framework underpinning frailty in this population of interest (Salem et al., 2014). Guided by this framework, the authors in this study have identified a number of potential drivers of frailty, in addition to those discussed earlier; (i) housing situation and recent incarceration (Situational Factors), (ii) chronic medical conditions, nutritional status, mobility status and mental health conditions (Health-related Factors), (iii) addiction (Behavioural factors) and (iv) a subjective feeling of frailty (Resilience factors). In relation to resilience, in this study, those who felt frail were frail (see Table 3.13). However, larger scale research is required to further explore these factors.

Finally, regarding practical utility both instruments performed well. The SHARE-FI required a minor terminology change to better exemplify low physical activity to the target population. Otherwise, it presented as a brief and simple tool for use in community settings to identify the presence of physical frailty in this population. The CFS, being a judgement-based tool, required collateral information in some instances

where substance misuse and recall may have impacted on the credibility of self-report responses. Similarly, Thorpe et al identified that fundamental to screening for frailty in acutely unwell hospitalised patients, is the collation of data from sources aside from self-report (Thorpe et al., 2022). The SHARE-FI was therefore superior in terms of its lower respondent burden, an important consideration for this population where low threshold services are recommended (Morton and O'Reilly, 2016). Dual trait frailty measures have been recommended (Theou et al., 2015) and this feature highlights another advantage of the SHARE-FI with its combined test-based and self-report feature. Nonetheless, a comprehensive appraisal of frailty is required especially when evaluating a heterogenous population such as people who experience SMD, and this is where the CFS triumphed (Lankelly Chase, 2024). Frailty is a multi-dimensional construct, therefore despite fair agreement between the frailty tools, selecting different yet complementary tools is important (Martin and Brighton, 2008). Additionally, it is known that higher levels of frailty are associated with higher health and social care needs and measurement is advocated in community settings to inform and improve the allocation and use of resources (Roe et al., 2017). This is another important consideration for addressing the evident health disparities and inequities in this population and highlights the suitability of this frailty instrument. The widely used CFS has also been shown to be predictive of transitions in frailty and therefore monitoring is recommended for every two years (O'Halloran et al., 2021). Therefore, it would not be surprising to observe no change over a short period of time as in this study. These findings highlight a gap, where a single, multi-dimensional tool is warranted, designed specifically for this population with SMD, reflecting their real-life experiences and challenges which contribute to frailty. In conclusion, in the absence of a single tool,

both tools are considered relevant and practical for use in people experiencing homelessness, addiction and mental health challenges and when used in harmony, they have potential to be beneficial if they identify distinct needs and result in the delivery of targeted interventions.

Effectiveness of exercise interventions with nutritional supplementation to improve the frailty status of older adults has been demonstrated (Travers et al., 2019, Travers et al., 2023). In this study, no significant effects were demonstrated for the collective 20 participants (Share-FI (categorical) or CFS). However, as mentioned, an improvement was observed in the CFS and the SHARE-FI continuous scores in the regular attenders. This appears to be due to two participants rather than the collective group. No overall improvement in frailty status was demonstrated, nonetheless, post-intervention frailty (frail/pre-frail) using both measures was lower. It is posited that even the postponement of decline, particularly in extremely vulnerable non-geriatric populations, is a positive outcome and such markers need to be acknowledged.

**PROTOCOL AND PUBLISHED PAPERS LINKED TO
CHAPTER 4**

STUDY PROTOCOL

Evaluation of a Low-threshold Exercise And Protein supplementation intervention for Women (LEAP-W) experiencing homelessness and addiction: Protocol for a single-arm mixed methods feasibility study

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Abstract

Background

Frailty is a complex multi-dimensional state of increased vulnerability to adverse outcomes and is associated with older age but there is growing evidence of accelerated ageing and frailty in non-geriatric populations, including those experiencing socio-economic deprivation and extreme social exclusion, such as people experiencing homelessness. Addiction, as a coping mechanism for prior trauma, is common among people who are homeless and can have a gendered dimension. Women experiencing homelessness and addiction have unique needs which require a gendered approach. The aim of this study is to evaluate the feasibility and impact of an exercise intervention to target the known physical functioning deficits and frailty which this population experiences.

Methods

This quantitatively driven, sequential single-arm mixed-methods feasibility study will evaluate the feasibility and impact of a low threshold trauma informed exercise intervention on physical functioning and frailty in women experiencing homelessness and addiction. Physical function (10m Walk Test, 2Min Walk Test, Single Leg Stance, Chair Stand Test, hand grip dynamometry), frailty (Clinical Frailty Scale and the SHARE-Frailty Instrument) and nutritional status (Mini-Nutritional Status), pain (Numerical Rating Scale) and quality of life (SF 12-V2) will be evaluated. The 10-week intervention will involve a 3-times weekly exercise programme with protein supplementation. Following this, qualitative interviews, which

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will be thematically analysed using Braun & Clarke methodology, will be conducted. This study will be conducted in Dublin from February to July 2024.

Discussion

Little is known about frailty-focussed interventions in women experiencing homelessness and addiction. This proposed study will help to increase the knowledge base regarding the physical health burden and frailty experienced by this vulnerable population and will deliver a targeted intervention with a gendered dimension to mitigate its affects. The findings of this research will help narrow the research gap and will guide clinicians and policy makers to implement unique gender-based treatment strategies for this population. (300).

Clinical trials.gov number

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Introduction

The world's population is ageing rapidly [1]. Frailty, a sometimes-preventable consequence of a rapidly ageing population, is a complex state of cumulative decline across multiple physiological systems which renders a person vulnerable to adverse health outcomes and greatly challenges healthcare systems [2]. Targeted interventions to manage frailty in older adults are recommended and exercise with nutritional supplementation has proven effectiveness in combatting and mitigating frailty [3–5].

Frailty as a construct is a geriatric concept which is strongly associated with increasing age [6]. Notwithstanding that biological age is closely linked to frailty, it is known that chronological age alone will not identify frailty as the health and functional life status of populations are so variable [7]. Growing evidence indicates the prevalence of premature ageing and frailty in non-geriatric populations [8, 9]. 'Younger frailty' has been identified in populations of lower socioeconomic status, who live in areas of greater deprivation and experience an earlier onset of illness and disability [10, 11]. In a study investigating people experiencing homelessness (PEH) admitted for inpatient care, 83% of participants had mobility problems and 70% were frail or pre-frail despite a low median age of 45 years [12, 13]. In an analysis of UK Biobank participants aged 37–73 years, 42% of individuals living with frailty were within the most socially deprived quintile of the cohort [10]. Females are known to experience higher levels of frailty compared to males [14, 15]. It is therefore not surprising that poor physical functioning and frailty is experienced by young women who are homeless and use drugs [16, 17].

Health services for PEH frequently focus on crisis-based medical, nursing and addiction services, often with a gender-blind lens [18, 19]. High levels of stigma, shame and fear result in women accessing services even less and seeking help at breaking point with complex coinciding physical and mental health needs [20, 21]. Homelessness and substance use in women is inter-sectoral and may overlap with trauma, abuse, domestic and sexual violence and exploitation, and the needs of these women are complex and unique [22]. Pathways into homelessness are frequently different to that of men and require a different approach [23]. Internationally, gender-based services for women who are experiencing homelessness and addiction are lacking and services are mostly delivered in mixed gender settings [18, 19]. Women-specific services are recommended to increase safety, stability, wellbeing, and psychosocial functioning to

respond meaningfully to the serious health and social care needs of women in this setting [24]. Gender specific and gender sensitive research is required to fill this knowledge gap [25].

Our prior research, the LEAP-I study demonstrated high retention (83% female v 42% males) with excellent engagement and feedback from its female participants, yet caution was observed around engaging in a mixed exercised programme with men [16]. Women have traditionally been underserved in research and policy, yet multiple sources cite women as the fastest growing homeless demographic [23]. No study has examined how targeted women-only exercise programmes with nutritional supplementation work in practice in this population.

The overall aim of this study is to evaluate the feasibility and impact of exercise with protein supplementation, delivered with a low threshold and trauma informed approach, on physical functioning and frailty outcomes in a group of (non-geriatric) women experiencing homelessness and addiction challenges, through the delivery of an exercise intervention, followed by qualitative interviews. The objectives are:

1. To evaluate recruitment, retention and adherence rates, and any adverse effects of the intervention.
2. To evaluate pre- and post-intervention levels of physical function, nutritional and frailty status, pain, and general health status.
3. To evaluate programme feedback and gain deeper insights into participants perspectives and experiences of the exercise intervention.

Materials and methods

Study design, setting and time frame

This single-arm quantitatively driven, sequential mixed-methods feasibility study will take place in Jane's Place, Merchants Quay Ireland (MQI), a five day per week drop-in day-service centre in Dublin city centre, which provides medical and support services for socially excluded women who are homeless and/or in addiction. Following the intervention qualitative research in the form of individual exit interviews will be conducted with 20 participants. This study has received ethical approval from the Faculty of Health Sciences, Trinity College Dublin on Jan 18th 2024 (Ethical Approval Reference Number: 211202).

Study population, eligibility criteria and recruitment strategy

Study population. This study will include a non-geriatric population of women who attend Jane's Place in Dublin city centre. These women are socially excluded, many with multiple disadvantage and complex needs and many experiencing homelessness, addiction and mental health challenges.

Eligibility criteria. Inclusion criteria:

- Adult women (18–65 years) accessing services in Jane's Place who consent to participation.

Exclusion criteria:

- Any person not meeting the age eligibility criteria.
- Any person identifying as a male.
- Any person lacking capacity to give consent.
- Any person with major physical/medical or cognitive challenges which would preclude ability to safely complete the assessment or

- Any person with insufficient English language ability to give fully informed consent.
- Women with a confirmed pregnancy.

Recruitment strategy. All potential participants will be provided with a participant information leaflet (PIL) detailing the purpose of the data collection, potential risks and benefits and data protection rights. Where possible a seven-day gap, between receipt of the PIL and obtaining consent, will be provided to allow people time to consider participation. However, if it is their preference to be seen at an earlier and more convenient time this will be facilitated due to the innocuous nature of the evaluation.

Once the research physiotherapist is satisfied that the participant has read and fully understands the PIL, they will proceed to obtain written informed consent. Obtaining consent will take place at the first face to face interaction with the participant prior to commencement of the assessment. The written consent informs participants that they are permitted to withdraw from the study at any time. They will be provided with their own copy of this consent form and PIL with their own signature and that of the research physiotherapist.

Stakeholder engagement. Recommendations from the linked LEAP II trial [17] included health education and awareness workshops preceding exercise interventions to enhance health literacy, target lifestyle behavioural change and improve retention rates. Prior to the LEAP-W programme, a number of exercise workshops will be delivered for staff and service users in Jane's Place. Feedback from this stakeholder engagement will inform the design of the intervention.

Primary outcome. The primary outcome is feasibility which will be measured by recruitment numbers, retention rate, adherence to the exercise programme and protein supplement, programme acceptability and adverse events (Table 1).

Secondary outcomes

Secondary outcomes will measure physical function, frailty and nutritional status, pain and self-reported health status using a broad test battery outlined in Table 2.

Table 1. Feasibility markers.

Primary Outcome: Feasibility	Method of reporting
Recruitment Numbers	Number of eligible consenting participants who completed the initial assessment
Retention rate Sub-group retention rate	Number of return visits and the frequency of attendance <ul style="list-style-type: none"> • attending at least once/week for > 50% of the duration of the programme (regular attenders) • attending at least once/week for < 50% of the duration of the programme (sporadic attenders) • did not return following initial assessment (non-attenders). • attendance by chronological age, and pre- and post-menopausal status.
Adherence rate (to the exercise intervention)	Percentage of sessions adhered to/completed by participants
Adherence rate (to the nutritional supplement)	Percentage of participants who consumed the protein supplement drink
Adverse events	An unfavourable and unintended sign, symptom, or disease having been absent at baseline, or, if present at baseline, appears to worsen and is temporally associated with medical treatment or procedure, regardless of the attribution [26]
Programme Acceptability	Participant feedback provided by Exit Interviews.

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Table 2. Test battery.

Construct Measured	Test
Sarcopenia and upper limb strength	Upper/Lower Limb circumference Hand grip dynamometry [27, 28]
Lower limb strength and endurance	30-sec Chair Stand Test [29]
Endurance and functional mobility	2-minute walk test [30]
Gait Speed	10m walk test [31]
Balance	Single leg stance [32]
Frailty	SHARE-FI [33], Clinical Frailty Scale [6]
Nutritional Status	Mini-Nutritional Assessment [34, 35]
Pain	Numerical Pain Rating Scale [36]
Health status/Quality of Life	Short Form 12 [37]

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1. Strength and muscular mass: Muscle strength will be measured, using a Jamar Digital Hand Dynamometer, while sitting with the elbow flexed at 90°, the forearm mid-prone, the wrist in neutral and the hand unsupported [27, 28]. Results will be compared to normative reference values [38]. Two measurements will be recorded and also used for the SHARE-Frailty Instrument (FI) assessment [33].

Mid-calf circumference girth will be evaluated as this measure correlates with appendicular muscular mass [39]. This will be measured using a flexible tape measure at the level of the largest circumference of the calf. Measurements will be compared to gendered cut-off values [40]. Mid-arm muscle circumference reflects both muscle mass and caloric and protein adequacy and may be used to signify wasting or malnutrition [41]. This test has been recommended in situations where lower limb swelling is present [42]. The maximum upper arm muscular mass will be measured using a flexible tape measure. These results will be compared to global reference values [43].

2. Physical performance and lower extremity physical function:

This will be measured using the following physical performance measures:

- i. The 10m Walk Test (10mWT). This test measures gait speed and functional mobility and is recorded in m/s. Gait speed is calculated as total distance/time [31].
- ii. The 2 Minute Walk Test (2MWT). This test of self-paced walking ability and functional capacity assesses a participants' ability to walk unaided over a 15m distance, as fast as possible, for two minutes. Rest breaks are permitted, and the distance covered is measured [30].
- iii. The Chair Stand Test (CST). This tests lower limb strength and endurance and records the total number of sit to stand repetitions performed in 30 seconds [29].
- iv. The Single Leg Stance Test (SLST). This balance test is performed on each leg. The participant is timed standing unassisted on one leg, with eyes open and hands placed on the hips [31].

3. Frailty: Frailty will be assessed using the Clinical Frailty Scale (CFS) [6] and the SHARE-Frailty Instrument (FI) [33]. The CFS is validated for people over 65 years. It is assessed by the tester. Each point on the scale correlates with a level of frailty and a visual chart aids classification from 1 (very fit) to 9 (terminally ill). Higher scores indicate higher levels of frailty. The SHARE-FI is validated for people over 50 years [33]. It consists of four brief questions related to the following variables: exhaustion, loss of appetite, walking difficulties and low physical activity, and grip strength measurement. The five results are entered into a freely available web calculator to generate a frailty score and a frailty category of non-frail, pre-frail and frail is also

generated. A minor modification was made to the terminology of the SHARE-FI to reflect the real-world experiences of this population.

4. Nutritional status will be assessed using the Mini-nutritional assessment (MNA) which assesses the risk of malnutrition [34]. The short form of the MNA (MNA-SF) [35] is an efficient screening tool consisting of six questions on food intake, weight loss, mobility, psychological stress, or acute disease, the presence of dementia or depression, and body mass index (BMI). The maximum score for this part is equal to 14. A score of 12 or higher indicates a normal nutritional status thus excluding malnutrition and/or risk of malnutrition. The terminology of two of the questions of the MNA (regarding acuity of illness and psychological stress) were slightly modified for the purposes of evaluation of this population in this setting.

5. Pain: Each participant will be asked if they are experiencing pain and will be questioned about its location and duration. Pain severity will be assessed using the Numerical Rating Scale (NRS) [36]. The NRS is a unidimensional measure of pain intensity from 0–10, with 0 being zero pain and 10 the worst pain imaginable.

6. Short-Form 12 (SF-12) The SF-12 V2 is a self-report measure of health used across age, disease, and treatment groups [37]. It uses eight domains including physical and social activities, pain, mental health, emotional health, vitality and general health perceptions to measure health. The tester will read and complete the 12-question survey with the participant. Results will be entered into a software program provided by the licensing company QualityMetric and two summary scores, mental health (MCS12) and physical health (PCS12) will be generated.

The assessor will document any issues with terminology of the outcome measures utilised, difficulties with completion or floor or ceiling effects reached, as these instruments were designed with geriatric populations in mind.

Using a bespoke data collection form, the following demographic data will also be collected: age, gender, ethnicity, living arrangement and environment, highest level of education, marital status, employment status, history of incarceration, history of addiction, self-reported health, and medical history (S1 File and Fig 1).

Intervention. The intervention will involve a 10-week low threshold, trauma informed exercise intervention (including a twice weekly exercise class with protein supplementation and a once weekly outdoor 'Park Walk'), delivered over 12 weeks to enable flexibility and maximum participation. An aim of this research approach is to enhance the programmes accessibility by providing flexibility and a level of awareness and understanding of past trauma, an approach which is recommended for people who have experienced chronic or complex trauma [44]. The LEAP-II trial, a linked study previously conducted a similar 12-week intervention [17]. While the results demonstrated evidence of effectiveness, the majority (91%) of those who attended regularly did not complete more than 10 weeks of the intervention. Behm et al (2023), proposed a minimal dose of once weekly multi-joint resistance training, with at least 6–15 repetitions using loads between 30–80% of one repetition maximum for 8–12 weeks to achieve a strengthening effect in untrained individuals [45]. Given that 10 weeks marks the midpoint of this finding, a pragmatic decision was made to shorten the duration of this feasibility study to prioritise and encourage increased retention and participation in this 'hard to reach' population who are known to engage poorly with mainstream services.

The intervention will be delivered by two research physiotherapists who will adhere to all safety procedures. Flexibility will be facilitated with the provision of a four-week window for pre-intervention evaluations prior to commencement of the programme. Using a trauma-informed lens [46] flexibly arranged group or one-to-one sessions will be delivered based on participant preference. Exercise programming strategies and variables are based on our earlier work (LEAP-I and LEAP-II trials) [16, 17] and also informed by prior stakeholder involvement from people with lived experience. The exercise classes will be multi-modal, with a

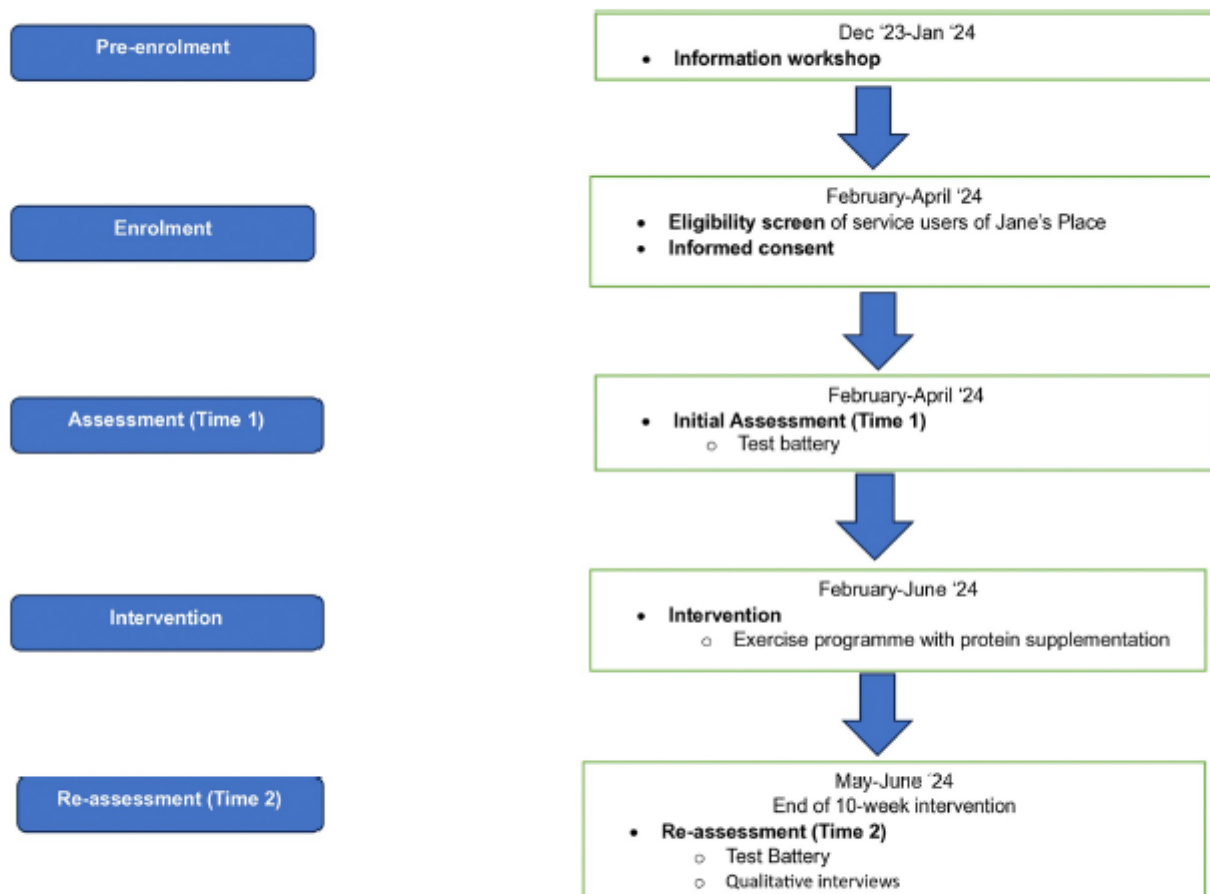


Fig 1. Spirit flow diagram.

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primary focus on strength and based on core set of resistance exercises (Table 3). Aerobic, balance and flexibility work will be integrated into the class and the exercises will be individualised based on initial assessment results and presentation of participants. Using a gender-based perspective, the following considerations and adaptations will be built into the class; (i) core-stability exercises to target pelvic floor and/or abdominal muscle weakness, (ii) bone building exercises to target peri- and postmenopausal bone loss and (iii) age-associated muscle mass loss. Music, dance and fun orientated physical activity games, an important feature of aforementioned linked studies, will be incorporated to optimize enjoyment and self-esteem. These features are incorporated to offer choice and enable empowerment in respect of a trauma informed approach, while carefully considering the exercise prescription parameters outlined above [45]. Borg's Rate of Perceived Exertion Scale will be used to monitor effort and scale the intensity of the workout [47]. To promote post-exercise muscle protein synthesis, a nutritional supplement (200ml pre-prepared 'protein shake', Fresubin) which consists of 20g of protein will be offered immediately post exercise. The 'Park Walk' will focus on the aerobic component of the intervention, using open green space to maximise physical and mental health outcomes. It will be a flexibly arranged 20–30-minute self-paced group or one-to-one walk. To build sustainability beyond the ten-week programme brief health promoting and physical activity

Table 3. Exercise circuit.

Core exercise	Initial Intensity	Progression/ Adaptations*
Sit to stand or squats or lunges	2 sets 10–15 reps	3 sets of 15 reps use of weights/ball/upper limbs
'Bicep curls'-Elbow Bends	2 sets 10–15 reps	3 sets of 15 reps use of weights/theraband
Step-ups	2 sets 10–15 reps	3 sets of 15 reps Vary height of step; use of weights & upper limbs
Arm elevations or boxing activity with research assistant	2 sets 10–15 reps	3 sets of 15 reps use of weights or boxing gloves/pads
'Penguin waddle'-alternate hip abduction in standing (unsupported if able)	2 sets 10–15 reps	3 sets of 15 reps additional upper limb abduction and elevation; movement with 360° turns
Scapular retractions	2 sets 10–15 reps	3 sets of 15 reps Weights/theraband
Aerobic, balance and co-ordination activity	5 mins	Exercise bike, ladders, hurdles (running forward, sideways, add in high knees or heel kicks), skipping ropes, end of session fun activity.
Core set (mat work) Women's health focussed exercises	5 mins	Deep breathing exercise, pelvic floor exercises; pelvic tilts, bridging, all 4's set with upper/lower limb extensions.

Adaptations: exercises performed in standing, individualised and progressed for each participant by research physiotherapist modified to chair-based exercise for those with mobility limitations.

Progression: 2–3 sets of 10–15 repetitions completed at each session; beyond that, low resistance weights (1.1kg–4.5kg), theraband or increased step height introduced to achieve a strengthening effect.

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educational interventions will be included in the exercise class setting to empower people to engage in unsupervised exercise following the study. As per routine procedure in the centre, which incorporates frequent reminders regarding upcoming appointments or events, phone messages will be incorporated to remind participants of the weekly schedule.

Each session will commence with a warm-up and will be completed with a cool down and stretch of the major muscle groups.

Qualitative data. Following the intervention one-to-one in-person semi-structured exit interviews will be conducted to enable participants to share their feedback and express their views, in order to enhance the understanding of behaviours, adherence and retention challenges and to provide insights for future programmes in this area [48] (S2 File). In order to gain a deep understanding of a complex phenomenon, multiple perspectives will be sought using purposive sampling, selecting participants who provided informed consent and completed at a minimum the initial pre-intervention evaluation as well as key stakeholders involved in service provision to women who attend the low threshold services in MQI. Data from 20 participants will be sought. The interviews will be audio-recorded in a private room in Jane's Place, by the lead researcher FK, using a Philips Dictaphone (DVT2050). Data will be immediately transferred to Sharepoint, a secure cloud-based system and then transcribed verbatim by FK. Member checking will be utilised. FK has knowledge and experience of quantitative and qualitative research methodology.

Braun and Clarke's reflexive thematic analysis will be used to interpret the qualitative data [49, 50]. An inductive approach will be utilised, guided by the 6-step framework. This will include 1) familiarisation with the data, 2) coding, 3) generating themes, 4) reviewing themes, 5) defining themes, and 6) writing up. Qualitative data will be coded manually by FK and software will not be used. An external validator will assist in coding, theme generation, review,

and definition. FK will conduct the narrative which will include integration with the quantitative data.

Using a hybrid design, the quantitative and qualitative data will be collected sequentially, as described, and the results will be analysed and presented separately [51, 52].

Sample size. A sample size calculation was conducted on the statistical package R, based on an expected adherence of 60%, a minimal acceptable adherence of 45% and a power of 80%, which indicated that a target sample size of 68 would be required. Due to the novelty of this study, the challenges of recruitment in this 'hard to reach' population and the feasibility focus of this study, while 68 will be the recruitment target, a minimal of 24 will be sought [53].

Data collection and management

Analytic plan

All data will be pseudonymised at point of entry into excel spreadsheets and then transferred into IBM SPSS V28 for analysis. For quantitative data, nominal or ordinal variables will be reported as frequencies and percentages. Continuous variables will be summarised as mean and standard deviation if normally distributed and median and inter-quartile range if non-normally distributed. Data will be tested for normality using the Kolmogorov-Smirnov/Shapiro Wilk test and will be compared across timepoints using the general linear model procedure (normally distributed data) and the Friedman's test (non-normally distributed data). Chi-squared t-tests will be used where appropriate and some data may be categorised to investigate relationships between variables. Exploratory regression models will be developed to explore correlates and predictors of frailty and poor physical functioning. For the qualitative data, Braun and Clarke thematic analysis methodology will be employed to provide an in-depth analysis of the exit interview data [50]. A *p*-value of <0.05 will be considered significant. To account for multiple comparisons, we will apply a Bonferroni correction by dividing the significance level by the number of tests conducted.

Discussion

Poor physical functioning and frailty has been demonstrated in younger populations who suffer from health disparities and an extreme form of social exclusion, such as PEH and addiction challenges [12, 13, 54]. Women who experience homelessness and addiction are especially vulnerable and have unique and complex needs which require a targeted and gender-sensitive approach. Little is known about frailty-focussed interventions in this population who are often excluded from services and research (18). However, this population have engaged well in two previous linked studies (LEAP-I and II). This study aims to address the research gap by providing a targeted exercise intervention to women experiencing homelessness and addiction challenges, thereby providing a gendered dimension, with gendered sensitivity. Its findings will guide clinicians and policy makers in implementing targeted interventions to assist in improving health outcomes in societies most marginalised and vulnerable groups.

Study status

Recruitment and data collection will commence in February 2024 and will be completed by July 2024.

Dissemination plans

Conference presentations and publications in peer-reviewed journals will be one method of dissemination. These will be done following the data analysis.

Supporting information

S1 File. Data collection form.

(DOCX)

S2 File. Exit interview schedule.

(DOCX)

S3 File. SPIRIT checklist.

(DOC)

S4 File. Primary and secondary outcomes.

(DOCX)

S5 File.

(DOCX)

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Chapter 4 THE LEAP-II trial: Quantitative inquiry

4.1 Introduction

Chapter 4 introduces the two-part LEAP-W trial, Part 1, a quantitative, pre-post intervention study which evaluated the impact of a targeted exercise intervention for women who experienced severe and multiple disadvantage (SMD) and Part 2, a qualitative inquiry to explore perspectives of participants and key stakeholders of the intervention (Lankelly Chase, 2024). The quantitative inquiry will be discussed in detail in this chapter.

LEAP-II raised questions regarding the holistic impact of low threshold targeted exercise interventions, questions which could be not answered by quantitative methods alone. The impact of the intervention beyond the physical domain, explanations for behaviours and attitudes of participants and the study's attrition remained unknown. Findings from the exit surveys suggest that the challenges to recruitment and retention may be potentially overcome and may translate to further improvements in physical function and frailty and other health domains. A study design utilising quantitative and qualitative components, was chosen to unearth factors which may contribute to the optimised delivery of behavioural change interventions such as exercise interventions and may have implications for policy and practice regarding improved access, engagement and participation for the wider population who experience severe and multiple disadvantage (Lankelly Chase, 2024).

This chapter will specifically present the methods, results and discussion of the quantitative inquiry of the LEAP-W trial, a targeted low threshold exercise and protein supplementation intervention for women who experienced homelessness, addiction

and mental health challenges. An overview of the content of this chapter is displayed in Table 4.1.

Table 4.1 Overview of Chapter 4

4.1 Introduction	
4.2 Methods	4.2.1 Study setting
	4.2.2 Study participants
	4.2.3 Study procedure
	4.2.4 Data analysis
4.3 Results	4.3.1 Baseline results
	4.3.2 Feasibility
	4.3.3 Pre-post Intervention results
	4.3.4 Exploring frailty
4.4 Discussion	4.4.1 Feasibility
	4.4.2 Impact
	4.4.3 Frailty exploration

The overall aim of the LEAP-W study was to evaluate the feasibility and pre-post intervention impact of a 10-week targeted exercise programme with nutritional supplementation in a non-geriatric group of women who experienced SMD, namely homelessness, addiction and mental health challenges (Lankelly Chase, 2024).

The objectives of the quantitative inquiry were:

1. To evaluate recruitment, retention and adherence rates and adverse events related to the intervention.
2. To evaluate pre- and post-intervention levels of physical function, nutritional and frailty status, pain, and general health status.

4.2 Methods

4.2.1 Study setting

This study was set in Jane's Place, a women's-only day service, which was part of Merchants Quay Ireland (MQI), a registered charity, who support people experiencing homelessness and addiction. Merchants Quay Ireland is funded by various organisations including state agencies such as the HSE, the Irish Prison Service and TUSLA, the Child and Family Agency. They have a number of centres located in Dublin city but also operate services in other locations nationally.

Jane's Place is located in Dublin city, Dublin 2 (see Figure 4.1). It was established in 2022, as a female-only service for women experiencing homelessness, addiction, and mental health challenges. As the LEAP-W study commenced, Jane's Place relocated simultaneously, from Dublin 8 on the south side to Dublin 2 in the city centre, 4km away. Jane's Place was an accessible purpose build. It included clinical rooms as well as dining and shower facilities and provided GP, nursing, mental health, counselling, addiction and wellbeing services. Due to the re-location, this new service set out with a small base of service users, with a view to expand and recruit a larger cohort of women from adjacent homeless services and accommodation sites.

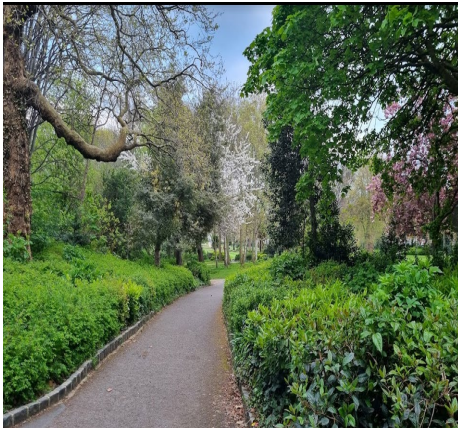


Figure 4.6 Jane's Place and nearby site of the Park Walk

4.2.2 Study participants

4.2.2.1 Eligibility criteria

The eligibility criteria were as follows:

Inclusion Criterion

1. All service users (18-65 years) of Jane's Place who consented to participate.

Exclusion criteria was any participant:

- who did not identify as a female,
- who was asked to abstain by their GP. This was following initial evaluation and PAR-Q and follow-up letter, sent by the researcher, to their GP advising of their intent to participate (see Appendix VI).

- With perceived acute, problematic behavioural issues or with major physical or cognitive impairments which precluded ability to safely participate in the programme. Problematic behaviour was defined, as per LEAP-II, as a perceived threat to the researcher or other participants, or behaviour which was deemed sufficiently challenging to impede the efficient running of the class. Problematic behaviour and confusion were established informally by expert clinical judgement.
- any participant with a confirmed pregnancy as physical functioning/performance test scores in advanced stages of pregnancy may vary from baseline values (Wowdzia and Davenport, 2021).

This study received ethical approval from the Faculty of Health Sciences, Trinity College Dublin (Ethical Approval Reference Number: 211202).

The quantitative inquiry of LEAP-W took place from the end of February 2024 until June 2024. Programme commencement was flexible to maximise recruitment and to enable those recruited early to commence as soon as possible. Maximum participation was facilitated by recruiting the last participant in April 2024. The exercise intervention was completed by mid-June 2024.

4.2.3 Study procedure

4.2.3.1 Initial Evaluation

The initial evaluation for LEAP-II was replicated in LEAP-W with the addition of a few questions relevant to women only (see Appendix I). The test battery utilised in LEAP-II was evaluated following this study and was recommended for use in community settings for this population (Kennedy et al., 2025). A bespoke data

collection form (Appendix I) gathered demographic data prior to the test battery and the following data were collected:

- (i) demographic data to develop a profile of participants. A number of additional questions were included for LEAP-W regarding parity and reproductive age of the study participants.
- (ii) baseline physical functioning, pain, frailty and nutritional status measurements and self-reported health status.

4.2.3.2 Study Measures

Primary outcome measures of this study's feasibility were discussed in Chapter 2 and like LEAP-II recorded recruitment numbers, retention and adherence rates to the exercise and nutritional supplement, the occurrence of adverse events and the acceptability of the programme (Chapter 2, Table 2.3). Acceptability of the intervention was explored in the qualitative inquiry and will be discussed in Chapter 5. Secondary outcome measures of physical function and frailty status were recorded using the same broad test battery utilised in LEAP-II and included physical performance measures, frailty assessment, nutritional assessment, pain rating and self-reported health status (also discussed in detail in Chapter 2, section 2.8.5-2.8.11). Table 4.2 below summarises the test battery briefly.

Table 4.2 Test battery (secondary outcomes LEAP-W)

Construct	Measures
1.Strength & muscular mass	Grip strength Limb circumference
2.Physical performance & lower extremity function	10m Walk Test 2 Minute Walk Test Chair Stand Test Single Leg Stance Test
3.Pain	Numerical Pain Rating Scale
4.Frailty	Clinical Frailty Scale Share-FI
5.Nutritional status	Mini Nutritional Assessment
6.Quality of Life	SF-12

These measures were recorded at baseline (T1) and at the completion of the programme (T2, at 10 weeks) to measure pre-post intervention change.

4.2.3.3 Measuring Frailty Correlates

Attributes and drivers of frailty were evaluated in this study. Demographics of the frail participants were observed and the relationships between frailty (using the SHARE-FI and the CFS) and selected independent variables (age, gender, addiction status, nutritional status, strength and gait speed) were explored.

4.2.3.4 Intervention

The intervention was 10 weeks in duration in comparison to the LEAP-II trial which utilised a 12-week intervention. While the results of LEAP-II demonstrated some evidence of pre-post intervention effectiveness, the majority of those who attended regularly (n=10, 91%) did not complete more than 10 weeks of the intervention. Behm et al (2024) propose a minimal dose of once weekly multi-joint resistance training, with at least 6-15 repetitions using loads between 30-80% of one repetition maximum for 8-12 weeks to achieve a strengthening effect in untrained individuals (Behm et al., 2024). Given that 10 weeks marks the midpoint of this finding, a pragmatic decision was made

to shorten the duration of this feasibility study to prioritise and encourage increased retention and maximum participation in this 'hard-to-reach population' who are known to engage poorly with mainstream services (Corr, 2003). See Table 4.4 for details of the exercise class which was based on recommendations from Behm et al (2024) and the LEAP-II trial (Behm et al., 2024). The initial pre-intervention evaluations commenced at the end of February and the final initial pre-intervention evaluation and last participant to commence the programme was in early April. Once 10 weeks of the programme were completed, the final post intervention evaluation was conducted. To be inclusive and trauma-sensitive, participants were permitted to continue to attend the programme if they wished until the last participant completed their final week. This took place mid-June 2024.

In keeping with the FITT principal parameters of the LEAP-II trial the intervention also proffered three exercise opportunities per week, in the form of a twice-weekly exercise circuit and a once weekly 'Park Walk' (Figure 4.1). The intervention components (exercise class and Park Walk) were flexibly delivered, initially over three days as per protocol and this was later extended to four days, in order to be as inclusive as possible and facilitate maximum participation. Participants were encouraged to attend the maximal number (three) of sessions and multiple options were available to attend (see table 4.3 for schedule of a typical week in Jane's Place). Self-selected music was used in tune with previous LEAP programme design features to create a nonchalant atmosphere. The LEAP-W programme utilised additional equipment including an exercise bike, boxing pads and gloves, and hoola-hoops to broaden the repertoire of exercise modalities and offer choice to participants.

Individual and one-to-one classes were organised in the mornings and afternoon. Like LEAP-I and II, the exercise circuit was multi-modal and included strengthening and aerobic exercises to target physical function and frailty as well as to meet WHO physical activity guidelines (WHO, 2020). Following the main exercise circuit, with a focus on women’s health and wellbeing, a floor-based, deep breathing, core stability, and pelvic floor exercise set was delivered using exercise mats. The programme was then tapered down with supervised stretching exercises for the main muscle groups. The programme ended with BP/HR monitoring and during this cool down and rest period, 20g of protein in the form of a 200ml shake (Fresubin) was provided and consumed if desired. Opportunistic, brief interventions, in the form of discussions around exercise, nutrition and women’s health and wellbeing, were interspersed throughout the exercise classes. The Park Walk took place initially on a Friday and was later introduced on additional days to offer choice and flexibility to the participants and was a 20-30 minute (one-to-one or group-based) self-paced walk with the study researchers.

Table 4.3 Schedule of a typical week in the LEAP-W intervention

Time	Mon	Tues	Wed	Thurs	Fri
10am	Exercise class	Exercise class	Exercise class	X	Exercise class
11am	Exercise class	Exercise class	Exercise class	X	Exercise Class
12pm	Exercise class	Exercise class	Exercise class	X	Park Walk
	/Park Walk	/Park Walk	/Park Walk		
2pm	Exercise class	Exercise class/	Exercise class/	X	X
	/Park Walk	Park Walk	Park Walk		
3pm	Exercise class	X	Exercise class	X	X

Blood pressure and heart rate monitoring were performed, prior to and immediately following the exercise class and Borgs RPE scale was used to gauge effort, pace and safely progress with the programme for those who attended regularly (Borg, 1982).

Daily phone messages were sent to participants, with their consent, in a What's App messaging group called 'Jane's Place Exercise Programme', with details of the classes and Park Walk for the coming week. The researcher had a work-related phone for this purpose, where messages or calls could be delivered as reminders, motivation and/or for participant cancellations if desired. This differed from the strategy utilised in LEAP-II where caller identification was not known.

An end of programme 'Park Walk', followed by tea, coffee and cake, was organised for participants and staff of the centre to enhance motivation and participation and enjoyment of physical activity. Certificates of completion of the Park Walk and the LEAP-W intervention were distributed at the end of the programme and participants were awarded a digital sports watch as a token of appreciation and celebration of their achievement.



Figure 4.7 The LEAP-W intervention Jane's Place

Table 4.4 Exercise circuit LEAP-W

Exercise Mode	Core exercise	Initial Intensity	Progression/Adaptations*
Strength			
1	Sit to stand/ squats/lunges	2 sets 10-15 reps	3 sets of 15 repetitions. use of weights/ball/upper limbs
2	Elbow Bends	2 sets 10-15 reps	3 sets of 15 repetitions. Weights
3	Step-ups	2 sets 10-15 reps	3 sets of 15 repetitions. Step height & direction/ weights/upper limbs
4	Arm elevations	2 sets 10-15 reps	3 sets of 15 repetitions. Weights & variation of direction of movement
5	Hip abductions	2 sets 10-15 reps	3 sets of 15 repetitions. With additional upper limb abduction and elevation; movement with 360° turns
6	Scapular retractions or boxing set	2 sets 10-15 reps	3 sets of 15 repetitions. Weights/therabands
Aerobic			
	Aerobic activity: Exercise bike (optional)	2-5 mins	5-15 mins ladders, hurdles, skipping ropes, jumping jacks, dance, hoola hoops
Balance			
	Balance (optional)	4-5 mins	5 mins Tandem; single leg stance, upper limb and trunk movements; weights and ball work
Core strength			
	Additional Women's Health focussed exercises	5	5-10 mins Pelvic floor set; Pelvic tilting; bridging with arm/leg movements, side-lying gluts variations, prone/all 4's gluts variations

*Progression: 2-3 sets of 10-15 repetitions completed at each session; beyond that, low resistance weights (1.1kg-4.5kg), theraband or increased step height was introduced to achieve a strengthening effect.

*Adaptations: exercises were individually tailored and progressed for each participant by the research physiotherapist. Chair based exercises included, where indicated.

Each session commenced with a warm-up and was completed with a cool down and stretch of all the major muscle groups.

4.2.4 Data analysis

Descriptive statistics were performed to summarise participant demographics. Data were tested for normality using the Kolmogorov–Smirnov test. Pre- and post-intervention data were then compared using paired t-tests or Wilcoxon signed-rank tests if normally distributed or non-normally distributed, respectively. A complete case analysis was performed due to the feasibility focus of the work.

To explore associations between frailty and selected covariates, a staged modelling approach was used. Univariable linear regression models were first fitted to examine unadjusted associations between frailty (CFS and SHARE-FI) and each explanatory variable. Further modelling using multiple variables were then specified. Two-variable models and a three-variable model were examined to explore how much these variables contributed to frailty. Model comparisons were made descriptively by examining changes in R^2 and adjusted R^2 values as additional variables were added to an existing model. Given the feasibility nature of the study and limited sample size, formal statistical testing between models was not undertaken and findings were interpreted descriptively. Binary logistic regression was used to estimate odds of frailty for each explanatory variable.

Pre-post intervention data were analysed using IBM SPSS V28 and a p -value with statistical significance was set at $p < 0.05$. Baseline frailty data and exploration analysis was conducted using Stata 18.

4.3 Results

4.3.1 Baseline results

Thirty-three women enrolled to participate, provided written informed consent and completed the initial evaluation for the LEAP-W study. Following the evaluation, which included the PAR-Q screening tool, highlighting any risk factors identified for participation in the physical activity intervention, a letter was sent to the GP of each potential participant (see Appendix VI). As a result, two women were advised by their GP to abstain from exercise until they underwent further investigation of their symptoms to ensure safe participation. The women were invited to attend at a later stage should approval from a medical practitioner be provided. As a result, baseline data was collected for thirty-three women, and thirty-one women proceeded to engage in the LEAP-W programme. See Figure 4.3 for detail of participant engagement through the programme.

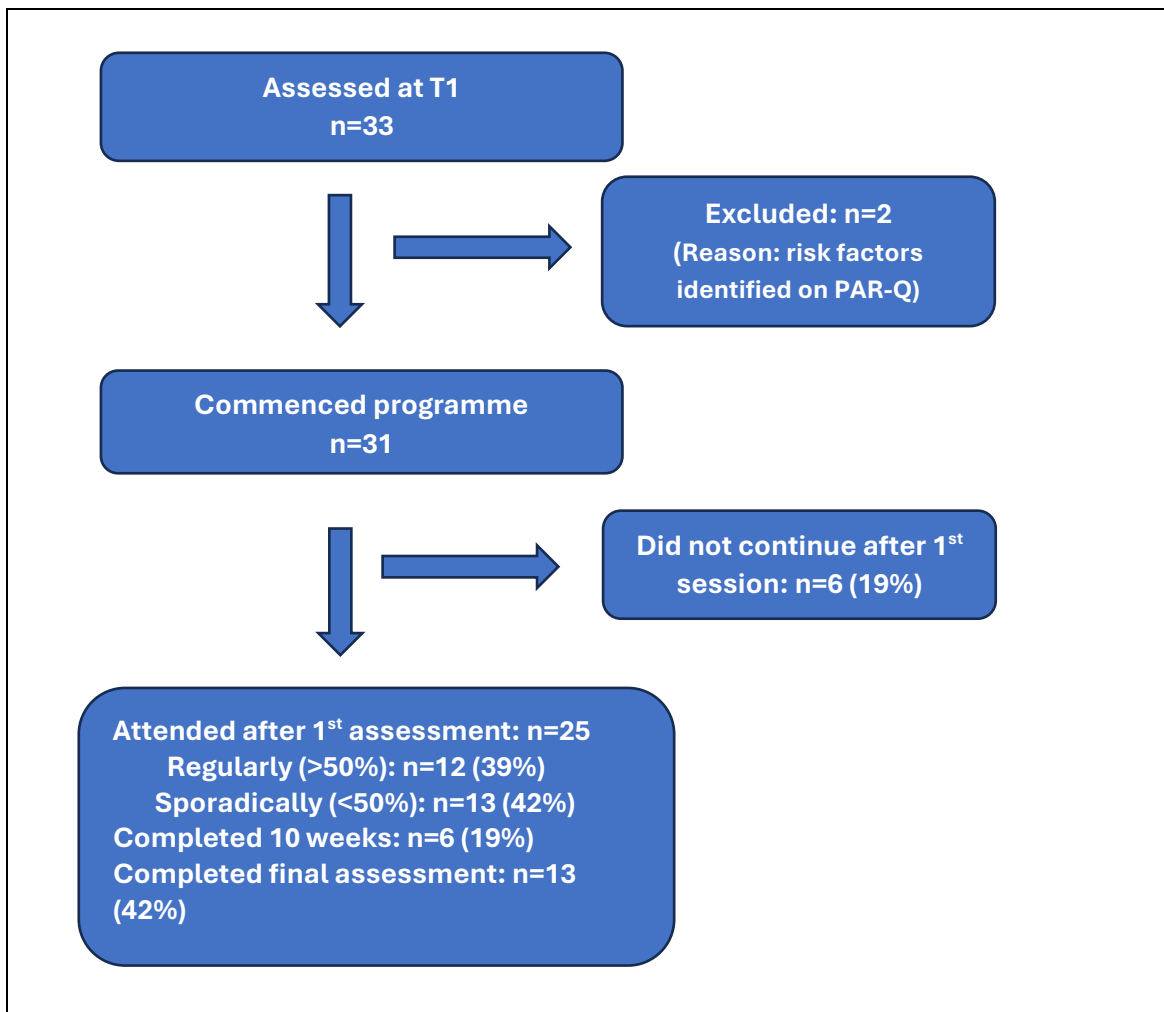


Figure 4.8 PRISMA flow diagram of participants through LEAP-W

4.3.1.1 Participant demographics

Baseline characteristics of the participants and their health challenges are presented in Table 4.5 and 4.6. The mean (SD) age of the female participants was 41 (11) years. The majority were single (n=20, 61%) and unemployed (n=31, 94%), had attended second level education (n=19, 58%) and were living alone (n=23, 70%), in a house/apartment (n=14, 42%) or homeless accommodation (n=10, 30%). In line with the ETHOS definition of homelessness, 82% had a past or present experience of homelessness (FEANTSA, 2005). Twenty-three participants (70%) had children, just under half (n=16, 49%) were pre-menopausal, fourteen (42%) were peri/post-menopausal and three (9%) were unsure. The pre-menopausal state is defined by a

reported routine menstrual cycle, while the peri-postmenopausal period was defined by a reported change in the menstrual cycle, often with peri-menopausal symptoms, such as hot flushes, night sweats and change in mood. Menopause or the post-menopausal time is defined as the time from reported amenorrhea or absence of a menstrual cycle for at least 12 consecutive months and usually occurs between 45 and 55 years (Hamoda, 2021). The average age of menopause is 51 years in high income countries, therefore for the purpose of this research, menopause occurring at or before the age of 44 was considered as early menopause (Mishra et al., 2024). If a participant was taking hormone replacement therapy, a commonly used treatment for menopausal symptoms, they were considered post-menopausal. Almost three-quarters of the cohort (n=26, 78%) were white Irish, three (9%) were from European countries and four (12%) from outside Europe. Half of the participants (n=18, 55%) experienced problematic drug or alcohol use, the majority had a mental health condition (n=22, 88%) and over one third (n=13, 39%) had a physical health condition, of whom twelve (36%) had multi-morbidity. The most common physical condition was musculoskeletal (n=13, 39%), followed by respiratory (n=7, 21%) and cardiovascular (n=7, 21%) conditions. The majority (73%) of participants reported pain. Almost two thirds of women in this study perceived their health as fair (48.5%) or poor (12%). Five (15%) participants had been to prison at least once. In terms of baseline physical activity levels, the majority (n=18, 54%) did not exercise beyond routine walking, while twelve (36%) rarely exercised at all.

Table 4.5 Participant demographics (n=33)

Demographic item	
Age (yrs)	
mean (std dev), median (range)	41 (11), 43 (22-64)
Sex	
	n (%)
Female	32 (97)
Transgender	1 (3)
Children	
	22 (67)
Menopause	
Pre-menopausal	16 (49)
Peri/postmenopausal	14 (42)
Don't know	3 (9)
Marital status n	
Single	20 (61)
Married/partnership	3 (9)
Separated/divorced	10 (30)
Widowed	0 (0)
Country of origin	
	n (%)
Ireland	26 (79)
England	1 (3)
Slovakia	1 (3)
Ukraine	1 (3)
Turkey	1 (3)
Brazil	1 (3)
Tanzania	1 (3)
Nigeria	1 (3)
Education	
Primary level	4 (12)
Secondary level	21 (64)
Third level	8 (24)
Employment status n (%)	
Full-time employment	0
Part-time employment	2 (6)
Unemployed	31 (94)
Living environment n (%)	
House/apartment	13 (39.4)
Hotel/hostel	11 (33.3)
Staying with friend/family/other	3 (9.1)
Rough sleeping	3 (9.1)
Other	3 (9.1)
Living Arrangement n (%)	
Alone	22 (66.6)
With spouse/partner	10 (9.1)
Other	1 (3)

Table 4.6 Health challenges

History of Addiction n (%)	
Active addiction	18 (55)
Stable/in recovery	15 (45)
No addiction issues	
History of incarceration	
	5 (15)
Mental health condition	
	30 (90)
Physical health conditions n (%)	
Musculoskeletal	13 (39)
Respiratory	7 (21)
Cardiovascular	7 (21)
Seizures	4 (12)
Diabetes	3 (9)
Hypothyroid	3 (9)
HIV	3 (9)
Fibromyalgia	2 (6)
Osteoporosis	1 (3)
Bowel disorder	1 (3)
Amputee	1 (3)
* >1 physical health condition	12 (36)

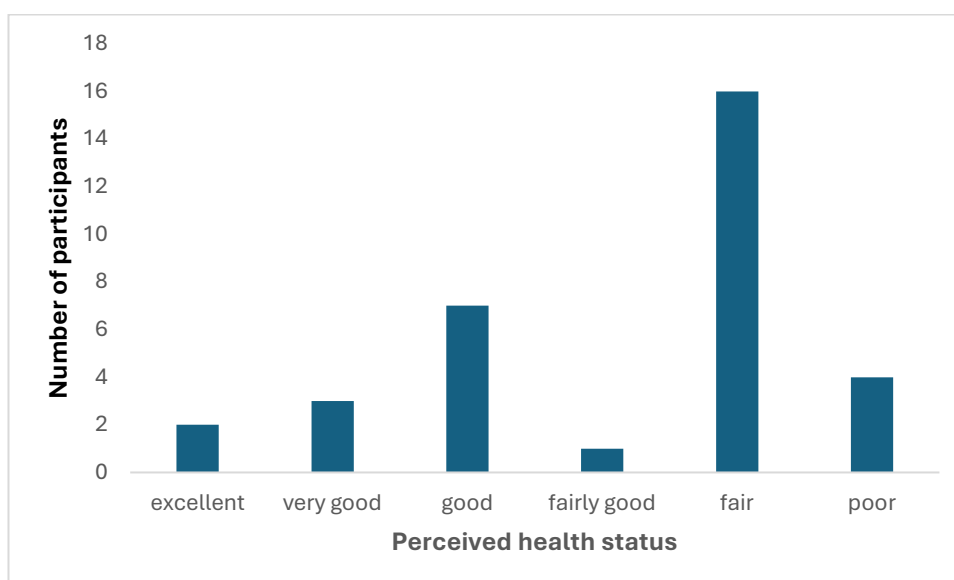


Figure 4.9 Baseline measure of perceived state of health

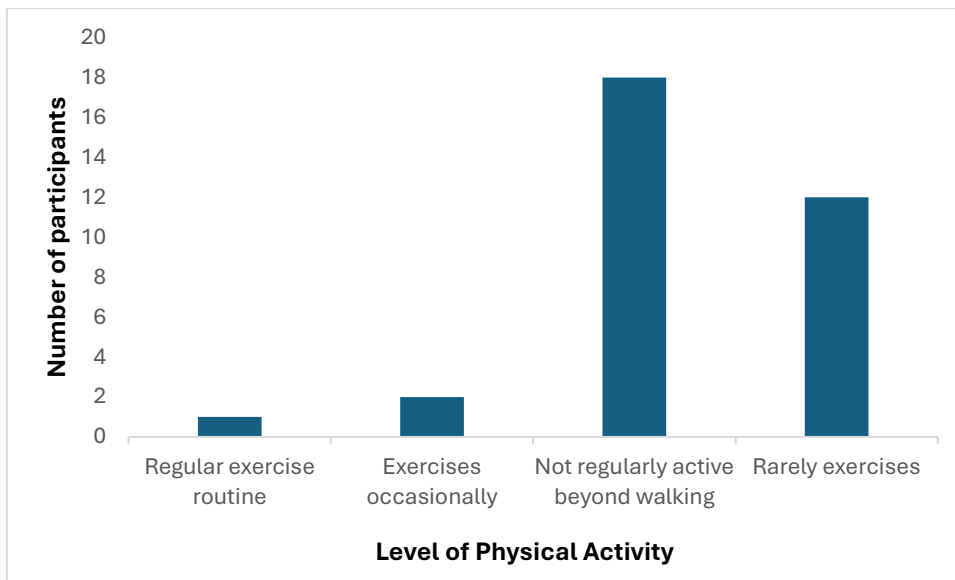


Figure 4.10 Baseline level of Physical Activity

4.3.1.2 Baseline physical function and frailty measures results

Limb circumference measures highlighted a portion of the group with sub-normative values, with 13% below the cut-off for upper limb girth and 17% with moderately-low or severely-low calf girth measures. Dynamometry results demonstrated that almost one third ($n=9/31$, 29%) were below the risk threshold, while half ($n=16/31$, 52%) were below the mean grip strength scores for women matching their age and height. The MNA revealed that one (3%) participant was malnourished, while half ($n=16/32$, 50%) of the group were at risk of malnutrition. Seventy percent of participants reported pain. Results from the physical function testing demonstrated a CST score ranging from 4-30 stands and of the six participants in their twenties none scored greater than 26 stands. An average of 33 stands is reported for healthy young adults aged 19-35 years (Lein et al., 2022).

Table 4.7 Baseline physical function and frailty scores (n=33)

	Mean (SD)	Median (IQR)	n (%)
Limb circumference			
Upper Limb (cm)	29.1 (4.7)	28.5 (26-31)	33 (100)
Lower Limb (cm)	37.9 (4.1)	38 (35-40.5)	33 (100)
Physical Performance			
10m Walk Test (m/s) (maximal)	1.81 (0.4)	1.82 (1.-6-2.1)	33 (100)
2 Min Walk Test (m)	182.5 (36.9)	181.5 (160.5-213.8)	33 (100)
Grip Strength			
Female (kg)	31.3 (5.4)	30.9 (26.9-35.9)	33 (100)
Chair Stand Test (n)			
	16.6 (6.2)	16 (13-21.8)	33 (100)
Single Leg Stance (s)			
	29.2 (21.3)	24.8 (11.3-53.3)	33 (100)
SF12 (score)			
PCS	47.1 (11.2)	48.1 (42.1-55.1)	33 (100)
MCS	29.7 (13.9)	27.4 (18.3-40.1)	33 (100)
Pain n (%)			24 (73)
Frailty			9 (6)
CFS n (%)			
CFS 2 (well)			1 (3)
CFS 3 (managing well)			17 (51.5)
CFS 4 (vulnerable)			11 (33)
CFS 5 (mildly frail)			4 (12)
SHARE-FI			
	Scores		Categories
	Mean (SD)		n (%)
Non-frail			19 (58)
Pre-frail			12 (36)
Frail			2 (6)
Nutrition			
MNA n (%)			
0-7 (malnourished)			1 (3)
8-11 (at risk of malnutrition)			16 (50)
12-14 (normal nutritional status)			15 (47)

*PCS=physical component summary score, MCS=mental component summary score

Three-quarters (n=23/30, 76.6%) of participants scored below the normative mean age-matched gait speed using the 10mWT and half (n=15/30, 50%) of the group were below the weighted mean for the 2MWT. Balance by uni-pedal stance measurement was below normative values for one third (10/30, 33%) of participants. In the SF-12, participants scored below average [mean (SD) 50 (10)] for physical and mental health summary scores with lower mental component summary score [MCS

[29.68 (13.86)] when compared to the physical component summary score [PCS: 47 (11.23)] (Larson, 2002).

The SHARE-FI identified frailty and pre-frailty in 6.1% (n=2) and 36.4% (n=12), respectively, while the CFS identified frailty and pre-frailty in 12.1% (n=4) and 33.3% (n=11), respectively. The absence of frailty was similar using both SHARE-FI (55.6%, n=19) and CFS (54.5%, n=18). The investigation of frailty also elucidated that the majority of participants reported their health as fair (48.5%, n=16) or poor (12%, n=4).

4.3.1.3 Women's health and risk of frailty and sarcopenia

The mean age of this cohort was 41 years. Thirty-two participants were biological females. Forty-two percent were peri-menopausal (n=8, 25%) or post-menopausal (n=6, 19%), with a portion having had early menopause (n=2, 6%), described as having had symptoms of the menopause between the age of 40-44years (Mishra et al., 2024). Two (29%) women were on hormone replacement therapy. Just under half (49%, n=16) had low grip strength. Half also had poor nutritional status (50% at risk of malnutrition) and the majority were not regularly active beyond routine walking (55%, n=18) or rarely exercise at all (36%, n=11). Forty-two percent of this cohort were living with some degree of physical frailty (by SHARE-FI).

4.3.2 Feasibility

Feasibility outcomes for this study were measured in the same way as LEAP-II, by the recruitment level, retention rate, adherence to the exercise intervention and protein supplement, and the safety and acceptability of the programme (see Chapter 2, Table 2.3).

4.3.2.1 Recruitment

Thirty-three people were recruited and consented to participate. Thirty-one were permitted to proceed to participate in the programme (Figure 4.3).

4.3.2.2 Retention

Twenty-five (80%) participants returned and completed at least one exercise (exercise class or aerobic walking session) intervention. A total of 238 interventions occurred over the course of the programme. Of these 78 were the walking session, the Park Walk. Sixteen participants (51.6%) partook in the walk. The number of walks over the course of the programme ranged from one walk to 17 walking session per person and seven participants (23%) completed at least seven walking sessions in total. Regular attendance was observed in 38.7% (n=12) of the group. Sporadic attendance was observed in 41.9% (13) and 19.4% (n=6) did not return to the programme following initial assessment. Five people (16%) attended the maximum sessions of three times weekly for more than 50% of the available sessions. Six women attended at least once weekly for 10 weeks and 11 attended at least once weekly for five weeks.

Table 4.8 Summary of retention

	Total attendance n=31 (100%)	Older (> 43 years-median age)
Regular attenders	12 (38.7%)	8 (66%)
Sporadic attenders	13 (41.9%)	6 (46%)
Did not attend	6 (19.3%)	

4.3.2.3 Adherence

Adherence to the exercise class component of the intervention (expressed as the number of sessions adhered to relative to the number of sessions (or contacts in the sessions) attended, identified a rate of 89%. Ninety percent (n=28) of the participants consumed and enjoyed the Fresubin, protein supplement. Three people (12.5%) declined the protein supplement, citing its adverse taste or reported gut issues.

Table 4.9 Summary of adherence

Intervention	Adherence rate
Exercise	89% (201/225)
Protein supplement	90% (28/31)

4.3.2.4 Adverse events

In accordance with LEAP-II, an adverse event was defined as an unfavourable experience during the exercise intervention which caused the participant to cease exercising and seek medical attention (Grimes et al., 2005). No adverse events occurred as a result of the intervention.

4.3.2.5 Acceptability

Programme acceptability was identified in the exit interviews and will be discussed in Chapter 5.

4.3.3 Pre-post intervention results

Secondary outcomes, measuring physical function, pain, nutritional and frailty status, and self-reported health status were recorded in the initial evaluation (Time 1-T1) for baseline scores for the 33 consenting participants. Outcomes were recorded again at week 10 (Time 2-T2), when the programme ended for 13 participants. Twelve of these participants (92%) were regular programme attenders. Measurement of limb circumference was not recorded post intervention, as no difference was observed following the post-intervention evaluation in the LEAP-II trial and therefore it was deemed inappropriate as a comparative outcome measure. This test was considered more fitting as a baseline marker of muscle mass and possible nutritional deficiency. Table 4.10 and 4.11, respectively, will present the results of the twelve regular attenders and also the thirteen participants who completed the pre-post intervention evaluation.

Pre-post intervention results obtained by *13 participants* (see Table 4.10) who completed the post-intervention evaluation revealed improvements in the following

outcome measurements: Chair Stand Test (CST) from 17.83 \pm 3.79 stands (T1) to 22.5 \pm 6.03 stands (T2), (95% CI: 1.65 to 7.69, $t(11)=3.4$, $p=0.006$), the Single Leg Stance Test (SLST) from 39.05 (13.9-60) seconds (T1) to 57 (20.69 to 60) seconds (T2) ($z=-2.244$, $p=0.025$), pain ($z= -2.251$, $p= 0.024$) and in the MCS score of the SF-12 from 30.65 \pm 15.3 (T1) to 42.51 \pm 13.07 (T2) ($t(12)=3.294$, $p=0.006$). The change observed in the 10mWT was approaching statistical significance ($p= 0.059$). No changes were demonstrated in any of the frailty measures.

Similarly, when the regular attenders only ($n=12$) were analysed alone (see Table 4.11), statistically significant results were also found in the CST from 17.45 \pm 3.72 stands (T1) to 22.09 \pm 6.16 stands (T2), (95% CI: 1.29 to 7.99, $t(10)=3.084$, $p=0.012$), the SLST from 43.03 (13.67 to 60) seconds (T1) to 57 (18.45 to 60) seconds (T2) ($z= -2.134$, $p=0.033$), pain ($z= -2.070$, $p= 0.038$) and in the MCS score of the SF-12 from 31.33 \pm 15.78 (T1) to 44.21 \pm 12.06 (T2) (95% CI: 4.61 to 21.15), $t(11)=3.429$, $p=0.006$). Change in the 10mWT in the regular attenders was approaching statistical significance with a p -value of 0.067. The line graphs in Figures 4.6a to 4.6c illustrates the individual change scores from T1 to T2 in the CST, the SLST and the SF-12 MCS for the 12 regular attenders who completed the final evaluation.

Line Graphs of individual change scores from T1 to T2 for regular attenders

(n=12)

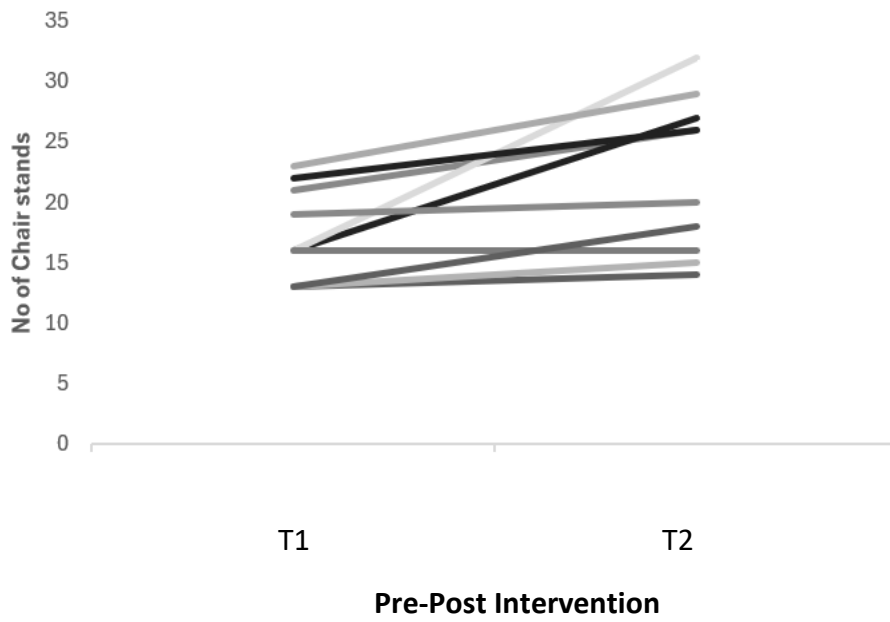


Figure 4.11 A Individual change scores for the CST

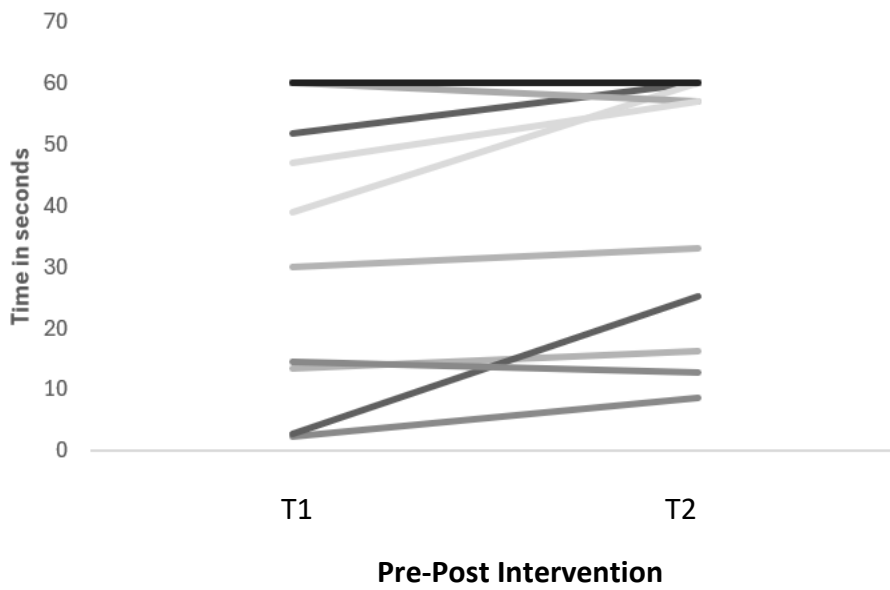


Figure 4.12 B Individual change scores for the SLST

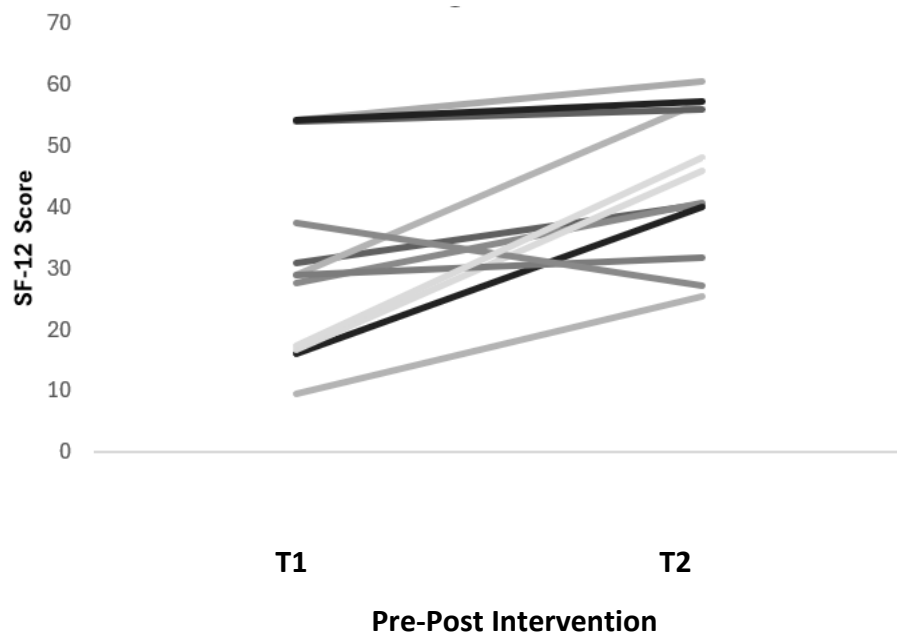


Figure 4.13 C Individual change scores for the SF-12 MCS of SF-12

Table 4.10 Secondary outcomes at 10-week follow-up (n=13)

	Pre-intervention		Post Intervention		Difference		
	T1	Number (%)	T2	Number (%)	Mean/median difference (95% CI)	P-value	Z-score
Chair stand test mean (SD)	17.83 (3.79) stands	12 (95)	22.5 (6.03) stands	12 (95)	4.66 (1.65 to 7.69) stands	*0.006 a	
Grip strength mean (SD)	31.25 (6.64) kg	13(100)	31.5 (5.2) kg	13 (100)	0.25(-1.91 to 2.41) kg	0.803 a	
10m Walk Test mean (SD)	1.90 (0.37) m/s	13 (100)	2.07 (0.42) m/s	13 (100)	0.17 (-0.07 to 0.35) m/s	0.059 a	
2min Walk Test mean (SD)	185 (37.2) cm	12(95)	196 (38.06) cm	12 (95)	10.8 (-5.54) to 27.21 cm	0.173 a	
Single leg stance median (IQR)	39.05 (13.9-60) secs	13(100)	57 (20.69-60) secs	13 (100)	(2.80 to 23.50) secs	*0.025 b	-2.244
MNA mean (SD)	11.23 (1.78)	13 (100)	11.23 (2.2))	13 (100)	0 (-.923 to .923)	1.000 a	
Pain median (IQR)	3 (3-3)	13 (100)	2 (1-3)	13 (100)	0 (0.00 to 7.00)	*0.024 b	-2.251
SF12							
PCS median (IQR)	52.33 (34.46-	13 (100)	47.92 (37.2-60.73)	13 (100)	10.7 (1.51 to 17.46)	0.753 b	-0.314
MCS mean (SD)	57.49)	13 (100)	42.51 (13.07)	13 (100)	11.86 (4.01 to 19.71)	*0006 a	
	30.65 (15.3)						

Frailty	Pre Intervention	N (%)	Post Intervention	N (%)	Difference	p-value	z-score
Clinical Frailty Scale	1 (1-2)	13(100)	1 (1-2)	13 (100)	-0.153 (-.38 to .07) test	0.157 b	-1.414
CFS 3 (Managing well)		7 (53.8)		9(69.2)			
CFS 4 (Vulnerable)		5 (38.5)		3 (23.1)			
CFS 5 (Mildly frail)		1 (7.6)		1 (7.7)			
SHARE-FI	1 (1-2)	13(100)	1 (1-1.5)	13 (100)	1(0.00 -0.00) test	0.317 b	-1.000
Non-frail		7(53.8)		10 (76.9)			
Pre-frail		6 (46.2)		2 (15.4)			
Frail		0(0)		1 (7.6)			
SHARE-FI continuous scores	-0.165 (-0.8225—	13 (100)	-0.596 (-1.295-	13 (100)	-0.595 (2.224) test	0.196 b	-1.293
Median (IQR)	1.224)		0.7485)				

a=paired samples t-test comparing pre- to post- intervention, b=Wilcoxon signed-rank test, * = significant result; SF12 PCS = Physical Component Score, MCS = Mental Component Score

Table 4.11 Secondary outcomes at 10-week follow-up (Regular attenders only, n=12)

	Pre-intervention		Post Intervention		Difference		
	T1	Number (%)	T2	Number (%)	Mean/median difference (95% CI)	p-value	z-score
Chair stand test mean (SD)	17.45 (3.72)	11 (91.6)	22.09 (6.16)	11 (91.6)	4.64 (1.29 to 7.99) stands	*0.012 a	
Grip strength mean (SD)	30.49 (6.32) kg	12(100)	30.56 (4.1) kg	12 (100)	0.07(-2.27 to 2.4) kg	0.951 a	
10m Walk Test mean (SD)	1.89 (0.39) m/s	12 (100)	2.07 (0.44) m/s	12 (100)	0.19 (-0.02 to 0.39) m/s	0.067 a	
2min Walk Test mean (SD)	184(38.5) cm	11(91.6)	197 (39.89) cm	11 (91.6)	12.86 (-4.61 to 30.33) cm	0.132 a	
Single leg stance median (IQR)	43.03 (13.67-60) secs	12(100)	57 (18.45-60) secs	12 (100)	13.97 (1.42 to 2.19) secs	*0.033 b	-2.134
MNA mean (SD)	11.33 (1.82)	12 (100)	11.33 (2.27)	12 (100)	0 (-1.01 to 1.01)	1.000 a	
Pain median (IQR)	3 (3-3)	12 (100)	2 (1-3)	12 (100)	1 (0.00 to 0.00)	*0.038 b	-2.070
SF12							
PCS mean (SD)	45.87 (13.43)	12 (100)	46.78 (13.02)	12 (100)	0.92(-5.82 to 7.65)	0.770 b	
MCS (SD)	31.33 (15.78)	12 (100)	44.21 (12.06)	12 (100)	12.88 (4.61 to 21.15)	*0006 a	

Frailty	Pre Intervention	N (%)	Post Intervention	N (%)	Difference	p-value	z-score
Clinical Frailty Scale (IQR)	1 (1-2)	12(100)	1 (1-1.75)	12 (100)	0 (0.00 to 0.00)	0.157 b	-1.414
CFS 3 (Managing well)		7 (58.3)		9(75)			
CFS 4 (Vulnerable)		4 (33.3)		2 (16.7)			
CFS 5 (Mildly frail)		1 (8.3)		1 (8.3)			
SHARE-FI (IQR)	1.5 (1-2)	12(100)	1 (1-1.75)	12 (100)	0.5 (0.00 to 0.00)	0.317 b	-1.000
Non-frail		6 (50)		9 (75)			
Pre-frail		6 (50)		2 (16.7)			
Frail		0 (0)		1 (8.3)			
SHARE-FI continuous scores Mean (SD)	0.202 (1.157)	12 (100)	-0.221 (1.416)	12 (100)	-0.423 (-1.0 to 0.156)	0.136 b	

a=paired samples t-test comparing pre- to post- intervention, b=Wilcoxon signed-rank test, * = significant result; SF12 PCS = Physical Component Score, MCS = Mental Component Score

4.3.4 Exploring frailty

Summary baseline frailty scores for all participants are presented in Table 4.7.

Frailty was identified in 12% (n=4) and 6% (n=2) using the CFS and the SHARE-FI, respectively, while pre-frailty was identified in 33% (n=11) and 36% (n=12) using the CFS and the SHARE-FI, respectively. The median (IQR) frailty scores were 1 (1-2) and 2 (1-2) using the SHARE FI and the CFS, respectively. A total rate of 45% and 42% were living with some degree of frailty, by CFS and SHARE-FI, respectively.

4.3.4.1 Profile of the frail participants

Four participants were frail by CFS or SHARE-FI and two were frail by CFS and SHARE-FI. The age of the frail participants ranged from 42 to 54 years, with a mean age of 46.5 years, while the age range of the non-frail was 22 to 55 (CFS) and 22 to 60 (SHARE-FI) years. Of those who were frail by SHARE-FI or CFS (n=4), 100% (n=4) were homeless (FEANTSA, 2005), 20% (n=1) had been previously incarcerated, 75% (n=3) had substance use dependency and one was in recovery with a long history of dependency, 75% (n=3) had poor nutritional status (data was incomplete for the 4th participant) including one who was malnourished, 100% (n=4) had co-morbidities and limitations in mobility (See Table 4.12).

Table 4.12 Profile of the study cohort who identified as frail/pre-frail (n=4)

UIN	Age	SHARE-FI	CFS	Nutritional status*	Homeless status**	Drug/alcohol dependency	Hx of incarceration	Medical conditions	Mobility
P16	39	Frail	Frail	8 (malnourished)	Yes	Yes	Yes	Bilateral amputee	Wheelchair dependent
P21	54	Pre-frail	Frail	9 (at-risk of malnutrition)	Yes	No	No	Msk***, respiratory condition, Hypothyroid, bipolar, depression	Stick
P25	51	Frail	Frail	10 (at-risk of malnutrition)	Yes	Yes	No	COPD, HIV, cardiac, osteoporosis, msk*** depression	Independent^
P29	42	Pre-frail	Frail	Missing data	Yes	Yes	No	Ca, asthma, hypertension, h/x MI, CVA	Independent^

*Mini-nutritional assessment scoring **ETHOS definition of homelessness (including insecure housing) ***musculoskeletal condition ^independent but limited due to shortness of breath

Due to the focus of this PhD on targeting physical function and frailty in a non-geriatric group of people experiencing SMD (Lankelly Chase, 2024), LEAP-II explored a number of variables of interest including gender, age, addiction (in active addiction or not), nutritional status (normal or poor nutritional status) and physical function (gait speed by 10mWT). Similarly, LEAP-W explored the same variables in its female-only cohort for comparison purposes and added the CST as a marker of strength and physical function.

As discussed in the methods section (4.2.4 Data analysis), univariable linear regression models were first fitted to examine unadjusted associations between frailty (CFS and SHARE-FI) and each explanatory variable. Univariable linear regression revealed that using the CFS, 27% of the variance in frailty was explained by age ($p=0.002$). Age-only models were then specified, given the established relationship between age and frailty. Two-variable models (age plus addiction status; age plus nutritional status) and finally a three-variable model including age, addiction status and nutritional status were examined to explore and clarify that these variables contributed to frailty beyond age ($p<0.05$) (Table 4.13).

In terms of physical functioning variables, 30% of the variance in frailty by CFS was explained by lower limb strength (by Chair Stand Test) ($p=0.001$) and 28% of the variance of frailty (by SHARE-FI) is explained by lower limb strength (by CST) ($p=0.012$). No association was found between frailty and gait speed using either instrument. Thus, lower limb strength was significantly associated with frailty in univariable analyses ($R^2=0.302$, $p=0.001$ [CFS] and $R^2=0.277$, $p=0.002$ [SHARE-FI]), but this variable was not included alongside age in multivariable models due to sample size constraints and the risk of model overfitting. With a sample size of 33 participants, models were restricted

to a maximum of three predictors. As such, age was prioritised a priori and physical function measures were examined in univariate results only.

Table 4.13 Linear regression models for frailty.

Model ID	Outcome	Predictors included	Comparator	R ²	Adjusted R ²	p-value
M1	CFS	Age	Reference model	0.266	0.2424	0.002*
M2	CFS	Age + Addiction	M1 (age only)	0.452	0.4150	<0.001*
M3	CFS	Age + Nutritional status	M1 (age only)	0.389	0.3472	0.001*
M4	CFS	Age + Addiction + nutritional status	M2 (age + addiction)	0.516	0.4642	0.023*
M5	SHARE-FI	Age	Reference model	0.105	0.0765	0.065
M6	SHARE-FI	Age + Addiction status	M5 (age only)	0.169	0.1137	0.026*
M7	SHARE-FI	Age + Nutritional status	M5 (age only)	0.216	0.161	0.055*
M8	SHARE-FI	Age + Addiction + Nutritional status	M6 (age + addiction)	0.247	0.1667	0.032*

Binary logistic regression modelling was conducted by categorising frailty into two categories: frail (frail/pre-frail) and non-frail. Results demonstrated that advancing age was associated with increased odds of frailty using both frailty measures (SHARE-FI: OR = 1.07 per year increase in age, $p = 0.049$; CFS: OR = 1.18 per year increase in age, $p = 0.004$). This indicates that even small year-on-year increases in age are associated with meaningfully higher odds of frailty. Additionally, increased lower limb strength by CST reduced the odds of frailty by 23% using the SHARE-FI (OR= 0.77, $p=0.008$) and 17% using the CFS (OR= 0.83, $p=0.017$). While addiction and nutritional status contributed to variance in frailty scores in linear models, these variables did not independently influence the odds of being classified as frail once frailty was dichotomised, suggesting that, in this sample, age and strength were more dominant predictors of frailty classification and that the effects of addiction and nutritional status may be less detectable once frailty is dichotomised.

Table 4.14 Binary logistic regression analysis (response variable: non-frail v pre-frail or frail; n=33)

Response Variable	Explanatory Variable	AOR*	p-Value	95% CI
Frailty: SHARE-FI	Age	1.07	0.049*	1.00 1.15
Frailty: SHARE-FI	Addiction status	1.2	0.797	0.30 4.81
Frailty: SHARE-FI	Nutritional status	3.29	0.093	0.82 13.25
Frailty: SHARE-FI	Gait speed	0.17	0.118	0.02 1.57
Frailty: SHARE-FI	Strength	0.77	0.008*	0.64 0.94
Frailty: CFS	Age	1.18	0.004*	1.05 1.32
Frailty: CFS	Addiction status	2.50	0.206	0.60 10.34
Frailty: CFS	Nutritional status	2.46	0.182	0.65 9.30
Frailty: CFS	Gait speed	0.26	0.200	0.32 2.04
Frailty: CFS	Strength	0.83	0.017*	0.71 0.96

*Adjusted Odds Ratio

A number of these important variables were explored descriptively.

4.3.4.2 Profile of those with active addiction

Eighteen participants (55%) were in active addiction. The age range of this sub-group was broad: 22 to 59 years with a mean age of 38 years. In this sub-group, 56% and 44% were living with some degree of frailty (frail/pre-frail) by CFS and SHARE-FI, respectively; 60% did not have normal nutritional status; 79% scored below average for gait speed (10mWT) and despite over a third (n=7) being under 35 years of age, all scored lower than the normative mean reference value healthy young adults aged 19-35 years in the CST (Lein et al., 2022).

4.3.4.3 Profile of those with poor nutritional status

No association was demonstrated between frailty and nutritional status alone, yet over half (n=17) of the LEAP-W cohort had poor nutritional status. Moreover, over half (n=10) of these women were living with some degree of frailty by CFS. One third (n=6) of this sub-group had an unhealthy BMI of 25 or above (overweight or obese), a common characteristic in this population, although often a misconception and sometimes referred to as the hunger-obesity paradox (Koh et al., 2012).

4.3.4.4 Age Profile of those living with some degree of frailty (frail/pre-frail) v non-frail

The age range of those living with some degree of frailty was 38 to 64 years, while the mean age was 48.9 years (CFS) and was 46 years (SHARE-FI). The age range of the non-frail was younger at 22 to 55 (CFS) and 22 to 60 (SHARE-FI) years, with a mean age of 35 and 38 years, for CFS and SHARE-FI, respectively

4.4 Discussion

Overall findings of this section of LEAP-W indicate its feasibility due to high retention, adherence and safety, and also positive quantitative health impacts on physical health (including physical function and pain) and mental health evidenced by the pre-post intervention results, demonstrating proof of concept of this intervention in this female population who experienced homelessness, addiction and mental health challenges. Of note, frailty was associated with advancing age and increased lower limb strength reduced the odds of frailty in this distinct cohort.

4.4.1 Feasibility

A myriad of factors influenced the recruitment numbers for the LEAP-W study. Prior to the opening of Jane's Place, all homeless services in the city centre were mixed gender and reportedly less frequented by the female homeless population (Merchants Quay Ireland, 2025). Jane's Place was therefore presumably unknown to the homeless population in the area, especially women, who engaged minimally or not at all, with the local services. The original setting for Jane's Place in Dublin 8, 4km away from the new setting, had a relatively small number of service users, many of whom lived nearby in Dublin 8. Travelling to a new centre was challenging for them in terms of knowledge and familiarity of the city and its transport services as well as the travel distance and duration, which required two modes of transport for some of the women. Additionally, the known fears, social stigma and mental health challenges of women in homelessness may also have been a contributory barrier to seeking support from Jane's Place (Morton et al., 2023, Milaney et al., 2020). The commencement of the LEAP-W trial coincided with the opening of 'new' Jane's Place, which is thought to have unavoidably hindered its' recruitment phase. Moreover, the researcher spoke to a

number of potential participants by phone who expressed interest in attending, and despite the willingness of staff in Jane's Place to facilitate potential participants to attend in terms of providing them with transport information and agreeing to meet them off the bus or Luas and accompany them to the centre, for a multitude of reasons, some unknown, many did not engage. It is surmised that recruitment following an initial settling in period of 6 months to a year, which anecdotally now has greater service user engagement, may have yielded a higher recruitment rate. However, due to time constraints this study could not have been postponed. On the other hand, the flexibility the LEAP-W programme offered in terms of commencement time, which extended from February to April 2024, and also the promptness of programme commencement following the initial evaluation facilitated those who were interested to enrol and start at their convenience. This maximised the number of participants who could possibly attend.

The overall retention rate in this study was considered high at 80%. When viewed alongside the LEAP-II trial, which was a mixed-gender study, the rate was higher, with a 70% overall recruitment rate in LEAP-II in comparison (Chapter 3, section 3.3.2.2). Similarly, the rate of regular attendance was higher at 38.7% in LEAP-W, when compared to 26% in LEAP-II. To recap, regular attendance was defined as the rate at which people attended at least once weekly for at least 50% of the programme duration. In LEAP-W, 19% (n=6) attended at least once weekly for the maximum 10 weeks in comparison to 2% (n=1) in LEAP-II. Moreover, in this current study, 41% (n=5) of the regular attenders reached the target attendance of three sessions per week, for more than 50% of the duration of the study, while there was no participant from LEAP-II who attended the maximal number of weekly sessions for at least 50% of the study's

duration. The retention rate of women across the preliminary LEAP-I trial and also LEAP-II was greater than that of men, so it is unsurprising that this women's-only study would yield a higher retention rate (Kennedy et al., 2024). Furthermore, LEAP-W was an enhanced programme as it was built on the foundations of the prior feasibility studies. The intervention itself had more exercise equipment than LEAP-II, including an exercise bike, boxing equipment and exercise mats for the women's health exercises. It had a gendered approach and was tailored for women and the unique and individual needs of this group. The WhatsApp phone messaging strategy appeared more successful than the phone messaging strategy utilised in LEAP-II which did not enhance retention. Participants responded positively to text messages and calls, plausibly as they were aware of the identity of the messenger. Moreover, it reminded them that they were part of a group who were also making a commitment. This was a homogenous group, women who were excluded, women who experienced SMD (Lankelly Chase, 2024), women who enrolled because they desired to improve their health, and this programme was designed and tailored to their unique health and social needs. The needs of this cohort were complex, necessitating a women's only environment and as the exercise intervention took place in this setting, a purpose-built centre for vulnerable women, the women felt that this was a safe space for them to attend and also avail of other support services in the centre, such as the GP, nurse or counsellor. The intervention based in this setting was accessible and enabled the women to feel safe, and it is felt that the group was the glue which offered social support and integration.

However, this study inevitably suffered loss to follow-up, with a number who did not return following the initial evaluation (n=6, 18%) and there was also a notable

level of sporadic attendance. There are a number of interacting and plausible reasons for this study's attrition. Albeit lower than in LEAP-II (81.4%), the rate of women in active addiction, a proposed barrier to engagement, was 55%. The higher rate in LEAP-II may be explained by the setting for LEAP-II, a service designed for people in chronic addiction. Of note, those in LEAP-W who were not in active addiction included four immigrants, four who were engaged in a course or college, four who lived with their child/children, were in contact with their children or were seeking custody of their children, and one transgender participant.

Six participants did not return to the intervention following their initial evaluation. One of these participants was excluded from the study due to a medical condition which precluded safe participation. Four of the remaining five lived in insecure or roofless accommodation, testament to the impact of housing insecurity and living a chaotic lifestyle and the immense challenge of considering commitment to anything beyond survival. Aligning with the literature as well evidence from LEAP-II, the prevalence of a mental health condition (90%) and often a co-existing substance use issue may also explain study attrition and the challenge of committing to the programme (Schulte and Hser, 2014).

Other reasons for loss to follow-up were long established patterns of unhealthy behaviour such as the reported low level of baseline physical activity participation, mobility limitations and disability, and chronic medical conditions, which were compounded by aforementioned lifestyle challenges.

The adherence to the exercise and protein supplement was notable in this study and attributed to the tailoring of the exercises to individual's mobility and need and observed motivation to progress. Choice was an important factor and integral to

trauma informed practice and facilitated an enabling environment and culture of trust, variability and independence leading to empowerment, which is at the heart of trauma informed care (SAMHSA, 2014b). Programme safety was demonstrated again, a similar trend in all LEAP interventions. Programme acceptability was evident and will be discussed extensively in Chapter 5.

4.4.2 Profile of the study participants

The demographic of this study portrayed a middle-aged female, likely a mother, living in homelessness - insecure, substandard or unstable - with a history of addiction or mental health condition or a dual diagnosis, and with a level of physical function and physical activity which was not on par with the general female population. To elaborate further, baseline physical function measures indicated low physical functioning in a portion of the women; half had low grip strength, all below average lower limb strength, three-quarters and half had lower mean gait speed and endurance, respectively and one third had lower mean balance when compared to normative data. Nonetheless, the physical functioning deficits were greater in the LEAP-II trial. Nutritional health was poor in half of the participants of this study and aligned with this, 42.5% and 45.4% lived with some degree of frailty, by SHARE-FI and CFS, respectively. Physical frailty was lower by SHARE-FI (6%) than the CFS at 12%, which mirrored the LEAP-II study frailty rate of 11.6% using both frailty instruments. As advancing age is known to be associated with a decline in physical function and frailty, it is conceived that the greater number of participants aged in their 20's in LEAP-W (n=6, 18%) than LEAP-II (n=2, 4.6%) was a protective factor, shielding from the destructive impact of homelessness, addiction and mental health disorders and thus inferring that age and duration of other health symptoms may have a cumulative effect

on these outcomes (Meulemans et al., 2025, Walsh et al., 2023). It is challenging to make comparisons to literature findings due to differing population demographics, settings and frailty measurement instruments (Cronin et al., 2025).

4.4.3 Impact

Pre-post intervention change was demonstrated in the physical function improvements observed in 13 participants who completed the final evaluation. When the regular attenders only were stratified (n=12), the same result was observed with pre-post intervention improvements in strength, balance, pain and in mental health (Table 4.10 and 4.11). These positive outcomes differ to the effects observed in the LEAP-II intervention, which was delivered to a different sample, in a different setting, nonetheless, both marked improvements in physical function. Considering that strength was the key exercise modality of the LEAP-W intervention, an optimised version of LEAP-II, it is encouraging to observe that strength improved, which may also have had a ripple effect on balance, which also improved. Regular exercise is known to have a pain-modulating effect as observed in the result here in LEAP-W and in the preceding LEAP-II trial (Lima et al., 2017). Pain relief itself has positive effects on mental health, the other improved outcome measure, as seen in the mental component summary of the SF-12 (Lima et al., 2017).

This study did not demonstrate pre-post intervention change in frailty scores. There are a number of proposed explanations for this. The NHS England recommend routine frailty monitoring to detect frailty and intervene early, and O' Halloran et al (2021) recommend frailty monitoring every two years using the CFS, based on their evidence of measuring transitions of frailty, therefore frailty transitions may not be seen in the shorter term (O'Halloran et al., 2021, NHS England, 2017). Frailty

improvements were demonstrated in LEAP-II but the numbers who transitioned were few and included those who had a notable low baseline level of physical activity and function and experienced more dramatic changes in function and behaviours following the intervention. This finding aligns with Haskell et al who posit that ‘the greatest health benefits from an increase in activity appear to occur when the sedentary persons begin a regular programme of moderate intensity, endurance-type activity’ (Haskell, 1994). Moreover, only one participant in LEAP-W was frail by CFS, which did not change over the course of the programme due to her sporadic attendance and also her medical condition and social circumstances. Longitudinal research with a larger sample size is required to further explore transitions of frailty.

4.4.4 Frailty exploration

4.4.4.1 Variables in this study associated with frailty

Linear regression illuminated that while age, addiction status, nutritional status and strength (by CST) influence the variance of frailty to some degree in this cohort, age and strength alone are associated with the variance on frailty by CFS and strength is also associated with frailty by SHARE-FI. Moreover, age-when tested with addiction, age-when tested with nutritional status and age-when tested with addiction and nutrition together was associated with the variance in frailty using both frailty instruments. This recurring finding of age and frailty association is not surprising considering that it is well established that advancing age is linked to frailty and in this study the mean age of those living with some degree of frailty (49 years by CFS, 46 years by SHARE-FI) is higher than the mean age of the non-frail sub-groups (35 years by CFS, 38 years by SHARE-FI) (Rockwood et al., 2004, Walsh et al., 2023). Age-related loss of muscle mass begins in the third decade of life and is incremental, thus, strength and age appear to be protective against frailty in the younger participants in this cohort

(18% (n=6) were in their 2nd decade and 36% (n=12) were aged 35 years or younger) (Wilkinson et al., 2018, Evans, 1995). Frailty is defined by the cumulative impact of deficits across physiological systems caused by chronic stressors (Rockwood and Mitnitski, 2007). It is conceivable that the impact of active addiction and poor nutritional status over time accelerated the frailty trajectory in this cohort. Results of the binary logistic regression indicated that advancing age increased the odds of frailty (1.07, $p=0.049$ by SHARE-FI; 1.18, $p=0.004$ by CFS) and increased strength reduces the odds of frailty by 23% by CFS and by 17% by SHARE-FI (0.77, $p=0.008$ by CFS; 0.83, $p=0.017$ by SHARE-FI), again testament to the view of the accumulating influence of a number of variables, including age, on frailty.

4.4.4.2 Gender and frailty

Another important dimension to frailty in this study is gender. Older women are known to experience greater frailty than men and a higher prevalence of frailty has also been reported in the homeless female population (Salem et al., 2013, Kiernan et al., 2021). Sex differences in frailty have been attributed to biological, psychological, behavioural and social factors (Liu et al., 2023, Gordon and Hubbard, 2019). Diet, gut microbiome and adiposity, as well as oestrogen and testosterone levels have been implicated in the recognised relationship between chronic inflammation and frailty in females (Gordon and Hubbard, 2019). Gordon et al (2019) present a number of hypotheses to explain the prevalence of poorer health of women and the sex-frailty paradox, however, what is also noteworthy in *this* unique population of women in homelessness is their distinct attributes in terms of lifestyle, health needs and healthcare experiences which differ to the general female population. For example, women who are homeless are more likely to engage in risk-related activities, such as

smoking and drug and alcohol use and may be less inclined to report minor or even major health issues and seek healthcare than the general female population (Gordon and Hubbard, 2019). Furthermore, this population are known to have trauma histories and its pervasive impact on health is well established, thus, the unique and intricate experiences of women who experience homelessness need to be considered (SAMHSA, 2014d, Milaney et al., 2020).

A host of other possible frailty risk factors were found in this female sample, including high body mass index (BMI), low physical activity levels, low handgrip strength and lower limb strength and their effects on this female cohort may have been compounded by those who were experiencing menopausal symptoms, adding another layer of complexity to this narrative which will be discussed in the next section.

4.4.4.3 Women, the menopause and frailty

The menopause, a natural stage of life for all women which is uniquely shaped by a myriad of interacting forces, including the effects of hormones and cytokines, has been shown to be associated with frailty (Ruan et al., 2020). Perimenopause marks the beginning of the transitional period in a woman's life when oestrogen levels begin to drop until they are depleted, and the menopausal period begins (Mishra et al., 2024). In the LEAP-W study, over 40% (n=14) of the participants were peri or post-menopausal, including 19% (n=6) who were post-menopausal. Two of the post-menopausal women reported that they had experienced early surgically-induced menopause (onset before 45 years of age) and the true figure of early menopause is likely to be higher due to poor health literacy and limited personal knowledge of the menopause, and also a limited exploration of this phenomenon in this present study

(Mishra et al., 2024, Ruan et al., 2020). Early menopause is linked with increased risk of frailty, cardiovascular disease and osteoporosis (Mishra et al., 2024).

Sarcopenia, a progressive skeletal muscle disorder which is recognised by reduced muscle mass, strength and performance, is associated with frailty and adverse outcomes in older adults (Cruz-Jentoft et al., 2019, Dodds and Sayer, 2015). It is also associated with menopause in middle-aged adults and its prevalence increases with age (Buckinx and Aubertin-Leheudre, 2022). As aforementioned, menopause marks the end of menses due to the depletion of female hormones (Nappi et al., 2022).

Oestrogens have immunomodulatory benefits for disease states and are also beneficial to skeletal muscle, as are progesterone and testosterone also, therefore the impact of decreased levels of these hormones in the body can have a detrimental effect on skeletal muscle mass and strength, mobility and physical function, particularly if chronic disease or disability is present. Additional risk factors for sarcopenia for middle-aged women include low protein intake, high BMI and low physical activity all of which were present in the female cohort in LEAP-W (Buckinx and Aubertin-Leheudre, 2022, V. Messier, R. Rabasa-Lhoret, S. Barbat-Artigas, et al, 2011).

Health issues of the menopause include physical, psychological, sexual, cognitive and social; therefore, it is unsurprising that the evidence base has found associations of poorer experiences of the menopause with a number of social determinants of health, including lifestyle factors, education, employment, income and support (Namazi et al., 2019). Further, Namazi et al (2019) report that lower socio-economic status is linked to lower quality of life and worse menopause symptoms and in some cases may also lead to early menopause. Social support, which influences one's ability to cope was another factor which was reportedly absent for the majority of

women in this cohort. Early menopause is more prevalent in low-income and middle-income countries and an inverse relationship between health literacy and severity of menopause symptoms is reported (Mishra et al., 2024, Takenaka and Sakai, 2021). Poor health literacy leads to poor health behaviours and cigarette smoking was a lifestyle habit of the majority (60%, n=20) of the LEAP-W participants and is an established risk factor for early menopause (Mishra et al., 2024). In summary, it is apparent that the menopause compounds the issues of women in homelessness.

In summary, it is evident that a multitude of interacting factors, including female specific factors, added to the complexity of the health issues experienced by this cohort of women who experience homelessness, addiction and mental health challenges. Frailty occurs from an accumulation of bodily deficits from stressors and has been proven to exist prematurely in people experiencing homelessness who have been exposed to chronic and enduring stressors from an early age. Homelessness, addiction, mental health challenges and their intersecting impact, along with other social disadvantages and harms are likely to exacerbate the existing risk of frailty and sarcopenia in middle-aged women. These results illuminate the critical need for a skilled and expert workforce to deliver targeted interventions which sensitively and appropriately address these needs and help modulate the physical functioning deficits and frailty in this vulnerable female population.

Chapter 5 The LEAP-W trial: Qualitative inquiry

5.1 Introduction

Chapter 5 presents Part 2 of the LEAP-W trial, which had quantitative and qualitative components to evaluate and explore the holistic impact of an exercise intervention with nutritional supplementation delivered to women who experienced severe and multiple disadvantage (SMD) (Lankelly Chase, 2024). This chapter will specifically present the methods, results and discussion of the qualitative inquiry of the LEAP-W trial. An overview of the content of this chapter is displayed Table 5.1.

Table 5.1 Overview of Chapter 5

5.1 Introduction	
5.2 Methods	5.2.1 Study setting and participants 5.2.2 Recruitment 5.2.3 Study procedure 5.2.4 Data Analysis 5.2.5 Rigour
5.3 Results	5.3.1 Theme 1 The power of exercise 5.3.2 Theme 2: Challenges to engagement 5.3.3 Theme 3: The LEAP approach
5.4 Discussion	5.4.1 Theme 1 The power of exercise 5.4.2 Theme 2: Challenges to engagement 5.4.3 Theme 3: The LEAP approach

The overall aim was to explore the perspectives of the programme participants and stakeholders on the impact of this targeted exercise intervention with nutritional supplementation.

The objectives were:

1. To explore the perceived benefits, enjoyment and holistic impact of the programme.
2. To explore the barriers and facilitators to attending the programme.

3. To ascertain physical health needs and the level of unmet need of this population.
4. To explore the intervention design, process and its acceptability and applicability to this population.

5.2 Methods

5.2.1 Study setting and participants

The final part of this PhD explored the role and the holistic impact of exercise in women who experienced homelessness, addiction, and mental health challenges through an exploration of the perspectives of the LEAP-W programme participants and the key stakeholders in Merchants Quay Ireland (MQI). Twenty people, who were informed of the end of programme interviews upon recruitment to LEAP-W accepted the invitation upon programme completion and took part in semi-structured one-to-one interviews. This included 14 programme participants who enrolled in the exercise intervention and six stakeholders from the two recruitment sites in Merchants Quay Ireland (MQI) (the Riverbank centre, a mixed gender setting and Jane's Place, the women's-only centre where the programme took place), who had extensive experience of working with this population of interest. The qualitative interviews took place in a private room in Jane's Place. Of the 14 participants who took part in the interviews, 12 had regularly attended the programme.

The eligibility criteria were as follows:

Inclusion Criteria

2. All consenting programme participants, that is, those participants who provided informed consent to participate in the programme, completed the initial evaluation and declared intent to engage in the LEAP-W programme.

3. Key stakeholders who were involved in direct service provision to the women who attended the low threshold services in MQI's Riverbank and Jane's Place centre, where the study participants were recruited from.

Exclusion criterion

- Any participant with a perceived acute, problematic behavioural issue which precluded ability to participate in the interview process.

This study received ethical approval from the Faculty of Health Sciences, Trinity College Dublin (Ethical Approval Reference Number: 211202).

5.2.2 Recruitment

The programme participants were recruited from the pool of 33 women who provided written informed consent to take part in the LEAP-W exercise intervention. Once the LEAP-W exercise programme was complete, participants were invited to participate in the interview process. If interested, a convenient time was arranged to conduct the interview in Jane's Place. The stakeholders were recruited from the Riverbank Centre and Jane's Place where the programme participants were recruited. Participant Information Leaflets (PIL) were provided through a gatekeeper in each centre and interested participants were advised to contact the researcher FK. Following this the researcher scheduled a time for the interview in a place of convenience for the stakeholders, in Riverbank or Jane's Place, MQI. One stakeholder interview took place online as the stakeholder was on leave at the time.

5.2.3 Study Procedure

Data collection took place between May 2024 and July 2024, once the first participant completed her 10-week intervention. Prior to the commencement of the interview, study participants were reminded of the content of the PIL and once any

questions were answered satisfactorily, they proceeded to provide written informed consent. Study data were collected through one-to-one semi-structured interviews using a Philips Dictaphone and once completed, they were immediately transferred to the secure cloud-based Sharepoint system and pseudonymised. Interview data were transcribed verbatim by FK within 48 hours of the interview procedure. Once transcribed the data were deleted from the Philips Dictaphone. Reflexivity was practised throughout the data collection process by retaining field notes and through regular debriefing sessions with the study Principal Investigator and PhD supervisor, JB. These processes addressed the subjectivity of the researcher and represented the capacity of the researcher to reflect on her assumptions, values and emotions. Moreover, it helped shape subsequent interviews. The duration of the interviews varied from 5 to 30 minutes for the participants and from 8 to 28 minutes for the stakeholders. Following each interview, participants and stakeholders were offered a copy of their transcript to review and validate the data collected. Two participants accepted and received their transcripts. See Appendix IV for the full exit interview schedule for the programme participants and stakeholders.

5.2.4 Data Analysis

This study applied an inductive reflexive thematic analysis approach and was guided by Braun and Clarke's 6-step reflexive thematic analysis framework and methodology (Braun and Clarke, 2014, Braun and Clarke, 2024). In doing so it applied a flexible approach to interpreting the data using codes and themes. The six steps involved:

1. Familiarisation with the data: this was established through the transcription process and repeated reading of the data, by noting patterns in the data and highlighting ideas for coding.

2. Coding: Initial codes were generated across the entire data set. Each code represented the building blocks of the themes.
3. Generating themes: Codes throughout the data set were linked and categorised into potential themes. Themes and subthemes began to emerge at this point.
4. Reviewing themes: Candidate themes were reviewed and refined to ensure cohesion of the data within the themes.
5. Defining and naming themes: Themes were defined to elucidate their meaning throughout the narrative.
6. Producing the report: Final data analysis took place, and a comprehensive narrative was produced which was interwoven with vivid and illustrative data extracts designed to evoke a compelling narrative and answer the overarching research question. This is outlined in the results and discussion section in this chapter.

FK initially coded the entire data set and SG was recruited as an external validator, to initially become familiar with the data set and later to validate the codes and assist in the generation and critical review of themes and subthemes. Reflexivity was practised again at the analysis stage through critical thinking and reflection with SG and PhD supervisor, JB. These meetings led to further iterations of codes, categories, subthemes and themes until the themes were finally defined.

5.3 Results

This section presents the results of the qualitative inquiry generated from thematic analysis of the entire data set produced from the 20 semi-structured interviews. It was believed that data saturation was reached at this point. Table 5.2 presents the demographics of the interview respondents.

Three broad themes were developed, namely:

- (i) The power of exercise, (ii) Challenges to engagement and (iii) The **LEAP** approach.

See Figure 5.1. The subthemes are depicted in Figure 5.2. Appendix VII provides the codebook with comprehensive detail of the categories and codes which formed the basis of the narrative that follows.

Table 5.2 Demographics of the interview respondents

Respondent: Programme participants	Background	Respondent: Stakeholder group	Background
P1	Experiencing homelessness, dual diagnosis* & chronic pain	S1	Project worker, MQI
P2	*h/o homelessness, tri-morbidity	S2	Mental health nurse, MQI
P3	h/o homelessness, mental health condition & chronic pain	S3	Counsellor, MQI
P5	Experiencing homelessness, mental health condition & chronic pain	S4	Project worker, MQI
P7	h/o homelessness, h/o substance use, mental health condition & chronic pain	S5	Project worker, MQI
P8	Experiencing homelessness and dual diagnosis*	S6	General nurse, MQI
P9	Experiencing homelessness, dual diagnosis* & chronic pain		
P11	Experiencing homelessness		
P12	H/o substance use disorder-stable, mental health condition & pain		
P18	Experiencing homelessness		
P19	Experiencing homelessness, substance use, mental health condition		
P21	Experiencing homelessness, tri-morbidity*		

P23	Experiencing homelessness, chronic pain	
P33	Mental health condition	

P=programme participant, S=stakeholder, dual diagnosis=co-existing substance use disorder and mental health condition, tri-morbidity=co-existing substance use disorder, mental health condition and physical health condition *h/o =history of.



Figure 5.14 Themes

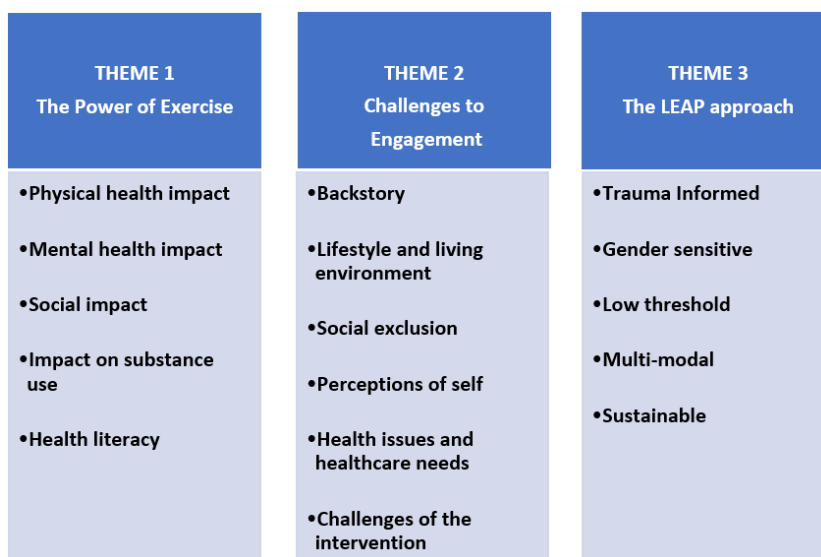


Figure 5.15 Themes and subthemes

5.3.1 Theme 1: The power of exercise

This programme delivered a low threshold multi-modal exercise programme with protein supplementation to address physical and nutritional health deficiencies

and target physical function and frailty in a cohort of women experiencing SMD (Lankelly Chase, 2024). The results presented here highlight the power of the intervention, specifically the power of exercise, to positively influence a multitude of health and wellbeing domains in this population.

Many of the participants discussed previous recovery programmes they had attended over the years that were different to this programme in their design, delivery and impact.

"I did a course since I'm ... 17/18 (years of age) .. but I've never got one like this ... this is the best course that I've ever got". (P9)

Gratitude was expressed by both participants and staff for the 'life changing' (P9) impact it conferred and the empowerment it provided for many.

"I think it has been really successful. And we're so grateful..." (S1)

"It was giving me new ideas of, if I'm at home, what kind of exercises can I do". (P19)

"I've loads of energy Fiona. I go home, I walk the dog, before I come in, I walk the dog." (P9)

Participants felt a pull to the programme.

"It keeps bringing me back." (P12)

"But there's definitely a couple of times I thought no wait hang on. I'm going into the exercise program this week I'm gonna be here this week." (P1)

The value of exercise and the possibilities of a ripple effect were evident from the behavioural changes reported and the desire to continue to exercise was evident from those who attended regularly.

“You feel a lot happier, you feel like good about yourself, that you're doing something healthy for yourself, and it kind of encourages you to eat healthy as well.” (P19)

“I can face most problems sober now as I'm making better choices with clearer thinking.” (P2)

Some were also engaging with other services as a result of attending the exercise programme.

“I even have a particular client in mind, who was very chaotic, it's very hard for her to come in, but since she started this programme, she's been coming ... during MDT we talked about her, and they are super, super, happy that she's engaging with the service here.” (S2)

Stakeholders measured the success of the programme by the level of commitment provided by a population who normally struggle with commitment.

“It's rare to see people who are in, who lead chaotic or disorganised lives commit to something and come every single week”. (S3)

“I think there has been a lot of momentum with the programme and you've had a lot of consistent service users attending.” (S1)

“You can see that the women who engaged, they really got, like so much out of it.” (S5)

“There’s always going to be people who are kind of very enthusiastic at the start and might kind of taper off but I actually I saw the improvement in a lot of the women, who joined the programme and stuck with it as well.” (S4)

It was questioned as to whether a sufficient focus was being placed on exercise as a low-risk and high return rehabilitative intervention for this population.

“I think it’s something that can be kind of forgotten about to a degree, in services, the exercise element of things, because other things become a little bit more prioritised. Em, but I think it’s very very important.” (S3)

The following subthemes demonstrate the main benefits of the programme across a number of health domains.

5.3.1.1 Physical health impact

The physical health benefits reported by participants, were enhanced strength, mobility, and function, findings which support the quantitative findings (see Chapter 4) of improved lower limb strength and balance.

“My strength, loads of it ... it gave me strength that I never knew I had”. (P9)

“I was finding their drumming workshops difficult. I kept having to stop all the time due to pain in my upper arm muscles... basically the pain was quite bad, so I just had to stop. But now, this week we’ve done the last class, and I actually had no pain.” (P2)

Other reported benefits were improved sleep, decreased weight, diminished pain with less reliance on pain relief medication and renewed energy.

“My body has woken up ... I just feel like I’ve more life in me.” (P7)

"I came here with, they think it's a trapped nerve, I've had that pain ongoing for about 3 years and it's constant ... then I just do an exercise that you showed me, and it eases it up." (P9)

"The loss of weight has made the pressure on my knees less." (P2)

Staff commented that participants had more stamina when out on day trips which enhanced the enjoyment of these social engagement interventions.

"We would do day trips and stuff like that, and we could see the improvement in how, just even how quick they could walk." (S4)

Another important and unexpected physical health benefit was improved pelvic floor control, which had ripple effect on confidence and mood.

"I no longer pee myself ... I no longer panic about the fact that that I need to go because I know I have the tools, the muscles, that can hold it... that was the most significant thing." (P2)

5.3.1.2 Mental health impact

The mental health benefits were discussed at length. Participants and stakeholders considered these benefits as more impactful than the physical rewards. Exercise was viewed as a coping strategy, assisting in modulating mood by its ability to distract one from the constant stresses of life.

"I think it's the mental health issues that have been impacted positively, more than the physical in some ways but all the physical ones did help the mental ones." (P2)

"I found exercise, like, was a healthier way to cope with your problems." (P19)

“It puts stuff that you have in your mind right at the back of your head and you know what I mean, and it doesn’t be such a challenging day then.” (P21)

Some referred to the benefit of pushing oneself to commit and complete something, normally considered too challenging to surmount. This led to a sense of pride and achievement. It was empowering.

“I’d be going home on the bus, and I’d say well I did an exercise class today. And I felt better. I felt a lot, lot, better for it.” (P21)

The consistency and dependability of the programme offered structure in the chaotic lives of many offering a focus and sense of purpose to the day for many.

“I’d set myself up for the morning, set myself up for the day.” (P7)

“Now I get up and I smile, and I look forward to coming into somewhere you know where I’m able to do the exercise.” (P7)

“I have a routine you know.” (P12)

“Every morning, I wake up and look forward to do something, to go somewhere, to do something.” (P18)

““It’s a distraction... You need to look forward to something every day.” (P21)

Some alluded to the ‘natural high’ obtained from exercising and synonymised exercise with substance use.

“It was like taking drugs to me.” (P9)

Others referred to the mental health benefits of the Park Walk, the restorative benefits of open green space and fresh air.

"I always enjoyed the walks around the Park, just in nature ... it's grounding me a bit." (P7)

"Walk in the park ... that was massive you know." (P12)

A number of participants discussed the gift of giving oneself more time and becoming more mindful during the programme.

"I deserve to put myself first.... it's quite painful, so we're not going to go deep into that but ... that's had a big impact on my life that I actually deserve this time for myself and to put myself first ... I deserve the time to make good choices." (P2)

"The fact that I'm doing something for myself." (P7)

Many reported improvements in confidence and self-esteem.

"It's awakening my confidence again." (P12)

"It gives me self-worth, confidence and self-esteem." (P9)

The positivity of the programme was evident in the reported fun, the laughter, the connectivity, and camaraderie which developed over the course of the programme.

"It was a very relaxed kind of environment ... it was actually, it was a really good laugh." (P7)

"The more you are in the group, the room, the happier you are, you get more motivated." (P18)

Exercise offered hope.

"That's why the programme was so good. Just to make that possible for them". (S1)

5.3.1.3 Social impact

The format of the exercise class with its flexible drop-in nature, empowering *“uplifting music”* (P9), casual conversations which were *“sprinkled with fun”* (P12) created a forum for a diverse group of people from different backgrounds and cultures to connect on a social level.

“Nice to get to know people and eh and talk, you know. Sometimes you just feel bored.” (P11)

“I've met very lovely people ... and having the chats in groups ... and just going out.” (P12)

Camaraderie was seen to develop over the course of the programme with people, who may not have usually connected, but now had a shared interest. It reduced their feelings of loneliness and isolation and enhanced their social capital.

“Women mixing with each other that would never usually mix with each other... they were just women who were interested in exercise.” (S4)

“Just it just helps each other you know and supporting each other and it's like yeah ... this is what it's about, yeah and it makes you stay strong as well for yourself, when you see other people with their difficulties.” (P12)

“It's cutting the loneliness.” (P21)

“It's allowing them to “build relationships with each other” and then they are more likely to keep coming back and engaging.” (S3)

Some discussed the fun and laughter they shared at the classes and on the walks and the support and positivity they gained from the group.

“Everybody kind of encourages each other along.” (P2)

“Like going for walk in the park yeah, like I mean it was like getting a one-to-one altogether, like to talk, with 3 or 4 ladies, I've never done that in my life!” (P9)

Stakeholders perceived that participants' enjoyment and appreciation of the exercise programme was reflected in the reported fear of it ending.

“The feedback we got from the women was that they were, kind of, they were enjoying it so much that they were kind of a bit worried that it was ending because then they were like, what are we going to do.” (S5)

5.3.1.4 Impact on substance use

Some participants discussed the impact that the exercise had on their substance use, with either a reduction or at least a delay in its use. The 'natural high' (P21) obtained from the exercise inferred its potential to act as a substitute for substance use.

“It makes me feel so good that I don't, I don't want it (referring to substances).”
(P12)

“Now I take none (referring to painkillers), like I can give them back to the doctor.”
(P9)

“The fact that they were there at the programme meant they weren't using that day ... Some of them said they were using that as a way to not use or delay the use.” (S5)

One stakeholder observed and attributed the effects of the programme to the absence of relapse in one participant.

“I can think of one client em, who would relapse and use cocaine, who, eh, recently has managed not to relapse, despite stressful situations and I'm sure that the exercise group is a big part of that.” (S1)

"It's my drug as I say." (P9)

5.3.1.5 Health Literacy

The impromptu brief health education discussions about physical activity, nutrition and women's health issues were enjoyed by participants and were viewed as empowering. It increased knowledge and provided a forum for many to learn from each other.

"It would spark up a conversation ... even if its only something small I always get something from it like ye know". (P7)

"You're empowering me you know." (P12)

It highlighted the importance of making every contact count, the ethos of working with this population.

"We try to tailor our care around making every contact count." (S2)

The protein supplement which was viewed as "a nice treat" (P19) at the end of the session and often stimulated discussion among participants on the food poverty they experienced and on the importance of protein and good nutrition for health. It served as a precursor to interactive health and nutritional discussions.

"It's important because in the hostel we get meals, but my meals, like our food isn't very nutritionally complete at all." (P1)

"Obviously it's for muscle, building muscle it is necessary, you have to have, you know, nutrition, proper nutrition."(P2)

"It's so important for to, to keep, to rehydrate." (P3)

People also discussed the simplicity of exercising and the exercise options they had which were free and accessible. They discussed their exercise preferences and how

these could be easily incorporated into daily life outside of the programme. It created hope and desire for future engagement in physical activity.

"You don't need all these exercise things." (P9)

"It's reinforced to try to keep exercising." (P23)

"You're showing me that I can move forward, and I can exercise somewhere else and take this with me." (P12)

The enhanced knowledge and learning were reflected in altered lifestyle choices.

"They are more aware of exercise and more aware of nutrition". (S1)

"Before I go to the gym (referring to exercise class), I try and not smoke a cigarette an hour before, like things like that, amazing like." (P9)

"If I wasn't coming here you know I'd get up and I'd be smoking constantly but now like it's amazing, I smoke 2 or 3 a day whereas if I hadn't got this place, I'd be spending €25 a day." (P9)

Staff at the centre saw the need for exercise to continue and the potential for sustainability.

"I think it's vital that this continues." (S2)

"The Park Walk is definitely something I think that we could do." (S4)

5.3.2 Theme 2: Challenges to engagement

This programme encountered many challenges with resultant loss of participants from the time of enrolment to completion of the flexible 10-week programme. Although intent to participate was apparent, the motivation to attend the programme was often overpowered by competing priorities, including basic needs such as nutrition, hygiene and accommodation issues, as well as addiction, chaotic living and mental health challenges.

“Things that maybe were important on your list of things to do get completely shifted ... you know and it’s only the top priority things for survival, that become important.” (S5)

Many other reasons were cited for programme attrition.

Stakeholder views:

“Maybe they weren’t ready for a programme that required a bit of commitment.” (S1)

“Transportation you know and also fear of walking in the street.” (S2)

“None of us could maintain any kind of energy level or motivation” ... How could you think about recovery?” (S6)

“The accessibility to get from service to service.” (S6)

“I suppose at the time we started we were opening the doors, so, we were new and that (the exercise intervention) was new, the programme was new as well so.” (S5)

Some accepted that this was just the way with low threshold services.

“It’s a part of low threshold services, in that you could see some not ready, you’re not stable enough, you’re on too many substances ... have a really good session with them and might not see them again for 6 or 7 months.” (S4)

Participant views:

“I found it hard to come because I’m not living in a good place ... sometimes I found my motivation wasn’t good because, I’d say I’ll do it tomorrow, it’s not really, I’m not really use to putting an effort into myself.” (P19)

"Stresses, yeah you know, like noise and stuff like that. I might get a bad night's sleep." (P1)

"That would have been again due to my mental health, em, ye due to me mental health and just kind of not having that motivation." (P7)

"I did find it difficult was if I had, if I had a bit of a blip. And eh, and I had a drink.... feeling sort of, of guilt and shame, that I'm not doing my best and that's kind of .. you know it's just horrible." (P2)

"To be honest, it was the withdrawals, it wasn't like I was sick in other way, it was just the withdrawals, and it was constant, constant and then just messing up again." (P8)

A number of participants (n=3) expressed hesitancy in starting the programme, due to the fear of it ending.

"I'm afraid to try new things or exercise as I had no confidence." (P2)

"At the very at the very beginning oh I didn't want to do... the thoughts of coming into something, because I didn't want it, I knew it was going to end, and the idea of that is like it just brings up that abandonment again." (P12)

"It will hit me hard, it will, if it's just taken away." (P9)

They were accustomed to things ending and expressed grief when it ended.

"I'm in bits, to be honest with you, I'm really devastated ... I have really severe abandonment issues, so when you have like .. form attachments in groups and stuff like that, when they finish, I find it extremely challenging." (P2)

Theme 2 presents the narrative of the backstory, lifestyle and social exclusion experienced by this population which impacted on their perceptions of themselves and

their interactions with the world and negatively influenced their health and wellbeing, expounding the critical need for a unique and targeted type of intervention to manage the adverse outcomes and complex health burden.

5.3.2.1 Backstory and life course

Participants discussed how their childhood experiences and life course, which were often traumatic, has shaped their current lifestyle, their views of their own health and their healthcare experiences.

“When you come from the backgrounds of you know, abusive relationships and abuse of, all through the years, because of who we are who come here, you know, it's either it's trauma it's addiction, it's homelessness for people” (P12)

“Childhood trauma that caused my addiction and my mental health issues ... I've been through domestic violence as well ... like with my bipolar I get panic attacks ... I was kind of rejected by my birth parents and then I was rejected by my adopted parents, and I have really severe abandonment issues.” (P2)

“Coming from a background of having an eating disorder ... mental health problems ... but my main reason for going was really ... at the time, I was young, I was naive ... it was all focussed superficially around losing weight.” (P7)

“I just started getting into drinking alcohol to cope with things.” (P19)

Stakeholders' views mirrored the participants. Reported histories of trauma, fear, violence, chaotic living, poverty and deprivation led to disadvantage and societal inequities and is reflected in the health issues and healthcare experiences of this population, which are different to the general population.

“Lifestyle is different from people in the community.” (S1)

“Bigger picture involved because a lot of people who are in homelessness and in addiction also come from deprived or disadvantaged areas too, so they’re probably not necessarily brought up with a very healthy lifestyle to begin with, so they would have health problems that, that tend to occur at an earlier age anyway ... But I do also think that, obviously the addition of addiction and homelessness is going to add and compound any other already underlying health issues” (S3).

The impact of the backstory and adverse childhood experiences was evident.

“They’ve had a huge amount of trauma in their lives.” (S5)

“So, we’re going back to childhood, all those adverse childhood events ... when they’re 18 there’s very poor aftercare services for most of them, so they’re in this hostel, this emergency accommodation system and surrounded by drugs.” (S6)

5.3.2.2 Lifestyle and living environment

Participants’ complex histories coupled with their current lifestyle including unstable or inadequate living environment contributed to their health and social challenges. Stress and overwhelming life challenges, limited resources and outlets, financial burden, limited social capital and its associated isolation and loneliness, and poor physical and mental health were reported by participants. Drinking and substance use was seen as a coping mechanism which in turn led to shame, guilt and stigma. Dual diagnosis was common and often a tri morbidity of substance use disorder, mental health issues and a physical health condition existed, which was compounded by homelessness.

Participants and stakeholders discussed the impact of homelessness on daily living.

Sleeping rough, hostel living, and insecure accommodation caused stress and chaos and affected self-autonomy.

“There's a lot of other things going on like ... there's mornings you get up, and it's just like, you know, good things could be going on, bad things could be going on, things that just slow you down stresses, yeah you know, like noise and stuff like that. I might get a bad nights sleep.” (P1)

“Housing issues and even if they are housed, some of them were in hostels, it might be that they just didn't get a good night sleep the night before and things like that and they didn't go (to the programme) and they were, you know, and so their lives are kind of chaotic anyway, you know, where they're not getting good sleep.” (S5)

Hostel living was likened to a prison and sleeping rough was sometimes preferred.

“Just being locked up” ... you are in a day prison.” (P5)

“A lot of people I see don't want to stay in the hostels. They just feel safer on the street, in a tent... being in a place where people are genuinely mentally unwell, and they're terrified” (S6)

This resulted in a survival mode of living with crisis management where self-care was not a priority. Stakeholders discussed the many unmet needs of women experiencing these multiple disadvantages. Sleep deprivation, poor hygiene, poor nutrition, food poverty, limited access to clean clothes, basic needs which need to be met before committing to any type of intervention. As a result, priorities were not about self-care or illness prevention and were primarily about the daily struggle.

“They’re in survival mode so they’re not thinking about exercise.” (S5)

“I haven’t been paying a lot of attention to any sort of physical health, kind of.”

(P7)

For those who tried to break the mould, maintaining motivation and energy to engage and commit was extremely difficult, and some tired of the status quo:

“Oh God, I have enough of this lifestyle.” (P8),

They lacked a readiness to commit.

“The living conditions there are just ... none of us could maintain any kind of energy level or motivation... how could you think about recovery?” (S6)

5.3.2.3 Social exclusion

One stakeholder referred to this population as the *“forgotten people”* or the *“forgotten women”* (S5). Another referred to the importance of each interaction with service users who are often so isolated and excluded and may only come once.

“You just think oh God am I the only person who’s going to listen to them today”. (S6)

The loneliness and isolation of homelessness, addiction and mental health challenges was clearly depicted,

“I live in a homeless hostel ... it’s very isolating ... like it was very lonely for me.”

(P19)

“I used to drink going back to my flat every day, as all I had there waiting for me was my demon friend, a bottle of gin.” (P2)

“In the hostel, I’ve only myself in the room, so I isolate myself.” (P18)

"I just realised how alone these people are." (S6)

and the consequences of the negativity and exclusion by healthcare professionals is seen to severely hinder engagement with health and social care services.

"So, it would always be, you know, encouraging someone to go and speak to their doctor, which very rarely happens anyway." (S4)

Referring to lifestyle and exclusion one stakeholder said that it has:

"A huge impact on their ability to commit and to engage with services." (S1)

Equally stakeholders bemoaned the approach of some healthcare services which were not always inclusive and compassionate to meet the needs of this population.

"Sometimes staff are so inflexible." (S6)

One participant discussed the lack of state support for people with addiction issues adding to her sense of being excluded.

"Was very tough because you wait in this country for treatment 3 months, so by that time you're dead!" (P8)

5.3.2.4 Perceptions of self

Perceptions of low self-worth and self-esteem emanated strongly from participants and stakeholders.

"Before the programme I wasn't thinking about me... self-esteem issues and drink ... I beat myself up thinking why am I not caring for myself and I feel bad about myself, so I feel a bit stupid because I'm not prioritizing myself, so then I drink." (P2)

“When you put on weight you just don’t want to be seen, (big sigh), you know it’s just hard”. (P5)

“I has lost all belief and confidence in myself, and I was at one of the lowest points in my life”. (P12)

The women described feeling undeserving of a happy and healthy life, leading to poor lifestyle choices and behaviours. Staff opinion concurred with this sentiment.

“Lacking in confidence or they don’t have that self-worth ... they feel like they don’t deserve a healthy lifestyle.” (S1)

“They carry so many issues with them and stigmas.” (S6)

Participants and stakeholders discussed feelings of fear, humiliation and a negative stigma which made it difficult for people to cope, to engage and trust others. As a result of these negatives perceptions of themselves, participants were seen to have low self-care and identified more easily with a chaotic lifestyle, which often led to negative cascading consequences such as addiction, mental health problems and homelessness.

“If you’re in addiction, you don’t really have much, you’re not really prioritising your selfcare.” (S3)

“A lot of the health problems that go on with people who are in addiction could be em treated with better lifestyle choices, especially with regards to exercise.” (S3)

One participant described it as surprising to be treated with dignity and respect.

“Because I’m a person that, eh, I don’t know if I’m hard to get on with ... I always question myself, why is people so nice to me, you know, why is people so good to me, ... when I came here, I was saying I’m not going to last here”. (P9)

Low self-care led to health issues.

5.3.2.5 Health issues and healthcare needs

Physical health conditions were common among participants, and this impacted on their physical function and independence.

“I have major health issues, I've got Diabetes Type 2, eh an eating disorder, addiction problems with too much gin, drinking too much gin, and mental health issues, with self-esteem issues and because of being disabled.” (P2)

“My physical pain had gotten so bad.” (P9)

“When you're in chronic pain from morning to night, you just don't be in the humour to do nothin.” (P21)

“Their diet is very poor, diet in turn affects their health, a lot of them are very underweight or overweight. Some people are struggling with diabetes ... physically they struggle, some people have problems with pain, arthritis in their legs and ye, they do have a lot of physical issues.” (S2)

“You can see that their physical health is not on par with somebody maybe you know their own age, who are maybe from a different section of society.” (S5)

Yet, despite the need, looking after their physical health was not considered a priority.

“Health needs are way down the list of priorities for women who kinda access low threshold services”. (S4)

Many views were expressed about the role of exercise to improve health. Stakeholders considered it important to target physical health issues, as well as social prescription to

target mental health, addiction, and wellbeing. A strong desire to participate in this physical activity programme was evident as participants enrolled in the programme.

"Give me a kick start to get back into that like a bit of a routine again." (P7)

"For my health, and for eh my mental health em (P21)

"Exercise would be good for me. I suffer with a terrible lot of pain." (P5)

Some participants discussed past positive experiences of exercise. Others were informed about exercise and had a positive outlook and curiosity about the programme.

"I suppose exercise has always been a big part of my life since I was 7 coz it was like a form of independence coz I realized I could cycle and I realised if I can cycle I can get myself anywhere, where I needed to go, I wasn't depending on anyone when I was a teenager actually, I was bullied in school quite badly ... it's a way of dealing with stuff.... things went very bad in my life." (P1)

"I'm a person who wants to take availability of any opportunity that are kinda going but the fact that it was exercise, I used to exercise in the past." (P7)

"I think that exercise is very vital for addicts, you know to, to recover, because you know, to release that energy, you know and eh, I never believed that eh when you feel tired and you exercise, you feel more energy". (P8)

"I used to work, work out and run and stuff." (P11)

"I would always have been health conscious." (P12)

Some participants had no prior exposure to structured exercise and exercise was viewed as unfamiliar activity.

“No, coz I had 3 sons to run around after and exercise never came in.” (P21)

Theme 2 has outlined the significant challenges and health burden of this population, who often have a background of disadvantage. Exercise was viewed as an unfamiliar and new concept to many participants yet was considered as an opportunity and even a possibility to assist recovery and improve their health and wellbeing. Stakeholders point to health disparities of this population when compared to the health of the general population which is largely driven by socioeconomic factors and societal inequity. The need for intervention to target these health issues and improve outcomes was clear. This was a population who evidently required comprehensive and targeted care due to a complex history and life course which has been delineated here. Such interventions were not seen to benefit the existing inflexible and structured mainstream health and social care system. Interventions would require a unique and participant-centered approach to be delivered effectively and sustainably. This approach and programme design will be discussed in Theme 3.

5.3.3 Theme 3: The LEAP approach

This final theme relates to addressing the barriers to engagement (as outlined in Theme 2) in health interventions which are evidently desired, and the need is indisputable. A bespoke design and targeted approach are called for and outlined succinctly in the subthemes which follow.

Gratitude and hope were expressed for delivering a programme which was so impactful.

“I really enjoyed it and thank you for the opportunity and it was great to be able to take part.” (P7)

"It has given me back something that I lost a long, long time ago and you've given me that back and I'm not going to lose it again you know." (P12)

"Definitely should be part of the programme on a regular basis." (S3)

"It's been something completely different and there is an absolute need." (S4)

Exercise was viewed as an important intervention to offer, and this exercise programme was designed with the needs of its participants in mind.

"The lack of judgement, the openness, the humour, having the music and the flexibility." (S4)

"We put so much emphasis on mental health support, addiction support and things like this and maybe we could be, em, you know maybe putting more of an emphasis on exercise." (S1)

It instilled hope and a sense of purpose.

"It has given me hope for the future". (P9)

"So important for people who might not commit to anything regularly." (S1)

Views on the inadequacy of the current inflexible and exclusionary healthcare system were expressed which were not aligned to the needs of this population. A different approach was required.

5.3.3.1 Trauma informed

Stakeholders discussed the importance of the sensitivity required in engaging with people with legacies of trauma and adversity. They advocated an approach which empathised with people, offered choice, provided consistency and security, built trust and empowered people.

"You are so valuable to us that we want to make you live as long and as healthy as possible ... We're treating the addiction, we're going to help you with that, but you, for yourself, for your own welfare, that you can be strong, and you can hopefully live an independent life and enjoy your families if you have them, whatever, but ye for their own intrinsic values as human beings." (S6)

"Just that human contact ... as a human being is interested in this other person"
(S6)

"It's about choice and empowerment and its behind everything that we do". (S4)

One stakeholder emphasised the importance of being provided with a safe place.

"This is the only place where they may feel safe or get some help." (S6)

This trauma informed approach helped people to feel included and want to return.

"There was real interest and again I think being invited to something, em was a huge part of that." (S4)

"Very encouraging and very welcoming." (P23)

Participants feedback concurred with these sentiments of a trauma informed approach.

"You don't have that judgement, you don't have to, you know, look over your shoulder." (P12)

"I came in here every single week and no judgment." (P9)

"You kind of know you can kind of let your guard down." (P1)

"Make you feel like you are in the best place and then you feel comfortable, you feel at home." (P33)

"Nobody's gonna be judging you." (P1)

Routine, structure and consistency was very important in the midst of chaos.

"It gave me a routine because I haven't had much of a routine outside of parenting." (P7)

"You need to know that something is going to be there, be routine" "your life is erratic enough." (P12)

"You're guaranteed that you're going to be here all the time you know and that's a huge thing." (P12)

"It's routine because routine is the most important thing when you're, especially when you're down." (P12)

The participants perceived the facilitators input as intrinsic to the approach. Trust was imperative. One participant discussed the difficulty of being questioned by someone in authority when having extremely low self-worth, and the importance of empathy and kindness. She conceded that *"the teacher makes a difference!" (P5)*

"I appreciate you being the teacher." (P33)

"Took an awful lot of gentle persuasion from yourself to get me in there." (P12)

"The way you listen and talk to us."

"Only for the facilitators I think I wouldn't have lasted." (P9)

The importance of each interaction was evident.

“You know, no matter how I'm feeling, and you've seen days where I come in and I just don't even want to know, but I always go away feeling so much better.” (P12)

“I think that exercise, eh looking at lifestyle in a way with regards to people who, no matter what your circumstances are, but especially if you're em dealing with addiction and homelessness, it's so, so important. Just making somebody feel better after they exercise makes such a big difference.” (S3)

5.3.3.2 Gender sensitive

This programme was designed for women and about women. It discussed women's health issues, physical activity recommendations and basic nutritional advice and it incorporated a core stability exercise set designed to strengthen the core and pelvic floor muscles for women with post-natal, pre- and peri-menopausal symptoms.

This gendered approach was appreciated for many reasons. Some just preferred the company of other women and were more at ease in a women's-only space.

“The fact that there were women, I think it was maybe it was more focussed, like on our wellbeing and stuff.” (P11)

“I reckon if there has have been men, I wouldn't have been so open, definitely I would pulled back.” (P9)

“I would never go to a gym, how embarrassing that would be! With men watching you!” (P2)

“You just let your hair down more just.” (P23)

Some reported that women support women, women connect and create a different dynamic when together.

"Because female support is very important you know. (P8)

"That we're all women and we can talk about anything and confide, which makes me more secure."

"You have other women there to motivate you as well." (P19)

Some had a history of trauma and domestic violence at the hand of men and felt safer among women.

*I've been through domestic violence as well, so I kind of find men a bit scary,
(P2)*

"It felt very safe place; (P19)

"It was important to me. I knew that once I walked in that door it was a safe space for me."

"They were really comfortable in this space, and they felt safe, and they felt like they could be themselves." (S2)

One stakeholder discussed how women are different (to men) and have unique needs.

"When it comes to women and their bodies there's is another element, there as well, because a lot of women have issues with their body and have different needs. And when it comes to the menopause and any hormonal stuff as well, exercise has a huge impact on that too." (S3)

Some had weight issues and were sensitive about it.

"I'm really insecure about my weight." (P19)

"Back was very sore and what you call it and I wanted to do that, plus to lose eh weight." (P5)

“Focussed superficially around losing weight.” (P7)

“We see a lot of eating disorders and those kind of body issues with a lot with women as well.” (S4)

5.3.3.3 Low threshold

In harmony with a trauma informed approach, the low threshold nature of the programme enabled this cohort, who normally have difficulty engaging in services, to attend the programme with minimum barriers to entry. They were accepted as they were. The flexibility and openness were appreciated and removed the stress of getting to the classes. It put them at ease.

“It was amazing for me because it gave me a chance, I didn't have to rush in you know.” (P9)

“Different times and a lot of understanding if you couldn't make it.” (P19)

“You were very flexible with the times and even if I came late or whatever, you tried to give me a chance.” (P23)

Other reported recovery programmes were conditional on abstinence from substances and the accessibility of this programme was viewed as really important.

“Other services you're not ready, you're not stable enough, you're on too many substances...” (S4)

5.3.3.4 Group-based

Although individual sessions were offered and delivered as requested, the LEAP-W programme was primarily delivered in a group setting. This feature was appreciated.

“Group work is really important because they engage with the other group members as well. The exercise isn't just working at purely physical level, it's also

working at a social level then as well and allowing them to build relationships with each other (S3)

One stakeholder felt that separate groups for people at different stages of their journey of recovery may improve the class dynamic and also help those who are more stable to better engage with mainstream services. It was agreed that 'one size fits all' model was not going to work in this setting.

"Tighter boundaries actually around the timing can actually be better for them ... They're seeing the routine and then they'll start to turn up for other appointments on time ... you know, and they'll see that this is how the real-world works." (S4)

On the contrary, many enjoyed connecting with people they may not normally meet and share experiences with others who had similar challenges.

"The way we talked through the exercise, it makes us get closer and be friends with each other." (P33)

"The buzz of the class... we're all in this together like". (P1)

5.3.3.5 Multi-modal

This programme was multi-modal to target physical functioning deficits and frailty and to meet physical activity recommendations, but within this framework it also offered choice to participants who could do an exercise class, or a Park Walk or both ideally. Within the exercise class, choice was also offered in terms of the variety of exercises within the circuit, as well as in tailoring the exercises for participants with a diverse range of fitness, co-morbidities and sometimes disability.

"I think you did it very well and you brought a lot of variety into it, different exercises and you were very flexible ... you'd have different people in the class doing different exercises at the same time." (P23)

"I really appreciated your tailoring the exercises to, you know." (P2)

"Really beneficial for it to be tailored to them." (S2)

5.3.3.6 Sustainable

Maintaining progress and incorporating physical activity into the daily lives of those who participated in the programme was discussed. Participants who attended regularly expressed a strong desire to continue exercising. Many hoped that the classes would continue and had expressed this to staff and plans were underway to introduce exercise as a regular intervention in the centre. Many felt they needed support and encouragement to start the programme and also to persevere with it and felt that they would need ongoing support.

"The chances of me doing it on my own are a lot smaller you know." (P1)

"I can't do it on my own, so I need some connection to people you know, so because I am a big isolator." (P8)

In addition to the low threshold, flexible and trauma informed approach discussed previously, perceptions of other facilitators and barriers to the programme provided further insight into how future programmes should be designed facilitate sustainability. The daily What's App reminders were viewed as hugely important in motivating people and instilled a sense of belonging to participants.

"That was a huge, it was a huge factor I think, in the engagement with the women, sending the reminders." (S4)

“Like the lovely messages that you send out in the morning ... I do say to myself, like for someone even to think of ye like that, to take time to send a message out to you like, that’s says something in itself, you know.” (P9)

Barriers to access were discussed and some participants and stakeholders had concerns about location. This was a factor in attendance for different people for a variety of reasons, including basic needs, security, distance and transport. Some participants with chronic medical conditions used public transport and walked some distance to attend and this was effortful.

“Access, again it’s fundamental, I mean people don’t have access to clean clothes, to clean underwear ... the humiliation of being asked to go anywhere... a lot of it goes back to basic hygiene and fundamental nutrition.” (S6)

“I’d just worry about the location. I tried to get women down there and they’re saying to me ‘oh where is it’ ‘what bus do you get’ ‘oh I’m not walking down there.” (S6)

While one participant talked about the importance of engagement with participants prior to the commencement of such programmes,

*“It would have been good to meet you and talk to you before the assessment.”
(P5)*

many spoke of the new learning from the brief interventions delivered throughout the programme, including the importance of exercise and nutrition.

"It definitely made me think of protein and nutrition and how important it is and sometimes my diet isn't really good so it's good to know there's supplement out there just like a protein shake if you find it hard to eat nutritious." (P19)

"I hadn't done those exercises before, so I wasn't really aware that they were important for women to be doing." (P23)

"It can improve your health if you stick with it, like if you really stick with it and get yourself into a structure." (P1)

However, a number of participants were empowered by the programme and were already exercising independently.

"I was doing me thing this morning, me stretches, me neck." (P9)

"A few times I would go to swimming or maybe use the gym facilities. (P19)

*"Exercises that you gave me and the band, I do that sometimes up in me room!
(P21)*

"I'll continue to exercise because I can see now that for you to live this life in a healthy .. you need to keep on" (P33)

Stakeholders and participants discussed sustainability of physical activity programmes and future plans. They felt that it would be important to incentivise people to attend.

*"Really great thing for the women to get and their certificates at the end of it."
(S4)*

"I'm trying to get a gym pass." (P9)

They discussed things they could do in the short-term following the programme, as a way to

“help people to reintegrate into their communities.” (S4)

Stakeholders saw the desire for continuity and the momentum the programme had created and had plans to nourish this.

“The Park Walk is definitely something I think that we could do.” (S4)

“We even have plans for a personal trainer to come once a week to continue exercise, with the ladies.” (S1)

They saw the merit in prescribing exercise for recovery and health and appreciated the simplicity and accessibility of the exercises utilised in the programme and how much of the programme content could be translated and sustained in the community.

“We social prescribe and exercise will be one of the main things that we would be use.” (S2)

The LEAP-W programme was impactful for those who participated.

“It has been really successful. And we’re so grateful.” (S1)

Speaking of one participant who attended: *“... like a miracle.” (S2)*

“The numbers in themselves have shown that the interest was there. Em, no, ye I do I definitely think it’s been successful.”

“Life changing.” (P12)

“I appreciate it has improved me, you know it has made me to be positive of myself. It has made me to have a positive energy, that, you know I can do this, and then we keep pushing, just to reach the target.” (P33)

5.4 Discussion

This study’s qualitative findings indicate that the LEAP-W targeted exercise programme with protein supplementation which was uniquely designed for this cohort of women who experienced homelessness, addiction and mental health challenges positively influenced health and wellbeing in multiple domains and had far-reaching impact. The approach to the delivery of the programme is considered key to the success of the programme.

5.4.1 Theme 1: The power of exercise

While the overarching aim of this study was to target physical function and frailty, the power of physical activity led to wider benefits as outlined in the results section of Theme 1. Exercise was strongly viewed as a vehicle for impacting not only physical health but also social and psychological well-being and for some these benefits were considered more important.

5.4.1.1 Physical health impact

Improvement in physical health and function was reported by participants and stakeholders. While positive effects of exercise on physical function and frailty in older people is well documented, there is little evidence of its effectiveness in people experiencing homelessness, addiction and mental health challenges, particularly in a population who have physical functioning deficits or frailty (Travers et al., 2019, Jadcak et al., 2018, Dawes et al., 2024). In a mixed-methods systematic review, Dawes et al (2024) found 11 qualitative studies of physical activity interventions in people

experiencing homelessness, albeit most studies involved vigorous exercise interventions (e.g. soccer), less suited to people with lower physical functioning, co-morbidities and frailty (Dawes et al., 2024). Two of these qualitative studies involved women and aligned to this study's findings of physical health improvements (increased fitness, increased energy, reduced pain, weight loss and increased levels of physical activity) (Dawes et al., 2019). Increased participation in physical activity with resultant increased fitness was also reported in mixed gender qualitative studies (Malden et al., 2019, Kendzor et al., 2017).

5.4.1.2 Mental health impact

The intrinsic benefits of the LEAP-W programme were seen to extend well beyond the physical domain. Exercise was viewed as a coping strategy, assisting in modulating mood by its ability to distract from the unrelenting stresses of life. While perceptions of low self-esteem and self-worth were commonly reported, feelings of enhanced confidence and self-worth, and a sense of pride in one's achievement were described following the intervention. The value of this programme for altering these negative self-perceptions needs to be acknowledged. These findings concur with Malden et al who reported subjective findings of improved self-esteem and well-being following a structured exercise intervention (Malden et al., 2019). Similar findings of improved mental health outcomes were reported in other women-only studies (Dawes et al., 2024, Grabbe et al., 2013, Shors et al., 2014, Miller et al., 2025).

The greater value placed on the mental health benefits than physical health in this study participants provides an important insight for planning of future interventions to target physical health, evincing how these two constructs of health are so deeply intertwined and intricately impact on each other (Ohrnberger et al., 2017). It

is felt that this interconnectedness should be utilised when designing future exercise interventions which aim to target the physical health burden of this population.

Enhancements in mental health may transfer to physical improvements. Moreover, these enhancements may alter mood and motivation to facilitate greater engagement and retention in programmes which require higher adherence to achieve effectiveness in physical function outcomes.

5.4.1.3 Social impact

The positivity this programme provided was evident in the reported fun and social connectivity. It gave participants an opportunity for interaction and enabled people, who would have been more accustomed to splintered connections with others, to come together and pursue a shared objective. It fostered a sense of community and belonging in the camaraderie which was seen to develop over time and is viewed as a vehicle for enhancing social capital and inclusion which is critical for physical and mental health.

The positive interactions and the observed connectedness appeared to be rewarding and regulating. This finding is consistent with Spaaij et al (2009) who found sport to contribute to 'the social mobility' of a disadvantaged population (Spaaij, 2009). While many participants and stakeholders alluded to negative perceptions of self and low self-worth, some felt that the programme had led to an altered positive sense of self where they began to prioritise their own needs. This is also borne out in the literature (Sherry, 2010a).

5.4.1.4 Impact on substance use

Participants and stakeholders referred to the reduction or in some cases the postponement of substance use which points to the value of exercise as a potential and

easily accessible auxiliary treatment for those with addiction issues. This is borne out in the evidence base, where reduced cravings, abstinence and reduced rate of relapse following exercise intervention has been documented, yet it must be acknowledged that results are mixed and there was heterogeneity in the quality and the design of the studies (Wang et al., 2014, Abrantes and Blevins, 2019, Linke and Ussher, 2015, Ye and Liu, 2023).

5.4.1.5 Health literacy

Informed by LEAP-II and the PPI engagement session prior to LEAP-W, the brief interventions were delivered in a deliberate, yet flexible and opportunistic fashion. Attempting to evade perceptions of a power dynamic between the researcher or educator, the researcher considered that the non-confrontational approach utilised facilitated successful interaction among the study participants and fostered a comfortable learning environment where participants were provided with a nugget of health information and could then share their knowledge and views and lived experiences with each other. Similarly, Malden et al (2019) reported positive attitudes towards workshops (of 2.5-hour duration) which were delivered alongside exercise intervention (Malden et al., 2019). Participants in this study, however, recommended briefer workshops with more structure in the topics of discussion, both of which were provided in the LEAP-W study. Enhancing health literacy is viewed as critical for long term sustainable impact on physical activity participation, particularly in a cohort with overall poor baseline levels of physical activity.

For most participants physical activity or good nutritional health was not a familiar or cherished health behaviour. Supporting this, quantitative results from LEAP-W, identified a negligible number who exercised regularly (3%) or even occasionally

(6%) at baseline. The literature concurs with these findings. In a cross-sectional study, Wilson (2005) reported that the least practiced health-promoting behaviours for women in homelessness were physical activity and nutrition (Wilson, 2005). This finding of reduced exposure to exercise or healthy nutrition may be attributed to limited resources, food insecurity, as well as poor health literacy, known to affect health outcomes (Magnani et al., 2018, Tong et al., 2019). The apparent lower health literacy which was observed is considered an obstacle to engagement in physical activity programmes.

In conclusion, despite an undertone of tension to engage, Theme 1 demonstrated the power of the exercise intervention to influence positive health behaviours and yield benefits beyond the physical domain. The multi-faceted ability of exercise to contribute to health and wellbeing was evident. These additional health benefits are considered critical for future programmes to target physical health, a domain of health which is not viewed as a priority by this population.

5.4.2 Theme 2: Challenges to engagement

5.4.2.1 Backstory and life course

Theme 2 identified significant challenges encountered by this population which explain this study's attrition and point to wider issues of this population's poor engagement in health interventions generally. It illuminated health and social disparity which was vividly described and borne by the participants of this study, a population known to experience greater obstacles to accessing healthcare than the general population (Ingram et al., 2023a, Marmot and Bell, 2012). Many alluded to adverse childhood experiences, disadvantage and deprivation which did not augur well into adulthood frequently resulting in risk-taking behaviours such as smoking, drug and

alcohol misuse. Drinking and substance use were viewed as coping mechanisms which in turn led to shame, guilt and stigma. Participants reported low self-care, expressed pessimism about improving their health and identified more easily with a chaotic lifestyle. This low regard for oneself is commonly reported in the literature (Paudyal et al., 2020). Low self-care led to health issues.

5.4.2.2 Perceptions of self

Another negative, acquired consequence of adversity and social exclusion which was commonly reported the low confidence and self-esteem. Concurring with this, Malden et al (2019) reported baseline levels of low confidence, anxiety and depression in their research of a physical activity intervention in people experiencing homelessness (Malden et al., 2019). Participants in this current study who reportedly felt undeserving of a better healthier life were therefore less likely to engage and commit to a health promotion intervention. This cognitive dissonance and sense of hopelessness was evident for many, who, despite cited immediate positive impact of initial exercise sessions failed to attend on a regular basis.

5.4.2.3 Lifestyle and living environment

For those living on the fringes of society in unstable and insecure accommodation such as hostel accommodation and rough sleeping, survival was inevitably prioritised over health and exercise. The literature concurs. O' Carroll and Wainwright (2019) describe homeless peoples' sometimes fatalistic perceptions of their health and future prospects (O'Carroll and Wainwright, 2019). While many of this study's participants enjoyed the distracting effects of exercise from life's stresses and 'street chaos', other factors like hygiene and limited resources such as clothing and footwear, travel and transport, unmet nutritional needs and sleep deprivation were

cited obstacles too great to overcome to commit to the programme in a meaningful way (O'Carroll and Wainwright, 2019). Dawes et al (2019) reported that women were sometimes hesitant to exercise due to poor self-image and perceived stigma and being provided with better exercise clothing and footwear improved their self-esteem and likelihood to engage in physical activity interventions (Dawes et al., 2019). Barke et al (2023) concurs with this sentiment and called for support for exercise in conjunction with adequate hygiene facilities enable this (Bark et al., 2023). This is an important consideration for future research.

5.4.2.4 Social exclusion

The social exclusion this cohort experienced appeared to be created by a complexity of individual and societal factors. Homelessness itself is considered an extreme form of social exclusion and accompanied by the isolating effects of addiction and mental health challenges, manifested in the loneliness and perceived imprisonment cited by many of the study participants. This was further compounded by a society and healthcare system which was viewed as inflexible and exclusive. This is also borne out in the literature, where mainstream services are viewed as poorly designed to meet the needs of this population (Gilmore et al., 2025, Siersbaek et al., 2021).

5.4.2.5 Health issues and healthcare needs

The women discussed their spiralling health conditions which included physical and mental health issues. For many these health conditions were often compounded by their unstable living environment including rooflessness, temporary, insecure or inadequate accommodation. This instability created an immense challenge to endure a dual diagnosis, or often a tri-morbidity, with an additional physical health condition to

manage. This in turn affected their motivation as well as their physical ability to participate in the programme. The presence of chronic and multiple health conditions highlighted the need for intervention to target physical health, but many conceded that this was rarely on their radar. Stakeholders concurred with the research findings that this cohort rarely engage with primary healthcare providers, excluding themselves from free healthcare in the community which to them is perceived as inaccessible, a commonly reported finding in the literature, resulting in crisis management and a reliance on acute care (Ní Cheallaigh et al., 2017, Ingram et al., 2023a). Nonetheless, it needs to be acknowledged that health system factors also play a role in this perceived healthcare avoidance (Siersbaek et al., 2021). On the other hand, some participants were informed about exercise and had a positive outlook and curiosity about the programme, while others discussed past positive experiences of exercise and interest was expressed in attending the programme. These factors were believed to positively influence attendance and perseverance with the programme. This is considered vital and needs to be nurtured.

Furthermore, a number of women in this study reported unhealthy relationship with food and body dysmorphia, and weight management was often a driver to participation rather than seeking to improve physical health and longevity.

The UKs ARMA (Arthritis and Musculoskeletal Alliance) report of 2023 identified that the most significant social and economic factors influencing poor musculoskeletal health and inequality were poverty, education, employment and environment and a culture that discourages physical activity and healthy nutrition (ARMA, 2024). These factors align with the findings in this study of extreme adversity through life, deprivation and disadvantage, accompanied by an unhealthy lifestyle and perpetual

exclusion from society and were thought to contribute to the extreme, premature and complex health profile of this population. ARMA also found that these disparities were avoidable. The need to approach health and its wider determinants in a more innovative and inclusive way is evident.

5.4.3 Theme 3: The LEAP approach

It is clear from Theme 1 that the intervention made an important impression on those who committed to it on a regular basis, yet Theme 2 highlighted many complex reasons for others who could not engage to a degree sufficient to reap such rewards. They were at a different stage in their life journey and coming from a trauma-permeated environment of unpredictability and chaos, made adapting to other more structured environments extremely challenging. This final theme reflects on the unique design and approach of this intervention, which was successful in making the journey navigable for some and provides insight for future accessible exercise interventions in this group.

5.4.3.1 Trauma-informed

It is evident that the situational and behavioural factors associated with the women in this study stemmed from intersectionality and the interconnectedness of gender, socioeconomic status, ethnicity and mental and physical health needs. Stakeholders alluded to their (participants) exposure to childhood adversity, adulthood trauma and their associated complexities which led to trauma-related behaviours and impeded meaningful engagement. Trauma informed practice is an approach which aims to reduce the negative impact of trauma, known to impact on physical, mental and social health and is advocated in health and social care interventions (GOV.UK, 2022). While evidence of its effectiveness is inconsistent across diverse domains (Han et al., 2021),

trauma informed practice has proven effectiveness in the provision of care to people experiencing homelessness and specifically, women in homelessness (Kirwan and McLaughlin, 2024). It is felt that trauma informed care may have increased service user engagement and had a domino effect on the attendance rate of the LEAP-W intervention. The trauma informed approach utilised in this study was appreciated by stakeholders who noted the positive engagement in the programme by participants and the participants, while not referring to the trauma informed terminology, alluded to the nature and approach of the programme which was designed with them and for them. This approach helped people to feel valued and included.

Integral to provision of trauma informed care (TIC) is the role of the facilitator. This was viewed as paramount to all respondents (programme participants and stakeholders) and seen as a contributory factor to the programme's success where people wanted to return and grieved at the notion of it ending. Consistency, empathy, trust, encouragement, and a non-judgemental attitude were characteristics which were greatly valued by the participants and staff, who felt that 'the teacher makes the difference'. These factors led to an environment where people could relax, feel safe and be themselves which enabled the benefits of exercise to build over time, as people felt compelled to return. Malden et al (2019) report similar positive feedback regarding interactions with programme facilitators (Malden et al., 2019). Trust and a trusting relationship built by the facilitator is considered the critical principal of trauma informed care, a cognitive concept and emotional state often eroded in people who have experienced deep trauma and is key to connectedness, healing and engagement (Gilmore et al., 2025). Future exercise programmes should be trauma informed and led by facilitators with trauma-informed training.

5.4.3.2 Gender sensitive

Historically women's experiences of homelessness have been hidden or not acknowledged (Oudshoorn et al., 2018). One stakeholder agreed and alluded to this sub-group as the 'forgotten' women, as services for women continue to lag behind those for men. The evidence, as discussed in Chapter 1, indicated that women's experiences and needs are very different to men with reported disproportionate rates of adverse childhood experience (ACE) scores, mental illness and suicidal ideation in women compared to men and linked to this, women are known to avoid or delay seeking help, especially when delivered in mixed-gender settings (Morton et al., 2023, Rog et al., 2007, Mutatayi et al., 2022). In this qualitative study many of the women were explicit about their insecurities around men and desired a safe space where they could go and 'let their hair down'. This finding was also observed in a linked study, the LEAP-I trial, which was set in a mixed-gender location (Kennedy et al., 2024). In this study, the women found security in Jane's Place and in the programme. Conversely, a number of women cited that they would not have objected to a mixed programme with men, but they expressed they preferred the company of other women and were more at ease in a women's-only space. Nonetheless, they appreciated, as did the stakeholders, the women-centred approach which focussed on the unique differences of women and their bodies and the way in which it was tailored to their specific needs. The majority of this cohort were over 30 years and were mothers and approximately half were either peri or post-menopausal. They reported low baseline physical activity and poor nutritional health. They found the brief interventions (which focussed on topics including the natural decline in muscle mass from the third decade, exercise and nutrition and commonly reported low back pain management and pelvic floor strengthening) both relevant and engaging. For a group with heightened markers for

physical decline and sarcopenia the relevance of a gendered focussed intervention is considered significant.

5.4.3.3 Low threshold

For people who experience trauma, stigma and face exclusion from mainstream services, low threshold services where minimal constraints are placed on service users assists in breaking down barriers to access. This includes not imposing conditions of abstinence from substance use, an unrealistic expectation of those with addiction issues. The LEAP-W adopted a non-judgemental 'come as you are' approach, facilitating inclusion and offering flexibility in the days and times of the programme's sessions, as well as flexibility withing the sessions (aerobic, strength-based, balance and flexibility exercises). This feature was important to people who led chaotic unstructured lives. Yet also they valued the routine and structure that the programme provided and its consistency for the 10 weeks it ran. Some participants, however, expressed grief at the thought of the programme ending, a grief which was considered disproportionate and attributed to 'abandonment issues' and childhood trauma. This finding warrants attention. A tapered exit is recommended where finite programmes such as the LEAP-W programme are delivered. However, planning beyond short-term funded interventions which have proven successful and yield impact is important to facilitate ongoing consistency and follow-through and avoid re-traumatisation.

5.4.3.4 Group-based

The effectiveness of group-based exercise interventions has been demonstrated in a range of sub-populations including people experiencing homelessness, people with mental health difficulties and people with frailty, and a myriad of health benefits have been reported (Shannon et al., 2020, Peng et al., 2023, Malden et al., 2019). The LEAP-

W trial was primarily group-based. Individual sessions were delivered upon request, and participants also noted the value of this time to focus on their own specific needs or sometimes to decompress after a difficult day. Tailoring the programme (in individual or group settings) was important to address the specific physical health conditions identified as well as to assist in providing participants with exercises which were suitable and replicable in their own living environment. Most importantly, however, was the concept that tailoring the exercises signified value which was placed on the individual and is a further marker of the trauma informed approach taken. The general consensus was that the group was the glue that built cohesion, fostered a sense of shared experience, connectedness and inclusivity. It was a social opportunity and enhanced social interaction. This is thought to have driven retention.

5.4.3.5 Multi-modal

In order to fulfil the aims and objectives of this study to target physical function and mitigate frailty an evidenced-based multi-modal and multi-component programme was designed (Travers et al., 2019). The WHO advocate combined aerobic and strength training to enhance physical health and fitness (WHO, 2020). Moreover, the evidence suggests that strength-based exercise with nutritional supplementation is the most effective and easiest to implement in targeting frailty in community-based older people (Travers et al., 2019, Puts et al., 2017). In fitting with the principles of trauma informed practice and low threshold services, the multi-modal and tailored approach to the exercise intervention enabled collaboration and choice within the programme, which was viewed as empowering. The main aerobic component of the intervention, the Park Walk was enjoyed by many of the group. Walking is known to provide therapeutic rhythm with its repetitive, patterned movement which positively stimulates neural

brainstem activity in trauma patients (Perry, 2009). This attribute coupled with the restorative benefits of green space and connectedness of the group provided an accessible therapeutic tool for those who participated in this activity (Liu et al., 2022). While its purpose was in promoting muscle synthesis (van Loon 2013), the palatable protein supplement following exercise was viewed as an additional benefit and reward at the end of an exercise session.

5.4.3.6 Sustainable

Sustainability of positive health behaviours is critical for long term change. Elements of the LEAP-W programme which facilitated this were the investment in health literacy to educate, empower and foster a sense of willingness and commitment to extend the benefits of the programme and also to address one's health issues and safeguard against future ill-health. With increased knowledge of exercise and nutrition, the programme enabled participants to set realistic goals to achieve physical activity recommendations.

Furthermore, a number of participants reported engaging in positive health behaviours including performing exercises at home and in the park, working on posture, taking more walks, skipping and using the therabands provided. Moreover, the brief interventions increased awareness of the role of nutrition in health, in particular muscle strength and performance. These reported behavioural changes in turn are likely related to reported improvements in confidence and self-esteem. Increasing physical activity performance outside of the programme is critical for autonomy and sustainability. Malden et al (2019) reported improved attitudes, mood and health behaviours following physical activity intervention for PEH (Malden et al., 2019).

In conclusion, this qualitative narrative has powerfully demonstrated that designing an intervention to meet the needs of this unique population, who experience poor health and exclusion from mainstream services, increases the likelihood of engagement and retention and can lead to wide reaching improvements in health and wellbeing. By expanding the scope of this research inquiry, into the role of exercise in a sub-population who experienced SMD, beyond the quantitative findings of Chapter 3, this qualitative inquiry converged to demonstrate the holistic impact of exercise. The complementarity of these findings and their implications will be discussed further in Chapter 6.

Chapter 6 Discussion and conclusion

This concluding chapter discusses the critical findings from each study in this PhD and outlines how these findings contribute uniquely to the evidence base. It will describe how the outcomes of these studies will inform future research, translate to routine practice, assist in policy change and support education and professional development of an attuned workforce who may advise, recommend and prescribe exercise to people experiencing homelessness, addiction and mental health challenges. Table 6.1 provides an overview of this chapter.

Table 6.1 Overview of Chapter 6

6.1 Reflection	6.1.1 LEAP-II: critical findings and implications 6.1.2 LEAP-W-Quantitative inquiry: critical findings and implications 6.1.3 LEAP-W-Qualitative inquiry: critical findings and implications 6.1.4 Comparisons, overarching themes and complementarity of the LEAP interventions
6.2 Strengths and limitations	
6.3 Implications	6.3.1 Implications for future research 6.3.2 Implications for practice 6.3.3 Implications for policy 6.3.4 Implications for education
6.4 Conclusion	

6.1 Reflection

This section reflects on (i) the main findings from each study and critical issues raised, (ii) comparison to existing research in this field and their novel contributions to the evidence base, and (iii) the progressive learning from each study which informed, enhanced and complemented the next.

This PhD was primarily about homelessness and health. The semi-heterogeneous nature of the participants in the studies of this PhD need to be acknowledged. While the majority of the participants experienced past or present homelessness (LEAP-II: 86%, LEAP-W: 82%), not all did. Nonetheless, as these statistics were self-reported, the true figure may be greater. Furthermore, all participants experienced severe and multiple disadvantage (SMD) and social exclusion and shared many important attributes which contributed to their poor health profile and physical health limitations, which underscored their eligibility for the interventions which were delivered to them (Lankelly Chase, 2024).

To recap, the aim of this thesis was to explore the feasibility and holistic impact of an optimised, low-threshold, multi-modal exercise intervention with protein supplementation delivered to a non-geriatric cohort of people with SMD (Lankelly Chase, 2024). In terms of impact, physical function and frailty outcomes were the principal constructs of interest and exploration, in advancing the work of preliminary research in the LEAP-I trial (Kennedy et al., 2024). However, to enhance future research and practice, and to address the barriers and facilitators to engagement with this perceived 'hard to reach' or 'seldom heard' population (Freeman, 2020), co-design and key stakeholder involvement was a further critical objective and design feature and facilitated an exploration of programme impact beyond the physical domain.

6.1.1 LEAP-II: critical findings and implications

In harmony with the LEAP-I trial, key findings from LEAP-II provided evidence supporting feasibility of targeted exercise interventions in people experiencing homelessness, demonstrated by safety and acceptability, high retention in subgroups of older people and women, and high adherence to the exercise and protein supplement.

The other principal finding of LEAP-II was its impact in the regular attenders where pre-post-intervention improvements were demonstrated in several outcome measures (gait speed, pain, nutritional status and frailty). The greater exercise frequency (in comparison to the preliminary LEAP-I trial) and accessibility of the exercise sessions appeared to assist retention and are likely to have contributed to the observed positive impacts. Therefore, proof of concept was indicated. A recommendation from LEAP-II was the inclusion of health promotion and education sessions for future interventions to target low health literacy which was considered important to achieving longer term benefits and sustainability of physical activity.

Another critical finding in LEAP-II was the concerning level of pre-frailty (by CFS) in this non-geriatric cohort and also the association between frailty and poor nutritional status ($p < 0.000$) and addiction status ($p = 0.023$). The CFS detected psychosocial and behavioural markers of frailty beyond the physical domain and beyond the scope of the SHARE-FI and help explain the findings of the regression tests, which suggest poor nutritional intake as a predictor of frailty ($p = 0.015$).

The test battery, which demonstrated acceptability, utility and feasibility, was subsequently proposed for use in evaluating physical functioning and frailty in community-dwelling people experiencing homelessness and addiction challenges (Kennedy et al., 2025). Considering the high usage of unscheduled acute care in this population, the timely surveillance of physical functioning deficits and frailty in community settings for this population is deemed important, to identify those with lower functioning and greater frailty, with a view to implementing targeted interventions to mitigate their adverse effects. Moreover, its relevance in promoting a primary care strategy for primary healthcare needs should be acknowledged. This

sentiment of screening for frailty in this setting has been very recently endorsed, in a Lancet opinion piece by Kamal and Vickery (2025), who point to a concerning level of frailty found in 18-24 year olds who experienced homelessness (Dawes et al., 2025b) and make recommendations for frailty interventions including structured physical activity to prevent or treat frailty (Kamal and Vickery, 2025).

While acknowledging its limitations, the exit survey in LEAP-II highlighted important issues regarding retention and the potential impact of exercise on abstinence, as well as psychological wellbeing on the study's participants. It also left unanswered questions regarding the impact of targeted exercise, beyond the physical domain, in this unique and under researched population and whether impact is different in certain subgroups, such as women. While all people experiencing homelessness should be included in health research and mainstream healthcare and should be referred for therapeutic exercise to manage their physical health deficits, LEAP-II highlighted a research gap and opportunity, where subgroups who engaged well and had complex and unique needs, which required a different approach. One of these subgroups was women, a traditionally under researched and highly vulnerable group within homelessness and addiction settings. This finding warranted attention and further investigation and led the LEAP-W trial.

6.1.2 LEAP-W-Quantitative inquiry: critical findings and implications

When compared to LEAP-II, it must be noted that LEAP-W was optimised in terms of the availability of additional gym equipment and it was located on site, in Jane's Place, a purpose-built site for women, which was warm, bright and inviting. LEAP-W had a gender-specific focus and therefore had a more homogeneous group, a

group of women who bonded through the shared experience and this was considered a factor which contributed to the higher retention rate in LEAP-W.

Key findings from the LEAP-W quantitative inquiry were its feasibility and impact in women experiencing homelessness, addiction and mental health challenges, through a higher retention rate (38.7%) in the study's' regular attenders, when compared with LEAP-II (26%). Safety, adherence and acceptability of the intervention, and also the detection of improvements in certain areas of physical functioning (strength, balance and pain) and in mental health outcomes in the regular attenders was also demonstrated. These findings align with LEAP-II demonstrating the value of targeted exercise in this population.

LEAP-W was a study designed for women only and baseline findings indicated important gender specific considerations, namely the proportion of women who were peri- and post-menopausal (42%), the occurrence of early menopause in some (6%) and the risk of premature frailty and sarcopenia. Notwithstanding that the aetiology of frailty and sarcopenia in women is complex and multifactorial, it is likely to have been accelerated and compounded by the addition of adverse physical markers such as sedentary lifestyle, poor nutritional health and the presence of physical functioning deficits and chronic conditions which were present in this study's participants. Acceleration of sarcopenia during the menopause appears to be driven by hormonal changes and primarily by estrogenic decrease and the risk of developing sarcopenia may be attenuated by healthy lifestyle changes such as regular physical activity and diet (ie, adequate protein intake, sufficient vitamin D intake, omega 3) the interventions of focus in this study and PhD (Buckinx and Aubertin-Leheudre, 2022). This is noteworthy and illuminates a need for further research.

Advancing age was associated with frailty in this female sample ($p=0.002$), a well-established phenomenon, however, unlike LEAP-II addiction or nutrition status were not associated with frailty when examined in isolation. Interestingly, when considered with age however, both addiction status and nutritional status were found to be associated with frailty ($p=0.001$). This finding speaks to the protective effect of age in the younger participants in this study who were in their twenties. These younger participants may have the strength and resilience, due to their age, not to decompensate and become unwell when exposed to stressors. Nonetheless, they were more likely to be progressing faster towards a vulnerable stage of pre-frailty than the age-matched general population. When coupled with multimorbidity and unhealthy lifestyle behaviours advancing age was seen to contribute to frailty. This points to the need for implementing early targeted interventions.

The finding of an improvement in the Mental Component Summary score of the Short Form-12 health questionnaire indicated impact of LEAP-W beyond the physical domain. Positive benefits to mental health were also reported in the exit surveys of LEAP-II. While a primary objective of this PhD was to target physical health, the impact of exercise in this population beyond physical health was evident and required further exploration which was the focus of the qualitative inquiry.

6.1.3 LEAP-W-Qualitative inquiry: critical findings and implications

Key findings from the LEAP-W qualitative inquiry indicated that targeted exercise with protein supplementation extensively yielded impact beyond the physical domain in women who experienced homelessness, addiction and mental health challenges and the critical finding was that ‘the LEAP-approach’ was required to attain these positive outcomes. Improvements were reported in physical health, mental

health, social health, substance use and health literacy. An unanticipated finding in the LEAP-W trial was the reported improvement in pelvic floor strength and its ripple effect on mental health, affirming the value of the innovative and gendered design of this study, which incorporated a women's health component to the intervention. The reported value of the gendered dimension of the programme elucidates the need for bespoke women's-only interventions, a sub-population with unique needs. The significant benefit of social engagement was observed in this female cohort, testament to the importance of relational health in a population with a history of trauma and need for trauma healing through connection (Perry and Winfrey, 2021). This highlights the need for targeted trauma-informed interventions and in this context trauma-informed healthcare interventions. It is well established that exercise needs to be prescribed and delivered in a form that is adequate to make physiological changes to improve physical health or fitness, however, if it is not delivered in a way which is accessible to a population who have experienced adversity and trauma, this goal may not be attainable (Katsukawa, 2016). The design and approach to the delivery of exercise interventions for this population requires the LEAP-approach, an approach which is trauma informed, low threshold, flexible, group-based and multi-modal and it is proposed that this approach take precedence over exercise parameters initially to secure engaged and committed participation.

Reflexivity, a practice known to enhance and shape qualitative research was uniquely important in the context of LEAP-W due to the potential therapist-researcher dilemma which presented here (Braun and Clarke, 2023). The therapist and researcher (PhD author) had connected and built relationships with the study participants through the lifespan of the exercise programme and this, it could be argued, may have

introduced an element of bias to the qualitative inquiry, posing a challenge to the provision of the participants' complete and honest experience of the intervention.

Averse to this sentiment a number of participant and researcher-related factors demonstrated rather the strength and benefit of the relationship in this context. A number of participants came to the interview with notes which they had prepared in advance of their interview, indicative of their own self-reflection and the importance to them of having their voices heard. Some participants expressed extreme gratitude to a point which moved them to tears during their interview, while one participant returned and requested an opportunity to repeat the interview (which was granted) as she felt that she hadn't given it justice on her first attempt. Critically, participants also spoke of the importance to them of a lack of judgement, and the value of trust and connection that they had developed with the facilitator signifying that, had they not established a strong alliance of trust with the therapist/researcher, they would have been very unlikely to attend for the interview or speak as freely and honestly as they did. This is an implicit example of the nuances of engagement with this population.

Reflexivity was practiced by FK through a period of reflection after each interview, maintaining field notes and debriefing with her supervisor. FK was well attuned, through the prolonged time she spent with participants, as well as through the pre- and post-interview reflective notes, to their unique characteristics and needs, deemed necessary for the smooth progression of the interviews which were at times emotive. As a result, FK could remain neutral and objective through the interview process. Through the collective factors outlined in this section, the researcher considers a comprehensive and honest account of the lived experiences of the

participants was provided, thus facilitating an authentic evaluation of the impact of the intervention.

6.1.4 Comparisons, overarching themes and complementarity of the LEAP interventions

The LEAP-II and LEAP-W interventions attest to the feasibility and positive impact of exercise on physical function, frailty deficits, mental health, social health and wider life in people with SMD (Lankelly Chase, 2024). They have demonstrated the prevalence of premature ageing and frailty in this non-geriatric population and reiterate the urgent call for early intervention. The quantitative and qualitative components utilised in the LEAP-W trial demonstrated complementarity and enabled a more comprehensive picture to emerge of the value and holistic impact of targeted exercise and importantly identified the significance of a unique approach required to drive successful exercise interventions for this population, whose needs are complex and vastly different to the wider general population. The introduction of 'the LEAP-approach', a low threshold, flexible, trauma-informed approach marks a novel contribution to the field of exercise prescription and delivery in this population.

While other exercise studies conducted in homeless populations also identified physical health, mental health and wider life benefits comparable to findings in the LEAP-II and LEAP-W trials, none provided a structured exercise framework of a suitable intensity to target low physical function and frailty syndromes, which are known to exist in concerning proportions in this population (Dawes et al., 2024, Kiernan et al., 2020, Aldridge et al., 2018). The majority of preceding studies targeted those with higher physical functioning levels required to participate in high level sports activities such as soccer (n=8), cycling (n=1) and running (n=1) (Dawes et al., 2024, Jiménez-Sánchez et al., 2024). The majority of studies were qualitative (n=11), and none used

mixed methods design to more comprehensively address the highly complex phenomenon of homelessness. Additionally, no study included the provision of protein supplementation post exercise to target muscle protein synthesis. One programme included an educational component considered critical for targeting low health literacy however the educational workshop was viewed by participants as too long, a reminder of the importance of PPI in study design (Malden et al., 2019). This thesis extends the work and recommendations of Dawes et al, (2024) with studies of 'specifically focused lower threshold physical activity interventions'. This emphasises the novel contribution to the evidence base provided by these studies. To the knowledge of the author of this thesis, this is the first time a frailty-focussed exercise programme with nutritional supplementation of a lower intensity and sufficient frequency has been conducted in this population.

Other studies provided more structured models in line with traditional mainstream healthcare systems. For example, one study provided two structured sessions per week for a maximum of one month and another provided two structured sessions per week for eight weeks (Jiménez-Sánchez et al., 2024). In contrast, Knestaut et al, (2010) boasted a more flexible approach and conceded that even further flexibility involving further exercise opportunities would have assisted in retaining participants who reportedly struggled with structure, routine and commitment. Their perspective concurred with the ethos of LEAP interventions, which emphasised that the flexibility offered within the programme, the emphasis on participant preference and choice, as well as familiarity with the instructor and the group, facilitated the positive psychosocial impact of the programme. The cornerstone of the LEAP interventions was the low threshold and flexible design, incorporating exercise, social engagement,

nutrition and education. These critical elements were embedded in the LEAP trials affirming the originality of this research approach.

Upon reflection on the work described in this PhD, a number of overarching themes emanated from the studies, which have important implications and will be discussed comprehensively in the final section of this chapter.

6.1.4.1 Positive engagement in exercise

Regarding engagement in exercise, participant feedback from LEAP-II and LEAP-W was overwhelmingly positive. Exercise session attendees, ranging from those who attended just one exercise session or to those who committed to the maximum number of sessions, engaged positively and meaningfully in each session. A myriad of reasons for this were evident from observation and qualitative feedback, which included enjoyment of (i) the physical activity and rhythmic movement (ii) the music, fun and social interaction, (iii) the positive engagement and interaction with the facilitator and the group, (iv) the informal educational discussions and associated learning, and also (v) the specificity the subgroup classes (gender and Traveller-specific classes) offered. This positive engagement even if transient led to immediate and for some potentially longer-term physical health benefits, mental health benefits and social benefits and is thus considered worthwhile and warrants further investment. This is a critical finding for a population who are perceived as 'hard to reach' and engage poorly with healthcare professionals.

6.1.4.2 Impact on addiction

Evidence from exercise intervention studies in substance use disorder recommends its use as an adjunct treatment, thus complete abstinence as a result of a stand-alone exercise intervention is unrealistic (Abrantes and Blevins, 2019, Wang et

al., 2014). Existing evidence has demonstrated the impact of exercise in enhancing mood, reducing drug cravings, improving cognitive functioning and improving sleep, assisting in reducing the risk of relapse (Abrantes and Blevins, 2019, Linke and Ussher, 2015). While not explored extensively in this PhD, the positive impact of exercise on substance use was evident in qualitative feedback, and stakeholders' views concurred with those participants who found that at times exercise provided a substitute for substance misuse or at least enabled its postponement. Concurring with the evidence base exercise is considered a powerful therapeutic tool and is recommended as a safe and cost-effective adjunctive intervention for people who experience dual diagnosis or tri morbidity and should be offered in any setting to assist in rehabilitation and recovery.

6.1.4.3 Impact on wider life

Anecdotally the legacy of LEAP-II was that the 'Park Walk' continued on an intermittent basis and as a result, a group of the female participants took part in the Dublin Women's Mini Marathon in 2023 and 2024. Moreover, one participant reportedly engaged in a rehabilitation programme following LEAP-II, and while we cannot attribute this to the programme, it was felt by the staff of the Ballyfermot Advance Project that the programme was a positive step for this participant, which may have had a ripple effect. A number of participants from LEAP-W referred to enhanced confidence as a result of the programme, which assisted in their engagement in the community. Following the LEAP-W, a once-weekly exercise class was initially established, however, this initiative lost momentum after some time and ceased. Nonetheless, it was replaced by yoga, selected by the service users, testament to the important of integrating the trauma-informed principles of voice, choice and

empowerment into all interventions designed for this population. This loss of momentum in follow up initiatives demonstrates the challenges of sustaining the momentum created by the intervention and should be further explored in future studies. Nonetheless these initiatives represent the ability of targeted exercise to enable people to take a step further in their recovery journey and point to longer term impact of exercise, which needs to be further explored.

6.1.4.4 Premature ageing, frailty and sarcopenia

The prevalence of premature ageing and frailty was evident in LEAP-II and LEAP-W, which aligns with literature findings (Dawes et al., 2025a). Developing frailty, a condition generally associated with older age, two to three decades prior to the chronological indicator of older age, is extremely concerning and it carries a premature risk of decline and syndemic disease. While explored more extensively in LEAP-W, and discussed in the previous section (6.1.2), women-specific factors, such as hormonal changes, perimenopause and early menopause likely accelerated the risk of sarcopenia and frailty (which are known to co-exist) in this female population specifically and undoubtedly contributed to the identified loss of muscle mass and function (Ye et al., 2023). This has significant implications for early morbidity and disability in this female population.

6.1.4.5 Challenges to recruitment and retention

Despite the aspiration and intent to make positive life changes, participants in LEAP-II and LEAP-W faced immense challenges and some struggled to commit to the programme. Aligning with the evidence base these challenges were rooted in habitual non-committal to health and social interventions due to personal and life factors, stigma, fear, a sense of hopelessness and futility and a comfort and familiarity with

chaos averse to the structure and routine of a programme (Reilly et al., 2022, O'Carroll and Wainwright, 2019). Moreover, they knew the programme would end and this led to familiar feelings of abandonment. This is borne out in the literature and needs careful consideration for future studies in this area (O'Carroll and Wainwright, 2019). Competing priorities, where survival and basic needs trumped the drive to attend an exercise programme, compounded by low health literacy where primary and preventative care was not practiced or well understood. While these challenges will remain difficult to overcome to optimise recruitment and retention, future programmes should better inform people, and in meeting people 'where they are at', attempt to build the programme to meet their complex and fluctuating needs. Timing is also an important factor which was evident in the qualitative narrative where one participant whose life circumstances changed felt ready to commit as programme neared completion, highlighting a further limitation of short-term interventions and need for long term programmes and studies.

6.1.4.6 Compensation for participation in research exercise studies

Partaking in research studies, which involve exercise in particular requires time, effort and motivation from participants and monetary or other forms of compensation needs to be considered. This is particularly pertinent in a population with low financial resources and who have lower levels of health literacy and may place less value on physical activity and exercise participation. Some research studies involving this population reimburse participants for travel expenses or provide tokenistic vouchers or even clothing/footwear to participate safely and comfortably in the intervention. While study funding limited the scope to significantly compensate participants, the author weighed up the value of a monetary reward on long term behavioural change and the

need to motivate participants to come to the intervention of their own will or desire. In this PhD, study participants were provided with basic pedometers/sports watches to encourage exercise participation outside of the programme. In both studies the protein drink was viewed as a well-deserved treat post exercise. Following LEAP-II and LEAP-W interventions, participants were provided with a certificate for their participation in the study. This non-monetary gesture was greatly appreciated as it was an acknowledgement of a significant accomplishment.

6.1.4.7 The effect of disadvantage and trauma and a trauma informed approach

A common thread in the majority of the study participants was a history of disadvantage, social exclusion and a legacy of trauma, which was reported by participants and stakeholders as the underlying cause of a number of the observed maladaptive behaviours, which often prevented or limited engagement. Challenging life events or often simple daily interactions could easily trigger and re-traumatise participants. Conflict among study participants was noted in LEAP-II and LEAP-W. This impacted on engagement to a degree, but the flexibility within the programme provided a strategy to circumvent this challenge. Moreover, competing priorities including dental and medical needs, housing issues and addiction issues reduced footfall to the centres and hence participation in both studies. Drop-off in attendance was particularly noted on bank holidays, where additional welfare payments were provided and anecdotally utilised to support addiction costs. Knowledge and awareness of trauma and practice of a trauma informed approach, which enabled the study researcher to identify and respond appropriately to maladaptive behaviours, was the bedrock of this PhD from which the exercise framework was built and developed from

the initial to the final study and is recommended for future targeted exercise interventions in this population.

6.2 Strengths and limitations

The primary strength of this work lies in the demonstration of feasibility and extensive impact of these targeted exercise interventions in this population with SMD and poor health, a population who are often excluded from traditional mainstream healthcare interventions including physiotherapy and exercise (Dawes et al., 2017, Lankelly Chase, 2024).

High feasibility of the suite of outcome measures utilised for this PhD was also demonstrated, as well as relevance, safety and usefulness of the test battery to evaluate physical function and frailty in this population in community settings (Kennedy et al., 2025). Another strength in relation to the outcome measures was the use of two distinct yet complementary frailty measures, which were easy to implement, and which identified important frailty attributes in this non-geriatric population. It is well established that frailty tools are plentiful and are developed and used for different purposes and different settings and often dual-trait measures are recommended due to the multi-dimensional nature of frailty (Martin and Brighton, 2008, Theou et al., 2015).

Another important strength was the pragmatic and flexible design of the studies, situated in real-world settings and which were designed to be inclusive and maximise participation in a 'hard-to-reach, hidden or seldom heard' population, who need a different approach, while cognisant of the need for fidelity to the exercise parameters required to establish effectiveness of the exercise on physical function and frailty (Freeman, 2020). As a result, high acceptability of the interventions was observed, and retention was considered high considering the extreme social challenges

faced by this population. The unique trauma informed approach is believed to have assisted this.

The use of co-design and qualitative methodology is considered a further strength as critically, it enabled the voices of people with lived experience of homelessness, addiction and mental health issues to be heard. In doing so it identified important design features which were incorporated into the interventions. It also facilitated a rapport and trust to be developed with a number of participants in advance of the intervention. The qualitative inquiry in LEAP-W captured the voices of participants who attended both regularly and sporadically, thereby providing a balanced view of the collective group.

Numerous limitations pertained to the LEAP-II and LEAP-W trials collectively. Firstly, while the sample size in each intervention study was relatively small, it was in line with recommended recruitment targets for feasibility studies and each sample was representative of the age and gender groups for which the methodology was developed (Sim and Lewis, 2012). Furthermore, small uncontrolled studies such as the LEAP trials make an important contribution to the evidence base (Dawes et al., 2024). The limited subject numbers however, made it difficult to extensively explore relationships between frailty and other variables of interest, such as housing, history of incarceration and unemployment and make inferences about effect size.

Although this research utilised a relatively small sample size and a convenience sampling method and the data was collected solely in the Dublin area, its findings may have generalisability to the wider population of people experiencing homelessness, addiction and mental health challenges and other marginalised groups. Dublin itself is a densely populated city, where the majority of the nation's homeless population reside.

Although homeless populations vary, for example veterans in the US are at higher risk of homelessness than the general population (National Coalition for Homeless Veterans, 2024), and substance use disorder is the primary cause of homelessness in Canada (Nasmith et al., 2021), the key factors contributing to homelessness primarily stem from the same structural factors such as economic hardship and lack of affordable housing, and also individual factors such as adverse life events and trauma, leading to mental health issues and substance use. Therefore, irrespective of setting, the demographics and health issues of homeless populations in Ireland and other middle to high-income countries may be comparable, supporting the generalisability of this work.

The absence of a control group and the inability to follow up a number of participants to ascertain a change in post-intervention results is another limitation. The time-period of re-evaluation at 12 weeks and 10 weeks for LEAP-II and LEAP-W, respectively, was unlikely to be sufficient to detect long term behavioural change, important for sustaining physical activity participation in this population.

Further, as the test battery outcome measures were primarily extrapolated from the geriatric setting, most (other than the SHARE-FI which is validated for use in people over 50 years) have been only validated in geriatric populations (Romero-Ortuno et al., 2010). This is a limitation, although it is known geriatric syndromes occur in this population. Additionally, it was difficult to make comparisons to the evidence base for some outcomes such as the Chair Stand Test, as the normative values came from a healthy young population (18-35 years) unlike the LEAP trials with a wider age range of 22-64 years. Finally, the interventions were multi-modal and multi-component (exercise

and nutritional supplementation) and did not assess the independent contribution of any mode of exercise or component of the intervention.

6.3 Implications

This PhD primarily set out to explore how exercise and nutritional supplementation influences physical function and frailty deficits known to contribute to the extreme health burden in people experiencing homelessness, addiction and mental health challenges. The targeted approach to the interventions has demonstrated impact in multiple domains beyond physical health where exercise with nutritional supplementation positively influenced health and wider life in this population. While acknowledging its limitations, this research has important implications for research, clinical practice, policy and education which will be outlined in this section.

6.3.1 Implications for future research

The main research question for this PhD related to the feasibility and impact of targeted exercise with nutritional supplementation in a non-geriatric cohort of people experiencing SMD (Lankelly Chase, 2024). While proof of concept has been demonstrated in the LEAP-II and LEAP-W studies, critical issues and new questions have emerged from study findings, highlighting research gaps and opportunities for further exploration of the role of exercise in this population.

Considering the small sample size in this PhD, there remains a need to further evaluate the effectiveness of targeted exercise interventions, such as the LEAP-II and LEAP-W trials, and higher-powered research is warranted. Aligning with the limited evidence base, we have shown that this intervention provides benefits and causes no harm, yet the studies lack the rigour and robustness of an RCT. This research area is in its infancy and to our knowledge only one RCT has been conducted on exercise in

people experiencing homelessness, which also had its limitations (Kendzor et al., 2017). For example, the sample size was small (n=17 in the intervention group) and the exercise component was delivered in the form of educational newsletters, which differs greatly to the supervised and tailored exercise intervention design of the LEAP interventions. Nonetheless, it used accelerometers and results demonstrated strong impact on increasing physical activity levels when compared to the control group. A similar approach to educational exercise has proven effect in reducing frailty levels in older people, thus this approach also merits consideration (Travers et al., 2023). An RCT to evaluate the effectiveness of supervised low intensity exercise in this population with poor physical functioning and health would be a first.

In taking the next step to develop an RCT in this area, a number of key factors need consideration. Outcomes should reflect the multiple domains which were impacted in the LEAP-interventions; physical health, mental health, addiction and quality of life and should be real-world, participant-based meaningful outcomes. Randomisation from a homeless service would be prudent to provide real world evidence. Retention, adherence and compliance should be measured. Future trials should include more participants and measure medium- and long-term outcomes. Evaluating the effect of exercise v exercise and protein would be useful to establish the benefit of nutritional supplementation in a population with nutritional deficiencies who are unlikely to ingest adequate protein by diet alone, despite recommendations. Additionally, exploring other models of exercise delivery would be useful such as exercise (using the LEAP exercise framework) in a group v standard care (no exercise) v another exercise mode (e.g. yoga) v 1-1 exercise (using the LEAP exercise framework) and physiotherapy-led exercise v exercise delivered by an instructor (trained by a

physiotherapist). Table 6.2 demonstrates an outline for the design of a future RCT in this area. This emphasises the urgent need for research in this emerging area.

While an RCT is the gold standard intervention to address the question of effectiveness, the challenges of undertaking such research methodology in this area need to be acknowledged and the merits of non-randomised studies and studies of mixed methodologies should also be considered due to the evidence from the LEAP studies and a recent systematic review (Dawes et al., 2024). A fundamental and critical consideration for further research is the translation of evidence to practice. In an era of resource constrained and pressurised health systems this is a challenge, and the reality is that it can take 17 years for evidence to translate to change in health care practice (Bauer et al., 2015).

Table 6.2 Design of a future RCT

Methods	Allocation: randomised (clearly described). Blinding: single blind (outcomes assessor) Duration: minimum 1 year. Design: parallel. Setting: community-based setting
Participants	People accessing services for homeless/addiction. History: patients randomised from homeless services and referred to research staff. N =minimum 30 people in each group Age: > 18 years. Sex: males and females. Inclusion criteria: people experiencing homelessness, age 18 years or older. Exclusion criteria: Presence of physical disability or illness, mental health problem, cognitive impairment or confusion that precludes safe participation in the exercise intervention; confirmed pregnancy.
Intervention	1: Exercise and protein supplementation: the exercise intervention should be low threshold and flexibly designed, and clearly described, and consist of the following components: (i) warm up of the main muscle groups for approximately 5 minutes, (ii) strengthening exercise (circuit of 3 upper and 3 lower limb exercises, major muscle groups-tailored and progressed for each individual) for approximately 20 minutes, (iii) core stability exercises and relaxation techniques for approximately 10 minutes (iv) aerobic exercise

	(within the class) and include a Park Walk for one session, (v) brief educational intervention as per LEAP-approach; Delivered in a mixed or gendered setting as per participant preference. Duration/intensity: for 10 weeks, 3 times weekly, mild intensity building to moderate (2 circuits, 1 aerobic session), follow-up at 6 months and 1 year, exercise delivered by a physiotherapist. Protein supplement provided following the exercise circuit session 2: Standard-care control: No exercise **Safety monitoring for exercise interventions: HR/BP as per LEAP interventions
Outcomes collected: <i>baseline, 10/52, 6/12, 1 year</i>	Physical health outcomes*; mental health outcomes; addiction outcomes; quality of life outcomes*. Costs: cost of services. Adverse events related to exercise (no & type of injuries).

*LEAP trials recommended test battery (Kennedy et al., 2025)

The emerging field of implementation science, ‘the study of methods to promote the systematic uptake of research findings into routine practice’, has directed the research focus to the rate and quality of use of evidence-based practice (EBP), rather than the effect of an intervention, thus reflecting the real-world effect of the intervention (Bauer et al., 2015). To adopt EBP, implementation interventions or strategies need to be utilised or translated to healthcare systems to stimulate necessary changes in behaviour (Bauer and Kirchner, 2020, Bauer et al., 2015). Implementation strategies will be discussed further in the following section on implications for practice. However, in terms of research, taking a step beyond a clinical effectiveness trial to an implementation trial or a hybrid effectiveness-implementation trial may shorten this ‘know-do’ period (Bauer and Kirchner, 2020).

Considering the high rate of pre-frailty detected in this non-geriatric population longitudinal research on the impact of exercise with nutritional supplementation to

prevent or delay premature ageing and frailty occurring is recommended. Moreover, while this research highlighted a number of predictors of frailty in this population, higher powered research would enable further exploration of other proposed risk factors in order to proactively implement strategies to mitigate frailty and its associated adverse outcomes.

Many of the measurement tools used in this PhD were primarily geriatric tools, which have been validated for use in older populations only. A suite of specific outcome measures for this population has been recommended but should be further explored in future research to provide evidence regarding their psychometric properties (Kennedy et al., 2025).

Homeless populations are diverse and heterogeneous as observed in this research, ranging from rough sleepers to those in emergency accommodation, those in chaotic addictions and those with tri-morbidities of physical and mental health condition in addition to their addiction issue. Therefore, their presentation and ability to engage and participate in research can be varied. Through this research we have observed positive engagement from subgroups; women, older people and the Traveller community. This warrants further attention. Yet, all people experiencing homelessness and closely associated severe and multiple disadvantages, should be included in future research and those hidden voices need to be heard (Lankelly Chase, 2024).

Retention rates in the two studies were considered relatively high (69.8% v 80% overall and 25.6% v 38.7% regular attendance) for a population known to engage poorly with healthcare interventions. A retention rate of 80% or higher is generally considered good while 70% is often accepted, as retention is dependent on many factors such as study population, context, design and duration (Hu et al., 2024, O'Grady et al., 2022).

Low retention can negatively affect study validity therefore requires attention. Further mixed-methods research would be useful to explore further increasing retention rates and identify retention-enhancing strategies to assist retaining regular attenders especially. Aiming for a retention rate of at least 80% overall retention and between 40-50% retention in regular attenders would be a realistic starting point considering the nature of the LEAP-W intervention, which was co-designed, optimised and shaped to meet the unique and extremely complex needs of the population.

6.3.2 Implications for practice

In order for intervention models such as those evaluated in the LEAP trials to translate to routine practice, implementation strategies are required to bring about significant change in behaviours and practices. These changes are required at multiple levels ranging from the frontline healthcare provider, the healthcare and social care systems, led by the policy makers. Strategies may include investment in services, as well as education and training, identification of Inclusion Health champions, audit feedback, team-based coaching, performance incentives, quality improvement techniques, system re-design, learning collaboratives or community engagement (Bauer et al., 2015). Contextual factors are important considerations such as the healthcare setting and the utility of low threshold, flexible and person centre trauma-informed care to benefit a population with unique and complex needs, who do not conform to traditional care settings or routine practice methods as evidenced in this PhDs literature review, and through the powerful narrative of the participants in the LEAP-W qualitative inquiry. This innovative research took place in a real-world setting, a centre for people with experiencing homelessness and addiction issues, a setting which was low threshold and accessible (right place), and flexible (right time), an intervention, which

was designed for the population's specific needs (right treatment), and using a trauma informed approach (by the right person), reflecting the ingredients of a truly integrated care practice, endorsed by the WHO and our national health service (WHO, 2023, HSE, 2024). Providing an intervention in the community may assist in the prevention of future complications and crisis presentations to acute healthcare which are regrettable customary practices.

In Ireland, people experiencing homelessness generally access services from the charity sector. These services are usually open-access, low threshold and flexible and share an ethos of harm reduction to appropriately meet the needs of this population in contrast to the monolithic nature of our mainstream healthcare services which often don't. However, funding in this sector is less reliable and more precarious, and services can be resultantly transient. Interventions such as the LEAP trials, set in such specialised services for people experiencing homelessness and addiction, may serve to bridge the gap to mainstream services, where people at a different or earlier stage of their recovery journey are less willing to engage in. People working with this population in these charity settings, who have experience of their unique needs, will benefit from training and education on the positive impact of exercise and physical activity, an adjunctive intervention to be offered as part of a suite of rehabilitative and restorative tools. Nonetheless, in harmony with HSE's Sláintecare principles this research paves the way for mainstream service reform and re-design in order to realise a truly inclusive, responsive and integrated healthcare service accessible to all citizens in Ireland.

Clinicians such as physiotherapists, working in primary care and community services, whose function is to provide primary health care locally, have expertise from their training and knowledge of exercise physiology, exercise prescription and complex

patient presentations and are thus best placed to prescribe and deliver exercise interventions. This PhD offers guidance, for physiotherapists in these settings, in selecting appropriate tools to efficiently and accurately screen for physical functioning deficits and frailty in community-based people experiencing homelessness, addiction and mental health challenges and presents a flexible exercise framework to implement appropriate and effective exercise interventions. Evidence from the LEAP-II and LEAP-W trials support the use of low to moderate intensity, individually tailored exercise training, delivered up to 3-times weekly for 10-12 weeks, with a trauma informed, low threshold and flexible approach. Brief interventions are advocated to target health literacy and sustainable behavioural change. A broad test battery to evaluate physical function and frailty outcomes is recommended for use in community settings for this population.

There is a well-established perception that this is a 'hard to reach population' who engage poorly with services and while this is true to an extent, the evidence has shown that it is not always driven by the individual but by the healthcare system (Siersbaek et al., 2021). This PhD has demonstrated that if services are designed to meet the unique needs of this population, then they will engage positively, and better outcomes are possible. In general, it is more challenging for mainstream services to reach this population, and low-threshold services utilising the LEAP approach are initially key to the delivery of interventions and may serve as a bridge to mainstream services and more positive health behaviours. The LEAP approach points to a gap in healthcare delivery and the need for significant health system reform in order to bring Inclusion Health to the mainstream.

Immediate recommendations for the delivery of exercise interventions are to incorporate *the LEAP approach* into service design and exercise prescription. Therefore, prescription and interventions should be co-designed and incorporate the following features:

- Trauma informed in recognition of the likelihood of past and present trauma.
- Gender sensitive and gender specific to acknowledge and address the unique needs of the population.
- Low threshold and accessible, to meet people where they are in their journey with minimal constraints placed upon them.
- Flexible; some people are further in their recovery than others and may respond well to a structured programme, but for others flexibility is essential. Therefore, a hybrid system of flexible, drop-in times as well as scheduled appointment times is recommended to meet the diverse needs of this population. No 'one size fits all' approach. Exercise interventions need to be tailored according to need thus providing person-centred care.
- Group-based: to foster social connection and use of sub-groups if appropriate to the diverse needs within a group.
- Multi-modal: by adopting multiple modes of exercise (aerobic, strength and flexibility) to reach targets (to manage frailty and physical functioning deficits and to reach physical activity recommendations) but also offer choice and provide a pathway to sustainability of physical activity participation through enhancing health literacy and empowering

people; multi-component: combining exercise with protein supplementation to enhance muscle protein synthesis.



Figure 6.16 The LEAP approach

These recommendations align with those of Harris et al, who suggest that physical activity interventions for older people with lower socioeconomic status should be accessible, offer social connectivity, inform participants of the health benefits of physical activity and should include exercises, which can be incorporated into daily life, to encourage long term engagement (Harris et al., 2024). In a recent review of crisis mental health support in the Irish context for this population, Gilmore et al (2025) call for person-centred, trauma-informed approach, which prioritises respect, flexibility and continuity, attributes that the LEAP interventions embodied (Gilmore et al., 2025). In harmony with the HSE's 'Better Together' approach, the concept of co-production is key to partnership and inclusion of people with lived experience to facilitate service re-design, which will meaningfully meet the unique and complex needs of this population (HSE, 2021).

It is recommended that exercise should be offered firstly in homeless services as a safe, free and accessible adjunctive therapeutic modality. It is a powerful and under-utilised rehabilitation modality. While delivery by an exercise expert is ideal, exercise should be recommended generally by service providers in homeless services as the evidence has shown that the benefits of exercise generally outweigh the risks (Reid et al., 2022). Where people are more stable in their recovery journey exercise interventions guided by the LEAP intervention framework and delivered by exercise practitioners may serve as a bridge to mainstream healthcare interventions, as seen in the LEAP interventions. Nonetheless, exercise should be prescribed for this population in mainstream Primary Care services and these service features should be embedded into service design. While radical change in service design takes time, specialist clinics within the current and developing Community Health Networks (CHNs) could serve as an interim service to begin to bring inclusion health to the mainstream. Considering the high physical health burden in this population compounded by additional health complexities, it would be useful to deliver an integrated intervention with other health professionals such as GPs, psychologists and dieticians or to explore alternative methods of delivery with other health practitioners in conjunction with the use of technology, such as Salaso (Salaso, 2025). The benefits and successes of integrating exercise in the local community have been seen in the ExWell programme, an established network of community-based clinical exercise programmes run by GPs and other health care professionals to target people with chronic disease nationally (ExWell, 2025). Another example is Dublin City Sport and Wellbeing Partnership (DCSWP), whose goal is to provide opportunities for everyone in the community to participate in sport and physical activity (DCSWP, 2022). The DCSWP hub have established dedicated

exercise programmes targeting populations with specific needs such as the Otago exercise programme, a dedicated physiotherapy-based strength and balance programme for older people at risk of falls. A variety of walking groups have also been established within DCSWP, thus integration of the LEAP intervention framework with exercise circuit and Park Walk for people with SMD presents a realistic future objective (Lankelly Chase, 2024).

6.3.3 Implications for policy

This research highlights a pressing need for policy change to reshape service design in healthcare settings to meet the needs of people experiencing homelessness, addiction and mental health challenges. This reflects a population health approach in working towards reducing health inequities and is in compliance with the Sustainable Development Goals of the WHO to create better health and a better future for all (United Nations, 2025).

Policy makers need to recognise the structural biases of our current healthcare system, a system which is 'fragmented, inflexible and often inaccessible' and continues to exclude and marginalise (Gilmore et al., 2025). We need to understand trauma and its pervasive effects and how it so closely related to the immense challenges and complexities faced by people who experience homelessness. Policy recommendations include a radical shift in service design for people experiencing homelessness and an approach, which includes trauma informed training and education, in order to deliver inclusive, appropriate and flexible person-centred interventions, reflective of the vision of our national health service to provide safe, compassionate and quality healthcare for all its citizens.

Physiotherapy and exercise prescription is one link in the chain of the holistic care that is required and has proven efficacy in meeting the specific needs of this population (Ní Cheallaigh et al., 2018). Physical rehabilitation and targeted exercise programmes should be made available and funded for this group and not rely on the charity sector and short term funded research interventions. While this transition will require a process of gradual development and adjustment specialised interim services providing accessible care in a flexible setting could bridge the gap between mainstream primary care and homeless services, as seen in this research.

6.3.4 Implications for education

Aligning with the evidence base this research points to the need for widespread education to provide flexible, integrated and holistic care for people experiencing homelessness (Ingram et al., 2023a, Brooder et al., 2025, Siersbaek et al., 2021). This ethos was the cornerstone of this PhD and is strongly advocated to improve accessibility and enhance service user experience. Education should begin at undergraduate level and extend to the workforce. Students should be enlightened, through lectures and clinical exposure, to the problems of homelessness to increase their awareness, understanding and compassion and to combat negative stereotypes and prevent stigma (Brooder et al., 2025, Broderick et al., 2020). This has proven effective through the implementation of a physiotherapy-led initiative in 2020, which provided students with knowledge and exposure to the healthcare issues and needs of this population through a student physiotherapy placement (Broderick et al., 2020). The outcome of this innovative research was embedding inclusion health education to the physiotherapy undergraduate curriculum in Trinity College Dublin (TCD). This continues

today in the form of an Inclusion Health module in TCD's physiotherapy undergraduate programme and is recommended for all universities to adopt.

Beyond undergraduate level all healthcare staff regardless of their setting should familiarize themselves with the unique medical, psychological, economic, cultural, and social challenges presented by this group. Trust, one of the key principles of trauma informed care is considered critical for engagement with this population and is the gateway to better care experiences, engagement and improved health outcomes (Gilmore et al., 2025). All health care providers working with this population, including physiotherapists, should be trained in the basics of trauma and trauma informed care.

Trauma informed training should be standardised and embedded into healthcare training and education programmes, including induction programmes for new staff at all levels of the healthcare organisation, including clinical and non-clinical staff, so they can treat this population with the same respect and empathy accorded to other patients. Being trauma informed means they can be predictable and available; listen actively and carefully to life stories; avoid a judgmental attitude and empower patients. This gap in training and education has already been identified and warrants immediate attention (Gilmore et al., 2025).

Education, improved awareness and patient advocacy, as well as involvement of people with lived experience as evidenced in this PhD may help reduce barriers to access for inclusion health populations such as people experiencing homelessness (Carruthers, 2023).

6.4 Conclusion

The overarching aim of this PhD was to ascertain the impact of exercise with nutritional supplementation in people experiencing homelessness, addiction and mental health challenges, a population with SMD (Lankelly Chase, 2024). It is evident that exercise is a powerful tool to positively impact on physical health but also has been shown to have a wide-reaching impact on other health domains and wider life.

When considering a population with limited resources, exercise could be viewed as a luxury and a privilege. One needs time to exercise, energy to exercise, resources to exercise (equipment, a class or a location to attend to participate) and social capital and social support to be motivated to exercise, therefore, exercise may not be available to everyone. However, exercise *should* be a standard offering to all and change is required to make this a reality.

This work makes a new contribution to the existing evidence base as we believe that the optimised LEAP-II and LEAP-W interventions are the first of their kind to deliver a supervised, tailored, low threshold exercise and nutritional intervention to target physical function and frailty deficits in people experiencing homelessness, addiction and mental health challenges, thus making exercise an accessible and attainable intervention. This work offers a valuable contribution to a nascent yet critical area of research. Greater consideration of the complex presentations of this population who face immense challenges to participation in health interventions, such as exercise, is warranted and consideration of the many markers of the success of exercise interventions is required such as the positive effects exercise on mental and social health and substance use, as well as physical health implications.

This pragmatic research is supportive of previous assertions of the urgent need for earlier intervention to enhance physical health, delay the avoidable onset of premature geriatric syndromes and improve outcomes in this extremely young and vulnerable population. Tension lies between the extreme complexities and challenges of homelessness and the need to adhere to exercise prescription recommendations to reap the benefits. Policy makers, healthcare systems and service providers need to look at service design and approach to reduce this tension and provide effective trauma informed, low threshold and flexible healthcare. Healthcare can be trauma-ignorant, exclusive, re-traumatising and toxic and policies can inadvertently favour disconnection and marginalisation. Disconnection is at the heart of trauma and this population need to connect to improve their relational health and this can only be built in an inclusive non-judgemental and compassionate environment. This research has shown that seeing people through a different lens and delivering interventions in a different way greatly helps people who have been harmed through trauma and perpetual exclusion. Greater collaboration and integration will help replace the destructive fragmentation of our siloed and inflexible healthcare systems. Changing mindset and reshaping services is required to provide equal access to health interventions.

This enlightening and transformative research journey has highlighted that the essence of this work has been about trauma and its devastating impact on the health and wellbeing of people, who as a result of trauma and disadvantage, are unfairly excluded from our society. This research has also importantly demonstrated that exercise is a powerful tool to promote trauma healing and recovery if it is delivered in the right way.

‘Until you heal the wound of your past, you will continue to bleed.’

Iyania Vanzant.

In conclusion, these powerful statements evoke the value of trauma-informed low threshold exercise on the research participants in this PhD and the need for continued research and its translation to routine practice.

"It's like a free drug."

"It keeps me off the streets for a while."

"It gave me strength I never knew I had".

"You are doing it instead of being alone".

"I feel alive, I walked out tall, and I didn't go in like that."

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Appendix I Data Collection Form for the LEAP Interventions

Unique Identifier No:

CONSENT

Date

GP

Ethnicity

Age

Sex

Living arrangement

Living environment

Education (1°, 2°, 3°)

Employment status

Marital status

H/o incarceration

H/o addiction

Self-reported health conditions

Women's health (no of children, pre-post menopause) (*LEAP-W only*)

Clinical Frailty Scale

Pain-Numerical Pain Rating Scale/*location/>3 months*

Mini Nutritional Assessment score

SHARE-Frailty Instrument score

Short-Form 12 score

Limb circumference

BP/HR

Dynamometry

Chair Stand Test

10mWT

2minWT

Single Leg Stance

Appendix II Physical Activity Readiness Questionnaire and

Borg Scale of Perceived Exertion

(i) Physical Activity Readiness Questionnaire (PAR-Q)

Name: _____

Date: _____

Regular exercise is associated with many health benefits, yet any change of activity may increase the risk of injury. Completion of this questionnaire is a first step when planning to increase the amount of physical activity in your life.

Please read each question carefully and answer every question honestly:
(Tick the appropriate answer)

1. Do you have a heart condition and should only do physical activity recommended by a physician? Y N
2. When you do physical activity, do you feel pain in your chest? Y N
3. When you were not doing physical activity, have you had chest pain in the past month? Y N
4. Do you ever lose consciousness, or do you lose your balance because of dizziness? Y N
5. Do you have a joint or bone problem that may be made worse by a change in your physical activity? Y N
6. Is a physician currently prescribing medications for your blood pressure or heart condition? Y N
7. Are you pregnant? Y N
8. Do you know of any other reason you should not exercise or increase your physical activity? Y N

If you answered yes to any of the above questions, talk with your doctor BEFORE you become physically active. Tell your doctor of your intention to exercise and which questions you answered 'yes' to. If at any stage your health changes, resulting in a 'yes' answer to any of the above questions, please seek guidance from a GP.

(i) Borg's Rate of Perceived Exertion Scale

Rating	Perceived Exertion
6	No exertion
7	Extremely light
8	
9	Very light
10	
11	Light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Extremely hard
20	Maximal exertion



Appendix III Exit Survey

1. What was the reason you agreed to participate in the programme?

Tick all of the boxes which apply

- a. Wanted to change my life around
- b. Wanted to improve my health
- c. Wanted to get back into exercise
- d. Wanted to reduce my substance use
- e. Because I was asked to/encouraged to

Additional information: _____

2. Did you attend the programme

- a. Regularly
- b. Attended but not regularly
- c. I only attended the assessment

If you attended the programme regularly/not regularly continue to Question 3

If you only attended the assessment, go to Question 7

3. Is there anything that you enjoyed about the programme- the exercise classes/Park Walk?

4. What benefits, if any, did you get from the programme?

Short term (immediately after the class): _____

Long term (over the course of the programme):

5. Did your substance use change over the course of the programme?

- a. Yes
- b. No

6. Has attending the programme changed your views of/future plans to participate in physical activity?

- a. Yes
- b. No

How? Would you do the Park Walk on a regular basis now?

7. Can you tell me what made it hard for you to attend?

8. Is there anything that you didn't like about the exercise programme?



9. Is there anything that you think which would have made it better/easier for you to attend?_

10. Is there anything else that you would like to add?

Thank you.



Appendix IV Exit Interview Schedule

1. Interview Schedule for LEAP-W Programme Participants

Intro and thanks for participation, then explanation of the interview process, use of recorder, can stop at any time, feel free to chat ... "We're here to talk about the LEAP-W exercise programme ...

(i) Can you tell me why enrolled in the first place?

Prompts: to change life around; to improve my health; to get back into exercise; to reduce substance use; was encouraged to; Had you attended Janes' Place before? Had you exercised in the past, was exercise important to you before?

(ii) What did you enjoy about the programme?

Prompts: exercise classes/Park Walk/music/the group dynamic/times and days offered/exercise options/women's health focus/ women only ... what about the protein supplement?

(iii) What benefits, if any, did you get from the programme?

Prompts: Short term (immediately after the class)/Long term (from beginning to end)

(iv) Did your substance use change over the course of the programme? In what way?

Prompts: reduced/increased use/how much Any other changes? Positive or negative?

(v) Has attending the programme changed your views of/future plans to take part in physical activity/exercise activities?

Prompts: In what way? Would you do the Park Walk on a regular basis now? With others/friends? What are your views about the role of nutrition and protein to help your physical health? In what way has the programme influenced this view?

(vi) Did you find it hard to come at times? Can you tell me why?

(vii) Is there anything that you didn't like about the exercise programme?

(viii) Is there anything that you think which would have made it better/easier for you to attend? What would you change?

(ix) Is there anything else that you would like to add?

Thanks, and end interview.

2. Interview Schedule for Stakeholders



Intro and thanks for participation, then explanation of the interview process, use of recorder, can stop at any time, feel free to chat ... “We’re here to talk about the LEAP-W exercise programme ...

- (i) What is your view of the concept of exercise interventions focussed for women who attend women’s only services, like Jane’s Place?

Prompts: do you think there is a need; considering the general health, physical function, nutritional needs of the women you see here... do you think the women who come here have poorer health than you’d expect to see for their age?

- (ii) Do you think this programme for women attending Jane’s Place was successful? In what way/s? What benefits have you seen, if any?

Prompts: physical changes, mental health, substance use

- (iii) What about those who did not engage or dropped out? We followed up with many, some came back briefly and left again, some never came after the initial assessment, in particular those recruited from Riverbank, those without phones, those sleeping rough. Why do you think they didn’t return, despite many expressing real interest and reportedly gaining immediate benefit from the initial intervention?

Prompts: What do you think are the reasons for this? Is this something you see in your day-to-day work? In your experience of working with this population, in what way do you think daily life challenges, addiction, trauma or life history have an impact on the ability to engage and commit?

- (iv) Do you have any suggestions for the design of future exercise programmes which may improve retention?

- (v) Jane’s Place offers many services and activities to assist and support the women who attend. Would you consider having a physical activity intervention as a regular event in this centre in the future?

- (vi) Is there anything else that you would like to add?

Thanks, and end interview.



Appendix V LEAP-II Ethics Approval documentation

Dr. Julie Broderick,
Discipline of Physiotherapy,
Trinity College Dublin, The University of Dublin,
Trinity Centre for Health Sciences,
St. James's Hospital,
Dublin 8
D08 W9RT

27th September 2022

Ref: 211202

Title of Study: A feasibility study to explore the role of a drop-in exercise class in a day care facility for people with problematic drug use and homelessness'

Dear Julie,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in September 2022, we are pleased to inform you that the above project (as amended with the following changes) has ethical approval to proceed.

Please give specific details of the requested amendment(s):

This amendment related to the extension of the exercise and nutritional programme to a new setting for 12 weeks.

Extension of the exercise and nutritional programme from Merchants Quay, Riverbank, and Jane's Place, Dolphins Barn, Dublin 8 to a new setting in called 'Advance Ballyfermot' a day services centre for people with addiction and homelessness issues in Ballyfermot, Dublin 10.

The original application stated that the exercise and nutrition programme would end in July 2022. We are requesting that this timeline can be extended so this programme can run from October 2022 to March 2023.

Based on stakeholder feedback the following features of the programme will be optimised in the following ways:



MQI/Jane's Place	Advance Ballyfermot	Reason for change
Programme was available on one full day per week (on a Wednesday)	Programme will be available on one full day per week (on a Monday) and there will be an additional class on Thursdays mornings.	Physiologically at least 2 classes per week are needed to achieve change in physical parameters. In the optimised programme, an additional exercise class on Thursdays will be available.
No Park Walk	Addition of a 'park walk'	This will be a 30 minute 'park walk' on Fridays which will be available for participants to come along to. This will be low intensity, self-paced, equivalent to 'going for a walk' and will be led by the research assistant involved in this programme. This is to build up exercise frequency during the week and is building in a habit which it is hoped can be continued by participants beyond the life cycle of the project.
'Drop in' exercise	Participants will be allocated to a time slot for the exercise class based on their preference where possible, but if they miss their class they can drop into another one when there is space available.	To build relationships between class participants, and build some structure into the programme, participants will be allocated to a set time for their exercise class eg Monday at 11.00. In an effort to be as pragmatic and low threshold as possible, if participants miss their time slot they can attend at another time and will be accommodated where possible.
	The Short Physical Performance Battery test was performed as part of the assessment (that is the ability to stand feet side-by-side, ability to stand semi- tandem and tandem, time to walk 8ft, time to rise from a chair and return to the seated position five times)	In practice the Short Physical Performance Battery was found to have a ceiling effect in the MQI intervention therefore the following was added in place of this test: <ul style="list-style-type: none"> ○ 10-Meter walk test ○ 2-Minute walk test ○ 30-second chair stand test ○ Single leg stance ○ Bodily pain (yes/no, if yes visual analogue scale to



		<p>quantify)</p> <ul style="list-style-type: none"> ○ Quality of life - Short Form-12
Additional safety measure at the pre-screening phase	<p>If 'yes' is ticked to any of the PAR-Q screening questionnaire (see Appendix 1). FK will, with permission contact the relevant GP and ensure it is safe for the participant to participate in the exercise intervention. If the individual does not have a GP, FK will discuss this individual case with Prof. Cliona Ní Cheallaigh, a specialist in Inclusion Health based in St. James's Hospital. The case will be outlined in broad terms, without revealing any personal details of the client, solely as a sounding board as to whether it would be suitable for the participant to attend or not.</p>	<p>As this programme will take place in a community setting, this additional safety measure has been built into the intervention.</p>
No pedometer	<p>A low-specification pedometer will be supplied to encourage increasing daily step count and goal setting will be discussed with participants.</p>	<p>This is to build a scientifically sound psychological framework into the intervention to encourage motivation to partake in physical activity.</p>

As a researcher you must ensure that you comply with other relevant regulations, including DATA PROTECTION and HEALTH AND SAFETY.

Yours sincerely,

Prof. Jacintha O'Sullivan
Chairperson Faculty Research Ethics Committee



Dr. Julie Broderick and Fiona Kennedy,
Discipline of Physiotherapy,
Trinity College Dublin, the University of Dublin,
Trinity Centre for Health Sciences,
St James' Hospital,
Dublin 8,
DO8 W9RT

31st January 2023

Ref: 211202

Title of Study: 'A feasibility study to explore the role of a low threshold exercise class and nutritional supplementation to target physical function and frailty in people with problematic drug use and homelessness'

Dear Julie,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in January 2023, we are pleased to inform you that the above project (as amended with the following changes) has ethical approval to proceed.

Please give specific details of the requested amendment(s):

This amendment relates to the addition of an exit survey for study participants following the exercise and nutritional intervention.

The reason we wish to introduce an exit survey for the following two reasons:

1. Due to the complex addiction issues of participants of the Advance Ballyfermot Project adherence rates were lower than expected. 45 people were assessed, of this cohort – 80% attended infrequently or not at all.
2. Given the novelty of the area it is important to tease out why a small number of participants adhered very well and to ascertain what could be changed to make this programme more appealing for the design of future programmes. If possible, participants who did not adhere will be included in the survey – as learning why they did not adhere is also very valuable for the design of future programmes.

Advance Ballyfermot Programme Changes Proposed	Reason for change
<p>Programme will be extended to include an exit survey upon completion of the exercise/nutritional supplementation programme. All participants who completed the initial assessment will be invited to complete the survey, which will be conducted, with the assistance of the research assistant, in-person or over the phone (if they can be reached by phone), if participants do not attend the centre in Advance Ballyfermot.</p> <p>As with other outcome measures, the questionnaire will be read to participants due to an expected high level of</p>	<p>To explore reasons for the unexpected low retention and adherence to the programme to inform future interventions.</p>



functional illiteracy in this population.	
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Additional information:

As a researcher you must ensure that you comply with other relevant regulations, including DATA PROTECTION and HEALTH AND SAFETY.

A handwritten signature in cursive script that reads "Jacintha O'Sullivan".

Yours sincerely,
Prof. Jacintha O'Sullivan
Chairperson Faculty Research Ethics Committee



LEAP-II: Participant Information Leaflet (Part 1 Intervention)

Name of Study: 'A feasibility study to explore the role of a drop-in exercise class in a day care facility for people with problematic drug use and homelessness'

Site	Merchants Quay Ireland (MQI) Riverbank House, Uscher's Quay, and MQI Women's Service, Jane's Place, Dublin 8.
Principal Investigator(s) and Co-Investigator(s)	Principal Investigator: Dr. Julie Broderick Co-investigator: <ul style="list-style-type: none">- Prof. Cliona Ní Cheallaigh, Associate Professor and Consultant in Infectious Diseases, School of Medicine Trinity College- Prof. Roman Romero-Ortuno, Associate Professor and Consultant Physician, School of Medicine Trinity College- Dr. Suzanne Doyle, Lecturer in Nutrition, Technical University of Dublin.- Fiona Kennedy, PhD student, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin.
Data Controllers	Trinity College Dublin Merchants Quay Ireland Ballyfermot Advance Project
Data Protection Officer	Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2

Why is this study being done?

- We are doing this study to explore how well an exercise programme with a protein drink afterwards works in Ballyfermot Advance, a service for people experiencing problems such as addiction and homelessness based in Dublin 10.
- The main exercise class will be provided once a week on Mondays – you will be allocated to a class at a time that suits you where possible. You can come and attend this exercise programme once, or if you enjoy it, you can drop into the class for repeat sessions. If you miss your class for whatever reason or you would like to attend a second class during the week, a class will also be available another day. As part of the programme, there will also be a guided 'park walk' available locally which you can also join if you wish.

Why have I been invited to take part?

- You have been invited to take part as you are accessing services in Ballyfermot Advance, Dublin 8.
- We are hoping that about 40 people will take part in this study.

Do I have to take part? Can I withdraw?

- You do not have to take part in this study. The choice to participate is **voluntary**, meaning it is your decision.
- A decision not to consent (agree to take part) will have **no adverse or bad consequences** and in no way will affect your ability to access services in Advance Ballyfermot.
- You can opt out of this study at any time. You do not have to give a reason for opting out. You can decide to leave this study at any time until the final results are published.
- If you decide to withdraw from this study, please contact Dr. Julie Broderick, (01) 8962110 and we will be able to organise this for you.

What happens if I change my mind?

- You can change your mind at any time by contacting Dr. Julie Broderick at (01) 8962110.
- If you choose not to continue to take part, this will not affect the services you access in Ballyfermot Advance in any way.
- If you choose not to take part anymore, you will be asked to fill in a withdrawal form. If you wish, you can ask for your data stored to be destroyed. If you request this, we will destroy all data that are still in our possession. We will no longer use or share your data for research from this point onwards. After the study is published, we will not be able to remove your data from the overall study results in that publication.

How will the study be carried out?

- This study is expected to commence in October 2022 and continue until March 2023.
- This study will take place in Ballyfermot Advance in Dublin 10.
- If you decide to take part, you will do some physical tests, and the physiotherapist will read out some questionnaires to you. If you are happy to take part in the exercise class that will follow, and you will be offered a protein drink at the end to have in the exercise room.
- About 40 people will take part in the study.

What will happen to me if I decide to take part?

If you decide to take part, we will do a quick assessment. As part of this assessment, we will check if it is safe for you to take part in the exercise programme by asking some questions such as have you ever felt dizziness or pain in your chest while exercising. If you answer yes to any of these questions, we will ask your permission to contact your GP to check if it is safe for you to participate in the exercise programme. If you don't have a GP, we will ask your permission to discuss the decision whether you can participate or not with one of the study investigators Dr. Cliona Ní Cheallaigh who is has a special interest in this area. The study investigator will solely mention any risk factors identified, without sharing any identifiable details such as your name or date of birth.

Part 1 - Testing

- If you decide to take part, you will firstly complete some simple physical tests. These will be checked quickly at the start of each session with us and will take no longer than 15 minutes.
- Firstly, the 30-second chair stand test is a quick test of your agility, and strength. You will also perform the Single leg stance which is a simple test of your balance. The balance part involves standing with your feet together and then side-by-side for 30 seconds and then balancing on one leg. We will then time you standing up from a chair and walking a short distance over 10 meters. We will also do a 2-

minute walking test. Then we will ask you to stand up from a chair without holding the armrest. See Fig 1 below for pictures of these tasks.



Fig. 1 – Picture to show some parts of the Physical Performance Tests



- Next, we will check your handgrip strength. You will have to squeeze an instrument called a dynamometer. See Figure 2 for a picture of this.

Fig. 2 – Hand grip strength test

- Next, we will measure the muscle bulk of your upper arm and calf. This test will involve the physiotherapist measuring the width of your calf muscle and upper arm. See Fig. 3 for a picture of this.



Fig. 3 - Upper limb circumference test

- Next your weight and height will be checked. See Fig. 4 below for a picture of this.

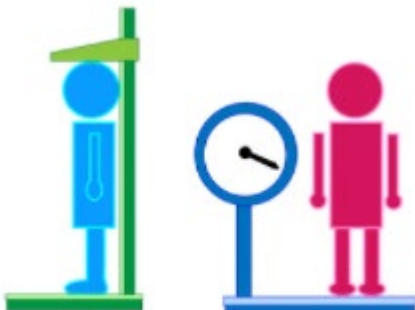


Fig. 4 Height and weight check

The physiotherapist will also read out short questionnaires to you about your physical ability, any medical conditions that you have, your diet and if you are experiencing any pain.

Part 2 - Exercise Class

- If you decide to stay for the exercise class, you will be guided through exercises by a Physiotherapist who will work out the best exercises for you based on your physical ability. We will check your blood pressure and heart rate before you start exercising and make sure you feel well.
- The exercise class will focus on your fitness and work on your strength and endurance.
- The exercises will take about 30 minutes but will start with a smaller amount of time such as 10 minutes, depending on how you are managing.
- You might be on your own exercising or in a group. We are aiming that the exercises will be fun and enjoyable.
- You can stop the exercises at any time, and you will need to tell the Physiotherapist if you don't feel well at any time.
- At the start of the programme, we will give you a step counter so you can keep track of your steps. This might help you to increase your physical activity during and after the programme.

Part 3 – The Protein Drink and end of the Session

- After the exercise, you will be offered a protein drink. You will be able to sit and relax and you will drink this before you leave the exercise room. A picture of the drink is below.
- We will also let you know about options available to continue exercising, for example using the Dublin Simon gym and how you could use real food to build up your protein levels, instead of a drink. We will ask you about your opinion on what type of exercise you like to do and what would work best if we were to design another exercise class in the future for people in Merchants Quay or other similar locations.



Figure 5: Protein drink

What will happen to my Samples and Data?

- Your data will be entered each day into a Trinity College Dublin laptop and will not be stored in Advance Ballyfermot, except for a code which we can use to identify you again if necessary.
- This code will be stored in a locked filing cabinet in Ballyfermot Advance.
- Your data will be coded (pseudoanonymised), meaning that it will be stored alongside a code and not your name.
- Your data will be added to that of the other people in this study and will not be shown separately.
- Your data will be stored securely for 7 years and then destroyed by Dr. Julie Broderick.

Are there any benefits to taking part in this research?

- They may be a small benefit to you from participating in the exercise class and taking the protein drink.
- In the future, findings from this study may help us design better exercise classes in settings similar to Ballyfermot Advance.

Are there any risks to me or others if I take part?

- There is a small chance of muscle soreness, an injury or fall as a result of the testing or exercise, but this risk is very low as the physiotherapist will be closely supervising you and the exercise is low level.
- You can seek a second opinion about participating in this exercise programme.
- There is also a possibility that a connection to your identity could be made. However, your data will be coded so this is unlikely and data from all participants will be analysed together, so the possibility of a connection to your identity is very unlikely.

What happens if something goes wrong when I'm taking part in the study?

- In the unlikely event that you do experience muscle soreness or sustain an injury, the physiotherapist running the study will be able to advise you what to do. If necessary, we will put you in touch with a member of the team in Ballyfermot Advance. The physiotherapist running this study is insured through Trinity College indemnity insurance.

Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?

- You will not be told the outcome of this study, but if you have questions about your own physical condition, the physiotherapist will be able to answer those questions.
- The results of the research will be reported in medical/scientific journals and disclosed at medical/scientific conferences. Nobody will be identifiable as everybody's data will be added together.

Part 2 – Data Protection

What information about me (personal data) will be used as part of this study? Will my medical records be accessed?

We will be seeking your date of birth, weight, height and information relating to any conditions you may have. As part of testing, we will be finding out about your physical condition and your nutritional status. For your safety, we may have to check in with the staff in Ballyfermot Advance about your history, but your medical records or other records will not be accessed by the study Physiotherapist.

What will happen to my personal data?

- The data controllers are Trinity College Dublin and Ballyfermot Advance. The data handlers are Dr. Julie Broderick and the study physiotherapist. Your data will not be shared with any third parties. Your data will not leave the state or be shared with any third parties.
- Only the information which we need about you for this study will be collected and nothing extra.
- To comply with data protection regulations, we will keep your data safely and in a way that it is not identifiable (pseudoanonymised) for 7 years.
- After 7 years, your data will be destroyed.

Who will access and use my personal data as part of this study?

- Only the study researcher, Fiona Kennedy and Dr. Julie Broderick will have access to your data. Prof. Cliona Ní Cheallaigh, Prof. Roman Romero-Ortuno and Dr. Suzanne are study co-investigators – but they will be just advising about the design of the study and contributing to the write up – they will not have access to any the raw study data.
- Your data will not be shared with anyone else and will not leave the State.

Will my personal data be kept confidential? How will my data be kept safe?

- Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Here are some examples of how we do this:
- **Data security arrangements** are in place.
- **A Data Protection Impact Assessment** has been carried out.
- No **presentation or publication** in relation to the study could identify you as all results will be analysed together.
- The research team having access to the personal data are **bound by a professional code of secrecy**.
- **Training in data protection law** and practice has been provided to the research team.

What is the lawful basis to use my personal data?

- The lawful basis for the processing of data is Article 6 and Article 9 of GDPR. Your personal data will not be collected without your consent.

What are my rights?

You are entitled to:

- The right to access to your data and receive a copy of it – that means we can give you a copy of your data if you wish
- The right to restrict or object to processing of your data – that means you can object to processes we perform to make data understandable
- The right to object to any further processing of the information we hold about you - that means you can object to any further processes we perform to make data understandable
- The right to have inaccurate information about you corrected or deleted – that means you can have any information that is not correct changed or erased
- The right to receive your data in a portable format and to have it transferred to another data controller – that means you can receive your data, and it can be used by a different service if you wish
- The right to request deletion of your data – that means you data can be deleted if you wish until the point at which your data is analysed together and published.

By law you can exercise the following rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting your study Doctor [INSERT CONTACT DETAILS] or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

Part 3 – Costs, Funding and Approval

Has this study been approved by a research ethics committee?

- Yes, this study has been approved by The Faculty of Health Sciences Research Ethics Committee, Trinity College Dublin. Approval was granted on [INSERT DATE].

Who is organising and funding this study? Will the results be used for commercial purposes?

- Dr. Julie Broderick from Trinity College Dublin is leading this research.
- This research is funded by Ballyfermot Advance.
- There is no payment for recruiting to this study
- The results of this study will not be disclosed for commercial purposes.

Is there any payment for taking part? Will it cost me anything if I agree to take part?

- There is no payment for taking part in this study.
- There will be no cost to taking part in this study.

Part 4 – Future Research

Will my personal data and/or biological material be used in future studies? (May not apply)

- Your data will not be used for any future studies. You have only given permission for your data to be used in this study.

Part 5 – Further Information

Who should I contact for information or complaints?

If you have any concerns or questions, you can contact:

- Principal Investigator: Dr. Julie Broderick (01) 8962110
- Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to lodge a complaint with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie.

Will I be contacted again?

If you would like to take part in this study, you will be asked to sign the Consent Form on the next page. You will be given a copy of the Consent Form to keep. After the study you will team.



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

LEAP-II: Consent Form (Part 1 Intervention)

STUDY NAME: 'A feasibility study to explore the role of an exercise class in a day care facility for people with problematic drug use and homelessness'

There are two sections in this form. Each section has a statement and asks you to initial if you agree. The end of this form is for the researchers to complete.

Please ask any questions you may have when reading each of the statements. Thank you for participating.

Please Initial the box if you agree with the statement. Please feel free to ask questions if there is something you do not understand.

General	Tick box
I confirm I have read and understood the Information Leaflet for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	

I understand that this study is entirely voluntary , and if I decide that I do not want to take part, I can stop taking part in this study at any time without giving a reason . I understand that deciding not to take part will not affect my future medical care.	
I understand that for safety the study physiotherapist may have to link in with members of the team in Advance Ballyfermot about my history, but the study physiotherapists will not access my records in Advance Ballyfermot. I understand that all information will be kept private and confidential and that my name will not be disclosed.	
I understand that I will not be paid for taking part in this study ¹ .	
I know how to contact the research team if I need to.	
I agree to take part in this research study having been fully informed of the risks, benefits and alternatives which are set out in full in the information leaflet which I have been provided with.	
Data processing	Tick box
[I understand that there are no major direct benefits to me from participating in this study. I understand that results from analysis of my personal information will not be given to me .	
I understand that I can stop taking part in this study at any time without giving a reason and this will not affect my future medical care.	

Participant Name (Block Capitals)

Participant Signature

Date

Witness Name (Block Capitals)

Witness Signature

Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.

I have given a copy of the information leaflet and consent form to the participant with contacts of the study team

Researcher name

Title and qualifications

Signature

Date

¹ Amend as appropriate.



LEAP-II: Participant Information Leaflet (Part 2 Exit Survey)

Name of Study: 'A feasibility study to explore the role of a low-threshold exercise programme in a day care facility for people with problematic drug use and homelessness'.

Site	Ballyfermot Advance Project, La Fanu Rd, Ballyfermot, Dublin 10
Principal Investigator(s) and Co-Investigator(s)	Principal Investigator: Dr. Julie Broderick Co-investigator: <ul style="list-style-type: none">- Prof. Cliona Ní Cheallaigh, Associate Professor and Consultant in Infectious Diseases, School of Medicine Trinity College- Prof. Roman Romero-Ortuno, Associate Professor and Consultant Physician, School of Medicine Trinity College- Dr. Suzanne Doyle, Lecturer in Nutrition, Technical University of Dublin.- Fiona Kennedy, Discipline of Physiotherapy, Trinity College Dublin
Data Controllers	Trinity College Dublin Ballyfermot Advance Project
Data Protection Officer	Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2

Part 1 – The Study

Why is this study being done?

- We are doing this study to explore how well an exercise programme, with a protein drink afterwards, works in the Ballyfermot Advance Project, a service for people experiencing problems with addiction and homelessness in Dublin 10.

Why have I been invited to take part?

- You have been invited to take part as you consented to participate in the exercise programme in Ballyfermot Advance Project.
- As this programme is finishing, we are hoping to find out what people liked and disliked about the programme in order to make this intervention more appealing for future programmes.

Do I have to take part? Can I withdraw?

- You do not have to take part in this study. The choice to participate is **voluntary**, meaning it is your decision.
- A decision not to consent (agree to take part) will have **no adverse or bad consequences** and in no way will affect your ability to access services in the Ballyfermot Advance Project.
- You can opt out of this study at any time. You do not have to give a reason for opting out. You can decide to leave this study at any time until the final results are published.
- If you decide to withdraw from this study, please contact Dr. Julie Broderick, (01) 8962110 and we will be able to organise this for you.

What happens if I change my mind?

- You can change your mind at any time by contacting Dr. Julie Broderick at (01) 8962110.
- If you choose not to continue to take part, this will not affect the services you access in Ballyfermot Advance Project in any way.
- If you choose not to take part anymore, you will be asked to fill in a withdrawal form. If you wish, you can ask for your data stored to be destroyed. If you request this, we will destroy all data that are still in our possession. We will no longer use or share your data for research from this point onwards. After the study is published, we will not be able to remove your data from the overall study results in that publication.

How will the study be carried out?

- This study/survey is expected to commence in February and be completed by the end of March 2023 following the exercise intervention.
- This study will take place in the Ballyfermot Advance Project setting.
- If you decide to take part, you will complete a survey with the research physiotherapist who will read out some questions to you.
- It is hoped that as many people as possible who took part in the programme will take part in the survey.

What will happen to me if I decide to take part?

- If you decide to take part, you will complete a brief survey with the research physiotherapist. It will take no longer than 5 minutes.
- The survey will consist of a small number of questions about the exercise programme which you signed up for in approximately October 2022.
- The research physiotherapist will read each question to you. The research physiotherapist will write down the answer and read it out, to allow you to confirm that this reflects your answer.

What will happen to my Samples and Data?

- Your data will be entered each day into a Trinity College Dublin laptop and will not be stored in the Ballyfermot Advance Project setting, except for a code which we can use to identify you again if necessary.
- This code will be stored in a locked filing cabinet in the Ballyfermot Advance Project setting.
- Your data will be coded (pseudonymised), meaning that it will be
- stored alongside a code and not your name.
- Your data will be added to that of the other people in this study and will not be shown separately.
- Your data will be stored securely for 7 years and then destroyed by Dr. Julie Broderick.

Are there any benefits to taking part in this research?

- In the future, findings from this study may help us design better exercise classes in settings similar to the Ballyfermot Advance Project.

Are there any risks to me or others if I take part?

- There is a possibility that a connection to your identity could be made. However, your data will be coded so this is unlikely and data from all participants will be analysed together, so the possibility of a connection to your identity is very unlikely.

What happens if something goes wrong when I'm taking part in the study?

- It is unlikely that anything will go wrong when completing the survey.

Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?

- You will not be told the outcome of this study, but if you have questions about your own physical condition, the physiotherapist will be able to answer those questions.
- The results of the research will be reported in medical/scientific journals and disclosed at medical/scientific conferences. No information which reveals your identity will be disclosed.

Part 2 – Data Protection

What information about me (personal data) will be used as part of this study? Will my medical records be accessed?

- For this survey, we will not need any personal data and we do not require access to any of your medical records.

What will happen to my personal data?

- The data controller is Trinity College Dublin. The data handlers are Dr. Julie Broderick and the research physiotherapist. Your data will not be shared with any third parties. Your data will not leave the state or be shared with any third parties.
- Only the information which we need about you for this study will be collected and nothing extra.
- To comply with data protection regulations, we will keep your data safely and in a way that it is not identifiable (pseudonymised) for 7 years.
- After 7 years, your data will be destroyed.

Who will access and use my personal data as part of this study?

- Only the research physiotherapist and Dr. Julie Broderick will have access to your data. Prof. Cliona Ní Cheallaigh, Prof. Roman Romero-Ortuno and Dr. Suzanne Doyle are study co-investigators – but they will be just advising about the design of the study and contributing to the write up – they will not have access to any the raw study data.
- Your data will not be shared with anyone else and will not leave the State.
- Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Here are some examples of how we do this:
- Data security arrangements are in place.
- A Data Protection Impact Assessment has been carried out.
- No presentation or publication in relation to the study could identify you as all results will be analysed together.
- The research team **having access to the personal data are bound by a professional code of secrecy.**
- **Training in data protection law and practice has been provided to the research team.**

What is the lawful basis to use my personal data?

- By law,² we can use your personal information for scientific research³ (in the public interest⁴). We will also ask for your explicit consent to use your data as a requirement of the Irish Health Research Regulations.

What are my rights?

You are entitled to:

- The right to access to your data and receive a copy of it.
- The right to restrict or object to processing of your data.
- The right to object to any further processing of the information we hold about you.
- The right to have inaccurate information about you corrected or deleted.
- The right to receive your data in a portable format and to have it transferred to another data controller.
- The right to request deletion of your data.

By law you can exercise the following rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting your study Doctor [INSERT CONTACT DETAILS] or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

² The European General Data Protection Regulation (GDPR)

³ Article 9(2) (j)

⁴ (Article 6(1)(e))

Part 3 – Costs, Funding and Approval

Has this study been approved by a research ethics committee?

- Yes, this study has been approved by the Faculty of Health Sciences Research Ethics Committee in Trinity College Dublin. Approval was granted on 31.01.23.

Who is organising and funding this study? Will the results be used for commercial purposes?

- Dr. Julie Broderick from Trinity College Dublin is leading this research.
- This research is funded by a grant from Trinity College.
- There is no payment for recruiting to this study.
- The results of this study will not be disclosed for commercial purposes.

Is there any payment for taking part? Will it cost me anything if I agree to take part?

- There is no payment for taking part in this study.
- There will be no cost to taking part in this study.

Part 4-Future Research

Will my personal data and/or biological material be used in future studies? (May not apply)

- Your data will not be used for any future studies. You have only given permission for your data to be used in this study.

Part 5 – Further Information

Who should I contact for information or complaints?

If you have any concerns or questions, you can contact:

- Principal Investigator: Dr. Julie Broderick (01) 8962110
- Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.
- Under GDPR, if you are not satisfied with how your data is being processed, you have the right to lodge a complaint with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie.

Will I be contacted again?

- If you would like to take part in this study, you will be asked to sign the Consent Form on the next page. You will be given a copy of this information leaflet and the signed Consent Form to keep. After the study you will not be contacted again by the study team



LEAP-II: Consent Form (Part 2- Exit Survey)

STUDY NAME: 'A feasibility study to explore the role of a Low Threshold exercise Programme in a day care facility for people with problematic drug use and homelessness'

There are two sections in this form. Each section has a statement and asks you to initial if you agree. The end of this form is for the researchers to complete.

Please ask any questions you may have when reading each of the statements. Thank you for participating.

Please Initial the box if you agree with the statement. Please feel free to ask questions if there is something you do not understand.

General	Tick box
I confirm I have read and understood the Information Leaflet for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	<input type="checkbox"/>
I understand that this study is entirely voluntary , and if I decide that I do not want to take part, I can stop taking part in this study at any time without giving a reason . I understand that deciding not to take part will not affect my future medical care.	<input type="checkbox"/>
I understand that for safety the research physiotherapist may have to link in with members of the team in the Ballyfermot Advance Project about my history, but the study physiotherapists will not access my records. I understand that all information will be kept private and confidential and that my name will not be disclosed.	<input type="checkbox"/>
I understand that I will not be paid for taking part in this study .	<input type="checkbox"/>
I know how to contact the research team if I need to.	<input type="checkbox"/>
I agree to take part in this research study having been fully informed of the risks, benefits and alternatives which are set out in full in the information leaflet which I have been provided with.	<input type="checkbox"/>
Data processing	Tick box
I understand that there are no major direct benefits to me from participating in this study. I understand that results from analysis of my personal information will not be given to me .	<input type="checkbox"/>

I understand that I can stop taking part in this study at any time without giving a reason and this will not affect my future medical care.	
--	--

Participant Name (Block Capitals)	Participant Signature	Date
-----	-----	-----
Witness Name (Block Capitals)	Witness Signature	Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.

I have given a copy of the information leaflet and consent form to the participant with contacts of the study team

Researcher name

Title and qualifications

Signature

Date



LEAP-II: GP Letter prior to participation

A feasibility study to explore the role of an exercise class in Advance Ballyfermot

Principal Investigator: Dr. Julie Broderick, Discipline of Physiotherapy, Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8.

Study Collaborators: Prof Cliona Ní Cheallaigh and Prof Roman Romero-Ortuno School of Medicine TCD and St. James's Hospital, Dr. Suzanne Doyle, Technical University of Dublin, Fiona Kennedy, Trinity College Dublin, Fiona Kennedy, Discipline of Physiotherapy, Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8.

Date:

Re:


D.O.B:

Dear Dr. _____,

I am writing to inform you that _____ has consented to participate in a research study, which is currently being conducted in Advance Ballyfermot, Dublin 10. This involves an exercise assessment and group exercise training followed by a nutritional supplement. The duration of the exercise intervention is 12 weeks. We are writing to you as the main contact GP for _____.

As part of our assessment prior to the start of the exercise programme, this patient indicated that they had or have some cardiac concern or history. Precautions we are taking are that blood pressure and heart rate will be taken prior to and on completion of each exercise session and symptoms will be closely monitored. We start each individual at a light level and progress the exercise gradually based on individual ability. The exercise class is led by a registered Physiotherapist with over 20 years clinical experience. However, as this is a community-based setting – we do not have access to medical notes therefore we are checking in with you as their GP. **We are intending to start this patient in this exercise programme but if you have any concern or there is a reason why this patient should not exercise with us – please get in touch as soon as possible as the programme is due to start in early November.**

Yours sincerely,



Fiona Kennedy, CORU registered Research Physiotherapist PT027553

Email: cromwelf@tcd.ie

Phone: (01) 8962110

Julie Broderick, Assistant Professor, Discipline of Physiotherapy, Trinity College Dublin

Email: julie.broderick@tcd.ie



Appendix VI LEAP-W Ethics approval documentation

Dr Julie Broderick,
Head of Discipline of Physiotherapy,
Assistant Professor,
Discipline of Physiotherapy,
Trinity College Dublin, the University of Dublin,
Trinity Centre for Health Sciences,
St. James' Hospital, Dublin 8,
D08 W9RT

18th January 2024

Ref: 211202 Title of Study: 'A feasibility study to explore the role of a drop-in exercise class in a day care facility for people with problematic drug use and homelessness'

Dear Julie,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in January 2024, we are pleased to inform you that the above project (as amended with the following changes) has ethical approval.

We would advise you to seek review and comments on your DPIA from the DPO if required prior to study commencement.

Please give specific details of the requested amendment(s):

For clarity; I have provided here firstly a summary of this project so far -

1. The original ethical application (approved 17.01.22) related to an exercise and nutrition programme based in Merchants Quay Ireland (MQI), in its Riverbank and Jane's Place facilities.
2. An amendment (approved 03.03.23) was follow on programme no. 1 and was for the same basic exercise and nutritional programme to be delivered in another setting (Advance Ballyfermot).

At this stage, both of these programmes; in MQI and Advance Ballyfermot have been successfully completed.

Results from both programmes strongly indicated that women adhered better to the programme, showed positive changes in physical outcomes and very positive feedback was generated from women in particular. However, some women indicated caution around exercising in a setting with men due to a history of past trauma.



This led to the submission of an Irish Research Council New Foundations grant for a targeted women's only programme based on the exercise and nutritional programme already completed in MQI/Jane's Place and Advance Ballyfermot.

This funding was successful – therefore I am applying for a further amendment to

1. Extend application to run the same core intervention which will be flexibly delivered and a targeted 10-week women's only exercise and nutrition programme in MQI/Jane's Place from February – June 2024.
2. Instead of an exit survey – an exit interview will take place. This is because reasons for non- adherence are complex and lend themselves to qualitative analyses to tease these out. This data is unexplored in the literature. If participants do not wish to complete the interview, it will be entirely optional. The interviews will be conducted on an individual basis, audio-recorded and transcribed by Fiona Kennedy. They will be conducted in a private room in Jane's Place/Merchants Quay Ireland. The data will be pseudonymised at point of entry and stored on Sharepoint. As Fiona Kennedy will lead the conduction of the intervention as part of her PhD, the recordings will be kept until her examination process is complete and will then be irrevocably deleted by Dr. Julie Broderick.
3. Dr. Deirdre Murray (Academic Unit of Neurology, TCD) will be added to the study team in an advisory capacity.
4. As part of demographic data to record the following additional variables - gender, ethnicity, educational and marital status, history of incarceration (yes/no), pre, peri or post menopause status. This is to enable comparison with literature in the area.

As a researcher you must ensure that you comply with other relevant regulations, including DATA PROTECTION and HEALTH AND SAFETY.

Yours sincerely,

Prof. Jacintha O'Sullivan

Chairperson Faculty Research Ethics Committee



Dr Julie Broderick,

Discipline of Physiotherapy
Trinity College Dublin, the University of Dublin
Trinity Centre for Health Sciences
St James' Hospital, Dublin 8,
DO8 W9RT

21st May 2024

Ref: 211202

Title of Study: A feasibility study to explore the role of a low threshold exercise programme in a day care facility for women with problematic drug use and homelessness.

Dear Julie,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in May 2024, we are pleased to inform you that the above project (as amended with the following changes) has Ethical approval.

Please give specific details of the requested amendment(s):

For clarity, I have provided here firstly a summary of this project so far -

1. The original ethical application (approved 17.01.22) related to an exercise and nutrition programme based in Merchants Quay Ireland (MQI), in its Riverbank and Jane's Place facilities.
2. An amendment (approved 03.03.23) was follow on programme no. 1 and was for the same basic exercise and nutritional programme to be delivered in another setting (Advance Ballyfermot).
3. Both of these programmes; in MQI and Advance Ballyfermot have been successfully completed.
- 4.

A further amendment was granted on 18.01.24 to extend the application and run the same core intervention, a 10- week targeted and flexibly delivered women's only exercise and nutritional supplementation programme in Jane's Place, MQI. This programme is funded by the Irish Research Council New Foundations grant and is running from February – June 2024.

This amendment includes an exit interview. This is because reasons for non-adherence are complex and lend themselves to qualitative analyses to tease these out.

Participants will be invited to interview at the end of the exercise programme. It will be entirely optional.



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In addition to participants inclusion in the exit interviews, a request to interview key stakeholders, staff in MQI (Jane's Place/Riverbank) who have experience and knowledge of participants in this study, is proposed. The relationships fostered with participants, their knowledge of the participants backstories and their extensive experience in trauma informed care are considered crucial to fully understanding the challenges to participation and retention in this study. In the same way as the exercise programme participants, the interviews will be conducted on an individual basis, audio-recorded and transcribed by Fiona Kennedy. They will be conducted in a private room in Jane's Place/Merchants Quay Ireland.

The data will be pseudonymised at point of entry and stored on Sharepoint. As Fiona Kennedy will lead the conduction of the intervention as part of her PhD, the recordings will be kept until her examination process is complete and will then be irrevocably deleted by Dr. Julie Broderick.

As a researcher you must ensure that you comply with other relevant regulations, including DATA PROTECTION and HEALTH AND SAFETY.

Yours sincerely,
Prof. Jacintha O'Sullivan
Chairperson Faculty Research Ethics Committee

Dámh na nEolaíochtaí Sláinte

Foirgneamh na Ceimice,
Coláiste na Tríonóide ,
Ollscoil Átha Cliath,
Baile Átha Cliath 2, Éire.

Faculty of Health Sciences

Chemistry Building,
Trinity College Dublin,
The University of Dublin,
Dublin 2, Ireland

www.healthscience.tcd.ie

LEAP-W: Participant Information Leaflet-Part 1 (Intervention participants)

Study Title	A FEASIBILITY STUDY TO EXPLORE THE ROLE OF A LOW THRESHOLD EXERCISE PROGRAMME IN A DAY CARE FACILITY FOR WOMEN WITH PROBLEMATIC DRUG USE AND HOMELESSNESS.
Research Site(s)	Merchants Quay Ireland (MQI)-Riverbank, Dublin and Jane's Place, Dublin.
Principal Investigator(s) and Co-Investigator(s) (Study Team)	<p>Principal Investigator: Dr. Julie Broderick</p> <p>Co-investigators:</p> <ul style="list-style-type: none"> - Fiona Kennedy, PhD student, Discipline of Physiotherapy, School of Medicine Trinity College - Prof. Cliona Ní Cheallaigh, Associate Professor and Consultant in Infectious Diseases, School of Medicine Trinity College - Prof. Roman Romero-Ortuno, Associate Professor and Consultant Physician, School of Medicine Trinity College - Dr. Deirdre Murray, Assistant Professor, Academic Unit of Neurology, Trinity College Dublin
Study Organiser/ Sponsor	Trinity College Dublin/Irish Research Council
Data Controller	Trinity College Dublin
Data Protection Officer	Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2

We would like to invite you to take part in a research study that is being carried out by Dr. Julie Broderick and her research team at Trinity College Dublin.

Before you decide whether or not you wish to take part, please take time to read this information leaflet carefully and discuss it with your family, friends or GP if you wish.

If there is anything which is not clear, or if you would like more information, please ask the researchers. You should understand the benefits and any risks of taking part in this study so that you can make a decision that is right for you.

Do I have to take part?

No, you don't have to take part in this study. It is entirely voluntary and up to you. If you decide not to take part, it won't affect the current or future services you receive from Merchants Quay Ireland (MQI). Don't feel rushed or under pressure to take part or to make a quick decision. You can change your mind and opt out even if the study has started.

This leaflet has six parts:

Part 1 - The Study

Part 2 - Data Protection

Part 3 - Approval, Organising and Funding

Part 4 - Future Research

Part 5 - Further Information

Part 6 – Next steps

Part 1 - The Study

Why have I been invited to take part?

We are interested in understanding the role of exercise and nutrition on physical health in people experiencing homelessness and addiction. You have been invited to take part as you are accessing services in MQI (Jane's Place or Riverbank). We are hoping to have 40-50 participants in the study.

Why is this study being done?

We are doing this study to explore how well an exercise programme with a protein drink afterwards, works in MQI, Riverbank and Jane's Place women's only service for people experiencing problems with addiction and homelessness in Dublin 2 and 8.

What does taking part involve?

This study is expected to commence in February 2024 and will continue for 3 months. The study will take place in MQI (Jane's Place and Riverbank). If you decide to take part, a member of the research team will discuss this information leaflet and the consent form with you. You will be given a copy of your signed consent form and this leaflet to keep.

Following consent there are 3 parts to the study:

(1) You will complete an initial assessment, involving simple physical tests (outlined below) and a few questionnaires with the research physiotherapist, Fiona Kennedy. She will ask your age, medical and social history and read out a few short questionnaires, which include questions about your physical ability, any medical conditions that you have, your diet and if you are experiencing any pain. If further information, for the purposes of this study, is required, the research physiotherapist may clarify information with MQI staff. The assessment is outlined here:

- Handgrip: Your grip will be measured using an instrument called a dynamometer. See Figure 2.
- The 30-second Chair Stand Test: This is a quick test of your leg strength. You will be asked to stand up and down as many times as possible for 30 seconds. See Figure 1.
- The Single Leg Stance: This is a simple test of your balance. You will be requested to balance on one leg, first the right, then the left.
- 10m Walk Test: You will be asked to walk a distance of 10m and you will be timed.
- The 2-minute Walk Test: You will be asked to walk up and down a 15m distance for 2 minutes (if able) and the distance covered will be recorded.
- Then we will measure the muscle bulk of your upper arm and calf. This test will involve the study physiotherapist measuring the width of your upper arm and calf. See Figure 4.
- Next your weight and height will be checked. See Figure 3.

Figure 1 Chair Stand and Walk Tests

Figure 2 Grip Strength

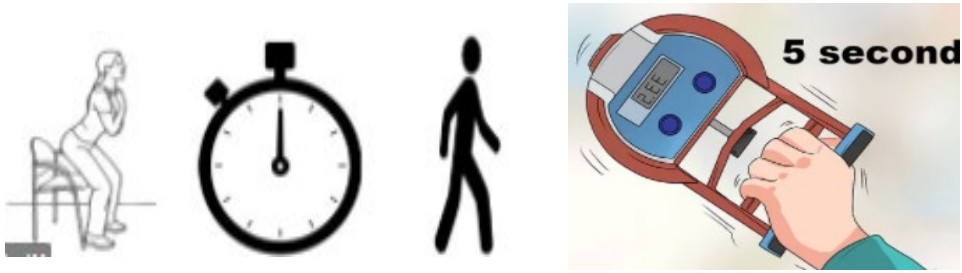
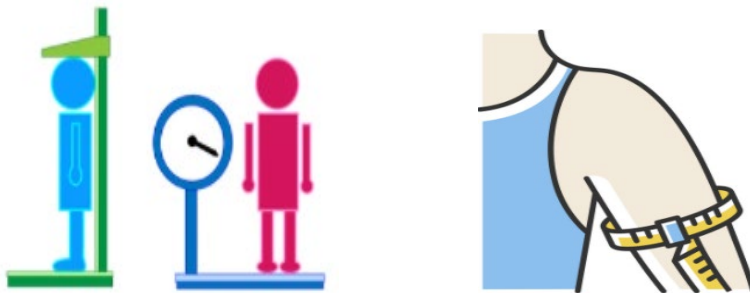


Figure 3 Weight and Height

Figure 4 Arm circumference



(2) The assessment will be followed by a 10-week exercise programme. The programme will involve two exercise classes per week and a Park Walk once per week. A protein drink will be offered to you after each exercise class.

(3) Following the exercise programme, you will be invited to do a one-to-one exit interview with the research physiotherapist Fiona, to get your feedback on the programme. This interview is entirely voluntary. During the interview you will be asked questions about your views on the programme, what you enjoyed about it and what were the challenges. We will arrange a time for your interview in MQI (Riverbank or Janes' Place) with Fiona Kennedy. With your permission, the interviews will be audio recorded. We will transcribe the interview and offer you an opportunity to check and verify the transcript for up to 4 weeks following the invitation.

What are the possible benefits of taking part?

You may see improvements in your mobility and physical health following the programme. In the future, findings from this study may help us design better exercise classes in settings similar to MQI (Riverbank and Jane's Place). By participating, you are helping to advance science and medicine/education for future generations.

Are there any possible disadvantages or risks from taking part?

- At all times, the well-being of participants takes priority over research activities.
- There is a very small chance of muscle soreness, an injury or fall as a result of the testing, but this risk is extremely low as the lead research physiotherapist will be closely supervising you and the physical tests are very brief.
- In the event of the interview triggering an emotional event, the interviewer will stop the session, and we will link you in with an appropriate staff member in Riverbank or Jane's Place.
- There is also a possibility that a connection to your identity could be made. However, we take many measures to ensure the confidentiality of all data and the risk to you of a breach of confidentiality is considered very low your data will be coded so this is unlikely and data from all participants will be analysed together, so the possibility of a connection to your identity is very unlikely.
- If you are harmed in any way, the researchers on this study are covered by insurance through Trinity College Dublin. This insurance will cover you in the unlikely event that you injured as a result of taking part in this study.

What will happen to the results of the study?

The information in this study is being used in part fulfilment of the study physiotherapists PhD. The results of the study will be reported in medical/scientific/educational journals and disclosed at medical/scientific conferences. Some quotations from the interviews may be used in reports. However, no information which reveals your identity will be disclosed.

You will not be told the outcome of this study, but if you have questions about your own physical condition, the physiotherapist will be able to answer those questions.

Part 2 - Data Protection

What information about me (personal data) will be used for this study

We will be using some personal information in our research to help us to identify problems with physical function. We will also use the information you provide in the audio recording, if you proceed with the exit interview, following the exercise programme.

We will be seeking your age, weight, height and information relating to any medical conditions you may have. As part of the assessment, we will be finding out about your physical condition, your nutritional status and any pain you may have.

Only the information which we need about you for this study will be collected and nothing extra. With your consent, we will inform your GP of your participation in this study using a standard letter which will be posted within 24 hours of your assessment. Once this letter has been posted your GP details will be deleted.

Who will access my personal data?

Only the principal researcher, Dr. Julie Broderick and the study physiotherapist, Fiona Kennedy will be able to identify you. They will keep the master file which links your identity to the research data (your health data and your interview transcript). The study physiotherapist Fiona Kennedy will replace your name with a code on all research data.

How is the information kept confidential and secure?

Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Here are some examples of how we do this:

- To protect your identity, we will replace your name with a code.
- The key to this code will be stored securely and separately from the other research information.
- Any identifying information will be removed from the interview transcript.
- **Data security arrangements are** in place. Only TCD provided secure systems will be used.
- **A Data Protection Impact Assessment** has been carried out and the risk identified was low.
- **No presentation or publication** in relation to the study could identify you as all results will be analysed together.
- The research team having access to the personal data are **bound by a professional code of secrecy**.
- **Training in data protection law** and practice has been provided to the research team.

How long will my personal data be needed?

The research data (data concerning health and physical function and the coded transcripts) will be retained until three years following the study physiotherapist's PhD examination process is completed which is expected to be in November 2028. At that point, the link between you and your personal data will be securely deleted.

The audio recording of the interview will be retained until it has been transcribed and the content verified after which it will be securely deleted. This is expected to take place within 4 weeks of the interview. The transcript with identifiable information removed, will be retained until three years following the study physiotherapist's PhD examination process is completed which is expected to be in November 2028.

Your consent form will be retained until the study physiotherapist's PhD examination process is completed and will then securely deleted.

What is the lawful (legal) basis to use my personal data?

We will only use your personal data for this research project, which we hope will improve the health of people experiencing homelessness and addiction. We will also ask for your consent as a requirement of Irish law (Health Research Regulations), but we do not rely on this as our legal basis under GDPR¹.

¹ The European General Data Protection Regulation (GDPR)

¹ *Article 9(2) (j)*

¹ *(Article 6(1)(e)*

What are my rights under Data Protection law?

You are entitled to:

- The right to access to your data and receive a copy of it.
- The right to restrict or object to processing of your data.
- The right to object to any further processing of the information we hold about you.
- The right to have inaccurate information about you corrected or deleted.
- The right to request deletion of your data.

By law you can exercise the following rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting your study researcher Fiona Kennedy or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

Part 3 - Approval, Organising and Funding

Has this study been approved by a research ethics committee?

Yes, this study has been approved by the Faculty of Health Sciences Research Committee in Trinity College Dublin. Approval was granted on [INSERT DATE].

Who is organising and funding this study?

This study is being undertaken by Fiona Kennedy as part of her Ph.D. in Trinity College Dublin. This study is being funded by The Irish Research Council (IRC) and Trinity College Dublin. The IRC will be provided with an anonymous report. They will not access any personal data.

Will I be paid for taking part?

No, there is no payment for taking part in the study.

Will my data be used for future studies?

Basic demographic details provided for the purposes of this study, such as age, biological sex, living arrangements and addiction status may be collectively compared to future studies.

Part 4 - Further Information

What happens if I change my mind?

Your participation in this study is voluntary and you can change your mind even if the study has started.

You do not have to give a reason for changing your mind.

If you would like to withdraw from the study, please contact Dr. Julie Broderick at (01) 8962110, who can organise this for you. She will discuss with you if you are happy for us to continue to use information about you (personal data) which has already been collected. If you do not consent to your personal data being retained for this study, we will delete any information that could identify you.

Please note that we will not be able to remove personal data which has been shared or pooled for use in publication before your request for deletion.

We will not contact you again.

Who should I contact for information or concerns?

If you have any concerns or questions, you can contact:

- Principal Investigator: Dr. Julie Broderick (01) 8962110

If you have any questions in relation to your rights under data protection law, you can contact the Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.dataprotection.ie.

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to raise a concern with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie

Part 5 - Next Steps

Will I be contacted again?

If you would like to take part in this study, you will be asked to sign the Consent Form on the next page. You will be given a copy of this Leaflet and the signed Consent Form to keep. Please retain these in case they are needed for future reference.

After the study you will not be contacted again by the study team.

Thanks

Thank you for taking the time to read this Participant Information Leaflet.



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LEAP-W: Informed Consent Form-Part 1 (Intervention participants)

STUDY: A FEASIBILITY STUDY TO EXPLORE THE ROLE OF A LOW THRESHOLD EXERCISE PROGRAMME IN A DAY CARE FACILITY FOR WOMEN WITH PROBLEMATIC DRUG USE AND HOMELESSNESS.

Recruitment Site: Merchants Quay Ireland-Riverbank and Jane's Place

There are **two sections** in this form.

Section 1 contains statements of understanding and asks you to tick each if you understand. Please ask any questions you may have when reading each of the statements.

Section 2 asks for your informed consent. Please select either 'yes' or 'no' to indicate your choice.

Thank you for participating.

The end of this form is for the researchers to complete.

1. General Understanding	Tick
I confirm that I have read and understood the Information Leaflet for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	
I understand that taking part in this study is entirely voluntary. I understand that not taking part will have no negative impact on me.	
I understand that I can leave this study at any time without giving a reason. I understand that leaving this study will not affect the services I receive from MQI, now or in the future.	
I understand that all information about me will be kept private and confidential and that my name will not be disclosed in any publication.	
I understand that I will not be paid for taking part in this study.	
I know how to contact the research team if I need to (contact details below).	
<p>By ticking each box above and choosing my options below <u>and</u> signing this document I agree to participate in 'X' study as described in the Participant Information Leaflet.</p>	

2. Consent	
I agree to take part in this research study, having been fully informed of the risks and benefits in the participant information leaflet provided to me.	Yes No <input type="checkbox"/> <input type="checkbox"/>
I agree to the use of information about me (personal data) including information from the exit interviews being used by the research team for this research study as described in the participant information leaflet.	Yes No <input type="checkbox"/> <input type="checkbox"/>
I consent to the research team informing my GP about my participation in this study.	Yes No <input type="checkbox"/> <input type="checkbox"/>
I consent to the research team clarifying information with MQI staff for my safety, where necessary for the purposes of this research study only.	Yes No <input type="checkbox"/> <input type="checkbox"/>

Participant Name (Block Capitals) Participant Signature Date

Witness Name (Block Capitals) Witness Signature Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above participant the nature and purpose of this study in a way that they could understand.

I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.

I have given a copy of the participant information leaflet and consent form to the participant with contact details of the study team.

Researcher name _____

Title and qualification _____

Contact details: Fiona Kennedy, Discipline of Physiotherapy, Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8, (phone: 01-8962110)

Signature _____

D



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

LEAP-W-Participant Information Leaflet (Stakeholders)

<p>Study Title</p>	<p>A FEASIBILITY STUDY TO EXPLORE THE ROLE OF A LOW THRESHOLD EXERCISE PROGRAMME IN A DAY CARE FACILITY FOR WOMEN WITH PROBLEMATIC DRUG USE AND HOMELESSNESS.</p> <p>(Interview with stakeholders)</p>
<p>Research Site(s)</p>	<p>Merchants Quay Ireland (MQI)-Riverbank, Dublin and Jane’s Place, Dublin.</p>
<p>Principal Investigator(s) and Co-Investigator(s) (Study Team)</p>	<p>Principal Investigator: Dr. Julie Broderick</p> <p>Co-investigators:</p> <ul style="list-style-type: none"> - Fiona Kennedy, PhD student, Discipline of Physiotherapy, School of Medicine Trinity College - Prof. Cliona Ní Cheallaigh, Associate Professor and Consultant in Infectious Diseases, School of Medicine Trinity College - Prof. Roman Romero-Ortuno, Associate Professor and Consultant Physician, School of Medicine Trinity College - Dr. Deirdre Murray, Assistant Professor, Academic Unit of Neurology, Trinity College Dublin
<p>Study Organiser/ Sponsor</p>	<p>Trinity College Dublin/Irish Research Council</p>
<p>Data Controller</p>	<p>Trinity College Dublin</p>
<p>Data Protection Officer</p>	<p>Data Protection Officer Secretary’s Office Trinity College Dublin Dublin 2</p>

We would like to invite you to take part in a research study that is being carried out by Dr. Julie Broderick and her research team at Trinity College Dublin.

Before you decide whether or not you wish to take part, please take time to read this information leaflet carefully.

If there is anything which is not clear, or if you would like more information, please ask the researchers. You should understand the benefits and any risks of taking part in this study so that you can make a decision that is right for you.

Do I have to take part?

No, you don't have to take part in this study. It is entirely voluntary and up to you. Don't feel rushed or under pressure to take part or to make a quick decision. You can change your mind and opt out even if the study has started.

This leaflet has six parts:

Part 1 - The Study

Part 2 - Data Protection

Part 3 - Approval, Organising and Funding

Part 4 - Future Research

Part 5 - Further Information

Part 6 – Next steps

Part 1 - The Study

Why have I been invited to take part?

We are interested in understanding the impact of exercise and nutrition on physical health in women experiencing homelessness and addiction, who attend MQI (Jane's Place). You have been invited to take part as you are a service provider in Jane's Place/Riverbank, with knowledge and experience of working with this population and the participants of this study and we are hoping that you will assist us by participating in a one-to one interview.

Why is this study being done?

We are doing this study to explore the impact of a low threshold exercise programme with protein supplementation, in MQI Jane's Place, a women's only service for people experiencing problems with addiction and homelessness in Dublin 2 and 8. This interview-based study will help us to better understand the benefits of the programme as well as its' challenges, for example recruitment and retention issues.

What does taking part involve?

This study is expected to commence in February 2024 and will continue for 3 months. The interviews will take place following the exercise programme with service providers from MQI (Riverbank and Jane's Place). Like the exercise programme they will take place in MQI (Jane's Place or Riverbank). If you decide to take part, a member of the research team will discuss this information leaflet and the consent form with you. You will be given a copy of your signed consent form and this leaflet to keep.

Following consent, you will be invited to do a one-to-one interview with the research physiotherapist Fiona Kennedy, to get your views on the impact and the challenges of running the programme which will have been completed. This interview is entirely voluntary. We will arrange a time of convenience for you for your interview in MQI (Riverbank or Janes' Place). With your permission, the interviews will be audio recorded. We will transcribe your interview and offer you an opportunity to check and verify the transcript for up to 4 weeks following the invitation.

What are the possible benefits of taking part?

There are no direct benefits to your participation in the programme. In the future, findings from this study may help us design better exercise classes in settings similar to MQI (Riverbank and Jane's Place). By participating, you are helping to advance science and medicine/education for future generations.

Are there any possible disadvantages or risks from taking part?

There is a possibility that a connection to your identity could be made. However, we take many measures to ensure the anonymity/confidentiality of all data. The risk of a breach of confidentiality is considered very low as your data will be coded. Data from all service providers will be analysed together, so the possibility of a connection to your identity is very unlikely.

What will happen to the results of the study?

The information in this study is being used in part fulfilment of the study physiotherapists PhD. The results of the study will be reported in medical/scientific/educational journals and disclosed at medical/scientific conferences. Some quotations from the interviews may be used in reports. However, no information revealing your identity will be disclosed.

Part 2 - Data Protection

What information about me (personal data) will be used for this study

We will use the information you provide in the audio recording. Only the information which we need about you for this study will be collected and nothing extra.

Who will access my personal data?

Only the principal researcher, Dr. Julie Broderick and the study physiotherapist, Fiona Kennedy will be able to identify you. They will keep the master file which links your identity to the research data (your interview transcript). The study physiotherapist Fiona Kennedy will replace your name with a code on all research data.

How is the information kept confidential and secure?

Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Here are some examples of how we do this:

- To protect your identity, we will replace your name with a code.
- The key to this code will be stored securely and separately from the other research information.
- Any identifying information will be removed from the interview transcript.
- **Data security arrangements** are in place. Only TCD provided secure systems will be used.
- **A Data Protection Impact Assessment** has been carried out and the risk identified was low.
- No **presentation or publication** in relation to the study could identify you as all results will be analysed together.
- The research team having access to the personal data are **bound by a professional code of secrecy**.
- **Training in data protection law** and practice has been provided to the research team.

How long will my personal data be needed?

The research data (the coded transcripts) will be retained until three years after the study physiotherapist's PhD examination process is completed which is expected to be

in November 2028. At that point, the link between you and your personal data will be securely deleted.

The audio recording of the interview will be retained until it has been transcribed and the content verified after which it will be securely deleted. This is expected to take place within 4 weeks of the interview. The transcript with identifiable information removed, will be retained until three years after the study physiotherapist's PhD examination process is completed which is expected to be in November 2028.

Your consent form will be retained until the study physiotherapist's PhD examination process is completed and will then securely deleted.

What is the lawful (legal) basis to use my personal data?

We will only use your personal data for this research project, which we hope will improve the health of people experiencing homelessness and addiction. We will also ask for your consent as a requirement of Irish law (Health Research Regulations), but we do not rely on this as our legal basis under GDPR¹.

¹ The European General Data Protection Regulation (GDPR)

¹ Article 9(2) (j)

¹ (Article 6(1)(e))

What are my rights under Data Protection law?

You are entitled to:

- The right to access to your data and receive a copy of it.
- The right to restrict or object to processing of your data.
- The right to object to any further processing of the information we hold about you.
- The right to have inaccurate information about you corrected or deleted.
- The right to request deletion of your data.

By law you can exercise the following rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting your study researcher Fiona Kennedy or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

Part 3 - Approval, Organising and Funding

Has this study been approved by a research ethics committee?

Yes, this study has been approved by the Faculty of Health Sciences Research Committee in Trinity College Dublin. Approval was granted on [INSERT DATE].

Who is organising and funding this study?

This study is being undertaken by Fiona Kennedy as part of her Ph.D in Trinity College Dublin. This study is being funded by The Irish Research Council (IRC) and Trinity College Dublin. The IRC will be provided with an anonymous report. They will not access any personal data.

Will I be paid for taking part?

No, there is no payment for taking part in the study.

Will my data be used for future studies?

Your data will not be used in future studies.

Part 4 - Further Information

What happens if I change my mind?

Your participation in this study is voluntary and you can change your mind even if the study has started.

You do not have to give a reason for changing your mind.

If you would like to withdraw from the study, please contact Dr. Julie Broderick at (01) 8962110, who can organise this for you. She will discuss with you if you are happy for us to continue to use information about you (personal data) which has already been collected. If you do not consent to your personal data being retained for this study, we will delete any information that could identify you.

Please note that we will not be able to remove personal data which has been shared or pooled for use in publication before your request for deletion.

We will not contact you again.

Who should I contact for information or concerns?

If you have any concerns or questions, you can contact:

- Principal Investigator: Dr. Julie Broderick (01) 8962110

If you have any questions in relation to your rights under data protection law, you can contact the Data Protection Officer, Trinity College Dublin: Data Protection Officer,

Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.dataprotection.ie .

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to raise a concern with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie

Part 5 - Next Steps

Will I be contacted again?

If you would like to take part in this study, you will be asked to sign the Consent Form on the next page. You will be given a copy of this Leaflet and the signed Consent Form to keep. Please retain these in case they are needed for future reference. After the study you will not be contacted again by the study team.

Thanks

Thank you for taking the time to read this Participant Information Leaflet.



LEAP-W-Informed Consent Form (Stakeholders)

STUDY: A FEASIBILITY STUDY TO EXPLORE THE ROLE OF A LOW THRESHOLD EXERCISE PROGRAMME IN A DAY CARE FACILITY FOR WOMEN WITH PROBLEMATIC DRUG USE AND HOMELESSNESS.

(Exit Interview with Stakeholders)

Recruitment Site: Merchants Quay Ireland-Riverbank and Jane's Place

There are **two sections** in this form.

Section 1 contains statements of understanding and asks you to tick each if you understand. Please ask any questions you may have when reading each of the statements.

Section 2 asks for your informed consent. Please select either 'yes' or 'no' to indicate your choice.

Thank you for participating.

The end of this form is for the researchers to complete.

1. General Understanding

Tick

I confirm that I have read and understood the Information Leaflet for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.

I understand that taking part in this study is entirely voluntary. I understand that not taking part will have no negative impact on me.

I understand that I can leave this study at any time without giving a reason.

I understand that all information about me will be kept private and confidential and that my name will not be disclosed in any publication.

I understand that I will not be paid for taking part in this study.					
I know how to contact the research team if I need to (contact details below).					
By ticking each box above and choosing my options below <u>and</u> signing this document I agree to participate in 'X' study as described in the Participant Information Leaflet.					
2. Consent					
I agree to take part in this research study, having been fully informed of the risks and benefits in the participant information leaflet provided to me.	<table border="1"> <tr> <td style="text-align: center;">Yes</td> <td style="text-align: center;">No</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	Yes	No	<input type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input type="checkbox"/>	<input type="checkbox"/>				
I agree to the use of information from the exit interviews being used by the research team for this research study as described in the participant information leaflet.	<table border="1"> <tr> <td style="text-align: center;">Yes</td> <td style="text-align: center;">No</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	Yes	No	<input type="checkbox"/>	<input type="checkbox"/>
Yes	No				
<input type="checkbox"/>	<input type="checkbox"/>				

Participant Name (Block Capitals) Participant Signature Date

Witness Name (Block Capitals) Witness Signature Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above participant the nature and purpose of this study in a way that they could understand.

I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.

I have given a copy of the participant information leaflet and consent form to the participant with contact details of the study team.

Researcher name _____ Title and qualification _____

Contact details: Fiona Kennedy, Discipline of Physiotherapy, Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8, (phone: 01-8962110)

Signature _____ Date _____

Copies to be created and retained: 1 for Participant, 1 for PI



LEAP-W- GP Letters prior to participation

A feasibility study to explore the role of a low threshold exercise programme in a centre for women with problematic drug use and homelessness’.

Principal Investigator: Dr. Julie Broderick, Discipline of Physiotherapy, Trinity Centre for Health Sciences, St. James’s Hospital, Dublin 8.

Study Collaborators: Prof Cliona Ní Cheallaigh and Prof Roman Romero-Ortuno School of Medicine TCD and St. James’s Hospital, Dr. Deirdre Murray, Academic Unit of Neurology, Trinity College Dublin Fiona Kennedy, Trinity College Dublin

Research Physiotherapist: Fiona Kennedy, Discipline of Physiotherapy, Trinity Centre for Health Sciences, St. James’s Hospital, Dublin 8.

Date:

Re:

D.O.B:

Dear Dr. _____,

I am writing to inform you that _____ has consented to participate in a research study which is currently being conducted in Jane’s Place, Merchants Quay Ireland. We are writing to you as the main contact GP for _____.

The aim of this study is to explore the feasibility of a fitness focused drop-in exercise programme with dietary supplementation to target physical functioning in people accessing services in Jane’s Place, Merchants Quay Ireland. It involves an exercise assessment and individualised exercise training followed by a nutritional supplement. The duration of the study is 10 weeks. If further details are required, please do not hesitate to contact me.

Yours sincerely,

Julie Broderick

Fiona Kennedy, CORU registered Research Physiotherapist PT027553

Email: kennedf4@tcd.ie Phone: (01) 8962110

Julie Broderick, Assistant Professor, Discipline of Physiotherapy, Trinity College Dublin

Email: julie.broderick@tcd.ie Phone: (01) 8962110



A feasibility study to explore the role of an exercise class in Jane's Place

Principal Investigator: Dr. Julie Broderick, Discipline of Physiotherapy, Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8.

Study Collaborators: Prof Cliona Ní Cheallaigh and Prof Roman Romero-Ortuno School of Medicine TCD and St. James's Hospital, Dr. Deirdre Murray, Academic Unit of Neurology, Trinity College Dublin, Fiona Kennedy, Discipline of Physiotherapy, Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8.

Date:

Re:

D.O.B:

Dear Dr. _____,

I am writing to inform you that _____ has consented to participate in a research study, which is currently being conducted in Jane's Place. This involves an exercise assessment and group exercise training followed by a nutritional supplement. The duration of the exercise intervention is 10 weeks. We are writing to you as the main contact GP for _____.

As part of our assessment prior to the start of the exercise programme, this patient indicated that they had or have some cardiac concern or history. Precautions we are taking are that blood pressure and heart rate will be taken prior to and on completion of each exercise session and symptoms will be closely monitored. We start each individual at a light level and progress the exercise gradually based on individual ability. The exercise class is led by a registered Physiotherapist with over 20 years clinical experience. However, as this is a community-based setting – we do not have access to medical notes therefore we are checking in with you as their GP. **We are intending to start this patient in this exercise programme but if you have any concern or there is a reason why this patient should not exercise with us – please get in touch as soon as possible as the programme is due to start in early March.**

Yours sincerely,

Fiona Kennedy, CORU registered Research Physiotherapist PT027553

Email: cromwelf@tcd.ie

Phone: (01) 8962110

Julie Broderick, Assistant Professor, Discipline of Physiotherapy, Trinity College Dublin
Email: julie.broderick@tcd.ie Phone: (01) 8962110

Appendix VII Code Book

Theme	Subtheme	Category	Code
1. The Power of Exercise			General codes
			<ul style="list-style-type: none"> -comparison to previous recovery programmes -importance of exercise in general -gratitude expressed by staff and participants -life changing impact -low risk, high return -possibilities of exercise -positive programme feedback -empowerment -desire to improve mental health & physical health -ripple effect of exercise -behavioural change -benefit of attending -Is enough been done in this population regarding exercise?

Theme	Subtheme	Category	Code
1. The Power of Exercise	<i>1. Physical health impact</i>	Physical health benefits	-health gains -physical health benefits (strength, function, sleep, energy) -the ripple effect of exercise
		Weight management	-weight loss -weight management
		Women's health benefits	-pelvic floor control
		Pain relief	-impact on pain -decreased reliance on pain relief
1. The Power of Exercise	<i>2. Mental health impact</i>	Mental health benefits	-positivity of the programme -a distraction -benefit of pushing oneself -importance of exercise for mental health -exercise as a coping mechanism -the hope it instils -gives a focus for the day
		Impact on mood	-'high' from exercise -helps with low mood/anxiety -exercise likened to drug use

Theme	Subtheme	Category	Code
		Self-esteem	-importance of achievement -sense of empowerment -increased confidence -increased sense of purpose
		Personal gains	-prioritised self -more time for self -more mindful
1. The Power of Exercise	<i>3. Social impact</i>	Social capital	-desire to increase social capital -social support from the group
		Connectivity	-benefit of company of other people -fun, laughter -proven enjoyable -closeness, shared experience -music
1. The Power of Exercise	<i>4. Impact on substance use</i>	Substitute	-exercise as a substitute for drug use -delay in substance use -possible shift from substance use to exercise
		Impact on relapse	-impact of exercise on relapse

Theme	Subtheme	Category	Code
1. The Power of Exercise	<i>5. Impact on health literacy</i>	Importance of brief interventions	<ul style="list-style-type: none"> -power of brief interventions -importance of making every contact count -importance of education in nutrition/views on protein -importance of discussing women's health issues (including continence) -commitment to continue -desire to continue
		Value of discussions for knowledge	<ul style="list-style-type: none"> -information base -forum for knowledge -source of knowledge -gained more knowledge on physical health -increased desire to continue exercise awareness of simplicity of exercise -awareness of walking as very accessible/free -knowledge of exercise possibilities outside of programme -making better choices

Theme	Subtheme	Category	Code
2. Challenges to engagement	1. Backstory and life course	Backstory	<ul style="list-style-type: none"> -relevance of backstory -implications of backstory -childhood memories -adverse childhood experiences -life course, lifestyle, fate -trauma -chaotic lives -importance of early intervention
		Poverty/disadvantage	<ul style="list-style-type: none"> -impact of poverty, deprivation -financial burden -inequity of background/societal position
		Prior experience of exercise	<p>Positive:</p> <ul style="list-style-type: none"> -Positive experience with exercise -Some had prior knowledge of exercise -nostalgia about past enjoyment of exercise -Past enjoyment of exercise -Were informed about exercise -Health literacy varied & impacts on participation

Theme	Subtheme	Category	Code
2. Challenges to engagement	<i>1. Backstory and life course</i>	Prior experience of exercise	Negative: Negative experience/views of exercise -Negative experiences-pain with exercise -No prior participation in exercise (health literacy & exposure) -Exercise as unfamiliar -No previous h/o a healthy lifestyle
		View of men	-negative view based on life experience

Theme	Subtheme	Category	Code
<p>2. Challenges to engagement</p>	<p><i>2. Lifestyle and living environment</i></p>	<p>Impact of lifestyle</p>	<ul style="list-style-type: none"> -lifestyle issues-stress -challenges of life -lifestyle compared to general population -isolation of lifestyle -impact of lifestyle on health -survival mode -no phones -priorities: survival V self-care -cost implications-poverty -weight issues -substance use issues -drinking as a coping mechanism -drinking leading to shame/guilt -poor health due to chaotic lifestyle -crisis management-rather than prevention -unreadiness to commit to exercise/anything

Theme	Subtheme	Category	Code
2. Challenges to engagement	<i>2. Lifestyle and living environment</i>	Living environment	<ul style="list-style-type: none"> -impact of sleeping rough -priorities when homeless -risks and dangers of homelessness -fear impacting on physical health -difficulty maintaining motivation and energy -difficulty of hostel living -less autonomy/control in hostel -hostel likened to prison -sleep issues in hostel -competing life priorities -difficulty of leaving homelessness -attachments to partners in homelessness -limited resources to exercise
		Unmet needs	<ul style="list-style-type: none"> -basic needs -sleep issues -self-care -access to clothes -hygiene -limited access to nutrition -impact of poor nutrition

Theme	Subtheme	Category	Code
		Compounding impact of homelessness, mental health and addiction on physical health	<ul style="list-style-type: none"> -dual diagnosis -tri morbidity
2. Challenges to engagement	<i>3. Social exclusion</i>		<ul style="list-style-type: none"> -impact of loneliness -loneliness of addiction -impact of isolation -socially excluded-the forgotten people -often seeing no-one else in a day -isolation and loneliness of homelessness -lack of social capital -lifestyle choices -inequities in different sectors of society -limited outlets for socially excluded people -lack of state support for addiction -poor engagement with healthcare services -negative experiences with healthcare professionals -consequences of inflexibility of healthcare professionals -impact of social exclusion on ability to engage

Theme	Subtheme	Category	Code
2. Challenges to engagement	4. Perceptions of self	Negative perceptions of self	<ul style="list-style-type: none"> -negative perceptions of self -self-worth issues -low self-care -self-care-not a priority -feeling undeserving -identity issues-identification with chaos -identity-feeling undeserving of a healthy lifestyle -fate-cognisant dissonance -poor self-esteem
		Impact of low self-worth	<ul style="list-style-type: none"> -stigma -humiliation -fear ability to engage. -feeling of being overwhelmed -mental health/addiction challenges -lack of motivation -inability to cope -ADHD -recognition of the need to improve self-confidence. -surprise when someone cares -resilience of some

Theme	Subtheme	Category	Code
2. Challenges to engagement	<i>5. Health issues/Healthcare needs</i>	Physical health issues	<ul style="list-style-type: none"> -impact of physical health issues -limitations of health issues -concerns for health -challenges of medical issues -impact of age
		Challenges associated with health issues	<ul style="list-style-type: none"> -physical health conditions-pain/mobility -health issues not prioritised -exercise needed for weight management -poor health due to poor diet -drive to participate was health issues -desire to improve health
		Views of exercise for health	<ul style="list-style-type: none"> -importance of exercise for mental health and addiction -views of exercise interventions for this population -priority needed for exercise prescription -exercise for social prescription too -constraints of the health service -poor engagement with healthcare services -less likely to attend for healthcare -lack of state support for people in addiction

Theme	Subtheme	Category	Code
<p>2. Challenges to engagement</p>	<p><i>6. Challenges of intervention</i></p>		<p>Negative:</p> <ul style="list-style-type: none"> -challenges to commence -difficulty committing -intent to attend -addiction issues -importance of exercise history -positive and negative experiences with exercise impacting on openness to participation -hesitancy with exercise -wary of committing -difficulty committing due to fear or grief of it ending -disproportionate -accustomed to things ending e.g. interventions -hesitancy about coming -challenge of routine due to chaos/lack of structure <p>Positive:</p> <ul style="list-style-type: none"> -for some it was opportunistic -for others curiosity/openness to participation -exercise as unfamiliar -some had a positive outlook -movement seen as a new concept -desire to overcome life challenges

Theme	Subtheme	Category	Code
3. The LEAP Approach			<p>General codes:</p> <ul style="list-style-type: none"> -gratitude, hope expressed, -programme design considered important -programme gave people a 'sense of purpose' -'short comings of the health service' fed into the need for programmes of this kind -problems with the current system -current healthcare approach not meeting the needs of this population -simple solutions to meeting needs -existing exercise interventions in addiction services -low retention common in low threshold services -expectations from low threshold services in general -positive feedback -success measured by consistency in attendance -commitment to the programme -to some exercise as an intervention/therapy is a novel concept -new staff learning from the programme -social prescription-sign post for staff to refer for exercise -importance of offering exercise as an intervention -hope/possibility -acceptance that things will go wrong at times

Theme	Subtheme	Category	Code
3. The LEAP approach	1. Trauma informed	Trauma informed design	<ul style="list-style-type: none"> - importance of trauma informed care -TIC more important than the exercise -sensitivity required -dislike of being questioned -importance of inclusivity -importance of choice -trust -non-judgemental approach -the value of someone being interested -importance of hope -importance of connection -basic needs-security/safety -routine, structure, consistency important -importance of putting self-first
		Facilitator	<ul style="list-style-type: none"> -importance of the facilitator -importance of teachers in their lives (good influence) -importance of positivity of facilitator -non-judgemental -consistent-always there -kind, fun, -messages made people feel wanted -being invited was a measure of positive impact

Theme	Subtheme	Category	Code
3. The LEAP Approach	<i>1. Trauma informed</i>	Making every contact count	-importance of social prescribing -positivity of the programme -importance of programme for health/social connection -importance of being invited
3. The LEAP Approach	<i>2. Gender sensitive</i>	Negative experiences with men	-importance of gendered space -importance of women's only due to traumatic experiences due to men -importance of security for women -importance of safe space
		Women's issues and differences	-different needs of women -need for connection with women -different environment with women -support of other women important -women specific issues-weight, menopause
		View of traditional services	View of traditional services

Theme	Subtheme	Category	Code
3. The LEAP approach	3. <i>Low threshold</i>	Low threshold	<ul style="list-style-type: none"> -importance of low threshold service -views of low threshold -no barriers to access -no cost-minimal/no equipment/walking free -variations of other programmes-kicked out if relapse -accessibility important-location as a barrier, transport, cost, fear -location important for those at-risk
		Flexible	<ul style="list-style-type: none"> -flexible times -flexible type of exercise -flexibility and accessibility
3. The LEAP approach	4. <i>Group-based</i>	Benefit of the group	<ul style="list-style-type: none"> -variety and diversity of backgrounds with shared interest -benefits of group work -awareness of others and their similar challenges -importance of group-connectivity -appreciation of diversity in the group -some suggest separate groups due to differing stages of journey; others oppose -inclusivity

Theme	Subtheme	Category	Code
3. The LEAP approach	<i>5. Multi-modal</i>	Multi-modal	<ul style="list-style-type: none"> -appreciation of multi-modal -enjoyment of variety -offered choice
		Tailoring	<ul style="list-style-type: none"> -importance of tailoring -challenge of disability-needed tailoring -importance of tailoring-music, dance, fun -personal goals for the programme -importance of 1-1 also (participant/staff) -importance of social prescribing (making it fun/social-also trauma informed)
3. The LEAP Approach	<i>6. Sustainable</i>	Positives and possibilities	<ul style="list-style-type: none"> -improved attendance may have a transfer effect to other services -new learning for staff -importance of prior engagement -importance of messages -importance of phone/What's App messages-behavioural change -future programmes-incentives important for retention

Theme	Subtheme	Category	Code
		Bridging the gap	<ul style="list-style-type: none"> -bridging the gap between low threshold and mainstream structures -bridge to mainstream -some people nearly ready to engage in mainstream services -translation to independent exercise in the community -acknowledging the design of a programme must have inbuilt plans for continuity -suggestions for future programmes
3. The LEAP approach	<i>6. Sustainable</i>	Education and health literacy	<ul style="list-style-type: none"> -awareness of importance of exercise and nutrition -simplicity of exercise – Park Walk -importance of education -targeting health literacy-desire to exercise for weight management, discussion on nutrition, importance of education, ad lib health education discussion
		Tackling the challenges	<ul style="list-style-type: none"> -difficulty committing -barriers and challenges to continuing -many expressed a fear of the programme ending -fear of programme ending -support needed to continue-needed persuasion and -encouragement to start and attend

Appendix VIII Data Extract LEAP-W

Participants

1. Reasons for participation in LEAP-W

P1	"It would be hard to tailor the exercises if you had men, coz men's bodies are so different."
P2	"I have major health issues, I've got Diabetes Type 2, eh an eating disorder, addiction problems with too much gin, drinking too much gin, and mental health issues with self-esteem issues and because of being disabled, because I've had mobility issues as well and walk with a stick, so em, I kind of find it difficult to do any exercises because of my knee problems and stuff and so I kind of find it a bit embarrassing... I've been through domestic violence as well, so I kind of find men a bit scary ..."
P8	"I personally do feel better after exercise. I feel better, I feel I have more energy, you know I feel more strength and mentally it's really good for me ..."
P12	"I has lost all belief and confidence in myself and I was at one of the lowest points in my life, em that was my initial reason (for enrolling) ... when it came to the crunch of actually coming into the programme, it took an awful lot of gentle persuasion from yourself to get me in ... the way you listen and talk to us you know, em I realized that, that was my drug of choice, you know, was to exercise, and I know you can't walk it out or run it out walk, your issues, but it helps, you know ... you gave me that confidence to come back in and belief in myself because it had been taken away completely you know and I was eroded of everything ... when you come from the backgrounds of you know, abusive relationships and abuse of, all through the years ... it's like it's just you could just breathe out and you can just be yourself and I've never even known what it is just to be myself but now I'm learning you know ... "
P19	"I enrolled in this program because I live in a homeless hostel and it's very isolating and I was going through a lot, like it was very lonely for me ... I felt like it would be a way to bring back my confidence and exercise is good way to make you feel better about yourself... I've had bad experience around men before and with women you can just be yourself and just be comfortable ... "
P21	"The thing I loved about it as well is because it's women only, it's a safe space... when you walk in the door you know, that we're all women and we can talk about anything and confide, which makes me more secure ... we had laughs in the classes ... "

2. Benefits of LEAP-W

P1	<p>“I enjoyed everything about it really, there wasn’t anything I didn't enjoy ... in the hostel you’ve no, look even we don't even have space to sit and talk to each other half the time ... You didn't have to put on a mask ... you'll come in the door and there's' somebody smiling and ok you might be late or show up in a bit of a heap coz you're tired or you're sore but like she'd know it wasn't for a bad reason, it's not because you're lazy.”</p>
P2	<p>“Everybody kind of encourages each other along ... I really appreciated your tailoring the exercises ... we did those pelvic floor muscle exercises, and I've now found a) I no longer pee myself because I no longer panic about the fact that that I need to go because I know I have the tools, the muscles, that can hold it. That was the most significant thing ... cause I'm drinking less you see ... another big, big benefit from the program because it about a self-esteem issue, and I deserve to put myself first ... I was finding their drumming workshops difficult. I kept having to stop all the time due to pain in my upper arm muscles. Em I don't use, ye, basically the pain was quite bad, so I just had to stop. But now, this week we've done the last class, and I actually had no pain ... Now I feel a lot more love for my body, if that makes sense and confident that it can do what I need it to do, especially my legs ... I now, I can find, I can lift my arms higher, I have no pain ... I have much more energy, I feel more agile, toned, I feel better about myself all-round like ... I'm sleeping better.”</p>
P7	<p>“It was a very relaxed kind of environment. It was all women, so I didn't feel so self-conscious or anything like that ... I feel like I'm more, my body has woken up ... my energy levels that were increasing... I feel I've done something for myself.”</p>
P9	<p>““I was just amazed because I never see any program like it ... no judgment, and no negativity ... if there has have been men, I wouldn't have been so open ... it's my drug ... Then the uplifting music feels like you wanna dance ... only for the facilitators I think I wouldn't have lasted, because I'm a person that, eh, I don't know if I'm hard to get on with or it's probably a bit hyper at times ... the ibrufen as well I find I don't' take as many ... the biggest thing for me was yous all took me for who I was, yous never, yous never turned your back on me ever ... I came in here every single week and no judgment ... I've loads of energy ... But now I get up and I smile, and I look forward to coming ... it gives me self-worth, confidence and self-esteem and like I'm able to, me posture, I hold my posture up a lot more ... I always question myself, why is people so nice to me, you know, why is people so good to me ... I was on a natural high (laugh) going out the door ... Energy, I feel alive! ... it gave me strength that I never knew I had ... it was like taking drugs to me ...”</p>

P12	<p>“It was giving me a reason to leave my home every day ... we need to know that you're not being judged ... you need to know that something is going to be there, routine you know ... life is erratic enough and can become very erratic and I know that over the last couple years when I took drugs how erratic your life can be when you have no confidence to begin with and then you lose everything you need to know what to do something there that's non-judgmental, that's going to encourage you ... it's awakening my confidence again ... you're guaranteed that you're going to be here all the time you know and that's a huge thing ... you're very, very, generous with your time ... I always go away feeling so much better, you know, I feel lifted and you know, like yeah I can do this you know ... it's not only a walk, it's a talk you know and it doesn't always have to be but you know you know it's like we're just friends walking ... you just sprinkle everything with fun, you know ... I feel so much stronger and healthier in myself doing this, you know ... then the advice that you give you know, you help us all with our you know bits and pieces that are wrong or aren't working right and you know and so you're empowering me by doing that ... you show me how to do the exercises properly and I've great trust and belief in you and you know and I feel that my body feels so my body so grateful first you know so ... you just make us feel wanted you know, good enough, to be here and that we deserve better you know and you don't just get that in any gym or any place like you know ... my physical health has improved greatly ... I sleep better ... my physical health has improved greatly ... it makes me feel so good that I don't, I don't want it (drugs) ... my pelvic floor, mother of God, I went out yesterday, I never used the bathroom all day long.”</p>
P18	<p>“You are doing it instead of being alone.”</p>
P19	<p>“It was giving me new ideas of if I'm at home, what kind of exercises can I do ... I think it's very good for your mood, after you do exercise even while you're in the exercise class. You, you feel a lot happier, you feel like good about yourself that you're doing something healthy for yourself, and it kind of encourage you to eat healthy as well.”</p>
P21	<p>“I loved as well, you didn't mind if I was 10-15 mins late, like”</p>
P23	<p>I hadn't done those exercises before, so I wasn't really aware that they were important for women to be doing, so I just thought it was good ... it would help you on the energy level.”</p>
P33	<p>“I enjoyed the programme because you are a very good teacher ... it has improved my mental state ... it has made me to be positive of myself ...”</p>

3. Challenges of LEAP-W

P1	"There was a lot of positive things, you know. I suppose it's your whole sense of like socializing and being around people ... There's mornings you get up, and it's just like, you know, good things could be going on, bad things could be going on, things that just slow you down could be going on ... And then stresses, yeah you know, like noise and stuff like that. I might get a bad night's sleep."
P2	"I would drink and I found it challenging to get up and I probably would be... I still came but I would be late. Also, there's a feeling sort of guilt and shame, that I'm not doing my best and that's kind of .. you know it's just horrible."
P5	"I was totally overwhelmed, living in a hostel with my life being, actually around that time I think my life was being threatened in, 3 times in one night in the hostel ... I've ADHD, I'm overwhelmed even when everything is going well, even if you had your own home and being overwhelmed would be a daily challenge. I've had bad experiences of assessments and I just feel when you've lost all control of your life and somebody is sitting in front of you questions about yourself, you already feel so bad about yourself ... I was very down, the doctor said it was just a crash after the pressure I'd been under and eh it was, you know I'd never been in that hostel ... when you become homeless in Ireland and go into a hostel, you are in a day prison."
P7	"Would have been again due to my mental health, em, ye due to me mental health and just kind of not having that motivation."
P8	"Exercise is very vital for addicts, you know to, to recover, because you know, to release that energy, you know and eh, I never believed that eh when you feel tired and you exercise you feel more energy ... it was constant, constant and then just messing up again ... it is the truth but by the time you get to treatment you're dead probably."
P9	"I struggle sometimes, every day, but it was that powerful that I made it ... something kept bringing me back ... Like the lovely messages that you send out in the morning ... I do say to myself, like for someone even to think of ye like that, to take time to send a message out to you like, that's says something in itself, you know ... I love coming here."
P19	"I found it hard to come because I'm not living in a good place, it's a homeless hostel."

4. Future plans and additional comments

P2	"I'm kind more confident about what I can do now ... I'm in bits, to be honest with you, I'm really devastated. I'm kind of, now, this is going to sound really mental but right because I was adopted, I was kind of rejected by my birth parents and then I was rejected by
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	my adopted parents and I have really severe abandonment issues, so when you have like .. form attachments in groups and stuff like that, when they finish, I find it extremely challenging... I'm feeling the benefits of it."
P9	"It will hit me hard, it will, if it's just taken away, like, you know like, I don't like doing things, I don't like doing programmes, they put it there and then 6 months later it's like, you're left ... Me final thought XXX would be that you could carry on... come back, come back, come back, come back ... but this course is after loosening me, it's after opening me, I was very sad when I came here, I was very lonely and I was very ... but yous, I know you're not counsellors but yous listened to me blabbing on, you know what I mean and I really appreciate it."
P12	"I'd like to see a program, an exercise program for the women like this, you know with someone would has understanding that yeah, they have issues ... I don't think there's one woman that has come to this that could would say I certainly I haven't heard them say that it didn't help them, yeah it's been, you know it's life changing in ways ... they need to have these programs you know ... you need to have something that's structured you know and it's routine because routine is the most important thing when you're, especially when you're down ... it has it has given me back something that I lost a long, long time ago and you've given me that back and I'm not going to lose it again you know... I'd just like to say thanks a million for everything that you did, I mean you're just, you saved me from a breakdown, I think, you know, yeah ... it just brings up that abandonment again, but what you've done, now I realise as it's coming to an end, you've given me a space doing the exercise, and talking to you as well, that you're giving me that space that I can see, yeah you've, you've, come into my life, and you've been in it for a season and you've definitely been in it for a reason, but you're showing me that I can move forward and I can exercise somewhere else and take this with me... I've use exercise as my way of getting away from the troubles that are going on in my life and the issues that have been there, but I have found here and I've only been learning it and that's why I think this is so important in a place."
P19	"Yeah, it just made me realize how important it is, and you don't have to be so strict that you must go to a specific gym or do one type of exercise. There's lots of different types of exercise you can do."
P21	"Like this is the first time I walked into an exercise class... it's not all really serious, we all had a laugh... I made a few friends anyway. But em, ye it's good for your mental health. It's good for the body, it's good for the soul."
P23	"I think you did it very well and you brought a lot of variety into it, different exercises and you were very flexible with the times and even if I came late or whatever, you tried to give me a chance ... I'd love if you could come back at some stage."

P33	“The way we talked through the exercise, it make us get closer and be friends with each other.”
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Stakeholders

1. View of the concept of exercise as a therapeutic intervention for this population

S1	“It’s a very important initiative ... doing it in a female only space is beneficial ... because of possible past trauma, em related to men, ye.”
S2	<p>“Very beneficial. A lot of women have come back to let us know that they really enjoyed it ... Eh it gave them a sense of purpose, something to wake up in the morning to go to and also ... since they’ve been attending a lot of them I find that the weight is shedding off slowly, the exercise is not too rigorous like you would do when you go into the gym, it’s tailor made and eh ye, they really find it very beneficial, ye... we social prescribe and exercise will be one of the main thing that we would be use especially for people with low mood... People with anxiety and the like, so if they would engage, they find it very beneficial, coz during exercise serotonin is released and that helps them, to help lift the mood ... they could just come in as they are and sweat it off ... they felt like they could be themselves ... It’s really beneficial for it to be tailored to them...</p> <p>This population have, very limited stuff ... they find exercise different. It’s more beneficial, less risk compared to taking medication to treat mood ... something for them to, to look forward to, and female-led it’s particularly important it makes them feel safe so this program is absolutely fantastic ... the staff are hoping by some miracle this can come back!”</p>
S3	“It’s really, really important (exercise), looking at lifestyle in a way with regards to people ... especially if you’re em dealing with addiction and homelessness, it’s so, so important ... Exercise as we know has a huge impact, not just on physical but on mental health as well. The whole mind body connection should be focussed on much more I feel, em apart from anything else. Just making somebody feel better after they exercise makes such a big difference. I think it’s something that can be kind of forgotten about to a degree, in services, the exercise element of things, because other things become a little bit more prioritised ... just because it’s women, it shouldn’t really change anything. But I do think that when it comes to women and their bodies there’s is another element, there as well, because a lot of women have issues with their body ...have different needs. And when it comes to the menopause and any hormonal stuff as well, exercise has a huge impact on that too ... menopause, their bone density and things like that going through menopause. They need to be much stronger.”

S4	<p>“I know exercise is brilliant, but low threshold exercise is a completely new concept ... it’s been something completely different and there is an absolute need ... same need exists for men, but I think women’s engagement wouldn’t be, or wouldn’t have been as much, if it was a male and female group. Similar to, I think, society in general.”</p>
S5	<p>“It’s lovely to see that, you know, there’s something out there anyway, for people who are like, you know, thinking of this population in the first place and I think that sometimes they are the forgotten people or the forgotten women ... once it’s introduced to them, they, quite surprisingly they’re quite interested.”</p>
S6	<p>“People come in here with none of the social contacts that we would just assume people have like ... and I just realised how alone these people are ... just that human contact ... me as a human being is interested in this other person ... that investment in them and particularly the individual programmes I think are/would be wonderful. I suppose about access, again it’s fundamental, I mean people don’t have access to clean clothes, to clean underwear ... So, they’re in clothes they’ve worn for days, they know there’s an odour from them and they’re very sensitive. I mean I wouldn’t go, we wouldn’t go (to an class), you know so ... I think if we could offer them, you know even the gym clothes or whatever ... but just but clean clothes... very practical things like that ... I think obviously they carry so many issues with them and stigmas, but I think that’s one that could be fixed fairly easily, with access to just clothing and hygiene. So, definitely I think, from my perspective it would be that human interest in them... a lot of women that are overweight too. And these are women who are probably in recovery, stable on methadone, but again their lives are so restricted ... they get threatened ... how do we meet their nutritional needs ... a lot of it goes back to basic hygiene and fundamental nutrition ... I think it’s good for women and men to be on their own like, either sex, but I think definitely with low threshold services... just to give them space to be themselves ... I don’t think it suits every woman ... lot of the clients here are very connected to their partners ... they’re completely dependent on each other ... ‘you are so valuable to us that we want to make you live as long and as healthy as possible. We’re treating the addiction, we’re going to help you with that, but you, for yourself, for your own welfare, that you can be strong, and you can hopefully live an independent life and enjoy your families if you have them’, whatever, but ye for their own intrinsic values as human beings ... they have to have hope ... exercise I think ye for health ... but particularly with addiction and your mental health.”</p>

2. Views of physical health of People Experiencing Homelessness

S1	"A lot of them have physical health conditions ... might not go to the doctor as often, so they might not be diagnosed."
S2	"Lifestyle is different from people in the community, it's chaotic ... diet is very poor, diet in turn affects their health, a lot of them are very underweight or overweight ... some struggling with diabetes and some people have problems with pain, arthritis in their legs and ye, they do have a lot of physical issues."
S3	"Bigger picture involved because a lot of people who are in homelessness and in addiction also come from deprived or disadvantaged areas too ... not necessarily brought up with a very healthy lifestyle to begin with, so they would have health problems that, that tend to occur at an earlier age anyway ... obviously the addition of addiction and homelessness is going to add and compound any other already underlying health issues ... There is definitely a health issue going on with their body, a physical health issue ... that's to do with mental health and addiction and/or addiction and or lifestyle ... I would think em, a lot of the health problems that go on with people who are in addiction could be em treated with better lifestyle choices, especially with regards to exercise."
S4	"Mobility or its pain, neck pain, back pain, em, swollen legs, ankles ... diet, their nutrition, their level of exercise, encouraging someone to go and speak to their doctor, which very rarely happens anyway, because health needs are way down the list of priorities for women who kinda access low threshold services."
S5	"You can see that their physical health is not on par with somebody maybe you know their own age, who are maybe from a different section of society. Em, I can see that their health is not the same... They're in survival mode so they're not thinking about exercise."
S6	"It's great to have a place where it's just women only... it's usually mixed services ... there's a different dynamic, so when they're with women only, their only focus then is really the exercise... we're going back to childhood, all those adverse childhood events ... what goes on in hostels- offered drugs all the time, everything being stolen, em, pimps there, female and male pimps you know, it's incredible I mean and then being in a place where people are genuinely mentally unwell, and they're terrified... sleep deprivation is huge ... the living conditions there are just... none of us could maintain any kind of energy level or motivation ... you have a bed in a frickin prison ... How could you think about recovery? The last

thing I'd want to do is go for a half an hour walk or you know ... you just think oh God am I the only person who's going to listen to them today ... if you're trying to survive sleeping rough, their priorities are survival not nutrition, well they're getting whatever nutrition they can get, whatever ... but safety, they're hyper vigilant, so exercise for them unfortunately, is probably way down."

3. Success of the programme

S1	<p>"I think it has been really successful. And we're so grateful to you, you know. It's been so successful you know, especially with harder to more reach clients who have committed and em, I think there has been a lot of momentum with the programme and you've had a lot of consistent service users attending ... there has been a physical health benefit because they are committing to exercising regularly and they are more aware of exercise and aware of nutrition ... social benefit of just committing to something and attending regularly ... so important for people who might not commit to anything regularly ... having that routine is so important ... camaraderie as well... one client em, who would relapse and use cocaine, who, eh, recently has managed not to relapse, despite stressful situations and I'm sure that the exercise group is a big part of that."</p>
S2	<p>"I even have a particular client in mind, who was very chaotic, it's very hard for her to come in, but since she started this programme she's been coming, which is like a miracle."</p>
S3	<p>"Just the fact that people just continued to come ... it's rare to see people who are in, who lead chaotic or disorganised lives commit to something and come every single week ... group work is really important because they engage with the other group members as well... So, the exercise isn't just working at purely physical level, it's also working at a social level then as well and allowing them to build relationships with each other."</p>
S4	<p>"I think, the numbers in themselves have shown that the interest was there... The biggest benefit was probably in changing mood. So, women's mood had improved even ... been even invited to something that was low threshold, where there's no barriers to access... was a massive thing... women mixing with each other that would never usually mix with each other ... just women who were interested in exercise. I think their connections with each other really developed because of that... there was less judgement ... what we do here in Jane's Place is trauma informed. So, it's about collaboration, but it's about choice and empowerment and its behind everything that we do. So, giving somebody choice was a huge part, so if you don't want to skip or you feel you can't, you just move on to the next part... very consistent with a trauma informed approach. But also adding in the walk means that, that's something</p>

	free. That anyone can do, any time of the day, 7 days a week, 4 seasons of the year, so it's almost like a coping skill, that you're offering somebody a reminder that you can do this when you're struggling, you can do this when you get out of the hostel or out of the house ... some of the women would have forgotten about certain pain complaints that they would have had before the programme."
S5	"I actually I saw the improvement in a lot of the women, who joined the programme and stuck with it as well... they felt that it was a safe enough place and a good enough programme that they could, if they fell of the band wagon for a week or two, you know, that they could come back... I know there were 2 friends and their focus for the day was to go to Jane's Place and do their exercise... then for the women then who kind of continued to go, you could see the improvement, in, in their mental health and you could see it in their health as well... we would do day trips and stuff like that, and we could see the improvement in how, just even how quick they could walk... they would have been a pair that would probably go and use substances together, but they decided, no we'll go and exercise together as well... there was a big shift for them to focus on that, the fact that they were there at the programme meant they weren't using that day."

4. Reasons for low retention

S1	"Maybe they weren't ready for a programme that required a bit of commitment... daily life challenges, addiction, trauma or life history- huge impact on their ability to commit and to engage with services ... they engage when it's gotten really bad, you know, em, so rather than doing things that are preventative, so I imagine it will be so hard for them to exercise regularly. That'll be the last thing they think about, so that's why the programme was so good. Just to make that possible for them... another reason why I think that eh, the attendance might be poor is that exercising regularly is something that people do when they like themselves and they have self-worth but a lot of the women coming here don't have em, ye they're lacking in confidence or they don't have that self-worth, so they feel like they don't deserve a healthy lifestyle or it might just have something to do with their identity. So, they don't see themselves as someone who has a healthy lifestyle, exercises regularly, can commit to exercise regularly. So, their identity is more that of 'my life is a mess', em... they just have this belief that they can't change."
S2	"If you go to Riverbank, you see sometimes we see them once a day, only once, that day or you never see them for another year... that's why we try to tailor our care around making every contact count, because as much as they really want to engage, they also

	have a different lifestyle, and that lifestyle might prevent them from coming. Sometimes they forget appointment, sometimes it's about getting someone to remind them also, transportation you know, and also fear of walking in the street.”
S3	“Their priorities are different. it's very difficult to get people to engage on a regular basis. They lead very chaotic lives ... if you're in addiction, you don't really have much, you're not really prioritising your selfcare. So, selfcare is very very low down in peoples priorities... self-care isn't huge... so when it comes to getting, returning and people engaging, group work is really important because they engage with the other group members as well... the exercise isn't just working at purely physical level, it's also working at a social level then as well and allowing them to build relationships with each other” and then they are more likely to keep coming back and engaging. That connection.”
S4	“It's a part of low threshold services, is that you could see someone once and have a really good session with them and might not see them again for 6 or 7 months... there was real interest and again I think being invited to something, em was a huge part of that because in other services you're not ready, you're not stable enough, you're on too many substances, all of those things can have an impact on somebody's self-esteem and their view of themselves, that they are a problem, as opposed to somebody with a problem... you were responding to the need and the low threshold requirements ... for some women, you know, there's less motivation there for personal development, for looking after their health and then there's other women who, their partners come first. And you know, their needs go way down the list of priorities.”
S5	“Housing issues and even if they are housed, some of them were in hostels, it might be that they just didn't get a good night sleep the night before and things like that and they didn't go and they were, you know, and so their lives are kind of chaotic anyway, you know, where they're not getting good sleep, they're not getting you know, that kind of thing so, then the exercise kind of goes from being at the top of their list of things to do right to the bottom of the list of things to do ... programmes out there where you need to not be using drugs, so and you need to be clean, so that's another thing that ... their own self-esteem, their own you know self-worth issues... their drug use as well can be up and down and up and down and although with all the good will in the world they wanted to go, their, their drug use takes over and so, they don't have the energy to go ... they've had a huge amount of trauma in their lives... things that maybe were important on your list of things to do get completely shifted... the top priority things for survival, that become important... the ones who did engage were able to come back because they were coming out of chaos ... the exercise was helping them to decompress.

S6	“Those very simple interventions that help ... sometimes staff are so inflexible ... (re flexibility) learn the rules well so you can break them properly! ... I’d just worry about the location. I tried to get women down there and they’re saying to me ‘oh where is it’ ‘what bus do you get’ ‘oh I’m not walking down there.”
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5. Future programme, additional thoughts

S1	Retention enhancing strategies: “Maybe if you had an incentive like, a prize or like a one-for-all voucher or something ... service users have expressed they want to continue and we even have plans for a personal trainer to come once a week to continue exercise, with the ladies... we put so much emphasis on mental health support, addiction support and things like this and maybe we could be, em, you know maybe putting more of an emphasis on exercise.”
S2	“I think it's vital that this continues ... the women they talk about it, and they really, really enjoyed it ... they were still finding their feet, it’s a new service... Come back, come back, come back, we want you back!”
S3	“It definitely should be part of the programme on a regular basis, yes, ye for sure.”
S4	“Was a really great thing for the women to get and their certificates at the end of it ... it has been really accessible, em you know, the hours, you know, the accessibility of the hours, the days, all of that was there. The Park Walk ... could tie in the health and nutrition or diet, you know. Coz we see a lot of eating disorders and those kind of body issues with, a lot with women as well. So, I suppose there’s so much that you could do with exercise ... It needs to be someone who can guide the women correctly and know when to stop, know about injuries and that kind of thing. But it is a multi-d, it is a multi-disciplinary team here. We have doctors, we have a medical team, and we have and are looking at getting someone in to continue it. Some of the barriers with that I suppose are the flexibility ... the Park Walk is definitely something I think that we could do ... to thank you just for all the flexibility and the real non-judgemental support that you offered the women. I mean that genuinely. I mean like we could get someone in to do exercise but it’s very hard to measure somebody’s judgement or levels of judgement and it’s something that the women felt so comfortable with you both and it was a huge part, like the lack of judgement, the openness, the humour, having the music and the flexibility, you know, they’re all things that you don’t always pick up in an interview ... That was a huge, it was a huge factor I think, in the engagement with the women, sending the reminders... I suppose at the time we started, we were opening the doors so, we were new and that (the exercise intervention) was new, the programme was new as well so.”

S5	<p>“If you’re looking at people who are in addiction or homeless you know or living in the chaotic kind of environments, and stuff like that, there is always going to be, some will engage, some won’t, some will come, some won’t... tighter boundaries actually around the timing can actually be better for them ... It’ll help them as well, they’re regularly going to an exercise class, they’re seeing the improvement, they’re seeing the results. They’re seeing the routine ... they’ll see that this is how the real-world works... It’s difficult with a certain group of women because they’ll probably never turn up for that 2-hour slot but then the women who as you said they started to come earlier and they regulated themselves a routine, for them actually it probably would be, you know, a really good, kind of set the boundary then for them ... the feedback we got from the women was that they were, kind of, they were enjoying it so much that they were kind of a bit worried that it was ending because then they were like, what are we going to do ... as a way to not use or delay the use ... But actually, what we learned from the exercise programme was yes, they will show up and they will. So, it informed us as well... like it was really good and you can see that the women who engaged, they really got, like so much out of it... you two were really good at engaging with the service users and getting them back and you know, knowing, you know what they needed and all, so it worked really really, well. And I know the feedback we got from them was that it was really well run.”</p>
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Appendix IX COREQ checklist; Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care. 2007. Volume 19, Number 6: pp. 349 – 357

Item No	Guide Questions/Description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/ facilitator	Which author/s conducted the interview or focus group?	Pg 488 Appendix VI
2. Credentials	What were the researcher's credentials? E.g., PhD, MD	Pg 485 Appendix VI
3. Occupation	What was their occupation at the time of the study?	Pg 485, Appendix VI
4. Gender	Was the researcher male or female?	Pg 485, Appendix VI
5. Experience and training	What experience or training did the researcher have?	Pg 485
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Pg 282
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research?	Pg 282
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Pg 76
Domain 2: study design		
Theoretical framework		

Item No	Guide Questions/Description	Reported on Page #
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Pg 285-286
Participant selection		
10. Sampling	How were participants selected? e.g., purposive, convenience, consecutive, snowball	Pg 76,
11. Method of approach	How were participants approached? e.g., face-to-face, telephone, mail, email	Pg 282
12. Sample size	How many participants were in the study?	Pg 282
13. Non-participation Setting	How many people refused to participate or dropped out? Reasons?	N/A
14. Setting of data collection	Where was the data collected? e.g., home, clinic, workplace	Pg 282
15. Presence of nonparticipants	Was anyone else present besides the participants and researchers?	N/A
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Pg 283, pg 287-8
Data collection		
17. Interview guide	Were questions, prompts, and guides provided by the authors? Was it pilot tested?	Appendix IV
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Pg 284
20. Field notes	Were field notes made during and/or after the interview or focus group?	Pg.284
21. Duration	What was the duration of the interviews or focus group?	Pg 76, pg 285
22. Data saturation	Was data saturation discussed?	Pg 286
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Pg 76, 285

Item No	Guide Questions/Description	Reported on Page #
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Pg 76, pg 286
25. Description of the coding tree	Did the authors provide a description of the coding tree?	N/A
26. Derivation of themes	Were themes identified in advance or derived from the data?	Pg 505-507
27. Software	What software, if applicable, was used to manage the data?	N/A, not used
28. Participant checking	Did participants provide feedback on the findings?	N/A
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g., participant number	Pg 289-325
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Pg 289-341
31. Clarity of major themes	Were major themes clearly presented in the findings?	Pg 289-325
32. Clarity of minor themes	Is there a description of diverse cases or a discussion of minor themes?	Pg 289-325