



Trinity College Dublin

Coláiste na Tríonóide, Baile Átha Cliath

The University of Dublin

**The development and feasibility of the occupational therapy-led
‘Work and Cancer’ intervention for women living with and
beyond breast cancer**

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This thesis is presented for the degree of PhD in Occupational Therapy,
Trinity College Dublin

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Declaration

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Summary

Background: Increased survivorship has prompted focus on optimising quality of life for those living with and beyond cancer, including reintegration into work. Despite frequently cited return-to-work barriers for women living with and beyond breast cancer, there are no conclusive work-focused interventions. The aim of this research was to design and assess the feasibility of a work-focused intervention to support return-to-work for women living with and beyond breast cancer.

Methodology: A four-phase study, following the Medical Research Council framework for complex interventions, included three development phases; (I) exploration of barriers and facilitators in return-to-work post-breast cancer diagnosis using a qualitative-descriptive design, (II) a systematic review and meta-analysis reviewing interventions that support return-to-work, and (III) a nominal group technique consensus study prioritising intervention content and delivery. A single-arm feasibility study with qualitative-descriptive design evaluated intervention feasibility and acceptability (Phase IV).

Results: Phase I identified a diverse range of barriers and enablers in return-to-work that could be amenable to change through rehabilitation. Phase II indicated a lack of methodologically rigorous and effective work-related intervention studies for women with breast cancer. Phase III prioritised a six-week intervention with group and individual sessions. Phase IV found the intervention to be feasible and acceptable to women living with and beyond breast cancer with 100% retention and 90% adherence.

Conclusion: A six-week online intervention to support women living with and beyond breast cancer in navigating work post-cancer was developed and found to be both feasible and acceptable. High adherence and retention rates were observed. A larger scale evaluation is warranted to determine the effectiveness of the intervention on work and other health-related outcomes.

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List of Abbreviations

ADL	Activity of Daily Living
CI	Confidence Interval
COREQ	Consolidated Criteria for Reporting Qualitative Research
DASH	Disabilities of the Arm, Shoulder and Hand
EMP	Employer
EORTC-QLQ-C30	European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire
GDPR	General Data Protection Regulations
HCP	Healthcare Professional
HER2+	Human Epidermal growth factor Receptor 2-positive
HRQoL	Health-Related Quality of Life
HRR	Health Research Regulations
MDT	Multi-Disciplinary Team
MRC	Medical Research Council
NGT	Nominal Group Technique
NIHR	National Institute for Health Research
OR	Odds Ratio
PIL	Participant Information Leaflet
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
PROM	Patient Reported Outcome Measure
QLQ-BR23	Quality of Life Questionnaire (Breast Cancer)
QoL	Quality of Life
RCT	Randomised Controlled Trial
RTW	Return to Work
SES	Socio-Economic Status
SWAT	Study Within A Trial
TIDieR	Template for Intervention Description and Replication
WBC	Woman living with and beyond Breast Cancer
WRFQ	Work Role Functioning Questionnaire

Dissemination

Academic Papers:

- Algeo, N., Bennett, K. & Connolly, D. (2021). Rehabilitation interventions to support return to work for women with breast cancer: a systematic review and meta-analysis. *BMC Cancer*, 21(1), 895. doi: 10.1186/s12885-021-08613-x.
- Algeo, N., Bennett, K. & Connolly, D. (2022). Breast cancer survivorship and employment: Legislative systems and the return to work of women with breast cancer in Ireland. *WORK*, 71(4), 927–939. doi: 10.3233/WOR-205044
- Algeo, N., Bennett, K. & Connolly, D. (in press-b). Prioritising the content and delivery of a work-focused intervention for women with breast cancer using the nominal group technique. *WORK*.

Planned dissemination:

- Algeo, N., Bennett, K. & Connolly, D. Perceptions on the content and delivery of a work-focused intervention for women living with and beyond breast cancer: a qualitative-descriptive design
- Algeo, N., Bennett, K. & Connolly, D. Evaluating the feasibility of a self-management intervention to support return to work for women living with and beyond breast cancer: A single-arm feasibility study and qualitative-descriptive design
- Algeo, N., Bennett, K. & Connolly, D. Policy Brief: Supporting work outcomes for those living with and beyond breast cancer in Ireland

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- Algeo, N., Bennett, K. & Connolly, D. (2022). *The development and feasibility of the occupational therapy-led 'Work and Cancer' programme: a mixed-methods study*. [Oral Presentation]. World Federation of Occupational Therapists Congress, 28th-31st August 2022, Paris Convention Centre, Paris, France. [ACCEPTED]
- Algeo, N., Bennett, K. & Connolly, D. (2022). *The development and feasibility of the occupational therapy-led 'Work and Cancer' programme: a mixed-methods study*. [3-Minute Thesis Presentation]. World Federation of

Occupational Therapists Congress, 28th-31st August, Paris Convention Centre, Paris, France. [ACCEPTED]

- Algeo, N., Bennett, K. & Connolly, D. (2022). *The feasibility and acceptability of the occupational therapy-led 'Work and Cancer' intervention: a mixed-methods study* [Oral presentation]. Irish Association for Cancer Research Conference, 1st April 2022, The Radisson Blu Hotel, Cork, Ireland.
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- Algeo, N., Bennett, K. & Connolly, D. (2021). *Developing a self-management intervention to support women with breast cancer to return to work in Ireland: Findings from a systematic review and meta-analysis, and consensus study*. [Oral presentation]. Irish Association for Cancer Research Conference, 26th March 2021, Online.
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- Algeo, N., Bennett, K. & Connolly, D. (2020) *BReast cAnCer surVivors and Employment (BRAVE): Facilitators and barriers in returning to and staying at work in Ireland following a breast cancer diagnosis*. [Oral Presentation]. Irish Association for Cancer Research Conference, 26th February 2020, The Galway Bay Hotel, Galway, Ireland.
- Algeo, N., Bennett, K. & Connolly, D. (2020) *BReast cAnCer surVivors and Employment (BRAVE): Facilitators and barriers in returning to and staying at work in Ireland following a breast cancer diagnosis*. [Oral Presentation]. SPHeRE Conference, 25th February 2020, RCSI, Dublin, Ireland.

Poster Presentations:

- Algeo, N., Bennett, K. & Connolly, D. (2020) *BReast cAncer surVivors and Employment (BRAVE): Facilitators and barriers in returning to and staying at work in Ireland following a breast cancer diagnosis*. [Poster Presentation]. Irish Association for Cancer Research Conference, 27th February 2020, The Galway Bay Hotel, Galway, Ireland.

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- 2021: Best Oral Presentation (Social, Nursing, Allied Health), Irish Association for Cancer Research Conference, 26th March 2021.
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CHAPTER ONE: INTRODUCTION

1.1 Background and Need

Breast cancer is the most common cancer worldwide (GLOBOCAN, 2020). Survival is increasing, largely due to advancing treatments and earlier detection, and is as high as 85-90% at five-years in developed countries (American Cancer Society, 2019; Cancer Research UK, 2020; O'Connor et al, 2019). By the end of 2016, there were an estimated 39,539 individuals living with and beyond breast cancer in Ireland (O'Connor et al, 2019). This figure is set to increase with the incidence of cancer expected to almost double in Ireland by 2045 (National Cancer Registry Ireland, 2018). In line with increasing survivorship, there is a focus on optimising quality of life (QoL), for those living with and beyond cancer, including return to work (RTW).

There is evolving evidence on the impact of breast cancer on work outcomes internationally (Blinder, 2012; Roelen et al, 2011; Tiedtke et al, 2012), however, there are no known studies exploring the experiences of women living with and beyond breast cancer when returning to or staying at work in Ireland. This is important as the average time to RTW after breast cancer treatment varies considerably by country and ethnicity (Islam et al, 2014). RTW rates vary across cancer types, and can be influenced by personal, societal, workplace, healthcare, and legislative systems (Parkinson & Maheu, 2019). For those living with and beyond breast cancer, the time it takes to RTW post-diagnosis can vary widely, however 11.4 months has previously been reported (Balak et al, 2008; Chaker et al, 2015). In Ireland, for example, only 16% of women diagnosed with breast cancer, continue to work immediately post-diagnosis, compared to 50.8% of men diagnosed with prostate cancer (Sharp, et al. 2014). This could be related to disease- and treatment-related factors which are often cited as RTW barriers. Women with breast cancer often receive an extensive treatment regimen (Arfi et al, 2018), where 85%, 69%, 55%, and 47% undergo surgery, radiation therapy, hormone therapy, and chemotherapy, respectively, in Ireland (National Cancer Registry Ireland, 2016). These treatments are known to impact several symptoms known to influence work including (but not limited to) cancer-related fatigue, pain, cognitive dysfunction,

menopausal symptoms, and upper limb dysfunction (Carlsen et al, 2013; Sun et al, 2017; Todd et al, 2011).

The importance of supporting RTW following a cancer diagnosis has been recognised in recent years internationally. A report by the European Commission (2021) has acknowledged that both assessment and intervention in working conditions for those with cancer should be integral parts of the survivorship pathway. Other countries including the United Kingdom, Canada, and the United States, have also underlined the importance of addressing work outcomes for those living with and beyond cancer (Canadian Partnership Against Cancer, 2019a; de Moor et al, 2018; Eva et al, 2012). This is echoed in an Irish context in recent years where supporting work outcomes post-cancer has been specifically highlighted in strategic plans of national organisations (Connolly, Russell & Henry, 2021; Irish Cancer Society, 2020).

A recent report from the Irish Cancer Society (2021a, p.4) recommends that “The Government should introduce a state-run pilot programme on reintegration into the workplace for cancer patients and survivors out of work at the time of their diagnosis or after their diagnosis”. Despite this, there has historically been a paucity of rehabilitation interventions to support women living with and beyond breast cancer to maintain or return to their work role (Algeo, Bennett & Connolly, 2021; de Boer et al, 2015; Hoving et al, 2009) and the development and evaluation of interventions to support women living with and beyond breast cancer in returning to, or managing, work, has been recommended (Algeo, Bennett & Connolly, 2021; Hoving et al, 2009; Sun et al, 2017). The development of a work-focused intervention for women living with and beyond breast cancer is therefore timely and relevant, and could potentially address the gap outlined in Ireland and beyond. Where RTW challenges can differ by cancer type, Lamore et al (2019) argue that RTW interventions should be tailored accordingly by cancer site. In addition, there are clear challenges for women with breast cancer in RTW, as evidenced by lower RTW rates compared to other cancer cohorts (Sharp et al, 2014). Therefore, the overall aim of this research was to develop and assess the feasibility of the occupational therapy-led *Work and Cancer* intervention for women living with and beyond breast cancer, with the view that the intervention could be adapted to other cancer cohorts in the future.

1.2 Developing a Complex Intervention using the Medical Research Council Framework

Complex interventions are defined as interventions encompassing numerous interacting components (Craig et al, 2008). They can be subject to flexibility and non-standardisation, taking on different forms in different contexts, while still conforming to specific, theory-driven processes (Craig et al, 2008; Hawe, Sheill & Riley, 2004).

Work-focused interventions can be considered complex as tailoring of the intervention may be required depending on job role and individualised side-effects, a variety of outcomes may be explored, and the number and extent of behaviours required by those in receipt of the intervention may vary (Petticrew, 2011). In 2000, the Medical Research Council (MRC) published a framework to assist researchers and funders in recognising and adopting appropriate methods when developing and implementing complex interventions. Original MRC guidance briefly referred to the development phase where emphasis was placed on evaluation of complex interventions (Medical Research Council, 2000). Since then, there has been recognition to optimize development of interventions to increase value and reduce waste (Bleijenberg et al, 2018), which was reflected in updated MRC guidance (Craig et al, 2008) (Figure 1.1). The development of the *Work and Cancer* intervention was informed by this framework.

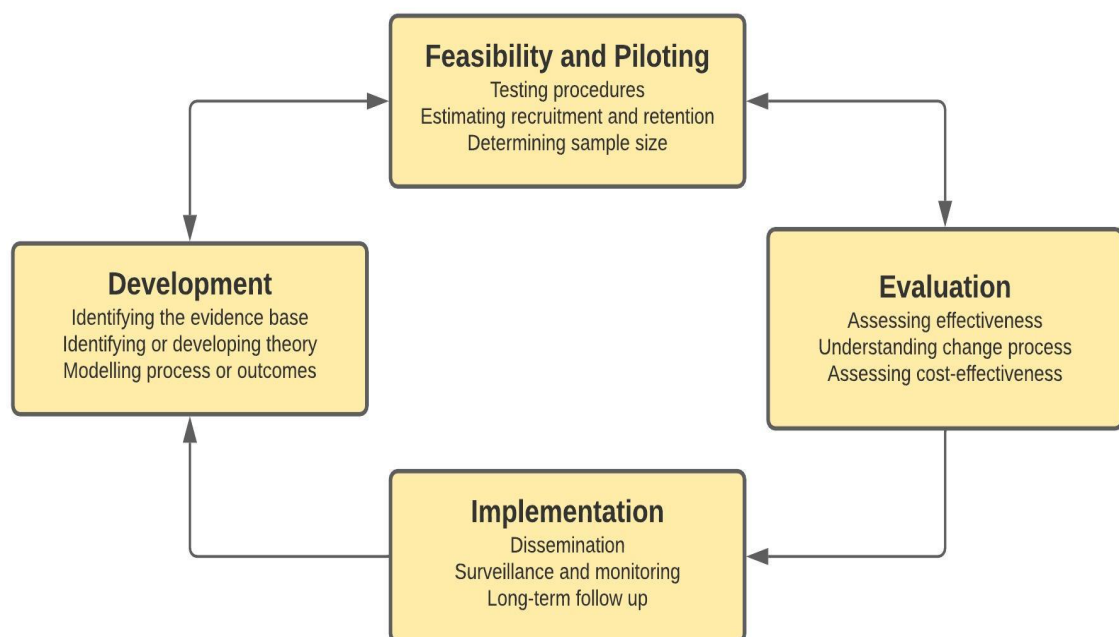


Figure 1.1: Medical Research Council Framework for Complex Interventions (2008)

An updated version of the guidance is expected in 2021 (University of Glasgow, 2021). In a recent consensus exercise (O’Cathain et al, 2019), key actions for consideration when developing a complex intervention were identified including (i) viewing intervention development as a dynamic, iterative process, (ii) involving key stakeholders, (iii) reviewing published evidence, (iv) drawing on existing theories, (v) undertaking primary data collection, (vi) understanding context, (vii) considering future realistic implementation, and (viii) designing and refining an intervention with iterative cycles of development with stakeholder input provided throughout the process. To address these key actions, several steps are required in the development phase of complex interventions. Therefore, a series of studies were conducted to inform the development of the *Work and Cancer* intervention, which will be described in further detail in Chapters Three-Six inclusive.

1.3 Overview of Study Designs

The overall aim of this research was to develop and assess the feasibility of the work-focused *Work and Cancer* intervention for women living with and beyond breast cancer. To achieve this aim, four separate studies were conducted, each with separate aims and objectives (Figure 1.2).

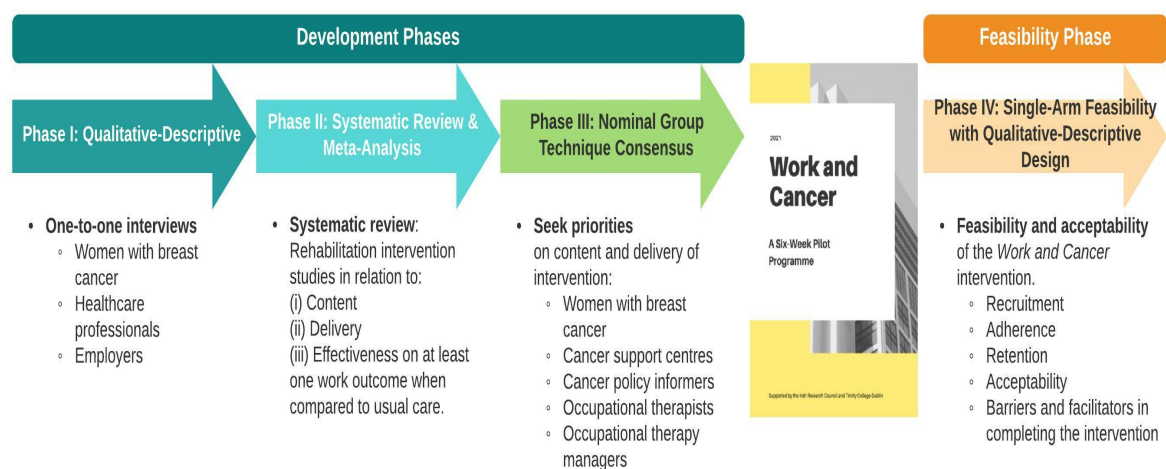


Figure 1.2: Development and Feasibility Phases

1.3.1 Phase I: Qualitative-Descriptive Design

A qualitative-descriptive design using semi-structured interviews was conducted with women living with and beyond breast cancer, healthcare professionals, and employers, to explore their perceptions on facilitators and barriers in returning to employment post-treatment in an Irish context. Qualitative-descriptive designs involve a rich, straight description of an experience or event (Neergaard et al, 2009) and can be useful in addressing many research questions in health care as it can focus on the experiences of patients, and other relevant stakeholders such as healthcare professionals and employers. This can provide important data when tailoring a clinical intervention and is therefore well-placed to be incorporated in the early stages of intervention development (Sullivan-Bolyai, Bova, & Harper, 2005). Chapter Three of this thesis will present the rationale for, methods used, findings, and discussion of findings for Phase I.

Aim: To explore the experiences and challenges of women living with and beyond breast cancer in returning to or staying in employment in Ireland with a view to inform a work-focused intervention.

Research questions:

1. What are the facilitators and barriers in staying at and/or returning to work for women living with and beyond breast cancer in Ireland?
2. What are the perceptions of key stakeholders on the content and delivery of a work-focused intervention to support work outcomes for women living with and beyond breast cancer?

1.3.2 Phase II: Systematic Review and Meta-Analysis

A systematic review was conducted of controlled studies of rehabilitation interventions measuring work outcomes for women living with and beyond breast cancer, informed by PICO principles (Higgins & Green, 2011). The primary research question asked: For women who have had breast cancer (Population), are rehabilitation interventions (Intervention) effective compared to standard care (Comparator), in supporting work

outcomes (Outcomes)? Six databases were systematically searched: EMBASE, Web of Science, MEDLINE (OVID), CINAHL, PsycINFO, and the Cochrane Central Register of Controlled Trials (CENTRAL). Chapter Four of this thesis will present the rationale for, methods used, results, and discussion of results for Phase II.

Aim: To systematically search the evidence-base and critically appraise and synthesize applicable findings to address the following research questions:

Research questions:

1. For women who have had breast cancer, are rehabilitation interventions effective compared to standard care, in supporting work outcomes?
2. How effective and cost-effective are rehabilitation interventions in improving work outcomes for women living with and beyond breast cancer?
3. What are the core elements (i.e., content, delivery, resources, length, and format) of rehabilitation interventions for women living with and beyond breast cancer to support return to work?
4. What measures are used to test the impact of these rehabilitation interventions on work and other outcomes?
5. What are the most frequently used theoretical frameworks underpinning rehabilitation interventions to support return to work?

1.3.3 Phase III: Nominal Group Technique

The Nominal Group Technique (NGT) is a consensus method that seeks consensus in groups through four steps; (i) idea generation, (ii) round robin discussion among the group, (iii) refining ideas, and (iv) ranking preference for ideas through anonymised voting. Key stakeholders including women living with and beyond breast cancer, occupational therapists, occupational therapy managers, directors/co-ordinators of cancer support centres, and policy informers were invited to participate in an online discussion using a NGT to determine priorities for a work-focused intervention. Chapter Five of this thesis will present the rationale for, methods used, findings, and discussion of findings for Phase III.

Aim: To seek consensus among key stakeholders on the content and delivery of a work-focused intervention for women living with and beyond breast cancer.

Research questions:

1. What is the preferred content for a work-focused intervention to support work outcomes in women living with and beyond breast cancer?
2. What format should the work-focused intervention take? (e.g., group-based, one-to-one, or blended)?
3. How should the work-focused intervention be delivered? (e.g., online, face-to-face, blended)?
4. If face-to-face, where should the work-focused intervention be delivered?
5. If online, where should the work-focused intervention be delivered?
6. What length should each individual session of the work-focused intervention be?
7. What overall length should the work-focused intervention be?

1.3.4 Phase IV: Mixed-Methods Feasibility Study with Qualitative-Descriptive Design

A single-arm feasibility study with qualitative-descriptive design evaluated intervention feasibility and acceptability. Following the development of a complex intervention, it is recommended to explore intervention feasibility prior to full-scale evaluation (Craig et al, 2008). This can uncover any potential issues with acceptability, compliance, intervention delivery, recruitment and retention, and ensure the opportunity to refine the intervention based on feasibility feedback. A qualitative-descriptive design was also conducted within the study to establish intervention acceptability. Intervention acceptability is a distinctive feature of feasibility studies, informing overall feasibility (Orsmond & Cohn, 2015). There is growing recognition that qualitative methods play an important role in optimising interventions and the design of randomised controlled trials, exploring any key uncertainties prior to a future trial (O’Cathain et al, 2015). For example, if problems with recruitment, adherence or retention arise, qualitative data can be used to explore reasoning for this.

Chapter Six of this thesis will present the rationale for, methods used, findings, and discussion of findings for Phase IV.

Aim: To establish the feasibility of a work-focused intervention including recruitment, adherence, retention, and acceptability among women living with and beyond breast cancer.

Research questions:

1. What length of time is required to complete participant recruitment and what are the reasons for declining participation?
2. What is the adherence to and completion (retention) rate of the intervention?
3. Is the intervention acceptable to women living with and beyond breast cancer?
4. What are the barriers and facilitators in completing the intervention?
5. Are outcome measures acceptable to women living with and beyond breast cancer, and what is the completion rate?

1.4 Overview of Thesis

Chapter One will present a brief background and need for this research, a description of the MRC framework for complex interventions, an overview of study designs and objectives, and reflexivity statement. Chapter Two will outline current literature in cancer survivorship and employment, and rationale for this research. Chapters Three, Four, Five and Six will present the rationale for, methods used, findings, and discussion of findings for Phases I, II, III and IV, respectively. Finally, Chapter Seven will provide an overall discussion of the results of the four studies.

1.5 Reflexivity Statement

To address potential researcher bias, methods that were applied to ensure trustworthiness and transparency in this research will be discussed in Sections 3.2.8 and 6.2.7. In addition, a statement of predispositions is outlined below. Phases I and IV of this research use qualitative-descriptive designs and have been influenced by Braun and Clarke's (2006) thematic analysis.

“As an occupational therapist and PhD Candidate, I have clinical and research experience in oncology, however, I lack the lived experience of a person living with and beyond a cancer diagnosis. As an occupational therapist, I view health and wellbeing

through a holistic lens, and believe that consideration of the person, occupation, and environment, is key in addressing any concerns with activities of daily living, including work. Despite this, I am aware that occupational therapy can be enhanced through multi-disciplinary working, where appropriate. Pursuing this doctoral programme has meant personal sacrifice, and, naturally, I am eager for the developed intervention to be successful. With this in mind, I am conscious of a potential researcher bias for acceptability of the intervention and will put several measures in place to attempt to bracket any biases. These include, but are not limited to, (i) identifying assumptions and preconceptions at the outset of this research and throughout using memos, and (ii) ensuring an additional researcher checks transcripts, codes, and final themes”

1.6 Conclusion

Breast cancer is now the most common cancer worldwide (GLOBOCAN, 2020). The impact of treatment- and disease-related side effects on work ability is well documented, and include cancer-related fatigue, pain, cognitive dysfunction, anxiety, and depression (Sun et al, 2017; van Maarschalkerweerd, 2020). A recent paradigm shift in survivorship care has focused on optimising QoL for those living with and beyond cancer, including reintegration into employment. Research recommends the development and evaluation of interventions to support women living with and beyond breast cancer in returning to, or managing, work (Sun et al, 2017). Despite this, there has historically been a paucity of rehabilitation interventions to support women living with and beyond breast cancer to maintain or return to their work role (Algeo, Bennett & Connolly, 2021; de Boer et al, 2015; Hoving et al, 2009). The aim of this research therefore was to develop and assess the feasibility of a work-focused intervention for women living with and beyond breast cancer. If successful, this intervention could support women living with and beyond breast cancer return to and/or remain at work, potentially supporting social, psychological and financial wellbeing for this cohort, and society.

CHAPTER TWO: LITERATURE REVIEW

2.1 INTRODUCTION

This chapter presents an overview of the literature on breast cancer survivorship and employment. The impact of a breast cancer diagnosis and treatment will be discussed and personal, interpersonal, institutional and societal/policy factors influencing employment post-diagnosis will be outlined. Finally, evidence for RTW supports for women living with and beyond breast cancer will be summarised.

2.2 Cancer Survivorship

Cancer refers to a group of diseases in which abnormal cells grow in almost any organ or tissue of the body, multiply, and can invade nearby tissues (World Health Organisation, 2021a). It is the second leading cause of death worldwide and was responsible for an estimated 19.3 million cases worldwide in 2020 (GLOBOCAN, 2020). In the European Union, it is estimated that approximately 2.7 million people received a cancer diagnosis in 2020 (Joint Research Centre, 2020). In Ireland, there are more than 200,000 individuals living with and beyond cancer (O'Connor et al, 2019) and it is estimated that by 2045, the incidence of cancer will have almost doubled (National Cancer Registry Ireland, 2018). In line with improved treatments and earlier detection, survivorship rates are projected to continue to grow and in 2020 it was estimated that one in 25 individuals in Ireland is a 'cancer survivor' (National Cancer Registry Ireland, 2020).

The term 'cancer survivor' has developed in definition in recent decades. Initially, when cancer was typically considered terminal, a 'cancer survivor' was recognised as a family member who had survived the loss of their loved one to cancer (Leigh, 1996). The definition has evolved in line with increasing numbers of people surviving their cancer diagnosis and is considered a term for those who have survived their cancer diagnosis with no recurrence within five years post-diagnosis or treatment (Centers for Disease Control and Prevention & Lance Armstrong Foundation, 2004). More recently, cancer survivorship is regarded to commence at the time of diagnosis and continue until

death regardless of how long post-diagnosis this may occur (National Cancer Institute, 2017). For the purposes of this research, the latter definition will be used, and the terms ‘living with and beyond cancer’, or ‘with cancer’ will be used where appropriate, which align with terminology more recently adopted in Ireland (Mullen & Hanan, 2019).

2.3 Breast Cancer Survivorship in Ireland: The Past, the Present and the Future

Breast cancer is the most common cancer impacting women, with an estimated 2.3 million women worldwide diagnosed annually (World Health Organisation, 2021b). Women are most at risk of developing breast cancer, however age, family history, genetics, activity levels, diet, and breastfeeding history can also, among other factors, impact risk (World Health Organisation, 2020). Breast cancer can sometimes be considered a disease of the developed world, where incidence rates vary greatly. For example, 26.2 per 100,000 women in South Central Asia are diagnosed with breast cancer compared to 90.7 per 100,000 women in Western Europe (GLOBOCAN, 2020). Differences in incidence can be partly explained by differing dietary habits in combination with later first childbirth in developed countries, and shorter breastfeeding periods (Peto, 2001).

Breast cancer is ranked the most common invasive cancer in women in Ireland, accounting for 31.5% of all cases (National Cancer Registry Ireland, 2020), however survivorship rates are also increasing in line with enhanced screening processes and treatment. By the end of 2018, there were over 190,000 individuals living with and beyond cancer in Ireland. Of this figure, 43,750 were women living with and beyond breast cancer. It is estimated that over 3,600 women are diagnosed annually (Irish Cancer Society, 2021b) and while the median age for diagnosis is 59 years, 64.6% of those diagnosed with breast cancer in Ireland are of working age at 64 years old or younger (National Cancer Registry Ireland, 2016). This is important to note as transitioning back to work following a cancer diagnosis has been cited as an unmet need internationally (Chae et al, 2019; Ruddy et al, 2015) and in Ireland (O’Connor et al, 2019).

2.4 Breast Cancer Treatment: Local and Systemic

Once diagnosed, a woman with breast cancer will be offered a treatment regimen dependant on several factors including but not limited to age, disease type, and staging of the tumour. Treatment can be delivered locally (i.e., in a specific area), or systemically (i.e., in the whole body), and typically a combination of treatments is required.

2.4.1 Local Therapy

Local therapy refers to treatment that targets a specific area of the body and can include surgery and radiation therapy.

Surgery: In Ireland, approximately 85% of women with breast cancer undergo surgery, the most common treatment modality (National Cancer Registry Ireland, 2016). Types of surgeries can include mastectomy, lumpectomy, breast reconstruction, axillary lymph node dissection, and oophorectomy.

Mastectomy: Mastectomy involves the removal of breast tissue and was the primary surgery for women with breast cancer in the 20th century (Zurrida et al, 2011). It typically takes the form of a simple or modified radical mastectomy. A simple mastectomy involves the removal of breast tissue, nipple, areola and skin but not all lymph nodes, whereas a modified radical mastectomy also removes most of the underarm (axillary) lymph nodes. It is more often used in more advanced breast cancers, unlike lumpectomy. Many women may also undergo breast reconstruction which involves constructing a new breast shape, usually using an implant, own body tissue or a combination of both (Irish Cancer Society, 2021c). It can take place during mastectomy or can be delayed for months or even years.

Lumpectomy: Lumpectomy, also referred to as breast conserving surgery or partial mastectomy, is increasing in use and involves the partial removal of the breast including the tumour and some breast tissue. Evolving research in recent years has supported it's use (de Boniface, Szulkin & Johansson, 2021). Common side-effects of mastectomy and lumpectomy include pain, restricted range of movement (ROM) in the

upper limb, body image-related distress, and changes in sensation. Pain and upper limb dysfunction are described in further detail in Section 2.5.1. Body image-related distress is further discussed in Section 2.5.2.

Other surgeries: A sentinel lymph node biopsy involves the removal of a sample of lymph nodes to test if the breast cancer has spread. Sometimes women may require an axillary lymph node dissection, which involves the surgical removal of lymph nodes. A potential long-term side-effect of axillary lymph node dissection is the development of lymphoedema, a build-up of fluid in the body's tissues in the affected arm. Incidence rates of lymphoedema post-axillary lymph node dissection vary widely and is often underdiagnosed (Moffatt et al, 2003).

Radiation Therapy: In Ireland, approximately 69% of women with breast cancer undergo radiation therapy (National Cancer Registry Ireland, 2016). It involves the use of high-energy X-rays or gamma rays that target the tumour and is typically administered post-surgery (Sharma et al, 2010). Unlike chemotherapy, radiation therapy is usually administered daily (Tobias & Hochhauser, 2010) and can be delivered in one of three ways: (i) at a distance (external beam radiotherapy), (ii) orally or intravenously (radioisotope therapy), or (iii) placing a solid radioactive nuclide (a species of an atom) within or close to the tumour (brachytherapy) (Bower & Waxman, 2015). Short-term side-effects can include cancer-related fatigue, skin irritation, and indigestion, whereas long-term side-effects include lymphoedema, hardening of the breast tissue (fibrosis), and nerve damage (Irish Cancer Society, 2021d). Cancer-related fatigue and lymphoedema are discussed further in Section 2.5.1.

2.4.2 Systemic Therapy

While local therapy affects a targeted area of the body, systemic therapy typically impacts the entire body and can include chemotherapy, hormone therapy, Herceptin and other targeted therapies.

Chemotherapy: In Ireland, approximately 47% of women with breast cancer undergo chemotherapy (National Cancer Registry Ireland, 2016). Chemotherapy involves the use of cytotoxic drugs which target all cells, cancerous and healthy. Because

chemotherapy can damage healthy cells, it is administered in cycles to enable healthy cells time to recover. It can be delivered pre- (neo-adjuvant chemotherapy) and/or post-surgery (adjuvant chemotherapy), and this is dependent on several factors including age, staging, risk of recurrence, and tumour size (Thompson & Moulder-Thompson, 2012). It is typically delivered intravenously, however, can also be administered orally. Acute side-effects include hair loss, nausea and vomiting, and cancer-related fatigue (Section 2.5.1) however other side-effects such as cognitive dysfunction (Section 2.5.2), sexual function, and induced menopause (Section 2.5.1) can be experienced as chronic side-effects which can impact on activity participation and QoL (Azim Jr et al, 2011).

Hormone therapy: Hormone therapy, also known as endocrine therapy, inhibits the effect of oestrogen on breast cancer cells, which typically thrive and grow in oestrogen's presence. In Ireland, approximately 55% of women with breast cancer undergo hormone therapy (National Cancer Registry Ireland, 2016). Frequently used hormone therapy drugs include tamoxifen, aromatase inhibitors (such as letrozole, anastrozole, and exemestane) and goserelin (zoladex). Dependant on which type of hormone drug prescribed, the regimen typically ranges from five to ten years. Common side-effects of hormone therapy include bone loss, osteoporosis, and menopausal symptoms such as hot flushes, changes in mood, pain, sleep disturbance, and reduced attention which are discussed further in Section 2.5.1 (Irish Cancer Society, 2021e).

Herceptin and other targeted therapies: Herceptin (trastuzumab) is a targeted cancer drug that is used in the treatment of Human Epidermal growth factor Receptor 2-positive (HER2+) breast cancer. HER2+ cells have too many HER2 receptors which send signals to the cells to grow and divide rapidly. Herceptin attaches itself to the HER2 receptors, inhibiting these signals, while also signalling to the immune system to destroy that cancer cell (Herceptin, 2021). It can only be delivered intravenously, although there is an injectable form of the drug that is combined with the enzyme hyaluronidase. Common side-effects include nausea and vomiting, shortness of breath, fever, and dizziness, and in rare cases cardiac dysfunction (Gemmete & Mukherji, 2011).

2.5 Personal Factors: The Impact of Breast Cancer and Treatment on Well-Being and Work.

A breast cancer diagnosis and its subsequent treatment and side-effects can directly and indirectly impact well-being and engagement in work. Numerous studies demonstrate that breast cancer treatment is a significant risk factor for impaired work ability (Fantoni et al, 2010; Hedayati et al, 2013). In particular, disease-related factors including physical and psychological sequelae have been observed to impact RTW post-breast cancer (Islam et al, 2014; Schmidt et al, 2019). This is in line with evidence in Ireland where 79% and 62% of those living with and beyond cancer report physical and psychological health issues as the most common barriers in RTW, respectively (Connolly, Russell & Henry, 2021).

2.5.1 Impact on Physical Well-Being

Commonly reported physical side-effects include cancer-related fatigue, pain, menopausal symptoms such as hot flushes, lymphoedema, and physical changes in appearance such as hair and breast loss. Other side-effects include but are not limited to cording (axillary web syndrome), nausea and vomiting, and changes in spinal alignment post-surgery.

Cancer-Related Fatigue: Cancer-related fatigue is common and is defined as “a distressing, persistent, subjective sense of physical, emotional, and/or cognitive tiredness or exhaustion related to cancer and/or cancer treatment that is not proportional to recent activity and interferes with usual functioning” (Bower et al, 2014, p.1844). Its cause can be multi-factorial, however both radiation therapy and chemotherapy are associated with worsening cancer-related fatigue in women living with and beyond breast cancer (Donovan et al, 2004). While there is no gold standard for treating cancer-related fatigue, several approaches including psychosocial intervention and physical activity have shown beneficial results (Bower et al, 2014). Cancer-related fatigue is most prominent in the first six months post-diagnosis but can persist for several years (Biering et al, 2020), and is associated with other debilitating symptoms.

In a cross-sectional cohort study of 350 women living with and beyond breast cancer at least five years post-diagnosis, one in four experienced multidimensional fatigue which

was associated with symptoms of depression and anxiety (Maass et al, 2021). This is important to note, as persisting cancer-related fatigue after five years is associated with reduced activity participation, such as work (Schmidt et al, 2019). Furthermore, cancer-related fatigue has also been associated with cognitive dysfunction and reduced physical endurance, all of which can impact on work ability (Feng et al, 2019).

In addition to the impact of physical fatigue on work ability, fatigue can also be psychological and have debilitating effects (Islam et al, 2014). For example, Dumas et al (2019) observed negative work outcomes with both physical and emotional fatigue amongst women living with and beyond breast cancer. Carlsen et al. (2013) also examined whether the work ability of those living with and beyond breast cancer differed from a control group. Findings indicated that health-related factors were most strongly associated with work ability, where cancer-related fatigue increased the risk of low work ability by almost 11 times. It is not surprising, therefore, that cancer-related fatigue has been cited as one of the most impactful factors which can impact on the ability of women living with and beyond breast cancer to return fully to the workforce (Carlsen et al, 2013; Tan et al, 2012), where higher levels of fatigue have been associated with a later RTW (Wolvers et al, 2018). Qualitative findings also underline the impact of cancer-related fatigue on work (Levkovich et al, 2019), where women living with and beyond breast cancer discussed a dramatic decline in functioning and fear of a loss of independence as a result of their fatigue. Therefore, it is important to consider cancer-related fatigue in a work-focused intervention for women living with and beyond breast cancer to support this cohort in self-managing this debilitating symptom within the workplace.

Pain: Chronic pain is common amongst women living with and beyond breast cancer (Villa et al, 2021; Wang et al, 2018) and can be caused by several factors including (but not limited to) axillary surgery (Villa et al, 2021), mastectomy or lumpectomy (Wang et al, 2018), radiotherapy (Wang et al, 2018), or disease progression (Satija et al, 2014). Typically, pharmacological intervention is most frequently used for pain management (Satija et al, 2014), although non-pharmacological interventions such as yoga (Carson et al, 2009; Vadiraja et al, 2009), physical activity (Reis et al, 2018), and acupuncture (Hershman et al, 2018) have demonstrated benefit.

Pain is known to compromise QoL (Abu Farha et al, 2017; Costa et al, 2017), and can particularly impact on mood, sleep, and engaging in work (Ferreira et al, 2015). It has been described as part of a ‘symptom cluster’ among women living with and beyond breast cancer and is associated with cancer-related fatigue, anxiety and depression (So et al, 2009). It is a commonly cited barrier in reintegration into employment post-breast cancer diagnosis (Fantoni et al, 2010; Islam et al, 2014; Tan et al, 2012) and can also manifest through breast cancer related lymphoedema and cording which are described in more detail in this section. Women living with and beyond breast cancer with post-mastectomy pain syndrome tend to be younger than those whose pain has resolved (Macdonald et al, 2005), and there are several studies exploring the negative association of chronic pain on employment for those living with and beyond cancer that are of working age (Cox-Martin et al, 2020; Tan et al, 2021). In addition, pain is associated with adverse financial outcomes, where the greater the pain, the worse the financial outcome (Halpern et al, 2021).

Menopausal symptoms: Menopause is the point in time in which a woman’s menstrual cycles permanently cease. While the average age of onset is between 50-52 years (Gold, 2011; Luoto, Kaprio & Uutela, 1994), early menopause can be induced following oophorectomy or menopausal symptoms can be experienced during hormone therapy. A range of symptoms can be experienced including (but not limited to) hot flushes (also known as hot flashes), sleep disturbance, changes in mood and cognitive changes. Menopause is known to impact negatively on QoL and is becoming increasingly recognised as a work, health, and safety issue to be considered in the modern workplace (Carter, Jay & Black, 2021; Whiteley et al, 2013). For example, hot flushes in women living with and beyond breast cancer have been found to be significantly associated with reduced work performance, even at the three-year period post-treatment (Lavigne et al, 2008).

Cognitive dysfunction, a menopausal symptom, is associated with hormone therapy such as tamoxifen and aromatase inhibitors and can also impact work ability, where hormone therapy is moderately related to attention difficulties in the workplace (Breckenridge et al, 2012). Cognitive dysfunction is described further in Section 2.5.2. While oestrogen replacement is a highly effective treatment for menopause, it is typically not recommended for women living with and beyond breast cancer

(Holmberg, Anderson & HABITS Steering and Data Monitoring Committees, 2004). Non-pharmacological interventions have been shown to be effective in managing menopausal symptoms, however. In a randomised controlled trial (RCT) of 150 women living with and beyond primary breast cancer, deep-breathing techniques, muscle relaxation and guided imagery in combination were shown to reduce hot flushes significantly after one month (Fenlon, Corner & Haviland, 2008). These type of strategies could be embedded into a work-focused intervention for women living with and beyond breast cancer to support self-management of menopausal symptoms in the workplace and elsewhere.

Upper Limb Dysfunction: Upper limb dysfunction can be made up of several side-effects post-treatment including (but not limited to) breast cancer-related lymphoedema, axillary web syndrome (also known as cording), restricted ROM, reduced strength and increased pain. Lymphoedema is characterised by swelling caused by a build-up of lymph fluid, and commonly occurs in the arm and breast area after the removal of lymph nodes or radiotherapy (Irish Cancer Society 2021f). While lymphoedema cannot be reversed entirely, it can be managed; usually by mindful positioning, compression, skin care, exercise and manual lymphatic drainage (Lymphoedema Ireland, 2019).

The presence of lymphoedema can impact negatively on QoL (Morgan, Franks & Moffatt, 2005), however even the fear of lymphoedema alone has been associated with lower functional status (O'Toole et al, 2015). In a qualitative study using a phenomenological approach, 14 individuals living with and beyond cancer described the challenge in managing lymphoedema, particularly in tasks involving manual or repetitive labour (Kalfa et al, 2019). In particular, pain and swelling associated with lymphoedema were found to impact on engagement in work activities such as lifting, typing and carrying, where women living with and beyond breast cancer described a loss of control and lack of function impacting on their job roles (Sun et al, 2020). Lymphoedema is a chronic condition and therefore challenges associated with it and work ability can be long-term.

Axillary web syndrome is another syndrome that can be commonly reported in women living with and beyond breast cancer, where prevalence rates vary widely from 10-85% (Yeung, McPhail & Kuys, 2015). It presents as a tightness from the site of the axillary scar and is characterised by an axillary pain that extends along the upper limb,

sometimes as far as the wrist, typically onset days to weeks post-surgery. It is often aggravated on stretching, but is treatable through exercise and massage (Harris, 2018). Axillary web syndrome can present challenges in ROM which is known to impact on activities of daily living, including work, but is amenable to rehabilitation (Gates et al, 2016).

2.5.2 Impact on Psychological Well-Being

Psychological sequelae are also commonplace during and post-treatment (Islam et al, 2014; Niedzwiedz et al, 2019). In particular, distress, cognitive dysfunction, and changes in body image and self-esteem are frequently reported.

Distress: Distress is an all-encompassing umbrella term for anxiety, depression, fear and panic (Andrykowski, Lynkins & Floyd, 2008) and is frequently experienced by those living with and beyond cancer (Sun et al, 2016). While psychological distress can improve over time, it can manifest years post-treatment impacting on QoL, where anxiety can be more prevalent than depression (Muzzatti et al, 2020). It is widely cited as a barrier in RTW for women living with and beyond breast cancer (Islam et al, 2014; Sun et al, 2016; Tan et al, 2012). It can, however, be amenable to psychological intervention; In a RCT of 227 women living with and beyond breast cancer, the intervention group who received psychological support (e.g., education re. coping strategies, progressive muscle relaxation, and effective use of social support) subsequently experienced lower levels of distress and higher functional status, compared to the control group (Andersen et al, 2007). Self-management interventions can also have a place in addressing psychological distress, however findings from a systematic review observed that there is a gap in intervention content on managing transitions, which could be important for those living with and beyond cancer, particularly when transitioning back into the workplace (Goldberg et al, 2019).

The ability to continue working during treatment or transition back to work following treatment can provide those living with and beyond breast cancer a sense of ‘normalcy’ (van Maarschalkerweerd et al, 2020), decreased social isolation, increased self-esteem (Park & Shubair, 2013), and an increased QoL (Schmidt, et al, 2019), compared to those who cease working. It should be noted however that not all women are initially

ready to return to the workplace, where physical and psychological side-effects can hamper work resumption (Tamminga et al, 2012). Therefore, the rehabilitation and self-management of both physical and psychological symptoms is likely to be important in supporting readiness to RTW.

Body Image and Self-Esteem: Body image-related distress is also frequently reported by women living with and beyond breast cancer with greater than half of women experiencing body image-related concerns about their body function and appearance (Sherman et al, 2018). Several studies suggest that changes in self-image may be more prominent in those living with breast cancer compared to other cancer cohorts (Arroyo & Lopez, 2011; Howard-Anderson et al, 2012; Peppercorn, 2009). Changes in body image have been associated with higher levels of psychological distress in women living with and beyond breast cancer which could impact QoL and functioning (Przedziecki et al, 2013). This can even extend to impacting on one's transition to employment post-treatment, where positive body image has been positively associated with RTW (Lee et al, 2017). In a qualitative study of multi-ethnic women living with and beyond breast cancer (Tan et al, 2012), dressing was described as a barrier in RTW, where attention to a more symmetrical appearance is common following mastectomy (Loh & Yip, 2006).

Physical changes in appearance such as hair loss and nail changes have also been identified as a barrier in work, where a discomfort has been described when interacting with colleagues (Sun et al, 2016). In a systematic review, three types of intervention to address body image and self-esteem among women living with and beyond breast cancer were identified; group therapies, physical activity, and cosmetic and beauty treatments, with varying levels of effectiveness (Morales-Sánchez et al, 2021). The authors were unable to conclude a definitive intervention for body image and self-esteem in women living with and beyond breast cancer, however, did suggest a combination of the three intervention modalities, which could be considered in a work-focused intervention.

Cognitive dysfunction: Cognitive dysfunction is a term used to describe the impairment of various domains of cognition such as memory, attention, executive function, and comprehensive (Pendergrass, Targum & Harrison, 2018). It is common among women living with and beyond breast cancer and is commonly termed as 'chemo-brain' or

‘brain fog’ which can persist and become chronic in some cases (Henderson, Cross & Baraniak, 2019). While cognitive dysfunction is usually self-reported as mild or moderate, even minor deterioration can impact occupational performance and QoL (Hutchinson et al, 2012). This functional decline is even more so prevalent when coupled with cancer-related fatigue (Joly et al, 2019). In a cross-sectional study of 1,393 women living with and beyond breast cancer, 47.2% reported cognitive difficulties and were more likely to be on sick leave than women living with and beyond breast cancer without cognitive impairment (Boscher et al, 2020). It can also impact those who are seeking employment who also report their cognitive dysfunction as a barrier in a RTW where reduced information processing and memory deficits can impact on perceived interview performance (Boykoff, Moieni & Subramanian, 2009). It is unsurprising, therefore, that increased support for women living with and beyond breast cancer in self-managing cognitive impairments in the workplace has been recommended (Munir et al, 2010), with the potential to enhance long-term employability (Klaver et al, 2020). Cognitive dysfunction is amenable to rehabilitation where interventions that centre on compensatory strategy training and/or computer training have demonstrated promising results post-cancer treatment (Fernandes, Richard & Edelstein, 2019), and therefore could be considered when targeting self-management of cognition in the workplace.

2.6 Interpersonal and Institutional Factors: The Impact of Sociodemographic and Work-Related Factors on RTW for Women Living With and Beyond Breast Cancer

The influence of interpersonal and institutional factors can also be considered where sociodemographic and work-related factors can also influence the RTW process for women living with and beyond breast cancer.

2.6.1 Sociodemographic Factors

In addition to disease and treatment-related factors, there are a wide range of socio-demographic factors that can contribute to the likelihood of a woman living with and beyond breast cancer returning to the workplace. This can include (but is not limited to) age, education level, marital status, number of dependants, ethnicity, household income

and social support. Those who are younger (Bouknight, Bradley & Luo, 2006), have higher levels of education (Wang et al, 2018), are single, and have high incomes (Drolet et al, 2005; Tamminga et al, 2012) and good social support from family and friends, are more likely to RTW following their cancer diagnosis. Women who are single, divorced, or widowed, are more likely to RTW (Fantoni et al, 2010), however can also be more financially compromised than their married peers. This is important to note as the loss of monthly income following a cancer diagnosis in Ireland is estimated at an average reduction of €1,527 (Irish Cancer Society, 2019) and the direct cost of cancer conservatively estimated at €756 per month, increasing to over €1,000 in some instances. Exploring the family unit further, high-quality evidence has demonstrated that unemployment following breast cancer surgery has been associated with childlessness (Wang et al, 2018).

Education levels have also been found to have a relationship with job type, where those with lower levels of education were more likely to work as manual workers with physically demanding roles, heightening cancer-related fatigue (Blinder et al, 2012). Similarly, low socioeconomic status (SES) has been identified as a risk factor for unemployment following breast cancer diagnosis (Carlsen et al, 2014). Those with low SES are more likely to have physically heavier job roles, and temporary employment contracts (Burdorf, 2015). This is echoed in a study by Bouknight, Bradley & Luo (2006), who found that those working in a blue-collar position were less likely to RTW than women with white-collar roles, although conflicting findings have been found in a recent systematic review (Wang et al, 2018), which demonstrated no association of employment with blue-collar working.

Ethnicity has been shown to impact the likelihood of RTW. For example, Korean women were less likely to maintain their job role after treatment, in comparison to Western country counterparts (58.9% Korean women returned to work vs. 72-80% women in Western countries) (Ahn et al, 2009). This could be due to several factors, although emphasis on family commitments has been previously suggested (Lee et al, 2008). Facilitators and barriers could also vary by ethnicity, where financial independence has been suggested as a facilitator for women living with and beyond breast cancer in China, whereas the desire for socialisation has been a facilitator for Malay women (Tan et al, 2012).

2.6.2 Work-Related Factors

As mentioned in Section 2.6.1, job role can have important RTW implications for women living with and beyond breast cancer. For example, roles that include interaction with the public, are high-pressured, physically demanding or shift work roles have been found to compound the effects of cancer-related fatigue which may impact on work ability (Blinder et al, 2012; Mock, 1998). Roles where there are high psychological demands are present have also been found to be associated with unemployment (Wang et al, 2018). This suggests that both physical and psychological health are influential in work ability (Islam et al, 2014; Schmidt et al, 2019).

Typically, work accommodations are put in place to manage physical and psychological side-effects of cancer and are associated with positive health benefits (Neumark et al, 2015), although involuntary job changes (i.e., unwanted work modifications since diagnosis) are negatively associated with women living with and beyond breast cancer's satisfaction with occupational development (Hiltrop et al, 2021). Work accommodations, or reasonable accommodations, can be defined as a change or modification to the tasks and/or structure of a job or work setting, which enables the qualified employee (with a disability) to complete the job and enjoy equal employment opportunities (Citizen's Information, 2020). Examples of work accommodations vary but can include flexibility in working hours, working from home, and environmental adaptations (Islam et al, 2014). Changes by employers to work schedules to facilitate cancer treatment and any follow-up appointments have also been shown to facilitate RTW and ease the workload (Johnsson et al, 2010; Nilsson et al, 2011).

The role of effective communication is another important work-related factor to consider, where continued employer-employee communication has been said to be 'critical', particularly for employees who may be absent for a long period of time (Fantoni et al, 2010). It is also acknowledged, however, that employer-employee communication following a cancer diagnosis can be complex (Tiedtke et al, 2017), where there can be lack of illness disclosure (Stewart et al, 2001). While disclosure is not mandated by legislation, employers perceive it as useful in communicating and managing expectations, and implementing work accommodations (de Rijk et al, 2020). On the other hand, women living with and beyond breast cancer have identified difficulty in communicating about their diagnosis to their employer and colleagues as a

barrier in their RTW (Sun et al, 2016), which can prompt reluctance to approach employers around any required accommodations (Murphy et al, 2013). It is unsurprising, therefore, that enhancing employer-employee communication has been recommended in supporting work outcomes following a cancer diagnosis (Sun et al, 2016).

2.7 Societal and Policy Factors: International and National Policy and Strategy on Cancer and Work

Should a woman with breast cancer wish to return to the workplace, RTW can also be in the interest of society and employers (Spelten, Sprangers & Verbeek, 2002). Impaired work ability has an economic impact both on the individual and society. For example, in 2009 productivity losses due to cancer-related morbidity accounted for approximately 83 million working days across the EU, equating to €9.43 billion. In Ireland, this figure stood at €63 million. While these figures represent all cancers, breast cancer had the second highest economic cost to the European Union however, accounting for 12% of all cancer costs in 2009 (Luengo-Fernandez, et al, 2013). While more recent data does not provide detail by cancer type, the total productivity loss across Europe due to cancer morbidity in 2018 stood at €20 billion, more than doubling from 2009 levels. Furthermore, it was estimated that productivity loss due to cancer morbidity in Ireland was €113 million (Hofmarcher et al, 2020). Therefore, successful transition back into the workplace for those who have had breast cancer can have societal benefits. Both individual and societal benefits of reintegration into work after cancer are now being recognised and this is reflected in international and national policy and strategy.

2.7.1 International Policy and Strategy

Although evolving, international policy and strategy specifically on work and cancer was scarce in the early 2000's, even in early survivorship policy (Canadian Partnership Against Cancer, 2008; Cancer Australia, 2014; CSCC Governing Council, 2006; National Health Service, 2007). The United States was the first country to outline

financial pressures resulting from work limitations post-cancer diagnosis and acknowledged that there is a potential for job loss, demotion, and the reduction or elimination of benefits which may stem from employer discriminatory beliefs (Centers for Disease Control and Prevention & Lance Armstrong Foundation, 2004; Hoffman, 1991).

It is only in recent years that international focus is being paid to work reintegration as a key component of cancer survivorship care. For example, in Canada the ‘Sustaining action toward a shared vision: 2012-2017 Strategic Plan’ was published where two work-focused actions were outlined including (i) to identify priorities with key stakeholders for workplace supports, and (ii) to explore a workplace strategy (Canadian Partnership Against Cancer, 2012). Since then, the ‘Approaches for Addressing Mental health & Return to Work Needs of Cancer Survivors: An Environmental Scan’ has been published (Canadian Partnership Against Cancer, 2019a) alongside the ‘Canadian Strategy for Cancer Control: 2019-2029’ which calls for the provision of community services to support RTW, and specifically appropriate educational and employment services (Canadian Partnership Against Cancer, 2019b).

Recommendations to develop work-focused interventions for those living with and beyond cancer have also been echoed at European-level. More recently, it is acknowledged in Europe’s Beating Cancer Plan that those living with and beyond cancer face obstacles in RTW, and it is recommended that “Measures to facilitate social integration and re-integration into the workplace, including an early assessment and adaptation of working conditions for cancer patients should be integral parts of the patient pathway” (European Commission, 2021, p.22). This has been reflected in the United Kingdom where recommendations stemming from a ‘Work and Finance’ workstream included investigating and developing (a) The effectiveness and cost-effectiveness of specialist vocational rehabilitation programmes for cancer patients who have complex work problems. (b) Employers’ perspectives on supporting people with cancer to remain in and return to work.” (Eva et al, 2012, p.50). Where there is now an amplified focus internationally on work and cancer as a priority in cancer care, this importance is now being reflected in Irish policy and strategy.

2.7.2 National Policy and Strategy

In 2006, the second national cancer strategy in Ireland, ‘Strategy for Cancer Control in Ireland’ was launched, which focused on the reduction of cancer incidence, morbidity and mortality rates with no reference to RTW post-cancer (National Cancer Forum, 2006). Since that time, the third cancer strategy in Ireland, ‘National Cancer Strategy 2017-2026’ has been published, with a new dedicated focus on survivorship, as well as maximising patient involvement and QoL (Department of Health, 2017). For the first time in national cancer strategy in Ireland, the importance of RTW was highlighted, where it is outlined, “The realisation of a life beyond cancer in the sense of optimising the quality of life. This could range from achieving a level of pain-free contentment to assimilation back into the workforce.” (Department of Health, 2017, p. 109).

Furthermore, it is acknowledged that RTW is part of a return to life for many, and that the overall economic benefit for society is substantial (Department of Health, 2017). This was an important milestone in cancer and employment in Ireland, and since this time, policy, strategy and evidence has been evolving further. For example, the Irish Cancer Society commissioned the Economic and Social Research Institute (ESRI) to conduct research on barriers and facilitators in RTW amongst those living with and beyond cancer in Ireland (Connolly, Russell & Henry, 2021). This then led to a report outlining key work recommendations from the Irish Cancer Society Advocacy team, which included the recommendation that for the introduction of a pilot programme on RTW for those living with and beyond cancer (Irish Cancer Society, 2021a). In addition, work was explicitly outlined as an area of priority for the first time by the Irish Cancer Society in 2020, when they outlined the development of a work-focused online hub for employers and employees as one of their ten strategic commitments (Irish Cancer Society 2020).

In addition to evolving work in the Irish Cancer Society, a priority of the National Cancer Survivorship Needs Assessment (Mullen & Hanan, 2019, p.24) was set to “address the impact of social, financial and practical issues on cancer patients and their families” which includes (i) developing information and (ii) advocating for improved employment access programmes and workplace supports. Emerging policy and strategy in cancer and work has prompted a new focus on RTW supports for those living with and beyond cancer to be developed and implemented in Ireland.

2.8 RTW Supports for Women Living With and Beyond Breast Cancer: A Paucity of Intervention and Need for Support

Despite known RTW challenges as outlined in Sections 2.5 and 2.6, there is a lack of evidence-based interventions to support women living with and beyond breast cancer to return to, or remain at, work (Algeo, Bennett & Connolly, 2021; de Boer et al, 2015; Hoving et al, 2009). This is despite women expressing a desire for additional resources to support work outcomes. For example, an interpretative phenomenological study highlighted the desire of women living with and beyond breast cancer for healthcare professional support on functional and work ability (MacLennan et al, 2021). Indeed, women living with and beyond breast cancer, up to ten years post-diagnosis, expressed regret that they had not received oral and written information regarding the RTW process for themselves and their employers throughout their cancer trajectory (van Maarschalkerweerd et al, 2020).

Internationally, there are limited RTW supports available however the effectiveness of such interventions has not been formally established. For example, in the United Kingdom, Macmillan offer training under the *Macmillan at Work* intervention which includes expert training, consultancy, information and support, and resources including e-newsletter and free work and cancer toolkit, yet there is no evidence available to demonstrate efficacy (Macmillan, 2019). There are several written resources on returning to work after a cancer diagnosis available in Canada (Beck & Amin, 2019), Australia (Cancer Council, 2019), and the United States (American Cancer Society, 2021), however these are not tailored to the individual and not necessarily applicable to someone living with and beyond a cancer diagnosis in Ireland, where legislative systems are different.

There are limited supports in Ireland, however employer-specific training is available via the Marie Keating Foundation as well as written information for both employees and employers (Marie Keating Foundation, 2019). Despite this, specific supports for those living with and beyond cancer are lacking and, as highlighted, the introduction of a pilot programme on reintegration into the workplace for those living with and beyond cancer in Ireland has been recommended (Irish Cancer Society, 2021a). Therefore, the development and feasibility of an intervention to support work outcomes for women living with and beyond breast cancer is timely. As outlined previously (Section 1.2), the

development of a complex intervention such as a RTW intervention, requires a series of stages in development including involving key stakeholders and understanding the context of the problem being addressed; in this case, overcoming barriers to RTW for women living with and beyond breast cancer.

Currently, there are no known studies exploring women living with and beyond breast cancer's experiences when returning to or staying at work in Ireland. This is important as the average time to RTW after successful cancer treatment varies considerably by country and ethnicity (Islam et al, 2014) (Section 2.6). Research exploring the impact of breast cancer on employment has been carried out in Sweden (Lilliehorn, 2013), the United States (Blinder, 2012; Hansen et al, 2008), the Netherlands (Roelen et al, 2011), South Korea (Ahn et al, 2009), and Belgium (Tiedtke et al, 2012), to name a few. While there remains moderate overlap in challenges between countries, different outcomes can be found stemming from country-specific variables. A myriad of ecological factors (such as individual, interpersonal, community and public policy determinants) can influence an individual's experience and it is, therefore, important to explore these within an Irish context. The most common reported barriers in RTW tend to be disease and treatment related, however this can alter over time where sociodemographic and work-specific factors can take precedence (van Maarschalkerweerd et al, 2020).

RTW rates among women living with and beyond breast cancer vary widely internationally. For example, RTW rates following breast cancer are significantly higher in the United States, where 93% of insured women return to their workplace within 12 months (Hasset, O'Malley & Keating, 2009). This can be in part explained by a heavy reliance on private health insurance which instils a fear of losing insurance benefits with companies if an employee goes on extended sick leave (Ahn et al 2009). In contrast, the Netherlands sees a lower RTW rate at 43% within 12 months, which can be partly explained legislation that protects employee benefits during extended medical leave (OECD, 2007). In Ireland, approximately 16% of women diagnosed with breast cancer, immediately continue to work post-diagnosis, compared to 50.8% of men diagnosed with prostate cancer (Sharp, et al. 2014). Such disparity is important to consider as it has been shown that those living with and beyond cancer who are able to continue working during their treatment, experience increased QoL and reduced psychological distress, compared to those who discontinue employment during

treatment or who cease working following their cancer diagnosis (Bieri et al, 2008; Mahar, Brintzenhofeszo & Shields, 2008). To be able to support this cohort, it is important to determine what can help and challenge the RTW process.

The following chapter will discuss the Phase I study which used a qualitative-descriptive design to explore stakeholder perceptions around facilitators and barriers in returning to employment following a breast cancer diagnosis, in Ireland.

CHAPTER THREE: QUALITATIVE- DESCRIPTIVE DESIGN

PHASE I STUDY: The experiences and challenges of women living with and beyond breast cancer in returning to or staying in employment in Ireland

3.1 INTRODUCTION

As outlined in Section 1.2, the intervention development process is iterative and dynamic, involving several interchangeable stages. A starting point in intervention development is planning the development process (O’Cathain et al, 2019). This includes, but is not limited to, understanding the problem and its context through stakeholder feedback, establishing if there a need for the proposed intervention, and if so, understanding context in which an intervention might operate. When interventions consider the needs and circumstances of a targeted population such as women living with and beyond breast cancer, they are more likely to be acceptable and appropriate to the population, therefore enhancing intervention engagement and adherence (Croot et al, 2019). Currently, there are no known studies exploring experiences of women living with and beyond breast cancer when returning to or staying at work in Ireland. This is important as the average time to RTW after successful cancer treatment varies considerably by country and ethnicity (Islam et al, 2014). This is also echoed by the European Agency for Safety and Health at Work (2018) who acknowledged that if developing and implementing successful RTW interventions for those living with and beyond cancer, national level differences should be considered. Therefore, exploration of experiences of women living with and beyond breast cancer when navigating work following breast cancer treatment in an Irish context will be considered in this Phase.

The aim of this study was to explore the experiences and challenges of women living with and beyond breast cancer in returning to or staying in employment in Ireland with a view to develop a work-focused intervention. Research questions included:

1. What are the facilitators and barriers in staying at and/or returning to work for women living with and beyond breast cancer in Ireland?
2. What are the perceptions of key stakeholders on the content and delivery of a work-focused intervention to support work outcomes for women living with and beyond breast cancer?

3.2 METHODS

An in-depth description of the methodology strengthens the dependability of this research (Shenton, 2004). The reporting of this study is guided by the consolidated criteria for reporting qualitative research (COREQ) (Tong, Sainsbury & Craig, 2007) (Appendix A), and draws on but largely extends on an accepted paper for publication in *WORK* (Algeo, Bennett & Connolly, in press-a).

3.2.1 Study Design

A qualitative-descriptive design using semi-structured interviews explored stakeholder perceptions around facilitators and barriers in returning to employment following breast cancer treatment, with a view to develop a work-focused intervention. A qualitative-descriptive design has been recognised as a useful method in providing useful, important data when tailoring a clinical intervention and is therefore well-placed to be incorporated in the early stages of intervention development (Sullivan-Bolyai, Bova, & Harper, 2005). While qualitative description is sometimes criticised for its lack of clarity and for not being theory-based, this criticism can only be justified when qualitative description is used for the incorrect purposes (Neergaard et al, 2009). There are several philosophical underpinnings of the qualitative-descriptive approach. First, it is an inductive process, describing a picture of the phenomenon being studied and context; in this case, the experiences of women living with and beyond breast cancer

transitioning back into the workplace in Ireland. Second, it recognises the subjectivity of each participant and the researcher, acknowledging that each participant has their own perspective or experience and that each account is important to capture. Third, it is designed to develop an understanding of a phenomenon, rather than provide evidence for existing theoretical constructions. Finally, it incorporates an emic stance, where an insider view is considered, that is, those directly impacted by the phenomenon (Bradshaw, Atkinson & Doody, 2017).

3.2.2 Participant Selection

Purposive sampling, a type of non-probability sampling, was used in the selection of participants in this study and involved the conscious selection of participants with specific characteristics that are of interest (Marshall, 1996). Three cohorts of stakeholders were recruited including (i) women who had breast cancer and were in employment at the time of diagnosis, (ii) healthcare professionals who have worked directly with women living with and beyond breast cancer, and (iii) employers who had experience of managing an employee with cancer. This type of sampling demands critical thinking about the parameters of the population being studied. Clearly defined criteria can justify sampling, minimising researcher bias which is sometimes cited as a limitation in purposive sampling (Macnee & McCabe, 2008). As a result, defined inclusion criteria were established (Table 3.1).

Table 3.1: Inclusion Criteria

Women living with and beyond breast cancer	Healthcare Professionals	Employers
▪ A past primary diagnosis of breast cancer. ▪ Completed all active treatment (defined as surgery, chemotherapy and/or radiation therapy). ▪ Have returned to work within the last 24 months (to minimise recall bias) ▪ Aged 18-66 years old (current adult employment age in Ireland) ▪ In employment at the time of diagnosis.	▪ Experience working directly with women who have had breast cancer.	▪ Employers and/or their staff who are involved in supporting return to work (e.g. Human Resources, Occupational Health, Managers) ▪ Have experience in managing sick leave and/or work accommodations due to cancer. ▪ Willing to take part in a semi-structured interview. ▪ Small, medium or large organisations. ▪ Public, Semi-State, or Private organisations.

Permission was obtained from several key cancer and healthcare related organisations for the advertisement of recruitment. Word of mouth also became apparent during the recruitment period across all three cohorts.

- *Women living with and beyond Breast Cancer:* Women living with and beyond breast cancer were recruited through three voluntary cancer-related agencies: the Irish Cancer Society, Europa Donna Ireland, and the Plurabelle Paddlers, via social media platforms, and email databases.
- *Healthcare Professionals:* Healthcare Professionals were recruited through the Irish Cancer Society, Irish Psycho-Social Oncology Network (IPSON), Irish Association for Nurses in Oncology (IANO), and the Association of

Occupational Therapists of Ireland (AOTI). This range in organisations offered a diverse membership base from which to recruit, including (but not limited to) nurses, occupational therapists, psychologists, doctors, and physiotherapists who work with women living with and beyond breast cancer.

- *Employers:* Employers were recruited via a voluntary cancer agency, the Marie Keating Foundation, who acted as a gatekeeper and promoted the study to any employers via their email database. The PhD Candidate also promoted the study via their social media channels e.g., Twitter & LinkedIn.

It was aimed to recruit at least 13 participants from each cohort. Sample size in qualitative research is regularly debated among researchers and is often poorly justified in qualitative health research (Vasileiou et al, 2018). In a systematic review (Kim, Sefcik & Bradway, 2017), most qualitative-descriptive design studies had sample sizes of 8-20 participants. Typically, one-to-one interviews were employed in these studies, whereas studies with larger sample sizes (e.g., 50) used survey instruments with analysis of open-ended questions. This is in line with consensus that qualitative research which incorporates in-depth interviews or intensive contact with participants, tends to have smaller sample sizes (Bradshaw, Atkinson & Doody, 2017). Data saturation was also considered and is defined as the process where no new insights are obtained from the data collection process (Glaser & Strauss, 1967). It can be enhanced through data triangulation (Denzin, 2012; Stavros & Westberg, 2009) which was incorporated into this study (See Section 3.2.8). It has been recommended (Bowen, 2008) for health-related studies to interview a sample of ten cases followed by at least a further three cases to determine if any new themes emerge. As a result, it was aimed to recruit at least 13 participants.

3.2.3 Patient and Public Involvement in Research

Patient and public involvement (PPI) refers to the engagement in research ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’, or ‘for’ them (National Institute for Health Research, 2021). Actively incorporating PPI throughout the research process is recognised as a marker of good research practice as it can lead to more relevant, better designed research with clearer outcomes, and its use is promoted in cancer research

both in Ireland (Irish Cancer Society, 2018) and the United Kingdom (National Institute for Health Research & National Cancer Research Institute, 2014). Early involvement of PPI in research has been found to have a greater impact and influence in the research process, compared to late involvement (e.g., trial steering committee) (Dudley et al, 2015). As a result, PPI was incorporated from the initiation of Phase I of this research. PPI members were identified through Europa Donna Ireland, an advocacy group and registered charity, launched in Ireland in 1998 for women living with and beyond breast cancer. They were invited to provide feedback in Phase I on (i) the suitability of this research for women living with and beyond breast cancer, (ii) whether the correct research questions were being explored, for women living with and beyond breast cancer (iii) the accessibility/readability of research documents such as the participant information leaflet (PIL) and consent forms, and (iv) questions posed in the interview guide. Feedback from PPI members influenced minor changes to the interview guide and provided recommendations for an additional recruitment source to approach in Phase I, the Plurabelle Paddlers, which was acted on following this feedback.

3.2.4 Study Procedure

Once full ethical approval was obtained, an e-mail was sent to all organisations who had previously agreed to promote the study. Advertisement was then distributed via e-mail, social media, and e-newsletters. Potential participants were invited to contact the researcher by email or telephone to express interest. The PhD Candidate then issued a letter to potential participants, PIL (Appendix B) and Consent Form (Appendix C). It was outlined in the PIL that this study was part of a larger phased study to inform a work-focused intervention. and that this was being completed as part of a doctoral degree. Potential participants were also made aware the rationale for the research topic in the PIL. The potential participant was contacted at least seven days following this, to allow time to reflect on their potential participation. If the potential participant wished to proceed with the study, they collaborated with the researcher to organise a time and date convenient to them for interview. Every participant was invited to pose any questions prior to participation and signing consent. No relationship had been established with participants and the researcher prior to study commencement. If the potential participant remained happy to proceed, both the participant and researcher

signed the consent form. A copy was made available for both researcher and participant for their records. Every participant who indicated interest in the study, took part.

3.2.5 Data Collection

Once-off semi-structured interviews, guided by a pre-determined interview guide, were conducted (Appendix D). The PhD Candidate (MRes, BScOT) led in all qualitative data collection and is a Registered Occupational Therapist by background with previous clinical experience in acute oncology and rehabilitation. She has early-stage career research experience in both quantitative and qualitative research methods, and holds a Masters in Clinical Research. Interview guides were developed for each cohort. Questions were adapted from previous research (Sun et al, 2016) exploring RTW facilitators and barriers, and minor amendments were made to interview guides following PPI feedback. PPI group members provided feedback on the suitability and accessibility of questions posed. For example, questions such as *'When you returned, had any changes been made to your role?'* and *'If you needed time off for the treatment/recovery from treatment, was there flexibility around this?'* were added. The first interviews of each cohort were used as a pilot interview where the interview guide was tested and adjusted. All interviews were audio-recorded using a Dictaphone and conducted by the PhD Candidate who took field-notes throughout. No one other than the PhD Candidate and participant, were present during interviews. Recruitment of all three groups, and data analysis were completed in parallel with one another. Interview averaged 53 minutes and were conducted in person with women living with and beyond breast cancer, usually in the university setting or at a pre-arranged setting such as a cancer support centre. Interviews were conducted with healthcare professionals and employers usually in their workplace.

3.2.6 Transcription and Data Management

The PhD Candidate independently completed all transcription work rather than outsource to transcription services as this stage of data processing is a research activity that involves the close, repeated listening to audio-recording that can often reveal

previously un-noted recurring features (Atkinson & Heritage, 1984). All transcripts were pseudonymised and uploaded onto NVivo (Version 12) for data analysis. Transcripts were not returned to participants. NVivo (Version 12) is a computer software package that supports qualitative data organisation, management, and analysis. The PhD Candidate received training in the use of this software NVivo (Version 12) in December 2018.

3.2.7 Data Analysis

Thematic analysis was used to analyse the data and involved a six-step approach (Braun & Clarke, 2006), where themes are derived from the data. It is typically used as primary strategy for data analysis in qualitative-descriptive designs (Kim, Sefcik & Bradway, 2017). Thematic analysis is a process of identifying patterns or themes within a qualitative dataset. The six steps include:

1. *Becoming familiar with the data:* The first step of thematic analysis involved reading and re-reading the transcripts. Familiarity of the entire body of data was required before proceeding any further. Notes were taken throughout this period, to record any early impressions or ideas.
2. *Generate initial codes:* In this stage, data are organised in a systematic or meaningful way. Interesting features of the data set were highlighted and coded. Open coding was used, where no pre-set codes had been determined. This permitted the development and modifying of codes throughout the coding process. This was led by the PhD Candidate however a second coder reviewed a sample of initial coding.
3. *Search for themes:* Codes were categorised into potential overarching themes and sub-themes. Where codes didn't fit into themes at this time-point, a 'miscellaneous' theme was generated to manage codes. Themes were characterised by significance and relevance.

4. *Review and refine themes*: Preliminary themes and sub-themes were reviewed, refined, and developed where appropriate. The researcher looked for themes that could merge or be omitted if not supported by sufficient data.
5. *Define themes*: Themes were then defined and named/labelled. Any sub-themes were finalised, and the researcher identified a narrative for each theme.
6. *Write-up*: A final report was produced. This includes the final themes, how they arose, what they mean, and examples of data as evidence to support. Participant checking did not feature in this phase of the study.

3.2.8 Pursuing Quality in Qualitative Research

Lincoln and Guba (1985) advocate four principles to ensure quality or in qualitative research: credibility, transferability, dependability, and confirmability (Figure 3.1).

Each principle was considered throughout this study.

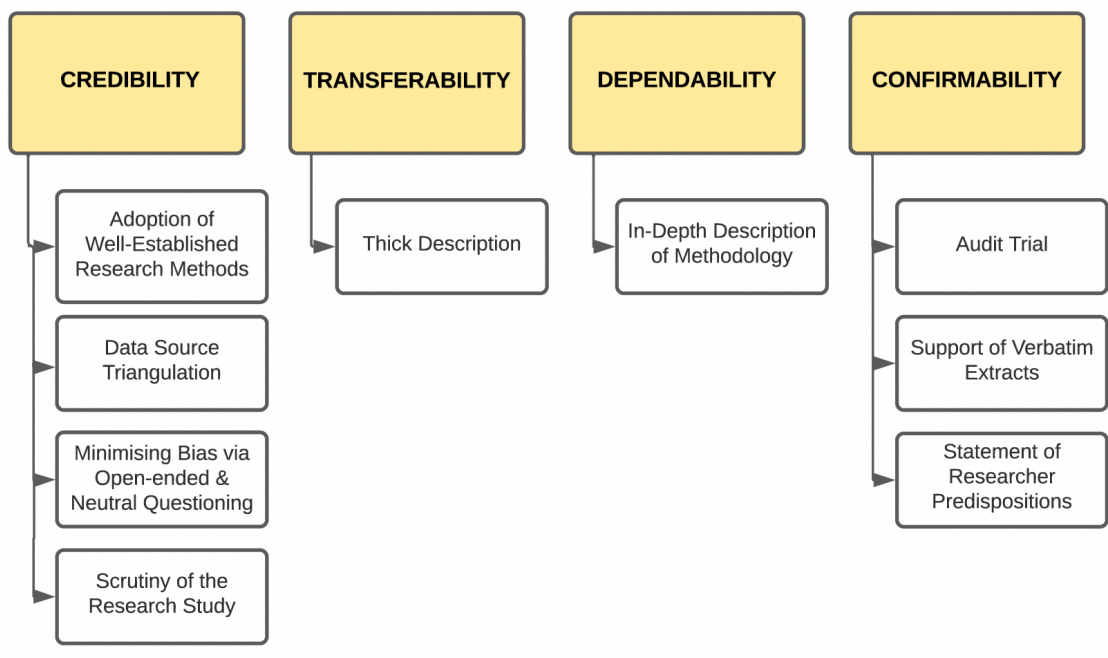


Figure 3.1: Strategies used to enhance Trustworthiness (Lincoln & Guba, 1985)

Credibility: Credibility involves confidence in the ‘truth’ of results, i.e., whether findings of the study are to be believed. Several strategies were used to enhance credibility in this research. First, well-established research methods were adopted. Semi-structured interviews are a common data collection method in qualitative research (Silverman, 2016). Second, data triangulation was used to promote credibility. The use of multiple data sources (women living with and beyond breast cancer, healthcare professionals, and employers) can develop a comprehensive understanding of breast cancer survivorship and employment in Ireland (Patton, 1999). Third, questions were open-ended and neutral in nature, minimising any bias in answers provided. Finally, peer scrutiny was obtained throughout the research through regular supervision with the principal investigator, and presentation of methodology to academic peers.

Transferability: Transferability concerns the extent to which the results of a study can be applied elsewhere (Merriam, 1998). Thick description was outlined, explaining the research context and a detailed description of the phenomena in question. This included the demographic data of participants (such as age, occupation, cancer treatment etc.), inclusion and exclusion criteria, data collection strategies used, and the time-period in which the data were collected, all outlined within this chapter (Cole & Gardner, 1979; Pitts, 1994).

Dependability: Dependability indicates that should the research be repeated, with the same context, methods, and participants, that similar findings would be achieved. The researcher addressed dependability by clearly describing the research design and its implementation. Additionally, the process of data collection is described in detail in Section 3.2.5 (Shenton, 2004).

Confirmability: Confirmability is concerned with the extent to which the research findings are shaped by participants and not that of researcher motivation, bias or interest. A clear audit trail from raw data, codes and final themes supported by verbatim quotes within results supports objectivity of results. Deviant cases, which are viewpoints considered to ‘deviate’ from the norm, were also reported for transparency, although there were no deviant themes. Deviant cases were sought within the data during analysis.

All codes are clearly themed and organised using NVivo (Version 12) data management software. Finally, the researcher outlined all predispositions towards the subject, and these are outlined under a reflexivity statement in Chapter One (Section 1.5) (Miles & Huberman, 1994).

3.2.9 Ethical Considerations

Ethical approval was obtained from the Faculty of Health Sciences, Trinity College Dublin Research Ethics Committee on 12th March 2019 (Appendix E). An addendum was also submitted following this to include employers as a cohort and was approved on 31st May 2019 [REF 190101] (Appendix F). There were several ethical implications to the study as outlined below. General Data Protection Regulation (GDPR) and Health Research Regulations (HRR) came into effect in Ireland on 25th May 2018, and 8th August 2018, respectively. The following ethical considerations in this research are in line with both these pieces of regulation. Ethical considerations included data protection and participant confidentiality, potential for discomfort, informed consent, coercion, and beneficence and the absence of non-maleficence.

Data protection and participant confidentiality: A challenge in maintaining respondent confidentiality is often presented when managing rich accounts in qualitative research e.g., use of semi-structured interviews. All participant identities were protected and were not revealed through any reporting of the study. The importance of the strict confidentiality of participants is highlighted in the Office of the Data Protection Commissioner's (2007) 'Data Protection Guidelines on Research in the Health Sector' report. All participants were allocated a study ID and the codebook with study IDs was kept in a secure locked cabinet in the principal investigator's office as per Trinity College Dublin, Guidelines for Good Research Practice.

Potential for discomfort/dissatisfaction re. discussing current function/work performance: As semi-structured interviews may contain content of a sensitive nature, there was the potential that participants could experience mild discomfort during interview. All participants were reminded that they could cease interview at any stage without reason nor penalty.

Informed consent: Consent is defined under Article 4 of the GDPR (2018) where “‘consent’ of the data subject means any freely given, specific, informed and unambiguous indication of the data subject’s wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her”. Consent was freely provided and voluntary, and it was noted to participants that they could withdraw their consent. Only the minimum amount of personal data necessary for the study was sought. All participants were required to provide informed consent prior to taking part in the study. Prior to providing this consent, all potential participants received a participant information sheet and invited to pose any questions if they had any further queries.

Coercion: Consent forms and PILs clearly stated that individuals were not obliged to participate, and that non-participation would not impact on any future medical care.

Beneficence and the absence of non-maleficence: Beneficence refers to striving to do good for others while also preventing harm (Beauchamp & Childress, 2001). In this case, challenges in the return to employment for women living with and beyond breast cancer was highlighted with a view for the findings to inform future practice and policy. Caution was taken however to protect the identity of each participant through pseudonyms and minimising demographic details which may lead to identification, for example, omitting geographical data. Non-maleficence refers to the protection from or minimisation of harm when striving to reach a beneficial outcome, or simply to do no harm (Morrison, 2009).

3.3 FINDINGS

This qualitative-descriptive study explored RTW barriers and facilitators experienced by women following a breast cancer diagnosis and perceptions around a work-focused intervention. Women, healthcare professionals, and employers were recruited to participate in a once-off semi-structured interview. Results from interviews with each cohort addressing the research questions will be integrated and presented. Six key-themes emerged from data analysis, were superordinate in nature, and comprised several sub-themes. An introduction into each key-theme will be provided, followed by a brief explanation of each sub-theme, illustrated by verbatim extracts. Thirty-nine participants nationwide took part in Phase I of the study between April and October 2019 inclusive: women living with and beyond breast cancer (WBC) ($n=15$), healthcare professionals (HCP) ($n=15$), and employers (EMP) ($n=9$).

3.3.1 Participant Demographics

Women living with and beyond breast cancer: The mean age of participants was 51.2 years (range 32-65 years). Most women had radiation therapy ($n=12$), chemotherapy ($n=9$), lumpectomy ($n=8$), and hormone therapy ($n=8$). Every participant took time off work at some stage post-diagnosis with an average of 11.3 months off (range 2-27 months), however one participant did return to her job role before active treatment was complete. The mean time taken off during the recovery period (from end of active treatment to RTW) was 13.9 weeks (range 0-13 months). Job roles were diverse in nature. Further details are reported in Table 3.2.

Table 3.2: Demographic Characteristics of Women Living With and Beyond Breast Cancer

Characteristic		Frequency (%)
Age	25-34	1 (7%)
	35-44	1 (7%)
	45-54	7 (47%)
	55-64	5 (33%)
	65-74	1 (7%)
Stage	I	2 (13%)
	II	2 (13%)
	III	6 (40%)
	Unknown	5 (33%)
Relationship status	Married/Civil Partnership	11 (73%)
	Single	3 (20%)
	Widowed	1 (7%)
Treatment	Lymph Node Dissection	6 (40%)
	Lumpectomy	8 (53%)
	Re-excision	1 (7%)
	Mastectomy	7 (47%)
	Breast Reconstruction	6 (40%)
	Surgical Complications	4 (27%)
	Chemotherapy	9 (60%)
	Radiation Therapy	12 (80%)
	Hormone Therapy	8 (53%)
	Herceptin	4 (27%)
	Oophorectomy	3 (20%)
	Hysterectomy	1 (7%)
Sector	Public	7 (47%)
	Semi-State	1 (6.7%)
	Private	7 (47%)
Field of Work	Business, Management and Administration	5 (33%)
	Community Services	1 (7%)
	Education	3 (20%)
	Health and Medicine	2 (13%)
	Law and Public Policy	1 (7%)
	Sales	2 (13%)
	Science and Technology	1 (7%)

Healthcare professionals: Fifteen healthcare professionals of varying backgrounds participated. The majority worked in the acute setting ($n=10$). Years of experience in the role averaged 10.6 years (Range 1-35 years). Further details are reported in Table 3.3.

Table 3.3: Demographic Characteristics of Healthcare Professionals

Characteristic		Frequency (%)
Discipline	Counselling	1 (7%)
	Medicine	1 (7%)
	Nursing	3 (20%)
	Occupational Therapy	2 (13%)
	Physiotherapy	4 (27%)
	Psychology	3 (20%)
	Psychotherapy	1 (7%)
Setting	Acute	10 (67%)
	Community	5 (33%)
Sector	Public	9 (60%)
	Private	1 (7%)
	Registered Charity	5 (33%)
Years of Experience	1-5	6 (40%)
	6-10	3 (20%)
	11-15	2 (13%)
	16-20	2 (13%)
	>20	2 (13%)

Employers: Nine employers participated. Most worked in large organisations ($n=8$) in Human Resources ($n=5$) and in semi-state companies ($n=4$). Further details are reported in Table 3.4.

Table 3.4: Demographic Characteristics of Employers

Characteristic		Frequency (%)
Role	Human Resources	5 (55%)
	Line Manager	2 (22%)
	Occupational Health Nurse	2 (22%)
Field of Work	Financial Services	1 (11%)
	Healthcare	3 (33%)
	Insurance	2 (22%)
	Marketing	1 (11%)
	Transport & Logistics	2 (22%)
Organisation Size	Medium	1 (11%)
	Large	8 (88%)
Sector	Public	2 (22%)
	Private	3 (33%)
	Semi-State	4 (44%)
Years of Experience	1-5	1 (11%)
	6-10	1 (11%)
	11-15	1 (11%)
	16-20	4 (44%)
	>20	2 (22%)

Company sizes are benchmarked against Irish standards where companies with <10 employees are classified as micro, 10-49 as small, 50-249 as medium, and 250+ as large (Central Statistics Office, 2018).

3.3.2 Key themes

Six key themes emerged following data analysis (Figure 3.2). RTW barriers and facilitators discussed varied over the trajectory of a RTW journey; during treatment and recovery (Theme I), when transitioning back to work (Theme II), and when maintaining work role (Theme III). Throughout this trajectory, employment rights and entitlement (Theme IV) and communication (Theme V) could impact on the RTW process. To mitigate these challenges, perceptions on a RTW intervention (Theme VI) were identified. Data saturation was achieved for women living with and beyond breast cancer and healthcare professional cohorts, but not employers.

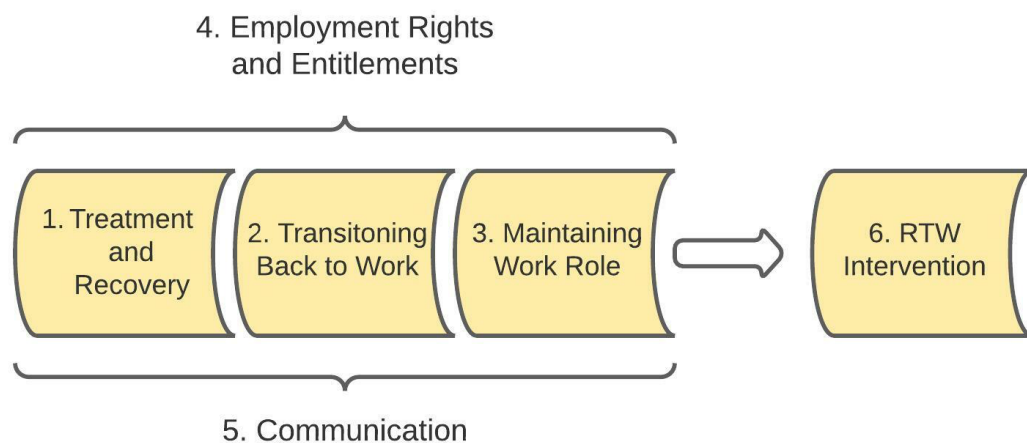


Figure 3.2 Key Themes

3.3.3 THEME I: TREATMENT & RECOVERY

This initial phase in the breast cancer trajectory focused on disease and treatment side-effects, and the recovery period. During this time, women noted inconsistency in survivorship supports available as well as a paucity in RTW supports in Ireland. Healthcare professionals echoed this, noting poor consensus around whose role it is to provide employment support.

Sub-theme I: Rebuilding physical and psychological strength post-treatment

Participants described a myriad of physical and psychological side-effects during and following treatment. Symptoms varied between participants and were both directly and indirectly treatment-related. Commonly reported physical side-effects included fatigue, hot flushes, nausea, hair loss, low immunity, lymphoedema, and joint stiffness. Less

commonly reported physical side-effects included burning, digestive changes, chest wall pain, ingrown eyelashes (following chemotherapy-related hair loss), cording, infertility, and peripheral neuropathy. Cognitive changes included foggianness of thinking or 'chemo-brain', concentration, forgetfulness, and word-finding difficulties.

Psychological side-effects reported included stress, loneliness, anxiety, depression and depressive symptoms, fear (of death, recurrence, the future, being able to carry out their work role), altered body image, changes in mood, and a sense of guilt. Often symptoms could interplay with one another. There was recognition that treatment side-effects needed to be managed effectively before returning to the workplace, including physical and psychological factors.

"I think after [the treatment] I needed to be mentally and physically stronger before I could actually contemplate going back." (P5-WBC)

"I wouldn't suggest anyone to come back to work straight from bed. You know, if you are very sick and you decide to come back to work straight away then I'd say 'No, just do other things first. Go for walks, meet with friends, meet with your family, do things that are going to challenge [you]'. " (P24-WBC)

Healthcare professionals also emphasised the benefit of accessing services to build on well-being prior to returning to the workplace, if feasible.

"If emotionally I feel they're not ready.. if some of them were rushing back and didn't (financially) need to...I'd say, 'What's the rush?' ...If they weren't ready to get back to work, I would be sending them directly to the GP...and to come into counselling, and try some of the support groups, try all of those steps first." (P3-HCP).

Despite a need for cancer-related support nationwide, participants noted inconsistency across the country around resources available.

"[It hits] you when you least expect it and you think you're doing alright and then you... something floors you... and you want to talk to somebody, then. And I found that an awful lot of the resources were based around Dublin and when you're sick, you're just not able to get into a car and drive all the way to Dublin. You think, 'No, I can't do that'. I need somebody more local." (P5-WBC)

Healthcare professionals echoed this inequity in resources across healthcare settings which can impact those in less populous areas.

“I have a lady who rings me from [the Midlands] so often saying, ‘I’ve still heard no word [from physiotherapy referral] and I can’t get to Dublin. What am I supposed to do?’ and you’re completely helpless with those so I do acknowledge we’re probably seeing a more positive side than what it looks like, than a lot of other places.” (P17-HCP)

Sub-theme II: RTW supports in Ireland and the role of the healthcare professional

Every woman with breast cancer and healthcare professional stated that they did not think that there is enough work-related support post-cancer diagnosis, in Ireland, whereas most employers were unsure. While general cancer supports available mostly through cancer support centres were mostly highlighted as helpful in recovery, there was limited knowledge of RTW-specific supports. Only two participants (P21-HCP & P35-EMP) suggested employer supports via the Marie Keating Foundation.

Most healthcare professionals viewed RTW as a positive step for well-being, however there was inconsistency around whose role it was to support work outcomes. While most healthcare professionals reported to initiate conversation around RTW, this initiation depended on clinical reasoning, or was sometimes avoided for fear it would put pressure on the patient.

“I don’t really want work to come into [consultations] as much...I don’t want it to influence in any way what they’re saying to me, and I certainly wouldn’t speak or talk to them or interfere with them at all with their outside life. Their job isn’t really my business and if they come directly to me or need help, fine. Yeah, I suppose I want them to feel that it’s an open confidential non-judgemental... and if they choose to tell me, ‘Look I don’t really want to return to work. I know I feel ok but I...’. Obviously, they should be allowed to tell me that.” (P31-HCP)

In contrast, women living with and beyond breast cancer report inconsistencies in healthcare professional initiation around RTW.

“It wasn’t discussed. I remember actually with surgery, I asked ‘How long will I be out for?’ And the answer was, ‘Well it depends...do you want the civil service answer or the self-employed answer?’.” (P28-WBC)

“[returning to work was initiated] once by the Oncologist...she told me to go to [a local cancer support centre], but it was slightly confusing because at the same time she was saying, ‘Yeah you can go back to work whenever you feel like it’. It wasn’t about ‘How are you going to do this?’. But she was the only one who mentioned work. (P33-WBC).

While all disciplines discussed how their intervention could support aspects of RTW, occupational therapy was the only profession to claim leadership of the role of RTW, however acknowledged that staffing levels of Occupational Therapists in oncology in Ireland are low.

“Well, I’d like [Occupational Therapists] to be [the leaders in RTW] because nobody else is trained in this area...Occupational Therapists can go into the workplace. I mean more and more work is being done on it but, you know, we’re so few and far between.”
(P16-HCP)

For Occupational Therapists and other professions who carried out work-related interventions with patients, a range of interventions to support RTW was discussed including managing side-effects, recommendations around communicating with employers including, work accommodations, and preparing RTW plans (Table 3.5).

Table 3.5: Work-Related Interventions Practiced by Healthcare Professionals

Managing Side-effects	Communication with Employer	Work Accommodations	Return to Work Plans	Other
Fatigue Management - Four Ps of Energy Conservation (Prioritising, Planning, Pacing, Posture) - Fatigue diaries - Advice around physical activity	Assertiveness Training Managing unwanted questions from colleagues	Ergonomics Phased Returns Flexibility in working Redeployment Task Grading Adaptation to Work Uniform Delegation Change of Role	Letters of support with recommendations for employer Tailored advice around RTW plans	Occupational Analysis Financial management Entitlements Information
Cognitive dysfunction - Cognitive strategies (remedial and compensatory)	‘Preparing your stall’ Role-Play			
Psychological sequelae - Stress management				
Physical Activity - Strength and endurance training, balance and flexibility				

3.3.4 THEME II: TRANSITIONING BACK INTO THE WORKPLACE

Women often transitioned back to the workplace whether they were physically and psychologically prepared to or not, depending on various motivations, often financial. For other women, however, work was viewed as a welcome distraction from their cancer experience. Regardless of motivation, mixed feelings were experienced on the initial day back to work, and many reported that open support from colleagues could sometimes be short-lived, compounded by invisible side-effects and by women sometimes masking limitations.

Sub-theme I: Motivations to RTW

Various motivations were discussed by women living with and beyond breast cancer around why they returned to work including “*mental gain*” (P10-WBC), “*interaction*

with other people” (P11-WBC), “identity” (P15-WBC), “getting back into a routine” (P5-WBC), and “to be contributing something” (P9-WBC). Despite this, the primary motivator discussed by most women living with and beyond breast cancer was financial concern, although this was more prevalent in women who were younger and/or single.

“Money, finance. That’s the only thing. You know, like you can deal with everything else, but you need money to live. There are still bills to be paid.” (P6-WBC)

While this motivator often expedited RTW, it was sometimes viewed as a barrier as it shortened a participant’s recovery period.

“I came back slightly earlier than what I wanted to...because of financial issues.” (P24-WBC)

Only one woman reported to have had income protection insurance and reflected that *“it would have been really really difficult” (P36-WBC)* without it, having needed to take sick leave for more than a year. While employers did not typically initiate conversation about income protection, one employer reflected that it could deter employees from RTW and viewed this as a negative outcome.

“I think the big thing...I think the negative side would have been when they just didn’t come back. They didn’t return to work. They just sat it out on income protection.” (P37-EMP)

Another commonly discussed motivator was work as a distraction or escape. There was an acknowledgement that work could offer benefits to mental and social well-being.

“Being able to forget about [my cancer] for those however many hours I was in work...I never even thought of it. From having it in my mind 24-7, not being able to sleep at night...So literally going to work, and for those hours in work not thinking about it at all...so for me, work was very therapeutic.” (P4-WBC)

“It’s therapeutic in the sense that while you’re there, you’re focused on the work and you – your mind is focused on what you’re doing on any given day and if it takes you away from – from thinking too much about your health” (P9-WBC)

In general, healthcare professionals advised that using work as a distraction can be helpful, and for the most part advocated work as integral to mental and social well-being.

“A certain amount of withdrawal, distraction, often considered negative coping strategies, when used flexibly are really important.” (P14-HCP)

Finally, the impact of Irish culture and an Irish work ethic on motivating RTW was discussed by both women living with and beyond breast cancer and healthcare professional cohorts.

“I do think it’s kind of an old school thing...I suppose you just did things and you got on with it and you just never complained. Do you know? And you came up on that system...because years ago it was religious organisations and by God when the nuns tell you to jump, you jumped and you jumped and you kept jumping [laughs] and I think it just stays with you...it’s bred in you, you know“ (P8-WBC)

Healthcare professionals also reflected on Irish culture where some women might return to work sooner than recommended.

“I think it’s a culture [thing]...Would you be on the doss? You know? There’s that Irish culture thing of you know like ‘if somebody saw me in the supermarket like? And I’m off sick, you’d have to be in bed, you know?’ We don’t have that kind of thinking that, you know, like the Eastern medicine...if it’s six weeks, then you take six weeks. Here? No. Here, the minute you’re not coughing [you must go back to work]” (P25-HCP)

Sub-theme II: Crossing the threshold: Feeling towards RTW

For those who returned to work post-treatment, a mixture of feelings was reported describing the first day back to work. Women described feeling ‘disengaged’ (P1-WBC), ‘very emotional’ (P11-WBC), ‘kind of nervous’ but ‘delighted’ (P15-WBC), ‘radiating happiness’ (P24-WBC), ‘terrified’ (P33-WBC), ‘wrecked’ (P36-WBC), ‘surreal’ and ‘strange’ (P5-WBC), ‘mixed feelings’ (P8-WBC), and ‘daunting’ (P9-WBC). One participant described transitioning from the world of treatment and hospitals, back into the world of work, reflecting that life went on in both.

“It was very strange walking back into work... You had been in this bubble of hospital and treatment and all of that world, and then you came back into this world and the two kind of never switched off... now all of a sudden I’m back into this one, which is where I wanted to be, but those first few weeks were kind of a bit surreal” (P5-WBC)

Sub-theme III: ‘Once you’re back, you’re back’: Reduced awareness among colleagues and employers of ongoing side-effects

In the initial days and weeks that followed the RTW, most women living with and beyond breast cancer described a welcoming environment with support from colleagues and their employer. For some women, this was generally short-lived, however.

“Obviously, Jesus they were so nice when I returned. The boss had lunch organised. We went out for lunch and, oh you know, ‘Anything you want?’ and, you know... ‘We’ll do what we can for you’...but look it, it didn’t last.” (P8-WBC)

One woman with breast cancer reflected on visibility and lack of awareness of ongoing side-effects which may contribute to fading support over time.

“There is also a piece though on the minute you’re visible then you’re back. So, when you’re back, you’re back and there isn’t...you can’t kind of stick up a sign that says, ‘Yes I am back but I’m still a little bit fragile’, you know?” (P28-WBC)

Healthcare professionals echoed this reduced awareness, reflecting that it is a wider challenge with society.

“Society does not know yet about this phenomenon of survivorship with fatigue and the challenges that women face after cancer treatment” (P21-HCP)

Employers acknowledged this initial supportive environment that can fade in time, attributing it to lack of visibility of any struggle.

“I think it’s early on there’s very much the extra support and the minding and the wrapping people in cotton wool and stuff and then I think when we see the person doing well, we just forget a little bit because they’re not talking about it, they’re not showing

any signs and we can very easily just let it go, you know? And forget about it.” (P27-EMP)

Unrealistic expectations by colleagues and employers can be shaped by past experiences or interactions with others who have had a cancer diagnosis.

“I remember having a patient who’d a really kind boss in many ways but his wife also had breast cancer, but she cycled to all her chemotherapy appointments...whereas this particular patient could barely walk from the LUAS...So there was a mismatch of expectations and she had a sense of failure around it.” (P23-HCP)

This lack of awareness could be exacerbated by attempts to mask limitations in the workplace, which several women living with and beyond breast cancer reflected on.

“It’s probably a bit of pride too...I can do it, you know, I always do it. I can do it. So, it could have been a little bit of that – an unwillingness to show any kind of need to be supported, you know? (P1-WBC).

“It’s a double-edged sword, part of you wants to go, ‘Absolutely nothing wrong with me now. I’m fine’. And actually, the other part of you is going, ‘Actually I’m exhausted and I can’t remember your name’. (P28-WBC)

3.3.5 THEME III: MAINTAINING WORK ROLE

Once back to work, women described a myriad of physical and psychological side-effects that impacted work ability. Women living with and beyond breast cancer spoke most at length about this, followed by healthcare professionals, and then employers. There was emphasis however that juggling other roles outside of work, particularly caregiving roles could add an extra pressure to women and was particularly evident following the return.

Sub-theme I: The impact of disease- and treatment-related side-effects on work

Once back in the job role, women described the impact of ongoing treatment side-effects on their job role. One participant described feeling significantly overwhelmed on

returning to work halfway throughout her treatment, emphasising the need for time for recovery.

“[The school] had a Mass and I was sitting up at the top and the next thing...I lost it...became overwhelmed emotionally...and I ended up leaving the Mass and I was really now seriously completely kind of out of it. I was crying...So I nipped into a cupboard because I thought ‘Oh God nobody can see me’ and I ended up going home” (P1-WBC)

Another participant reflected on loss of confidence and how that impacted on her work role going forward.

“I really struggled with my confidence going back...I used to wake up at night and ruminate on the fact that I thought that I wasn’t going to be able to do my job” (P36-WBC)

Physically, the most cited treatment side-effect to impact on work was cancer-related fatigue. For the most part, this tended to be most pronounced during and shortly after treatment, however still impacted on work performance in later months and years.

“So last week I pushed a little bit harder. I worked two, three days straight until five-thirty and then Friday I basically crashed, and I slept for I don’t know, 16 hours straight and, you know, I have a baby so I can’t really.” (P24-WBC).

Some participants described how they self-managed this common side-effect by employing energy conservation strategies such as pacing.

“Correcting at night-time, I can’t do as much as I used to. Like, I could get through 30 essays a night. Now I have to kind of say, ‘Right. I have to correct’ so I’ll do about ten at a time and then take a break.” (P11-WBC)

The impact of hormonal changes on work was also commonly cited by women who discussed how hot flushes impacted on their day-to-day work life.

“The chemo-pause. So hot flushes. I had to on Tuesday, I had to go out [from work] and buy a top because I stupidly wore silk...” (P28-WBC).

*“Since I went on the hormone therapy, I’ve gone into the menopause so if you’re in a heated room...oh my God. Last week, when I came [into a meeting]... I could feel myself... the room was getting so warm and I’m thinking, ‘Oh f***’, and I said, ‘Can we leave the door open?’ Do you know that kind of way?” (P15-WBC)*

Cognitive side-effects were found to commonly impact on the day-to-day work roles of participants. The most cited issue was word-finding difficulties.

“I’d be standing there at the top of the class and I could not think of the river that flows in Northern India. I was like, ‘You know the river now lads? It’s in the Himalayas, flows down to the Bay of Bengal. Do you know what I’m talking about? Calcutta’s on it’, and the lads are looking at me going, ‘Is she on something?’” (P11-WBC).

Cognitive changes were observed by the minority of employers in this study.

“Well, the first thing I saw was that [my employee] was panicking about answering the phone, actually answering the phone and handing it out, getting cross because she couldn’t verbalize what she wanted to say” (P34-EMP)

Sub-theme II: Juggling RTW with other roles

Several women discussed challenges in juggling their work role with other roles such as looking after their children or parents, although this guilt was not reflected on by employers. One participant spoke about the impact of this on her physical and mental health. Another participant touched on the guilt felt trying to juggle her caregiving role as a mother with her job role.

“I hate it. I hate getting up every morning but I don’t have a choice because I can’t leave mam for too long on her own. So, I thought in my wisdom that if I was working five mornings, that’s great, I would come home at one o’clock and I’d have a rest in the afternoon. I have never yet had a rest. There’s always something to do...I’m permanently tired and I’m getting cross.” (P6-WBC)

“There’s definite mummy guilt or at least there used to be although I think culture has shifted a bit.” (P28-WBC)

One healthcare professional reflected on juggling various demands and suggested that women tend to be assigned the care-giver role through gender expectations.

“And very often, the people who are in the kind of occupational age are also in the same age as childcare, or they might be a primary carer for parents. So, they do tend to have multiple caring roles in addition, so I think there’s more demands. Whereas men who are returning to work at that age rarely have the same levels of demand on them from a kind of social role perspective. Not never, but just not as often.” (P14-HCP)

3.3.6 THEME IV: INCONSISTENT KNOWLEDGE OF EMPLOYMENT LEGISLATION AND RIGHTS IN IRELAND

Women living with and beyond breast cancer and healthcare professional cohorts shared a reduced awareness of employment rights, particularly pertaining to cancer diagnoses; *“I would probably be fairly vague” (P1-WBC), “I’m a bit shocked that I didn’t know about the legislation. So, how are patients supposed to know then?” (P13, HCP), “limited” (P17, HCP), and “I have no idea” (P24-WBC).* One participant reflected she was not aware of the legal obligation on employers to offer accommodations; *“Not by law, I thought they were just being nice.” (P10-WBC).* The few participants who were aware of rights including reasonable accommodations, reflected how those living with and beyond cancer might not recognise the applicability to their situation, instead associating accommodations solely with physical impairment.

“And in terms of reasonable accommodations...I’d tend to think about someone who had an injury or in a wheelchair. [I] don’t even know how I would consider it in terms of my situation.” (P28-WBC)

“I think some employees might think ‘reasonable accommodations’ and they think disability and when they think ‘disability’ they think of visual impairment or a physical wheelchair user rather than coming back from breast cancer.” (P29, EMP)

This is in contrast to the employer cohort who were aware of employment legislation, particularly around reasonable accommodations; *“We definitely would provide accommodations.”* (P39, EMP) and *“We’re obliged to look at reasonable accommodations”* (P32, EMP). One potential explanation for this contrast in awareness is the everyday nature in which employers from large organisations deal with the area.

“In HR...because we have so many employees, like every day we’d get a new request or questions [related to reasonable accommodations]. But we’re not surprised by it.”

(P29, EMP)

Despite employer awareness, some participants reflected on poor employer-employee communication, a disconnect between cohorts. One woman with breast cancer discussed insufficient information from her employer around accommodations.

“I didn’t know [about the right to reasonable accommodations]. That slipped by me. God, I think that’s fantastic. I have never heard that or been told that by our HR department.” (P8-WBC)

From the employer perspective, one participant queried how they could better disseminate knowledge to employees.

“I’m just trying to think if we could communicate this better...Now in fairness, our HR department would know about it, but it’s possibly something that we could better communicate with our employees who are returning from sick leave.” (P29, EMP)

Additional barriers implementing accommodations were identified. Employers discussed reduced employee engagement, and employees not wanting to draw attention to themselves.

“Absolutely we have to make reasonable accommodations but that’s very much the grey area. There’s that whole piece of trying to engage with the person when they’re off to facilitate that...better return to work. The legislation may be there, but I don’t think it’s [enough]” (P27, EMP)

“What I’m seeing is that the returning cancer survivors don’t want a fuss made. They’re likely to want to keep it discreet.” (P30, EMP)

One healthcare professional noted some women choose not to proceed with recommendations.

“I always find [when I suggest accommodations], and people are like, ‘Yeah. I’m not going to do that’.” (P17, HCP)

Despite barriers, there were examples provided across all three cohorts of work accommodations implemented in practice in Ireland (Table 3.5). Other legal aspects discussed included resumption of previous job role, a safe working environment under the Health & Safety Act, legal working hours under the Working Hours Act, correct wages under the Payment of Wages Act, equal opportunities, and discrimination. Fortunately, most women interviewed, did not experience discrimination in the workplace. One participant, however, described new-found resistance by some colleagues over whether she should be promoted, shortly after returning to work post-treatment, despite meeting professional requirements.

“I have had some negative feedback that people feel I’m not ready to be [promoted] yet despite the fact that I’ve been training forever and have all the skills. They don’t have any objective evidence as to what they mean. But I feel that I’m nearly being disadvantaged for having been sick because I don’t think they would have had these queries about me before I was sick.” (P36-WBC)

Once prompted, one employer described a fear of discrimination experienced by an employee, potentially hindering career progression.

“[Our employee] felt she couldn’t apply for the role given her history of having been out for so long. So, while she felt that she was quite senior on the team and had the experience, she felt that she would be judged by people applying for this senior promotion, so I think that had an effect on her career goals.” (P30, EMP).

3.3.7 THEME V: COMMUNICATION

It was acknowledged that communication should be a two-way process with shared responsibility between the employer and employee throughout the sick leave period. The desired frequency of this communication can vary across individuals and expectations should be agreed from the onset. Equally, the style of language should be considered, where open questioning from the employer can give the woman an opportunity to reflect on what she would find helpful, rather than responding to closed questions. There can be an apprehension to ask for help, however this was typically not evident in women who held more senior positions and felt they had these assertiveness skills.

Sub-theme I: Two-way communication between employee and employer

Most participants across the three cohorts welcomed consistent communication between employer and employee during sick leave citing it as “*really important*” (P14-HCP), “*a massive thing*” (P22-HCP), so that employers “*can know how to help and support*” (P37-EMP), however noticeable differences were evident by women living with and beyond breast cancer depending on timing of the communication and the language used.

“In the middle of [my treatment], my boss was phoning me, ‘How are you? When are you coming back? When are you coming back? When are you coming back?’ and this was kind of getting in on me as well.” (P6-WBC)

“Oh [my employer] would call me, definitely every two weeks. At least. And maybe twice in the week, do you know? He even called when I was in hospital, do you know? Knowing I was in hospital.” (P8-WBC)

Positive interactions were experienced when asking open questions around the sick leave and return to work processes.

“They said, ‘What would you like?’, They said, ‘What do you want?’. ‘Do you want to take a finish for a year? What would you like to do?’. So, they said, ‘Why don’t we support you and if you want to work, you can work and if you don’t want to work, you don’t have to work...And so it was amazing” (P15-WBC)

Women also found it helpful to provide leaflets to employers to help explain any treatment side-effects that they were experiencing. This also gave an opportunity for employers to reflect on the issue and pose any questions at a later stage.

“I gave them all the leaflets...then I told her, ‘This is what I’m going through and I don’t know how I’m going to feel, they’re estimating six weeks of treatment’....But [my employer] was very... she was involved with everything and she did read [the leaflets] and she was saying, ‘So next week you have such a such a thing’” (P7-WBC)

Employers underlined the importance of continuous engagement with employees throughout the sick leave process.

“That engagement piece is really good. So that’s why we have them come in on-site to see people...Do you know that fear that you have on a Sunday night when you come back to work and you say, ‘Oh here we go again’. Well then when you’re out sick a few days, never mind a few months, that fear must be unbelievable...But actually in coming in and out to see us in Occupational Health or to meet with the Line Manager for a conversation, it’s breaks that cycle of you haven’t been here” (P38, EMP)

“The newsletter is perfect at least because we have [our version of a newsletter], which comes out every quarter and, like that, just stick it in the post and you can pinpoint, you know, bits of interest, and like that, it’s engaging. It’s keeping the engagement up.” (P37, EMP)

Sub-theme II: Apprehension to ask for help

Levels of assertiveness varied across women, although most did suggest that they did not feel confident in asking for help in the workplace. Typically, women who held senior jobs felt that they had skills in assertiveness which impact positively on being able to carry out their work role.

“I don’t know where I am in terms of pecking order, but it’s certainly not in the bottom where I would have been at times before. And I know how to say, ‘No’. I know how to ask for what I need.” (P33-WBC)

“And I do feel a little bit in a bit of a privileged position in that I do have the confidence to manage expectations, do you know what I mean? Whereas if I wasn’t as senior, I think the stress and the pressure would feel a lot more because you, you know, I’m well able to stand up for myself.” (P28-WBC)

One woman touched on how she developed assertiveness skills through local counselling support.

“Through counselling, I learned to say the word, ‘No’, ‘I’m sorry. I can’t do it’. You can say – you don’t have to say to [a colleague], ‘No’ you can say it in a nice way, ‘I’d love to do that for you but today unfortunately I’m tired. But I will do it for you one another day if you come to me’. So, you’re saying ‘No’, but you’re doing it in a polite way.” (P11-WBC)

Poor communication skills can impact on negotiating how the return to work can look like or initiating a RTW plan.

“I suppose the big thing for me I should – when I went back, I should have said, ‘Look, this is it now’, but I went straight back into it and I went back the same way, the same pattern of working long hours and you know? I was putting a lot of hours in the three days. Do you know that kind of a way?” (P8-WBC)

3.3.8 THEME VI: RTW INTERVENTION

Both women living with and beyond breast cancer and healthcare professional cohorts discussed perceptions on the content and delivery of a RTW intervention, including any temporal factors to consider. While the employer cohort did not discuss the delivery of an intervention, they did inform the content, based on their experiences of supporting employees with cancer, alongside the other stakeholders.

Sub-Theme I: Delivery

Two aspects of intervention delivery were discussed: format (group vs. individual) and hosting (face-to-face vs. online). There was no clear preference for intervention format

among women living with and beyond breast cancer. This differed from healthcare professionals. Some women living with and beyond breast cancer described the benefits of a group, whereas others discussed preference for individual formats.

“I’m probably a bit more of a one-to-one person. I’m not really a group person...I’m not really into that kind of thing.” (P15-WBC)

“I loved meeting the people because we’re all in the same boat...you could say things out loud in confidence that you wouldn’t necessarily say to your friends” (P6-WBC)

Healthcare professionals, however, tended to favour group formats for pragmatic reasons.

“If you want to cover a lot of the population and get it done speedily...I think one-to-one could take ages...You’re better off doing group core issues, I think” (P18-HCP)

“I think you’d potentially have more people [with the group]...if this is a new thing, and you can hit a load of people, I’d say more people will benefit from your group.” (P23-HCP)

Despite this, healthcare professionals acknowledged that there is no one-size-fits-all approach, and suggested merging group and individual formats.

“I think a combination of group and one-to-one is probably the most beneficial because one-to-one people might open up a little bit to you. But in a group, someone might be afraid to ask a question and somebody else might ask that.” (P22-HCP)

There were mixed feelings among women living with and beyond breast cancer around intervention hosting (face-to-face vs. online). There was some hesitation around online information where there was the possibility that information wouldn’t be up to date.

“I think with a digital thing, there’s so many apps out there and they’re not updated all the time.” (P15-WBC)

Instead, an interactive approach was welcome, whether it be by one-to-one or group format.

“I kind of needed my hand held and I think that’s what worked for me.” (P36-WBC)

One healthcare professional reflected on the potential accessibility of online interventions but queried if those with cancer would access online platforms.

“Digital for myself, it’ll be easier to be accessed from home. But would the person be inclined to access it at home?” (P22-HCP)

A no one-size-fits-all approach was underlined by one healthcare professional who acknowledged that preferences can vary among women living with and beyond breast cancer.

“It depends...some people find face-to-face fantastic and other people would rather eat their hat, chew glass, almost.” (P23-HCP)

Sub-Theme II: Content

A range of RTW barriers and enablers were discussed. The most frequently discussed barrier was treatment- and disease-related side-effects impacting on RTW, however employment rights and entitlements, and communication were also frequently discussed (See Sections 3.3.6 and 3.3.7).

Physical and psychological side-effects were discussed widely by all cohorts (See Sections 3.3.4 and 3.3.5 for further detail). Every cohort discussed cognitive changes such as *“brain-fog”* (P11-WBC), *“chemo-brain”* (P21-HCP) and *“getting overloaded”* (P34-EMP). Specifically, cognitive functions such as attention, memory and verbal fluency could be impacted.

“It’s concentration primarily. Sentence structure. Forgetfulness. Focus. All of that...it’s hard. And memory, short term memory. I write a lot of notes. I have a lot of lists.”

(P28–WBC)

Where invisible side-effects such as cognitive changes weren’t disclosed by an employee, employers reflected on challenges in managing limitations appropriately.

“But if you didn’t know that the person had come through a long illness or a life-changing illness, you’d probably just put [cognitive changes] down to daydreaming.”

(P32–EMP).

In addition to cognition, all cohorts discussed physical side-effects such as pain, lymphoedema, cording and deconditioning, although only women living with and beyond breast cancer referred to hot flushes. In particular, cancer-related fatigue was discussed by all cohorts.

“Fatigue is the biggest problem I have, my work-life balance...Take me off the floor tired” (P11–WBC)

“The biggest [side-effect] is the fatigue” (P25–HCP)

Employers reflected on potential accommodations such as flexibility in managing this.

“We have definitely observed that massive fatigue that people would talk about but yet not being able to sleep...that flexibility about coming in a little bit later would be so important.” (P27–EMP)

Fear of recurrence, low self-esteem, anxiety, depressive symptoms, and stress were reported as psychological barriers in RTW. Psychological symptoms could sometimes initiate a symptom cycle with stress exacerbating decision-making processes at work.

“Sometimes when you feel under stress...your decisions might be a little bit, like, be a little bit off.” (P1–WBC)

One deviant case, an employer, reflected on emotional readiness of employees in RTW, and underlined the importance of communication.

“You’ve got this recovery period then the tumbleweed when you’re not in work...then all of a sudden on Monday morning, you’re sitting back in your office as if nothing had happened... that’s why I think it’s important that people have that conversation with us. That’s the important piece, to have that conversation.” (P32-EMP)

Sub-Theme III: Temporal

Three aspects of intervention timing were explored; preferred length of the overall intervention, session length, and the time at which it was best to offer the intervention to women living with and beyond breast cancer post-diagnosis.

Reflecting on length of intervention, most participants across both cohorts favoured weekly sessions over four to six weeks.

“I would think maybe four weeks or something.” (P33-WBC)

“I like the idea of having four to six [sessions], it’s more compact” (P16-HCP)

One deviant case, a healthcare professional, suggested a two-day condensed intervention.

“I think a short two-day course or something like that would probably be best” (P18-HCP)

The suggested length of each session varied widely across cohorts from an hour per session to a half day.

“I think max an hour. I think an hour is a long time from my experience.” (P20-HCP)

“Not making it too long. So maybe half the day” (P22-HCP)

One participant reflected that enough time was required to facilitate a flow in conversation, in a group setting.

“I think you need a reasonable chunk of time so that people can get into it and get comfortable. Some of our best conversations came in the last half hour.” (P33-WBC)

Finally, perceptions on timing of a work-focused intervention differed widely across women living with and beyond breast cancer and healthcare professionals. While some women suggested readiness during treatment, others considered post-treatment, when they were better psychologically ready, suggesting that no specific time criteria should be placed on a RTW intervention.

“I suppose halfway through your treatment because the first half everything is so overwhelming that you don’t know what you’re thinking.” (P10-WBC)

“When you’ve finished treatment or are starting to think about [it] ...it’s not the day you come back [to work] because that’s too late. You need to have gotten your headspace.”
(P28-WBC)

Healthcare professionals also offered conflicting timeframes.

“It’s very hard to know when’s the best time to give information.” (P17-HCP)

“I think probably you’re talking maybe three-to-six months after the acute phase of treatment” (P18-HCP)

3.3.9 Minor Items

While most reported RTW barriers and facilitators discussed over the course of this study are embedded within these key themes, there were a minority of additional items which have been collated and reported in Table 3.6.

Table 3.6: Barriers to and Facilitators of RTW Post-Breast Cancer Diagnosis: An Irish Context

Domain	Barriers to and facilitators of staying at or returning to work following a breast cancer diagnosis	WBC	HCP	EMP
Personal system	Treatment side-effects (physical, cognitive and psychological)	-	-	-
	Permitting self, time to rebuild physical and mental strength before RTW	+/-	+	
	Age / Life Stage	+/-	+/-	
	Reduced visibility of side-effects	-	-	
	Internal motivations	+/-	+/-	
	Family support	+	+	
Societal and Cultural Context	Irish work ethic	+	+/-	
	Traditional gender roles and norms – juggling work role with caregiving roles	-	-	
	Reduced awareness/knowledge of ongoing side-effects	-	-	
Workplace system	Unclear who takes lead in employer-employee communication	-	-	-
	Option of accessing a survivorship network/buddy system	+/-	+	+/-

Workplace system (continued)	Maintaining engagement between employer/employee throughout sickness period (e.g. newsletters, touch-bases)	+/-		+
	Use of open questioning in employer-employee communication when assessing needs of employee	+		+
	Job Description/Role and differing levels of physical, cognitive and psychological demands.	+/-	+/-	+/-
	Contract type (fixed vs permanent) providing (in)security	+/-		
	Education for employers/colleagues	+	+	+
	Sick Leave Entitlements	+/-		
	Disclosure of personal information to employer (such as functional prognosis) to aid in RTW plan.	+/-		+
	Developing a RTW plan	+	+	+
	Dedicated time for re-induction on RTW	+		+
	Lack of occupational health support in Small-Medium Enterprises.	-	-	
	Physical environment e.g. (in)ability to make structural changes,			+/-
	Work Accommodations e.g. flexibility in working, graded RTW, ergonomic changes.	+	+	+
	Employer/Employee amenability to work accommodations	+/-	-	+/-

Workplace system (continued)	Insurance that confidentiality will be maintained.	+		
	Communication methods between employer-employee (e.g. email, phone, face-to-face, text)	+/-		+/-
	Company strategy / ethos			+
	Option of redeployment			+
	Change of role on return	+/-	+/-	
	Occupational health criteria for the need to be 100% fit for work	-		+
	Changes in technology		-	-
	Length of commute/availability of parking	+/-	+/-	+/-
	Potential risk of infection	-	-	-
Healthcare system	Lack of clarity around whose role it is to lead in support of return to work.	-	-	
	Reduced staffing and resources to address return to work		-	
	Inconsistent communication between medical teams and employers/occupational health systems			-
	Limited knowledge around return to work supports and information		-	
	Individualisation of care	+	+	
	Inconsistent follow-up support available nationwide	-	-	

Healthcare system (continued)	Follow-up			
	Tapping into general cancer supports via cancer support centres	+/-	+	
	Letters of recommendation/support from HCP	+	+	+
	Logistics of managing work and appointments.		-	
Legislative and Insurance systems	Lack of understanding of employment rights e.g. Reasonable Work Modifications.	-	-	
	Lack of awareness of RTW entitlements in Ireland e.g. Partial Capacity Benefit	-	-	-
	Verbal and written information re. RTW entitlements/rights.	+	+	+
	Using the Partial Capacity Benefit to grade back into work.	+	+	+
	Lack of awareness of work modification grants for private companies			-
	Income Protection	+		+/-

Facilitators which emerged during interviews are marked with a plus sign (+), barriers with a negative sign (-). Cohorts are represented with the abbreviations WBC (Woman living with and beyond Breast Cancer), HCP (Healthcare Professional), EMP (Employer).

3.4. DISCUSSION

A qualitative-descriptive approach was used in this study to identify factors that facilitate and challenge staying and/or returning to work for women living with and beyond breast cancer, to inform a future work-focused intervention.

3.4.1 Facilitators and Barriers in the RTW Process: An Irish Perspective

Findings indicate that several factors impact on RTW for women living with and beyond breast cancer that change over time. Facilitators and barriers identified by participants were mostly in line with the literature where disease and treatment-related side effects, work-related factors, and socio-demographic variables are commonly cited concerns in transitioning back to the workplace. Despite this, several factors less commonly reported emerged in this study in an Irish context. Indeed, the European Agency for Safety and Health at Work (2018) acknowledged in a recent European Risk Observatory Report that national level differences should be considered when developing and implementing successful RTW interventions for those living with and beyond cancer.

First, the impact of disease and treatment-related side effects such as cancer-related fatigue, cognitive impairment, and psychological sequelae, were commonly cited issues which impeded the RTW process. These varied between physical and psychological factors, and have been widely reported elsewhere (Islam et al, 2014; Park & Shubair, 2013; van Maarschalkerweerd et al, 2020). However, a lack of public/colleague awareness of these side-effects was illuminated in this study which can impact on the RTW process. This is noteworthy as a qualitative study acknowledged that levels of information and awareness around cancer and work by employers, could dictate the success of RTW (Tamminga et al, 2019). While there is some emerging evidence in the area for employer-specific intervention (Greidanus, et al, 2020), there is no known evidence-based programme available to educate employers and colleagues in Ireland around cancer and the workplace, although the Marie Keating Foundation do offer training in this area (Marie Keating Foundation, 2021). Furthermore, it is acknowledged that there is a shared responsibility between employer and the employee in communicating with one another (Tiedtke et al, 2017). However, varying levels of employer-employee communication were reported among participants within this study.

A recent qualitative study also observed that employer-employee communication was often avoided, to the detriment of both parties (Tamminga et al, 2019). Effective communication can be vital, particularly when developing a joint RTW plan between employee-employee, which was widely advocated across the three cohorts.

Sociodemographic factors were also discussed by study participants. Financial burden was cited as a primary motivator in RTW, yet this is not unanticipated. As outlined in Chapter 2 (Section 2.6), recent figures in an Irish context, estimate that those living with and beyond cancer experience markedly increased financial costs and reduced income directly related to their cancer diagnosis (Irish Cancer Society, 2019). This could either expediate a RTW before feeling mentally and physically ready, as highlighted in this study and therefore could impact RTW rates in some cases. Most women in this study returned to work within a mean time of 11.3 months (range 0-27). This is in line with other studies where most women RTW somewhere between shortly after the end of active treatment to one-year post-treatment (Balak et al, 2008; Sun et al, 2017). RTW rates following breast cancer differs by country and ethnicity, where prevalence ranges from 43% (The Netherlands) to 93% (United States) within one year of diagnosis (Islam et al, 2014) (Chapter 2, Section 2.6). While there are several shared facilitators and barriers across countries in the RTW of women living with and beyond breast cancer, there are also unique aspects that differ between countries which often stem from specific culture, legislation and policy. Indeed, gender roles or attitudes could impact perceptions towards work. Findings of this study highlighted feelings of guilt and challenges associated with juggling the caregiver role with work roles. This is perhaps not surprising in an Irish context, where traditionally females were bound by Ireland's traditional patriarchal society that confined them to their home and out of the workforce (Patterson, 2001). Similar feelings of guilt have been cited as a barrier in RTW for some participants in The Netherlands (Tamminga, 2012) however have not been reported widely elsewhere.

3.4.2 Inconsistent Knowledge of Legal Rights and Entitlements

Most women living with and beyond breast cancer, and healthcare professionals reported lack of awareness of employment rights following cancer treatment, including

the right to reasonable accommodations. This contrasts with most employers interviewed who, unprompted, cited legal rights. While factors (including legal constraints) impacting RTW for women living with and beyond breast cancer has previously been reported (Sharp & Timmons, 2011), this study illuminates a lack of awareness around this legislation, and the potential mismatch of awareness across stakeholders. It also offers an insight that women living with and beyond breast cancer may not always apply the legislation to their own circumstances. Poor awareness of rights amongst the general population is not surprising. When asked to self-report rights in Ireland, only 5% of the general population surveyed cited ‘equality in the workplace’ and ‘equal pay’ (Irish Human Rights and Equality Commission, 2018). Similarly, in England and Wales, substantial lack of understanding of employment rights was reported, even amongst the general population for whom particular laws had specific bearing (Plesence, Balmer & Denvir, 2017). A 2015 EU Report (European Commission, 2015) found that 45% of respondents self-reported to know their rights if they were the victim of discrimination or harassment. This figure deviates among countries, where the EU average conceals wide national differences in awareness, where 78% of Finnish respondents self-reported knowledge, compared to 31% and 59% of Bulgarian and Irish counterparts, respectively. Perceived awareness of employment rights may not always be representative of actual knowledge however, prompting recommendation for further research to explore actual knowledge of awareness. Some steps have been taken in Ireland in recent years to raise public awareness of employment rights. In secondary-level education, all students are taught the nine grounds of discrimination under the Civic, Social and Political Education (CSPE) curriculum (National Council for Curriculum and Assessment, 2021). The Marie Keating Foundation, a cancer charity in Ireland, also released a booklet for employees and employers, ‘Back to work after cancer’, outlining employment rights (Marie Keating Foundation, 2019).

Recommendations for future research include the development of employer education in legal issues protecting employees with health problems such as cancer. Educating employers around best practices for accommodations and discrimination awareness, in the workplace are also recommended (de Moor et al, 2018). Education should extend beyond this cohort of employers, however, and be targeted towards those with cancer to support informed work-life decisions. Furthermore, healthcare professionals could

consider explicitly highlighting accommodations beyond physical modifications that enhance occupational performance such as a graded return, flexible hours, and working from home structures.

3.4.3 RTW in Ireland: A Lack of Support, Paucity of an Evidence-Base, and Need to Develop a Work-Focused Intervention

Every participant in this study indicated that there is not enough currently being done in Ireland to support those living with and beyond cancer to transition back into the workplace. This gap in survivorship care has been acknowledged in a recent unmet needs report, where work-related issues have been identified as needing attention in Ireland (O'Connor et al, 2019). There is a paucity of evidence evaluating RTW interventions following breast cancer, although several have been piloted (Algeo, Bennett & Connolly, 2021; Sun et al, 2017). For example, in the United Kingdom, a pilot intervention referred women living with and beyond breast cancer onto relevant services that could support specific side-effects and provided a booklet 'Work and Cancer'. No significant differences were observed in self-reported sick leave (primary outcome) or change in employment pattern, QoL or fatigue (secondary outcomes) which may be explained by a small sample size (Hubbard et al, 2013).

In the absence of evidence available for breast cancer specific interventions, work-focused supports available for all cancer types can be reflected on. A Cochrane systematic review exploring RTW interventions for all cancer types found variations in intervention types (de Boer et al, 2015). In fact, they found no studies on vocational-specific intervention, but rather cancer generic interventions such as psycho-educational ($n=2$), physical training ($n=1$), and medical intervention ($n=7$) all of which demonstrated low-quality evidence when exploring work-focused outcomes. It was only multidisciplinary (MDT) interventions ($n=5$) which included vocational components that offered moderate-quality evidence and demonstrated higher RTW rates. Looking specifically at work-focused interventions for those living with and beyond cancer, a systematic review yielded ten intervention studies, most of which did not significantly improve outcomes when compared to usual care (Lamore et al, 2019). One consideration however is that interventions were mostly classified as 'low-quality'

($n=6$) and ‘medium quality’ ($n=3$) in methodology. Furthermore, programme development is not clear in the included studies where interventions tested in RCTs were not piloted, and those tested with quasi-experimental and longitudinal studies do not report program development strategy (Lamore et al, 2019). The majority of interventions in the systematic review took place in a hospital setting (60%) and varied widely in terms of intervention format and content. These variations in preference were echoed in findings of this study, where participants offered differing perspectives around the preferred content and delivery of a work-focused intervention.

3.4.4 Moving Forward: Perceptions on a RTW intervention

Findings from this study indicated a preference for a face-to-face component, although there were mixed perceptions towards a group or individual format. It is widely acknowledged that there is no one-size-fits-all approach to cancer survivorship care (Jefford et al, 2013; Klemp, 2015; O’Connor et al, 2019), likely explaining mixed preferences for format. Therefore, it is possible that a range of interventions may be needed to address preference variability. Researchers could also consider development of hybrid interventions encompassing both group and individual formats. While typically interventions that have been tested are self-guided or group-based, hybrid delivery is less common. Despite this, emerging evidence has indicated promising potential for this format (Newman et al, 2019). An evolving body of research into hybrid intervention models is warranted to further explore potential benefits. Online and face-to-face delivery was also considered, with mixed views on digital formats. This research was conducted pre-pandemic in 2019, and the use of telehealth has since accelerated, necessitated by public health guidance. Emerging evidence has suggested positive outlooks on the use of telehealth more recently. For example, a mixed-methods study (Lopez et al, 2021) explored perceptions of those receiving cancer rehabilitation adapted online during the pandemic and found that it was an acceptable alternative to in-person, where required. However, while a digital format could facilitate some, there is the potential that other cohorts could be negatively impacted where there is limited access to internet or devices (Zhai, 2021). Therefore, consideration should be given to both in-person and online delivery.

Several RTW barriers and enablers were discussed, including ongoing side-effects, communication, and employment rights and entitlements, which could inform the content of a work-focused intervention. Side-effects such as cancer-related fatigue, cognitive changes and psychological sequelae are frequently reported by women living with and beyond breast cancer to impact on work (Lewis & Mackenzie, 2021; Sun et al, 2017) and can be amenable to rehabilitation and self-management interventions, although warrant further investigation (Fernandes, Richard & Edelstein, 2019; Goldberg et al, 2019; Pearson et al, 2018). Researchers could consider targeting self-management of side-effects in the context of work for future interventions. Work-specific content is important although not always embedded into interventions that measure work outcomes. For example, a recent systematic review found that only three of nine rehabilitation intervention studies included work-specific content, despite measuring work outcomes (Algeo, Bennett & Connolly, 2021). This gap is important to highlight as literature suggests that targeting specific outcomes in interventions, leads to greater likelihood of enhancing those specific outcomes (Howell et al, 2017). Therefore, content discussed in this study including awareness of employment rights and entitlements, and effective communication with employers could be beneficial to include in a work-focused intervention.

Most participants suggested an intervention length of four-to-six weeks, however there were wide variations in views on session length ranging from one-hour to a half-day. Typically, intervention and session length vary widely across cancer survivorship interventions, and while intervention length is regularly reported, session length can be underreported (Algeo, Bennett & Connolly, 2021). Timeframes could be adapted depending on whether the intervention was hosted face-to-face or online. For example, there are several face-to-face cancer survivorship interventions that are facilitated over two and a half hours (Boland et al, 2019; Gibbons et al, 2020), however this length of time could lead to fatigue if completely online. In contrast, online interventions are typically shorter in session length, varying from 30-minutes to two-hours (Bantum et al, 2014; Grimmer et al, 2013; van den Berg, 2015). Therefore, session length should be carefully considered based on the context in which they are hosted. On exploring perceptions around timing of a work-focused intervention, no clear conclusions could be drawn. This perhaps reflects the individual nature of navigating cancer treatment and recovery. The timing of survivorship interventions has been explored. Boland et al

(2019) when evaluating a self-management survivorship intervention, concluded that timing within the first year of finishing treatment could be most beneficial. This is echoed by authors of another self-management intervention evaluation study that suggested providing the intervention closer to time of treatment would be optimal (Foster et al, 2016). Despite this, timing of a work-focused intervention may be different. For example, support might be required when struggling to return to work. Ongoing challenges in work ability post-breast cancer are well documented (Lewis & Mackenzie, 2021; van Maarschalkerweerd et al, 2020). Therefore, eligibility criteria could be kept broad for future interventions, or additional interventions could be targeted post-RTW.

3.4.5 Strengths and Limitations

Data source triangulation can offer comprehensive understandings of a topic. In this study, participants with different experiences of women living with and beyond breast cancer returning to work, provided multi-faceted viewpoints. Furthermore, there were various categories of employment and age amongst women living with and beyond breast cancer. Healthcare professionals also offered viewpoints from a range of disciplines.

Limitations of the study include that employers stemmed from medium-large organisations which may be more likely to have occupational health supports in place compared to smaller organisations. It is possible that employers who do not have occupational health structures, may be hesitant to participate, excluding a viewpoint of this cohort. Another limitation is that most employers in this study self-assessed their organisations as progressive and equipped in supporting employees. Employers who may feel less competent in addressing cancer-related concerns in the workplace may be less likely to participate, and this could be a reason for not reaching recruitment rates of other cohorts. In addition, data saturation was achieved for women living with and beyond breast cancer and healthcare professional cohorts, but not employers. This may have limited additional insights, from an employer perspective on the topic. Finally, women who had not returned to the workplace were not included in this research. While this was to focus on aspects within the workplace that may impact on the RTW journey,

speaking with the cohort of women may have provided valuable insights as to why they did not return.

3.4.6 Conclusion

This study identified several factors that impact on the RTW of women living with and beyond breast cancer, changing over time, from time of diagnosis and following the return to the workplace. Of note, every cohort indicated a need for greater support in RTW post-cancer diagnosis, particularly in the areas of symptom management at work, navigating employer-employee communication, and enhancing knowledge in entitlements and rights. While there was mostly agreement in topics areas of content to target in a RTW intervention, there were mixed perceptions among women living with and beyond breast cancer and healthcare professionals on intervention delivery. Where there is literature available, it could be useful to draw on existing RTW intervention studies for women living with and beyond breast cancer, and explore how the content and delivery aligns with perceptions of stakeholders in Phase I of this research. A RTW intervention specific to women who have had breast cancer is warranted and could assist with the RTW process.

CHAPTER FOUR: SYSTEMATIC REVIEW AND META-ANALYSIS

PHASE II STUDY: Rehabilitation interventions to support return to work for women living with and beyond breast cancer: A systematic review and meta-analysis

4.1 INTRODUCTION

When developing a complex intervention, it is recommended to review published research evidence to identify whether effective or cost-effective interventions for the target population already exist (O’Cathain et al, 2019). As part of this research, a systematic review of rehabilitation interventions that support RTW for women living with and beyond breast cancer was undertaken. This was published in *BMC Cancer*, volume 21, issue 1, article no. 895 (Algeo, Bennett & Connolly, 2021). As previously noted (Chapter 2, Section 2.8), there has long been a paucity of evidence-based interventions that support RTW following a breast cancer diagnosis (de Boer et al, 2015; Hoving et al, 2009). Despite potential to enhance work outcomes, the last systematic review published in 2009 yielded only four intervention studies for women living with and beyond breast cancer, three of which were non-controlled (Hoving et al, 2009). An updated systematic review was warranted and undertaken as part of this overall study. This review is reported as per Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) checklist (Moher et al, 2009) (Appendix G).

4.1.1 Research Question and Objectives

The PICO model is a framework that defines a clinical research question by identifying key components and is endorsed by the Cochrane Collaboration (Higgins & Green, 2011). The population (P), intervention (I), comparators (C), and outcomes (O) are defined (Table 4.1).

Table 4.1: PICO Framework

P	Patient / Population	Women living with and beyond breast cancer who were >18 years old at time of diagnosis
I	Intervention	Any type of non-pharmacological intervention which aimed to rehabilitate women living with and beyond breast cancer. Interventions could be group-based, individual, and/or online in format, and could be vocational, psychosocial, physical or MDT (combination of vocational, psychosocial, and/or physical) in nature.
C	Comparator	No limits on comparator.
O	Outcome	Studies were included only if they reported a minimum of one work-related outcome (primary outcome) e.g., RTW status, working hours, sick days. Secondary outcomes included physical, psychological and quality of life outcomes.

The aim of this review was to systematically search the evidence-base and critically appraise and synthesize applicable findings to address the following research questions:

1. For women who have had breast cancer (P), are rehabilitation interventions supporting return to work (I) effective compared to standard care (C), in supporting work outcomes (O)?
2. How effective and cost-effective are rehabilitation interventions in improving work outcomes for women living with and beyond breast cancer?
3. What are the core elements (i.e., content, delivery, resources, length, and format) of rehabilitation interventions for women living with and beyond breast cancer to support return to work?
4. What measures are used to test the impact of these rehabilitation interventions on work and other outcomes?
5. What are the most frequently used theoretical frameworks underpinning rehabilitation interventions to support return to work?

4.2 METHODS

4.2.1 Protocol and Registration

An initial protocol for the review was registered via the International Prospective Register of Systematic Reviews (PROSPERO) [ID: CRD42019145557] on 1st August 2019 exploring work-specific interventions between 2004-2019 inclusive (Appendix H). Following completion of this review, only one study was included for data extraction (Hubbard et al, 2013). As a result, inclusion criteria were expanded to include rehabilitation interventions that measured the impact of the intervention on one or more work outcomes, across unrestricted years. An updated review was then conducted.

4.2.2 Eligibility Criteria

Eligibility criteria were important to consider when developing the search strategy for this review (Table 4.2). Studies included those published in English exploring rehabilitation interventions for women living with and beyond breast cancer. At least one work-related outcome was required, and designs included RCTs and quasi-experimental designs (with a comparator). No limits were set on year, setting, intervention length, or intervention facilitators.

Table 4.2: Inclusion and Exclusion Criteria

Inclusion criteria			Rationale
Participants	(i)	Women who have had a breast cancer diagnosis (>18 years old)	Exploring a working adult population.
Interventions:	(ii)	Rehabilitation interventions that were group-based, individual one-to-one, and/or digital interventions. Could be vocational, psychosocial, physical and/or MDT in nature.	Open to all non-pharmacological intervention types
Comparators	(iii)	No limits on comparator e.g., standard care, waiting list, etc.	If no control group, it can be unclear if changes in outcomes are due to intervention or not.
Outcomes	(iv)	Primary outcome: At least one work-related outcome (e.g., working hours, sick leave, employment status) Secondary outcomes: physical, psychological and QoL outcomes.	An objective of review is to establish what interventions enhance work outcomes.
Study Designs	(v)	Experimental designs including RCTs and Quasi-Experimental studies (that include a control)	If no control group, it can be unclear if changes in outcomes are due to intervention or not.
Setting	(vi)	No limits set	Open to all settings including community, acute, online, etc.
Years	(vii)	No limits set	Open to all years to capture maximum yield.

Exclusion criteria		Rationale
<i>Language</i>	(i) Studies written up in languages other than English.	English is the native tongue of all reviewers. For pragmatic reasons, other languages were excluded.

4.2.3 Information Sources

Studies were sourced predominantly via bibliographic databases, but also through backwards and forwards chaining, and contact with study authors. The search was re-run on 29th April 2021 prior to the final analysis to identify any additional studies for inclusion, however no additional studies were eligible for full-text inclusion.

Bibliographic databases: Search terms were developed in consultation with a medical librarian and were applied to the following databases: EMBASE, Web of Science, MEDLINE (OVID), CINAHL, PsycINFO, and the Cochrane Central Register of Controlled Trials (CENTRAL).

Searching other (re)sources: When screening of abstracts and titles had been completed, backwards and forwards chaining of all full texts was completed. Backwards chaining involves searching the reference list of a text to source any potential papers that may be included. Forwards chaining involves screening citations stemming from the original paper. Where a full text was not available, access was requested from the corresponding authors by email or ResearchGate, and by Inter-Library Loan.

4.2.4 Search Strategy

A search strategy was co-developed with a medical librarian. Numerous search techniques were employed during the systematic review, including using wildcards, truncation, and proximity operators. Each search concept was examined for any additional related terms, ensuring maximum search yield. Thesauri and indexes of

databases were also searched to gather any related subject terms or phrases. Variant forms of the same term were also assessed, e.g., employment, employability, employee etc. In cases like this, truncation was used, e.g., 'employ*'. Where there were multiple spellings for the one term e.g. tumour/tumor, a wild card was used to search for both, e.g. 'tumo?r'. Finally, a proximity operator was used to search for terms that were close to each other but not necessarily beside one another e.g., Work NEAR/3 Return, included phrases such as 'Return to work' or 'Return at work'. For full search strategy, see Appendix I.

4.2.5 Study Selection

EndNote was used to manage all retrieved studies which were organised into folders divided by database. EndNote also screened for duplicated texts. Once all references were organised, the EndNote library was uploaded onto Covidence, an online software tool used for screening and data extraction. References were initially imported for the screening of all abstracts and titles. All retrieved studies were screened by one reviewer for suitability based on their abstracts and titles, using the review protocol. Where it was clear that the study did not meet the inclusion criteria, it was excluded. Where lack of clarity remained during screen, the study was sent to be examined in the full-text review to determine eligibility. Three reviewers were involved in the full text review of studies. Where disagreement occurred between two reviewers regarding the inclusion/exclusion of a full text, a third reviewer intervened and cast a concluding vote for inclusion/exclusion. Once the full text review was complete, data were extracted from included studies.

4.2.6 Data Collection Process

One reviewer used a data extraction tool based on the Cochrane Handbook for Systematic Review of Interventions (Higgins & Green, 2011) to independently extract data from each study onto an excel spreadsheet. Once this was complete, the completed spreadsheet was sent to a second reviewer to approve. In the case where any

disagreements occurred at any timepoint in the study selection and data extraction periods, a third reviewer was available to resolve any issues.

4.2.7 Data Items

Predetermined information to extract included information under two categories: (i) study and participant characteristics and (ii) intervention characteristics, outcomes and findings.

Study and participant characteristics

- Author(s), year of publication
- Study-design, setting, inclusion/exclusion criteria
- Sample n
- Eligibility criteria
- Age

Intervention characteristics, outcomes and findings

- Type of intervention: format, duration, content, and facilitators
- Theoretical framework (as per MRC framework for complex interventions (Craig et al, 2008))
- Outcomes: primary (work) and secondary (physical, psychological, and QoL) outcomes, outcome measures and follow-up periods
- Key findings

Outcomes such as physical and psychological sequelae have frequently been reported to impact on the RTW process (Ibrahim et al, 2014; Sun et al, 2017) and were therefore considered as secondary outcomes.

4.2.8 Risk of Bias in Individual Studies

Two reviewers assessed the risk of bias of each study using the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2011). Biases assessed

included sequence generation (selection bias), allocation sequence concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective outcome reporting (reporting bias), and other potential sources of bias. This step is important in ensuring that the true intervention effect is not overestimated or underestimated. Judgements for each of these domains were made as ‘low risk’, ‘high-risk’, or ‘unclear risk’. ‘Low risk’ indicates that the domain was performed adequately, ‘high risk’ if it was performed inadequately, and ‘unclear risk’ if there was not enough information to make a sound judgement. In cases where disagreements occurred, discussion was prompted by the two reviewers, with a third reviewer available for any unresolved disagreements.

4.2.9 Summary Measures

Where outcomes were continuous (e.g., working hours, number of sick days), the estimated effect size was calculated from each published study using mean differences and standard deviations (SDs) from each group (intervention and control) to calculate a standardised effect size using the Hedges *g* formula. For binary outcomes (e.g., have you returned to work? Yes/no), odds ratios were used.

4.2.10 Synthesis of Results

Meta-analysis of primary and secondary outcomes was planned where there was sufficient information available and studies were not too heterogenous in relation to interventions, study designs, outcomes and measures of effect. Where statistical synthesis was not possible, a narrative synthesis was conducted. This includes a descriptive summary of the included studies in both text and table format. Descriptive findings of included studies were structured around core elements of intervention (i.e., content, delivery, resources, length, and format), study design, target population characteristics, type of outcomes, outcome measures used, and theoretical frameworks used.

4.2.11 Heterogeneity and Pooling (Meta-Analysis) across Studies

An I^2 index was used to calculate the percentage of variance in the meta-analysis that was attributable to study heterogeneity. However, this should be interpreted cautiously when a meta-analysis has few studies and can provide substantial bias, in which case confidence intervals (CIs) should supplement biased point estimate I^2 (von Hippel, 2015). The H^2 statistic was also estimated, where 1 is equal to perfect study homogeneity. The H^2 statistic was considered where there were common measures across studies that could be pooled.

In the case of binary outcomes (e.g., yes/no), odds ratios (OR) and 95% CIs were extracted or calculated for each study from available data. In the presence of significant heterogeneity, meta-analysis was performed using a random effects approach (random effects model to consider between and within variation in studies). Penalised likelihood is used for computing 95% CIs for continuous measures. For pooling ORs, the peto method is used for fixed (or random) effects. For continuous measures reporting means (SDs) the effect size (mean standardised difference in intervention vs control) is computed for each using Hedge's g .

4.3 RESULTS

4.3.1 Study Selection

1,526 records were identified using the search strategy following removal of duplicates, of which 28 papers met the inclusion criteria for full-text review (Figure 4.1). In addition, 1,191 references were screened during backwards chaining, and 2,140 citations were screened for forwards chaining. From this, eight papers met inclusion criteria for further review. One of these eight papers was included in the final synthesis. Of the 19 excluded papers, reasons for exclusion included (i) no work-related outcomes ($n=15$), (ii) study design other than RCT or quasi-experimental ($n=3$), and (iii) no clear reporting of work outcomes ($n=1$). Further details on excluded studies can be found in Appendix J.

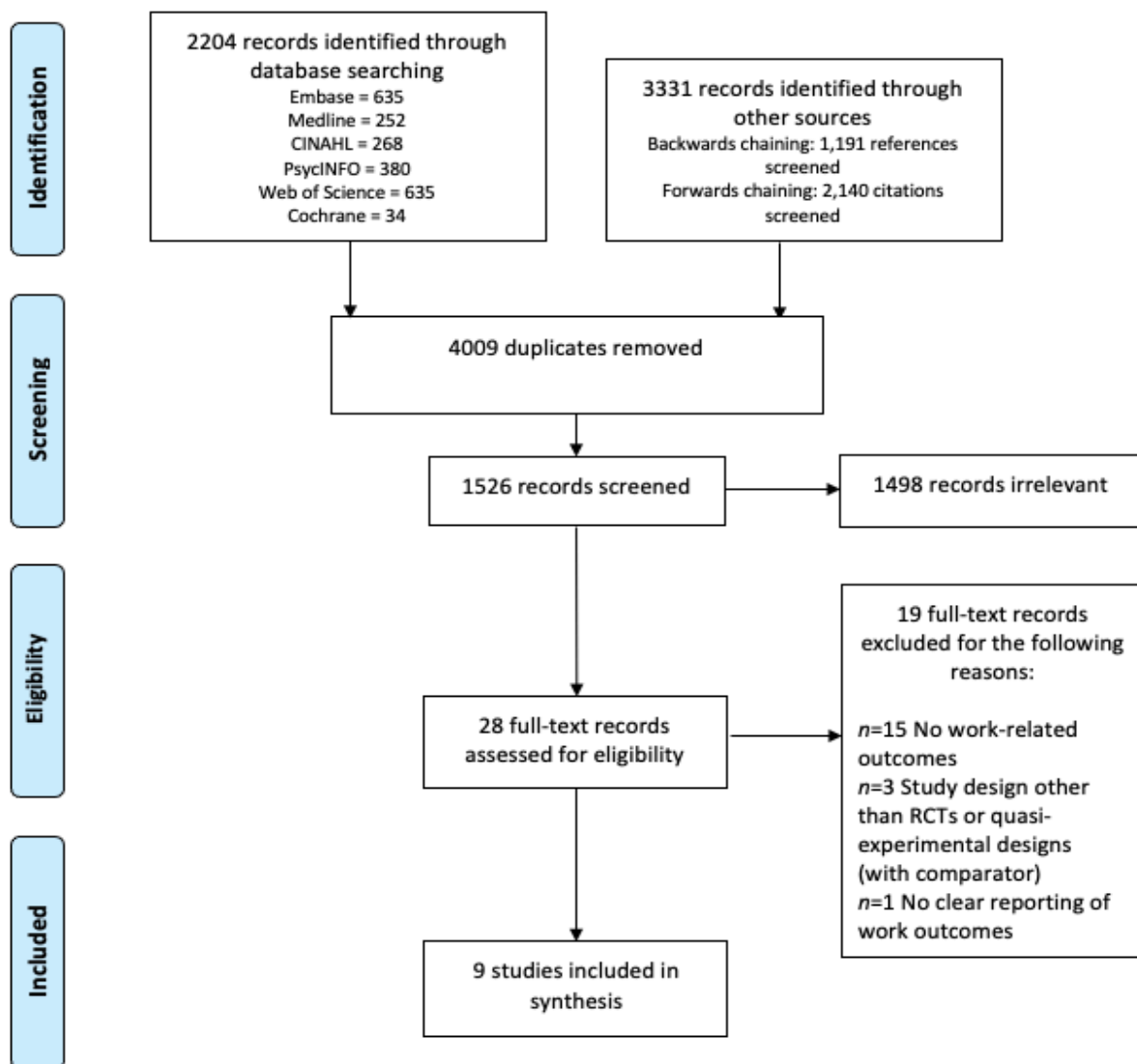


Figure 4.1 PRISMA Diagram

4.3.2 Study Characteristics

Study and participant characteristics are presented in Table 4.3.

Study design, year, and setting: Of the nine included studies, all were RCT in design, and three of which were pilot RCTs. Most studies stemmed from the 2010's ($n=6$) with the remaining three studies spread across the 1980s, 1990s, and 2000s. Most studies were set in Europe ($n=6$), two in Canada, and one in the United States. Most interventions were delivered in the hospital setting ($n=6$). One study (Rogers et al, 2009) did not specify where group interventions took place however did indicate that

the intervention was partially home-based. Full study characteristics are outlined in Table 4.3.

Participants: While all studies focused on women living with and beyond breast cancer, there were variations in eligibility criteria. Age criteria varied across studies. Of the six studies specifying age in the inclusion criteria, three studies included 18-70-year olds. Mean age in the intervention and control groups across the seven studies which specified it, ranged from 49.7-57.8 years and 51.0-58.7 years, respectively. Four studies specified a staging criteria of stages I-III. Over sample sizes widely varied across studies, ranging from 22 (Hubbard et al, 2013 – Pilot RCT), to 382 (Björneklett et al, 2013) at allocation. Full participant characteristics are outlined in Table 4.3.

Table 4.3: Study and Participant Characteristics

Study Characteristics					Participant Characteristics		
Author	Year	Design	Country	Setting	N (at allocation)	Inclusion Criteria	Age
Björneklett et al.	2013	RCT	Sweden	Resort (type not specified)	382 Intervention =191 Control =191	- Newly diagnosed primary breast cancer - No previous malignancy - The physical and mental capability to participate in group interventions and to fill in questionnaire - Expected survival time of > 12 months - Analyses limited to those under the age of 65 years old.	Overall = Unknown Intervention = 57.8 Control = 58.7
Bolam et al.	2019	RCT	Sweden	Hospital	240 RT-HIIT ¹ = 79 AT-HIIT ² = 80 Control = 81	- Women - 18-70 years - Stage I-IIIa breast cancer - Scheduled to receive chemotherapy directly	Overall: Unknown RT-HIIT = 52.7 AT-HIIT = 54.4 Control = 52.6
Hubbard et al.	2013	Pilot RCT	Scotland, UK	Hospital and Community	22 Intervention = 8 Control =14	- 18-65 years - In paid employment or self-employed - Living or working in Scotland, UK - Diagnosed with invasive breast cancer tumour or ductal carcinoma in situ - Treated first with surgery	Overall = 50.5 Intervention = 49.7 Control = 51.0

¹RT-HIIT = Resistance Exercise and High-Intensity Interval Training; ²AT-HIIT = Moderate Intensity Aerobic Exercise and High-Intensity Interval Training

Study Characteristics					Participant Characteristics		
Author	Year	Design	Country	Setting	N (at allocation)	Inclusion Criteria	Age
Ibrahim et al.	2017	Pilot RCT	Canada	Community (Cancer Support Centre)	59 Intervention = 29 Control = 30	- Stage I-III breast cancer - 18-45 years - Scheduled to receive post-operative adjuvant treatment - Have an ECOG performance status 0-1.	Overall = 39.2 Intervention and Control =Unknown
Jong et al.	2018	RCT	The Netherlands	Hospital and Home	83 Intervention = 47 Control = 36	- Women between 18-70 years - Stage I–III breast cancer - Scheduled for (neo)adjuvant chemotherapy - Able to understand and speak Dutch - Phone and internet access	Overall: Unknown Intervention = 51 Control = 51
Maguire et al.	1983	RCT	England, UK	Hospital (Inpatient Surgical Unit)	172 Intervention=Unknown Control =Unknown	- Women admitted for modified radical mastectomy with full axillary clearance. -	Unknown
Maunsell et al.	1996	RCT	Canada	Hospital	250 Intervention=123 Control =127	- Newly diagnosed breast cancer patients with localised or regional stage disease. -	Overall: Unknown Intervention=54.6; Control = 56.3

Study Characteristics					Participant Characteristics		
Author	Year	Design	Country	Setting	N (at allocation)	Inclusion Criteria	Age
Mourgues et al.	2014	RCT	France	Hospital	232	- Complete remission of invasive non-	Overall: Unknown
					Intervention=117	metastatic breast carcinoma	Intervention=51.9
					Control =115	- < 9 months after completion of chemotherapy/radiotherapy	Control =51.9
						- No contraindication for physical activities	
						- No cognitive disorders	
						- Body mass index between 18.5-40 kg/m ²	
Rogers et al.	2009	Pilot	USA	Unknown and	41	- English-speaking female	Overall: 53;
		RCT		Home	Intervention=21	- 18-70 years	Intervention=52
					Control =20	- Diagnosis of stage I, II, or IIIA.	Control =54
						- Currently taking aromatase inhibitors or selective oestrogen receptor modulators and expected to remain on hormonal therapy for study duration (>8 months)	
						- Medical clearance.	
						- If surgical procedure undertaken, enrolment delayed >8 weeks post procedure.	

4.3.3 Intervention Characteristics

Content: Content of interventions varied widely. The majority of interventions delivered a combination of physical and psychosocial interventions ($n=6$) (Björneklett et al, 2013; Hubbard et al, 2013; Jong et al, 2018; Maguire et al, 1983; Mourgues et al, 2014; Rogers et al, 2009). Two studies delivered physical intervention only (Bolam et al, 2019; Ibrahim et al, 2017) and only one study a psychosocial intervention (Maunsell et al, 1996).

Only three interventions (Björneklett et al, 2013; Hubbard et al, 2013; Maguire et al, 1983) delivered work-focused components to the intervention, including encouragement to return to the workplace (Maguire et al, 1983), an information session on the sick leave, insurances and economic consequences of illness (Björneklett et al, 2013), and a vocational rehabilitation case management intervention which included referrals to other disciplines (Hubbard et al, 2013). Every intervention in this review was person-directed, meaning that the intervention was focused on the person as opposed to the physical environment such as the workplace (which would be work-directed). While three of the nine studies encompassed work components to the intervention, only one intervention referred to work-directed components such as workplace adjustments, or modifying work tasks, hours, or workplaces although this was not provided to every participant (Hubbard et al, 2013). Detailed information on the content of each intervention can be found in Table 4.4.

Format: Four interventions were group-based (Björneklett et al, 2013; Bolam et al, 2019; Jong et al, 2018; Mourgues et al, 2014), four were 1:1 (Hubbard et al, 2013; Ibrahim et al, 2017; Maguire et al, 1983; Maunsell et al, 1996), and one intervention was blended (group and 1:1) (Rogers et al, 2009).

Delivery: Every study included a face-to-face component as part of the delivery of the intervention. Two studies also delivered part of the intervention by telephone (Hubbard et al, 2013; Maunsell et al, 1996). Three of the four physical interventions encouraged part of the intervention to be delivered at home with self-directed activity (e.g., exercise programme) (Ibrahim et al, 2017; Jong et al, 2018; Rogers et al, 2009).

Duration: The overall length of interventions varied from a once-off consultation (Hubbard et al, 2013) to one year (Maunsell et al, 1996). The length of

each session was not described in all papers, however, was usually indicated in physical interventions where session lengths varied between 60 and 120 minutes. Frequency of these sessions ranged between daily and once a week.

Theoretical framework: The majority of studies ($n=6$) did not report a specific theoretical framework/model used to guide intervention design or delivery. Of the three which did report a theoretical framework, one intervention was based on the Biopsychosocial Model (Hubbard et al, 2013), one on the Brief Crisis Intervention Model (Maunsell et al, 1996), and one on social cognitive theory (Rogers et al, 2009).

Comparator: All studies offered a comparator, which varied across interventions. This most frequently included provision of written materials (e.g. physical activity – Bolam et al, 2019; Rogers et al, 2009; ‘Work and Cancer’ – Hubbard et al, 2013). In addition to written materials, usual care could also include encouragement to maintain a healthy lifestyle (Ibrahim et al, 2017), oncology nurse support (Jong et al, 2018), a minimal psychologic follow-up care programme, and meeting with a physiotherapist (Maunsell et al, 1996), or a consultation with a dietician (Mourgues et al, 2014).

Outcomes and Outcome Measures:

Work outcomes: Every work outcome was assessed by self-report. The most commonly measured work-related outcome was sick leave/return to work (binary yes/no question to assess if the participant had returned to work in some capacity). The second most commonly measured outcome was number of working hours, followed by number of sick days. Finally, one study (Mourgues et al, 2014) measured occupational (work) capacity by asking women if their health problems adversely affected the ability to complete occupational activities. See Table 4.4 for further detail.

Patient reported outcomes: The most frequently measured patient-reported outcomes included physical ($n=7$) and psychological ($n=6$) sequelae, and quality of life ($n=4$). Other outcomes included sleep, symptom burden, impact on household tasks, impact on social activities, and marital adjustment. Outcome measures typically varied across studies, with little overlap in most cases. See Table 4.4 for further detail.

Table 4.4: Intervention Characteristics and Outcomes of the Studies included in the Systematic Review and Meta-Analysis

Author	Intervention Characteristics					Outcome measures
	Format	Content	Facilitator(s)	Duration	Theoretical Framework	
Björneklett et al. (2013)	Face-to-face Group.	Physical/Psychosocial: Information-based programme supplemented with relaxation, qigong, liberating dance, social activities. - Psychological reactions to serious disease, & coping strategies. - Practicalities of sick leave, insurance & impact of illness on finance - Food and nutrition	Oncologists, social workers, a psychologist, an art therapist, massage therapists, a dietician and a person trained in qigong and mental visualisation.	One-week inpatient stay followed by four-day follow-up. Duration of individual sessions not specified.	None	Sick Leave: Single item question (Yes/No) and number of days taken for sick leave. Health care utilisation: Asked the frequency and types of healthcare visits. Cost-effectiveness <i>Measured at:</i> - 2, 6 and 12 months
Bolam et al. (2019)	Face-to-face Group.	Physical: RT-HIIT¹: Resistance Exercises using machine and free weights followed by HIIT on a cycle ergometer. AT-HIIT²: 20 min of moderate intensity continuous Aerobic Exercise followed by HIIT on a cycle ergometer.	Exercise physiologist, oncology nurse.	60-minute sessions twice per week on non-consecutive weekdays, over 16 weeks.	None	Sick leave: Single item question (% of leave taken; 0, 25, 50, 75, 100%) Cancer-related fatigue: Revised Piper Fatigue Scale (PFS) Quality of Life: EORTC-QLQ-C30 ¹ Symptom and Symptom Burden: Memorial Symptom Assessment Scale (MSAS) <i>Measured at:</i> 1 Year and 2 Year

¹RT-HIIT = Resistance Exercise and High-Intensity Interval Training; ²AT-HIIT = Moderate Intensity Aerobic Exercise and High-Intensity Interval Training

Intervention Characteristics						
Author	Format	Content	Facilitator(s)	Duration	Theoretical Framework	Outcome Measures
Hubbard et al. (2013)	Individual Face-to-face, Telephone	Physical/Psychosocial: Tailored Vocational Rehabilitation Case management. Based on assessment, participants were signposted to at least one of the following services: occupational therapy, physiotherapy, counsellor, psychology, occupational health nurse, and/or complementary therapy.	Case manager, occupational therapist, physiotherapist, counsellor, psychology, occupational health nurse, and complementary therapist	No set duration as interventions varied.	Bio-psychosocial model	Sick leave: Self-report questionnaire (days) Employment: Questionnaire inc. left or remained in work, job role, hours worked Quality of Life: Functional Assessment of Cancer Therapy-Breast Cancer (FACT-B) [Version 4] and Breast Cancer Subscale. Cancer-related fatigue: Functional Assessment of Chronic Illness Therapy-Fatigue Scale (FACIT-F) <i>Measured at:</i> - 6 months - 12 months
Ibrahim et al. (2017)	Individual Face-to-face (and encouragement for home exercises)	Physical: One-to-one teaching session supervised by exercise physiologist. Cardiovascular exercise, strength training, endurance programme, stretching programme	Exercise physiologist	Encouraged to perform the programme 2-3 times/week over 12 weeks.	None	Working hours: Post hoc questionnaire Upper limb function: The Disability of Arm, Shoulder and Hand (DASH) <i>Measured at:</i> - Baseline (pre-radiation), - post-radiation - 3, 6, 12, and 18-months post-radiation

Author	Intervention Characteristics					Outcome measures
	Format	Content	Facilitator(s)	Duration	Theoretical Framework	
Ibrahim et al. (2017)	Individual Face-to-face (and encouragement for home exercises)	Physical: One-to-one teaching session supervised by exercise physiologist. Cardiovascular exercise, strength training, endurance programme, stretching programme	Exercise physiologist	Encouraged to perform the programme 2-3 times/week over 12 weeks.	None	Working hours: Post hoc questionnaire Upper limb function: The Disability of Arm, Shoulder and Hand (DASH) Measured at: - Baseline (pre-radiation), - post-radiation - 3, 6, 12, and 18-months post-radiation
Jong et al. (2018)	Face-to-Face and Home- Based work Group	Physical/Psychosocial A Dru-based Yoga. Programme which includes 15-minute blocks of the following: - Breathing awareness - Energy block release - Body awareness - Relaxation In addition, women were provided a CD/MP3 download with 20-minute relaxation and breathing exercises to complete at home.	Yoga instructors	75-minute sessions once a week for 12 weeks.	None	Reintegration to work: Assessed via telephone interview. Returned to work: Binary Yes/No. Fatigue: Multidimensional Fatigue Inventory [MFI]; Fatigue Quality List [FQL] Quality of Life: EORTC-QLQ-C-30 ¹ Psychological Distress: Hospital Anxiety Depression Scale [HADS]; Impact of Events Scale [IES] Treatment expectations: Participants Expectations questionnaire. Measured at: - Baseline (T0) - 3 months (T1) - 6 months (T2)

Intervention Characteristics						
Author	Format	Content	Facilitator(s)	Duration	Theoretical Framework	Outcome Measures
Maguire et al. (1983)	Individual	Physical/Psychosocial	Nurse specialist	Throughout	None	RTW: Yes/No/ Non-Applicable
	Face-to-face	Counselling/Education: - Nurse advised range of movement exercises for arm. - Encouragement to look at and discuss scar and loss of breast. - Demonstration of possible external breast prostheses. - Home-visit post-discharge to assess upper limb monitor adherence to exercises and counselling. - Encouragement of return to work and social reintegration.		inpatient stay post-surgery (varied among participants). Followed up at home visit every two months until deemed fit for discharge.		Response to scar, prosthesis and breast loss: Interview response (satisfied, neutral, dissatisfied) Perceived Impact on Swelling, Pain, and Disability: Self report Social adjustment: Single item question on problems with social adjustment Housework: Single item question on problems with housework Marital adjustment: Concurrent physical illness: <i>Measured at:</i> - 3 months - 12 months - 18 months

Author	Intervention Characteristics					Outcome Measures
	Format	Content	Facilitator(s)	Duration	Theoretical Framework	
Maunsell et al. (1996)	Individual Face-to-face and Telephone	Psychosocial: Interventions included mix of information, education, support, counselling and referral where required.	Social worker	Telephone screening every 28 days for total of 12 screening calls.	Brief crisis intervention model.	RTW: Binary Yes/No returned to work Working hours/week: Number of hours. Psychologic symptoms: General Health Questionnaire [GHQ] Psychologic distress: Psychiatric Symptom Index Social support: Social Support Questionnaire Stressful Life Events: Life Experiences Survey Marital satisfaction: The Locke-Wallace Marital Adjustment Test [LWMAT] Depression and Anxiety: Diagnostic Interview Schedule [DIS] Physical Health: Self-report Outcomes measured: Baseline (T0), 3 months (T1), 6 months (T2)
Mourgues et al. (2014)	Face-to-face Group	Physical/Psychosocial Multicomponent including physiotherapy, nutritional advice, thermal water treatment, daily two-hour physical activity, running and basic dietary follow-up. Consultation with dietitian every six months.	Physiotherapist, Dietitian,	15-day programme. Daily two-hour physical activity.	None	Occupational activity: Total hourly volume of overall & occupational activity. Daily abilities: Perception whether health problems impacted on activities. Outcomes measured: Baseline, 6 & 12months

Intervention Characteristics						
Author	Format	Content	Facilitator(s)	Duration	Theoretical Framework	Outcome Measures
Rogers et al. (2009)	Face-to-Face and home-based exercises Group and Individual	Physical/Psychosocial The BEAT Cancer programme: • 12 individual supervised exercise • Home-based exercise • 3 individual face-to-face counselling sessions. • Six discussion group sessions addressing: Social support, Journaling, Time Management, Stress Management, Dealing with Exercise Barriers, Behaviour modification	Clinical Psychologist, Exercise specialists (certified by American College of Sports Medicine or certified eligible).	12-week programme.	Social Cognitive Theory	Sick days: Self-report number of days off work Quality of life: Functional Assessment of Cancer Therapy—Breast (FACT-B) & FACT-G (General) Fatigue: FACT—Fatigue (FACT-F) Endocrine symptoms: FACT—Endocrine Symptoms (FACT-ES) Cognitive function: FACT—Cognitive Sleep dysfunction: Pittsburgh Sleep Quality Index (PSQI) Physical activity behaviour: The Godin Leisure-Time Exercise Questionnaire Motivational readiness for physical activity: Self-report of stage of change Lower extremity pain and function: Western Ontario and McMaster Universities Arthritis Index (WOMAC)

4.3.4 Risk of Bias within Studies

A risk of bias assessment summary for each included study is indicated in Figure 4.2. For further detail on assessment rationale, see Appendix K.

	Sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessors	Incomplete outcome data	Selective reporting	Other biases
Bjornekleit et al. (2013)	+	?	-	?	-	+	-
Bolam et al. (2019)	+	?	-	?	-	+	?
Hubbard et al. (2013)	+	+	-	?	+	+	-
Ibrahim et al. (2017)	+	?	-	?	?	+	-
Jong et al. (2018)	+	?	-	?	-	+	-
Maguire et al. (1983)	+	?	-	?	+	+	?
Maunsell et al. (1996)	+	+	-	?	+	+	?
Mourgues et al. (2014)	?	?	-	?	+	+	?
Rogers et al. (2009)	+	?	-	?	+	+	-

Low Risk: Unclear Risk: High Risk:

Figure 4.2: Risk of Bias Assessment

Sequence generation (selection bias): All studies except one (Mourgues et al, 2014) were deemed low risk for sequence generation. The study by Mourgues and colleagues was deemed an ‘unclear risk’, as although it was reported that randomisation was balanced and stratified, it was unclear how this was carried out. Studies deemed ‘low risk’ used computer-generated randomisation (Bolam et al, 2019; Rogers et al, 2009), blocked randomisation (Björneklett et al, 2013; Ibrahim et al, 2017; Jong et al, 2018), a Bernoulli probability distribution with a specified probability of 0.5 (Hubbard et al, 2013), the use of sealed envelopes (prepared using a random numbers table) randomly

varied block sizes used (Maunsell et al, 1996), and use of a random numbers table (Maguire et al, 1983).

Allocation concealment (selection bias): Most studies demonstrated an unclear risk for allocation concealment. Only two studies (Hubbard et al, 2013; Maunsell et al, 1996) were deemed low risk. Reasons for deeming studies an unclear risk included lack of clarity around who completed the randomisation (Maguire et al, 1983), lack of clarity around how blinding of allocation sequence was achieved (Jong et al, 2018), lack of clarity around the status of sealed envelopes (Rogers et al, 2009). While envelopes were sealed, it was unclear if they were opaque or sequentially numbered, as per the SNOSE technique where envelopes should be Sequentially Numbered, Opaque, Sealed Envelope (Doig & Simpson, 2005).

Blinding of participants and personnel (performance bias and detection bias): Every study was deemed high risk for blinding of participants and personnel as due to the nature of the intervention it was not possible to blind participants.

Blinding of outcome assessors (performance bias and detection bias): The blinding of outcome assessors was assessed as an unclear risk for every study as most outcomes were self-reported by participants who were not blinded to the intervention.

Incomplete outcome data (attrition bias): Most studies were deemed low risk for incomplete outcome data. Three studies were deemed high risk where attrition rates were not explained (Björneklett et al, 2013; Jong et al, 2018), or no allowance was made for attrition in the analysis (Bolam et al, 2019). Finally, the study by Ibrahim et al (2017) was deemed an unclear risk as there was no explanation provided around if those who dropped out or died were included in the analysis.

Selective reporting (reporting bias): It appeared that all pre-specified outcomes were reported across all studies.

Other biases: Examples of other biases identified included health status prior to randomisation unknown (Björneklett et al, 2013), lack of clarity of statistically significant differences between groups (likely due to small sample) (Hubbard et al,

2013), and higher baseline levels of activity in exercise vs. control groups (Ibrahim et al, 2017).

4.3.5 Results of Individual Studies: Results of individual studies are indicated in Table 4.5

Table 4.5: Results of Individual Studies included in the Systematic Review and Meta-Analysis

Author	Work outcomes			Other outcomes			
	Sick Leave / RTW (Y/N)	Working hours	Other:	Physical	Psychological	QoL	Other
Björneklett et al. (2013)	<i>(Sick Leave – Days):</i> No significant differences at 0, 2, 6, or 12 months.						<i>Healthcare utilisation:</i> Not significant re. visits to medical specialists, GPs or physiotherapists. However, women treated with chemotherapy in intervention group had significantly more visits with ‘Other’ healthcare professionals than the control at 6 and 12 months. <i>Health economics:</i> Intervention was significantly greater in cost compared to control.
Bolam et al. (2019)	% of sick leave at that timepoint: No significant differences between the two groups at 2 years.			<i>Cancer-related fatigue (CRF):</i> Significant differences between RT-HIIT and control groups for CRF and Cognitive CRF in favour of RT-HIIT who experienced improvements in both. <i>Physical symptoms (Item MSAS):</i> No significant differences	<i>Psychological symptoms (Item of MSAS):</i> No significant differences between groups. <i>Emotional functioning (item of EORTC):</i> No significant differences	<i>QoL:</i> No significant differences between the two groups.	<i>Total symptoms:</i> Sig. ↓ total symptoms than UC at 2 years in favour of AT-HIIT intervention. <i>Symptom burden:</i> Sig. ↓ symptom burden than UC at 2 years in favour of AT-HIIT intervention.
Hubbard et al. (2013)	<i>Number of days sick leave:</i> No significant differences			<i>Change in employment pattern:</i> No significant differences between groups	<i>Fatigue:</i> No significant differences <i>Physical functioning (item of FACT-B):</i> No significant differences	<i>Emotional functioning (item of FACT-B):</i> No significant differences	<i>QoL:</i> Significant differences between groups on breast cancer specific QoL in favour of intervention who experienced improvements.
QoL: Quality of Life; RT-HIIT = Resistance Exercise and High-Intensity Interval Training; AT-HIIT = Moderate Intensity Aerobic Exercise and High-Intensity Interval Training							

Author	Work outcomes			Other outcomes			
	Sick Leave / RTW (Y/N)	Working hours	Other:	Physical	Psychological	QoL	Other:
Ibrahim et al. (2017)		Not reported for control group therefore unable to ascertain if significant.		<i>Upper limb function:</i> No significant differences			
Jong et al. (2018)	<i>Return to work (Y/N):</i> No significant difference between groups			<i>Fatigue:</i> No significant differences <i>Confidence in fatigue reduction:</i> Significantly more confident in fatigue reduction in favour of intervention group. <i>Adequate relief of fatigue (Y/N):</i> Significantly more relief of fatigue in favour of intervention group.	<i>Psychological distress:</i> No significant differences in levels of anxiety Significantly less depressive symptoms at 3 months in favour of intervention. <i>Emotional functioning (item of EORTC):</i> No significant differences	<i>QoL:</i> Significantly less nausea and vomiting at six months in favour of Intervention group. No significant differences for other outcomes.	<i>Impact of events:</i> No significant differences. <i>Treatment expectations:</i> Intervention group had significantly higher treatment expectations compared to control.
Maguire et al. (1983)	<i>RTW (Y/N):</i> No significant differences			<i>Upper limb swelling, pain and disability</i> No significant differences	<i>Reaction to scar, prosthesis and breast loss:</i> Intervention group were significantly more satisfied with scar, prosthesis, breast loss, compared to control.		<i>Housework, Social adjustment, Martial adjustment:</i> No significant differences between groups.

QoL: Quality of Life; RT-HIIT = Resistance Exercise and High-Intensity Interval Training; AT-HIIT = Moderate Intensity Aerobic Exercise and High-Intensity Interval Training

Author	Work outcomes			Other outcomes			
	Sick Leave / RTW (Y/N)	Working hours	Other:	Physical	Psychological	QoL	Other:
Maunsell et al. (1996)	<i>RTW (Y/N):</i> No significant differences	<i>Working hours (per week):</i> No significant differences		<i>Physical health:</i> No significant differences	<i>Psychological distress:</i> No significant differences		<i>Perception of health. Functional status, Social activity, Marital relations:</i> No significant differences
Mourgues et al. (2014)			<i>Occupational activity (Work):</i> Significant improvement in ability to perform work activities at 12 months in favour of intervention group.				<i>Overall activities:</i> Significant differences between groups in favour of intervention who had increased resumption of overall activities in first 12-month period. <i>Non- occupational activity (Family, household tasks and volunteerism):</i> Significant improvement in ability to perform family activities at 12 months, in favour of intervention. <i>Cost-effectiveness:</i> Significant differences at 12 months, in favour of intervention
Rogers et al. (2009)	<i>Number of sick days in past month:</i> No significant differences			<i>Fatigue, Joint pain, Physical function:</i> No significant differences <i>Physical functioning (item of FACT-B):</i> No significant differences <i>Joint stiffness:</i> Significantly greater perceived joint stiffness in intervention group compared to control.	<i>Emotional functioning (item of FACT-B):</i> No significant differences	<i>QoL:</i> Significant improvement in social well-being in favour of intervention Not significant for other QoL outcomes	<i>Cognition, Perceived health, Endocrine symptoms, Sleep dysfunction:</i> No significant differences

QoL: Quality of Life; RT-HIIT = Resistance Exercise and High-Intensity Interval Training; AT-HIIT = Moderate Intensity Aerobic Exercise and High-Intensity Interval Training

4.3.6 Synthesis of Results

Meta-analysis was only possible for a limited number of outcomes and in a limited number of studies. However, because interventions and reported outcome measures varied, narrative synthesis was also completed.

4.3.6.1 Effectiveness of Interventions on Work Outcomes – Meta-Analysis:

Limited meta-analysis was possible on work outcomes including number of sick days taken (at six and 12-months), if someone remained on sick leave (at 12 months), and the number of working hours (at 12 months).

Number of sick days taken (six and 12 months)

Data for the number of overall sick days taken were available for two studies at six and 12 months (Björneklett et al, 2013; Hubbard et al, 2013). At six months (Figure 4.3), pooled analysis resulted in a non-significant overall effect of -0.080 (95% CI: -0.48, 0.38). Heterogeneity measures indicated the studies were homogenous with an I^2 value of 0.00 and H^2 value of 1.00. Note: the non-chemotherapy group was used for the intervention and control for effect size (Björneklett et al, 2013).

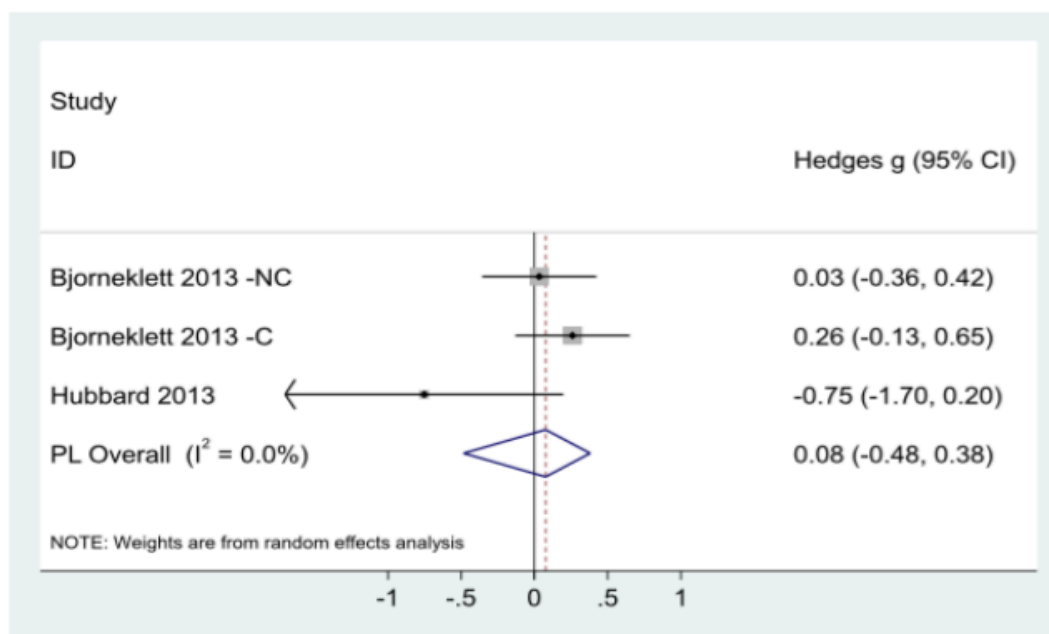


Figure 4.3: Meta-Analysis of number of Sick Days taken at Six Months.

NC: Non-Chemotherapy Group; C: Chemotherapy Group

Figure 4.4 provides the results from meta-analysis at 12 months. Björneklett et al. (2013) observed an effect close to zero of 0.09 (Hedge's *g*) between non-chemotherapy intervention and control groups (95% CI: -0.33, 0.52) and a small effect size of 0.21 (Hedge's *g*) between chemotherapy intervention and control groups (95% CI: -0.20, 0.61). Hubbard et al. (2013) observed a small effect size of -0.43 between intervention and control groups (95% CI: -1.36, 0.49). Pooled analysis indicated a non-significant overall very small effect of 0.10 (95% CI: -0.28, 0.39).

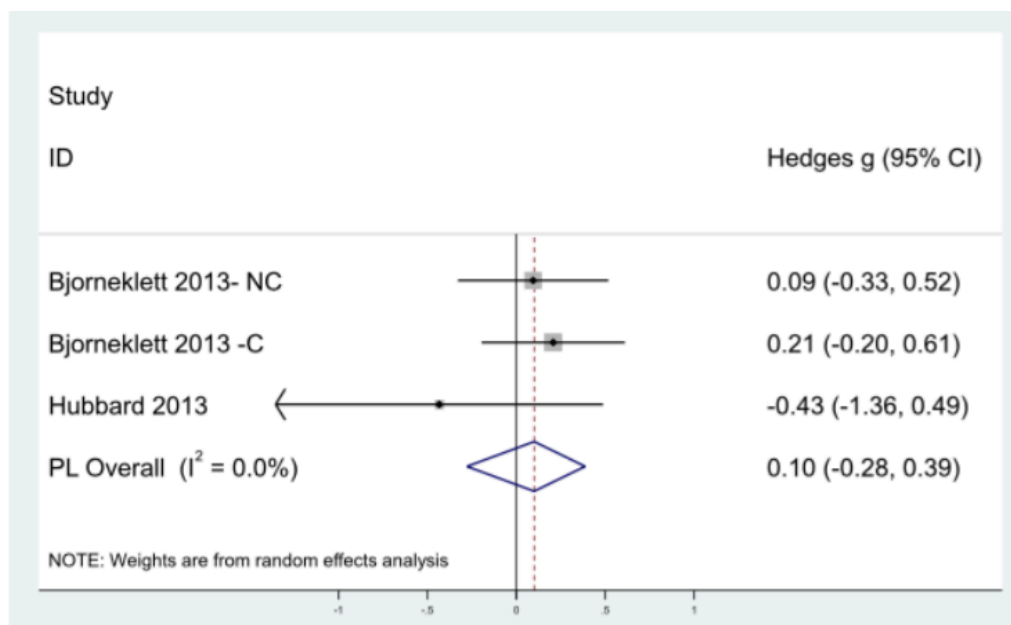


Figure 4.4 Meta-Analysis of number of Sick Days taken at 12 Months.

NC: Non-Chemotherapy Group; C: Chemotherapy Group

Sick leave (Y/N) at 12 months

Sick leave data were available for two studies at 12 months (Björneklett et al, 2013; Maunsell et al, 1996), however results were not statistically significant between intervention and control groups (Figure 4.5). Björneklett et al (2013) observed an OR of 1.10 (95% CI: 0.57, 2.12) for the association of any (vs no) sick leave between intervention vs control groups, whereas Maunsell et al (1996) observed an OR of 1.13 (95% CI: 0.48, 2.68) for the associations of any sick leave between the intervention and control groups. Pooled analysis indicated an overall OR (peto) of 1.11 (95% CI: 0.66,

1.87), which was close to 1. Heterogeneity measures indicated a I^2 value of 0.00 and H^2 value of 1.00. Peto Odds Ratio (OR) fixed effect model used.

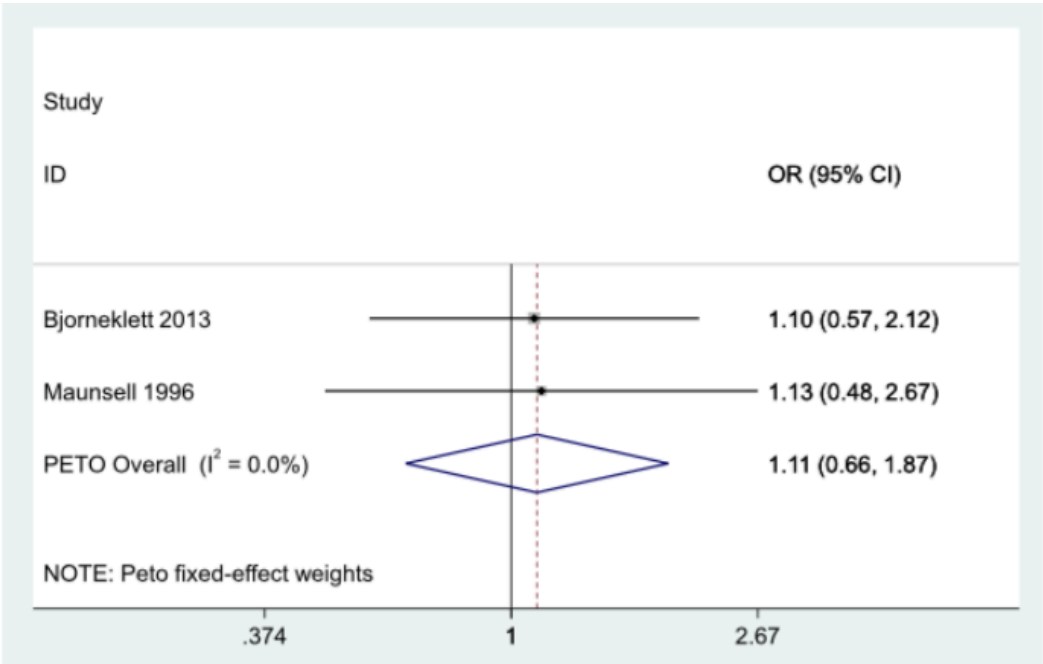


Figure 4.5: Meta-Analysis of Sick Leave (Yes/No) at 12 Months

Working hours at 12 months

Working hours data were available for two studies at 12 months (Maunsell et al, 1996; Mourgues et al, 2014), however there was no statistical significance between the control and intervention groups (Figure 4.6). At 12 months, Maunsell et al (1996) observed an effect size close to zero of 0.05 (Hedge's g) between intervention and control groups (95% CI: -0.20, 0.30), whereas Mourgues et al (2014) observed a small-medium effect size of 0.4 (Hedge's g) between groups (95% CI: 0.08, 0.72). Pooled analysis indicated

an overall effect of 0.19 (95% CI: -0.20, 0.64). Heterogeneity measures indicated a I^2 value of 28.27 and H^2 value of 1.39. A random effects model was used.

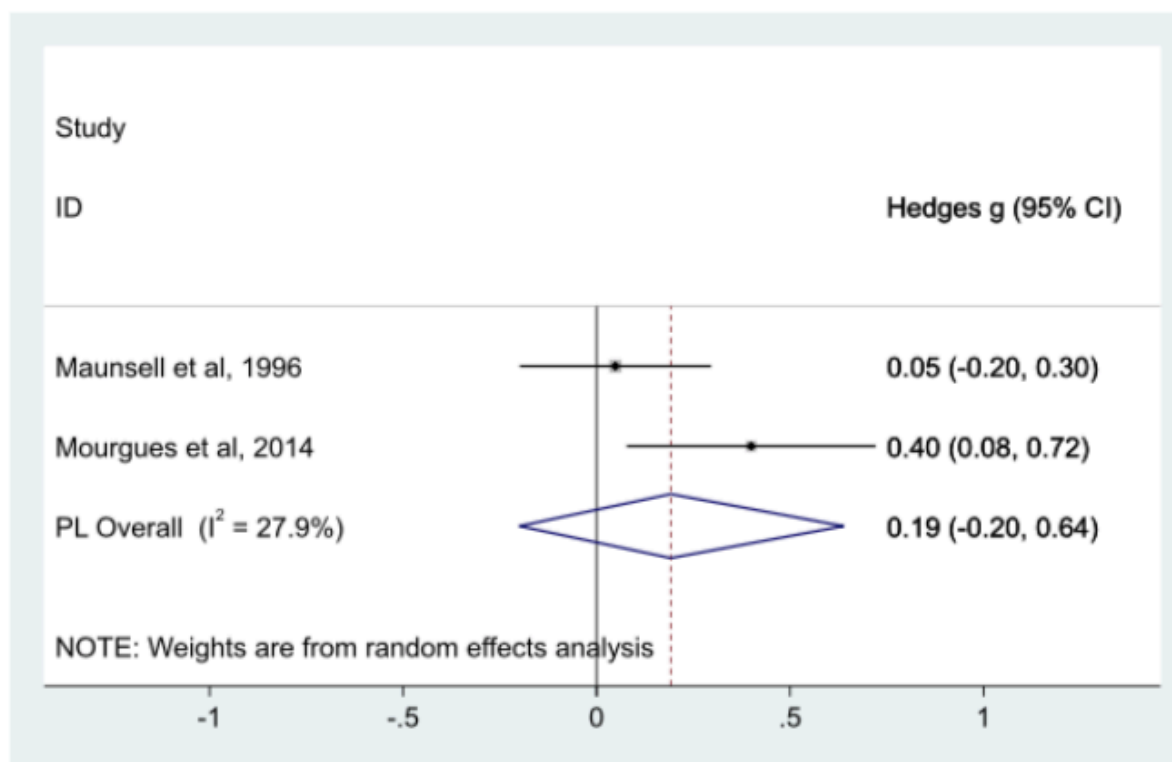


Figure 4.6 Meta-Analysis of Working Hours at 12 Months

4.3.6.2 Effectiveness of Interventions on Work Outcomes – Narrative Synthesis

Work outcomes: Of the nine included studies, only one study (Mourgues et al, 2014) reported statistically significant differences in work outcomes (which they defined as increase in ‘occupational activity’) in favour of the intervention group (Table 4.5). Findings indicated that the intervention group had a greater resumption of overall activities (defined as ‘occupational’ (work activities) and ‘non-occupational’ (family-related, household and voluntary activities)) during the first 12-month period compared to the control group ($p=0.0025$). No significant differences were found at any other timepoint (baseline or six months) between the groups. While Ibrahim et al (2017) explored working hours, these were not reported for the control group, making it impossible to determine if there were any statistically significant differences between groups. Three studies found increased numbers of the intervention group returning to work or taking less sick leave compared to the control, however, did not report

statistically significant differences between intervention and control groups. First, the intervention group in Hubbard et al's (2013) study reported 53 fewer days of sick leave compared to the control group, but this difference did not reach statistical significance, perhaps due to the small sample size ($n=22$). Second, Jong et al (2018) found 53% of the intervention group had returned to work at six months compared to 23% of the control group, however this also did not reach statistical significance. Third, 76% of Maguire et al's (1983) intervention group returned to work compared to 54% of the control, but with no statistical significance. The four remaining studies (Björneklett et al, 2013; Bolam et al, 2019; Maunsell et al, 1996; Roger et al, 2009) did not find any statistically significant differences between intervention and control groups.

4.3.6.3 Cost-Effectiveness of Interventions – Narrative Synthesis

Only two studies reported cost-effectiveness outcomes with varying results (Table 4.5). Mourgues et al (2014) reported cost-effectiveness for the intervention at 12 months, but not at six months. They adopted a societal perspective to perform their cost effectiveness analysis (CEA) and included direct and indirect costs. Direct costs included consultations, hospital stays, prescriptions, blood tests, medical interventions, transport between home and hospital, and thermal treatment. Indirect medical costs included out-of-pocket expenses associated with the disease. Most costs were established from data from the regional health insurance fund for salaried workers. Indirect costs and length of hospital stay were established via questionnaire. In contrast, Björneklett et al (2013) concluded that costs to society were not reduced with the intervention in its present form. They found that total costs for the intervention group (cost of sick leave and consumption of health services) were higher at all timepoints (2, 6, and 12 months) and this reached statistical significance at 12 months ($p=0.036$). As the authors did not have data on participant's actual income, they based sick leave costs on the average monthly income for Sweden of €2,900 which amounted to a sickness benefit of €73.62 per day. They calculated the economic cost of healthcare utilisation using the sum of the number of visits for (i) a primary care doctor (€192), (ii) a consultation with a medical specialist (€471), and (iii) a physiotherapist (€87), however lacked information on the costs of other healthcare visits to other healthcare specialists. When adding the cost of the intervention (€2,300) in addition to the costs of

sick leave and healthcare utilisation, the higher costs for the intervention group were statistically significant at all timepoints.

4.3.5.4 Effectiveness of Interventions on other Outcomes – Meta-Analysis

Limited meta-analysis was conducted on Global QoL and Physical Functioning QoL. Global QoL data were available for two studies at 3-4 months (Bolam et al 2019; Jong et al, 2018) (Figure 4.7), however there was no statistically significant difference between the intervention and control groups. At 3-4 months, Bolam et al (2019) observed an effect size of 0.22 (Hedge’s *g*) between RT-HIIT and Control groups (95% CI: -0.14, 0.57) and 0.21 (Hedge’s *g*) between AT-HIIT and Control groups (95% CI: -0.15, 0.57), whereas Jong et al (2018) observed an effect size of 0.04 (Hedge’s *g*) between groups (95% CI: -0.42, 0.51). Pooled analysis indicated an overall effect of 0.18 (95% CI: -0.06, 0.40). Heterogeneity measures indicated a *I*² value of 0.00 and *H*² value of 1.00.

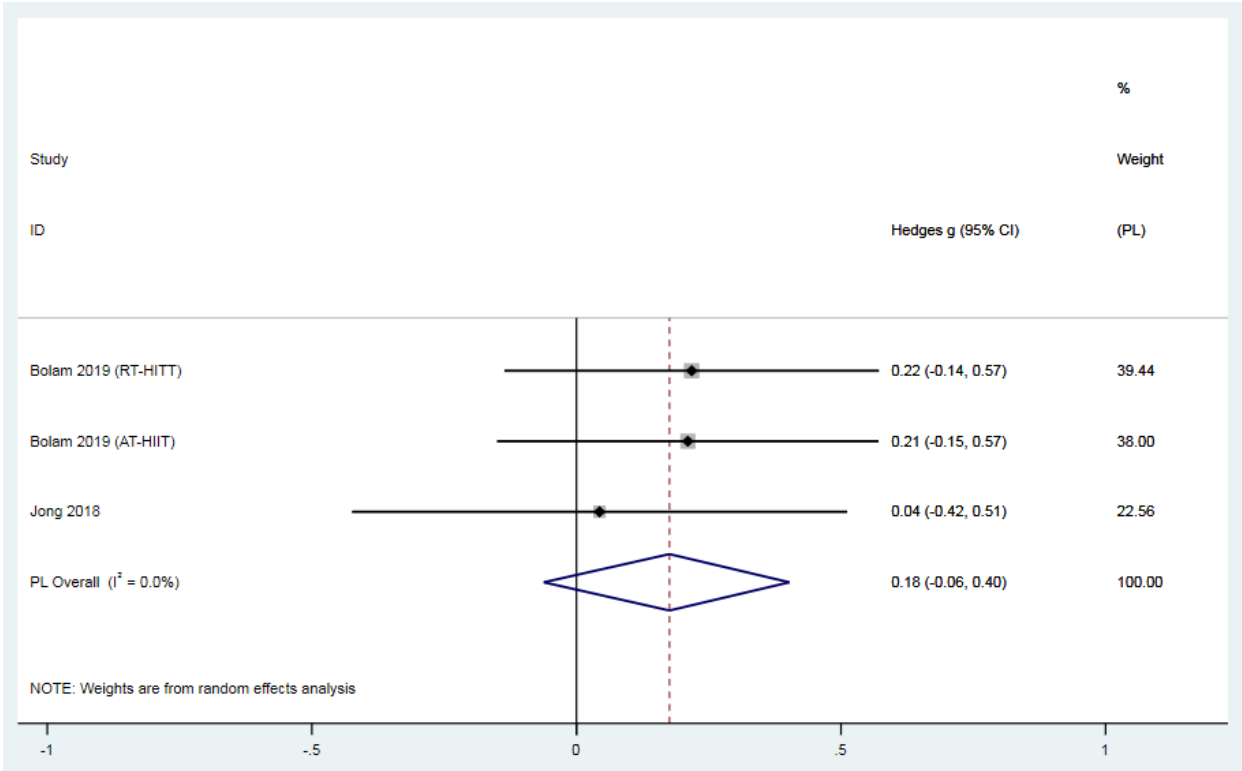


Figure 4.7: Meta-Analysis of Global QoL at 3-4 months

Taking into consideration the changes in values from baseline to 3-4 months for Global QoL, analysis indicated statistical significance for the interventions (Figure 4.8). Bolam et al (2019) observed an effect size of 0.39 (Hedge's *g*) between RT-HIIT and Control groups (95% CI: 0.04, 0.75) and 0.26 (Hedge's *g*) between AT-HIIT and Control groups (95% CI: -0.10, 0.63), whereas Jong et al (2018) observed an effect size of 0.40 (Hedge's *g*) between groups (95% CI: -0.08, 0.87). Pooled analysis indicated an overall effect of 0.35 (95% CI: 0.11, 0.58). Heterogeneity measures indicated a I^2 value of 0.00 and H^2 value of 1.00.

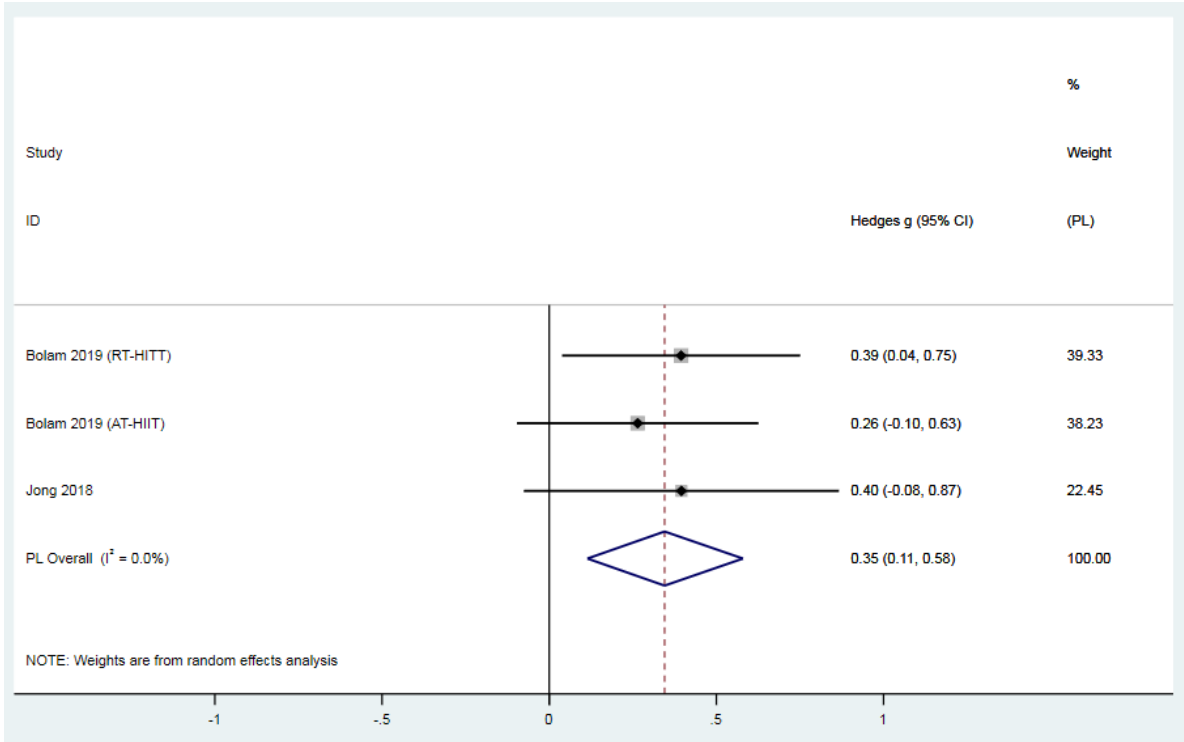


Figure 4.8: Meta-Analysis of Global QoL at 3-4 months (Change in Values from Baseline to 3-4 Months)

Physical Functioning QoL data were also available for the two studies at 3-4 months (Bolam et al 2019; Jong et al, 2018), indicating statistical significance for the interventions (Figure 4.9). At 3-4 months, Bolam et al (2019) observed an effect size of 0.49 (Hedge's *g*) between RT-HIIT and Control groups (95% CI: 0.13, 0.85) and 0.50 (Hedge's *g*) between AT-HIIT and Control groups (95% CI: 0.13, 0.86), whereas Jong et al (2018) observed an effect size of 0.05 (Hedge's *g*) between groups (95% CI: -0.42,

0.52). Pooled analysis indicated an overall effect of 0.39 (95% CI: 0.06, 0.66). Heterogeneity measures indicated a I^2 value of 0.00 and H^2 value of 1.00.

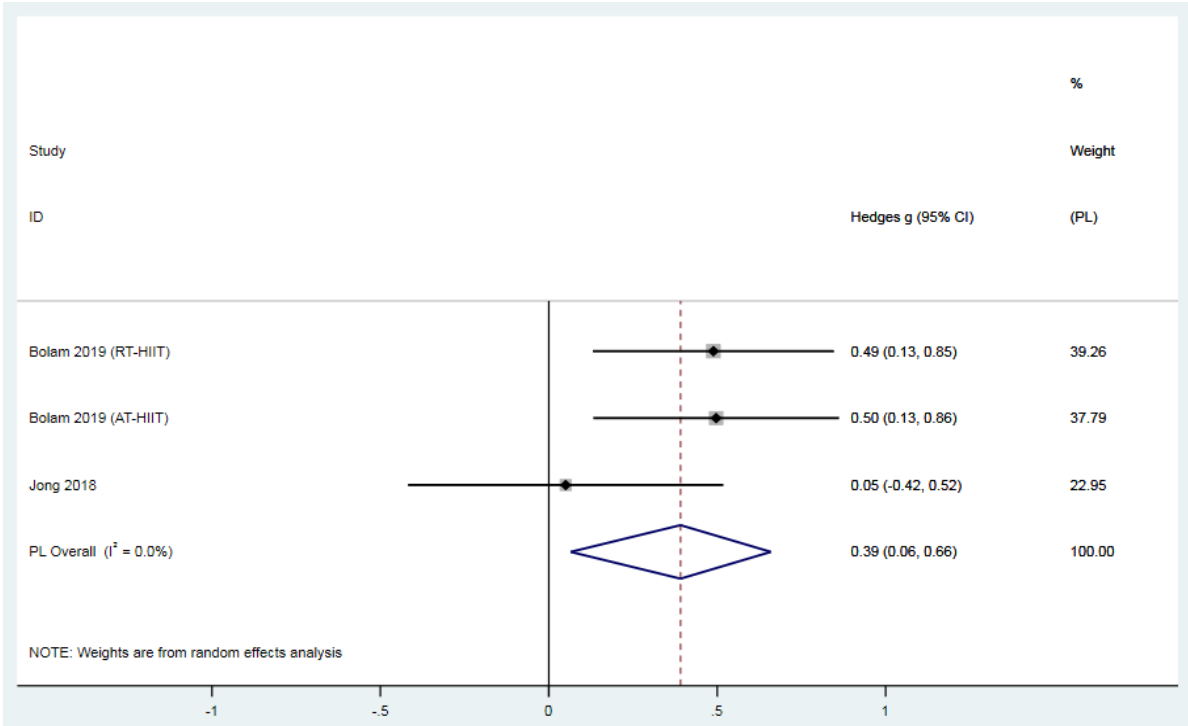


Figure 4.9: Meta-Analysis of Physical Functioning QoL at 3-4 Months

Taking into consideration the changes in values from baseline to 3-4 months for Physical Functioning QoL, analysis indicated statistical significance for the interventions (Figure 4.10). Bolam et al (2019) observed an effect size of 0.41 (Hedge’s *g*) between RT-HIIT and Control groups (95% CI: 0.05, 0.65) and 0.39 (Hedge’s *g*) between AT-HIIT and Control groups (95% CI: 0.03, 0.76), whereas Jong et al (2018) observed an effect size of 0.39 (Hedge’s *g*) between groups (95% CI: -0.08, 0.87). Pooled analysis indicated an overall effect of 0.40 (95% CI: 0.17, 0.63). Heterogeneity measures indicated a I^2 value of 0.00 and H^2 value of 1.00.

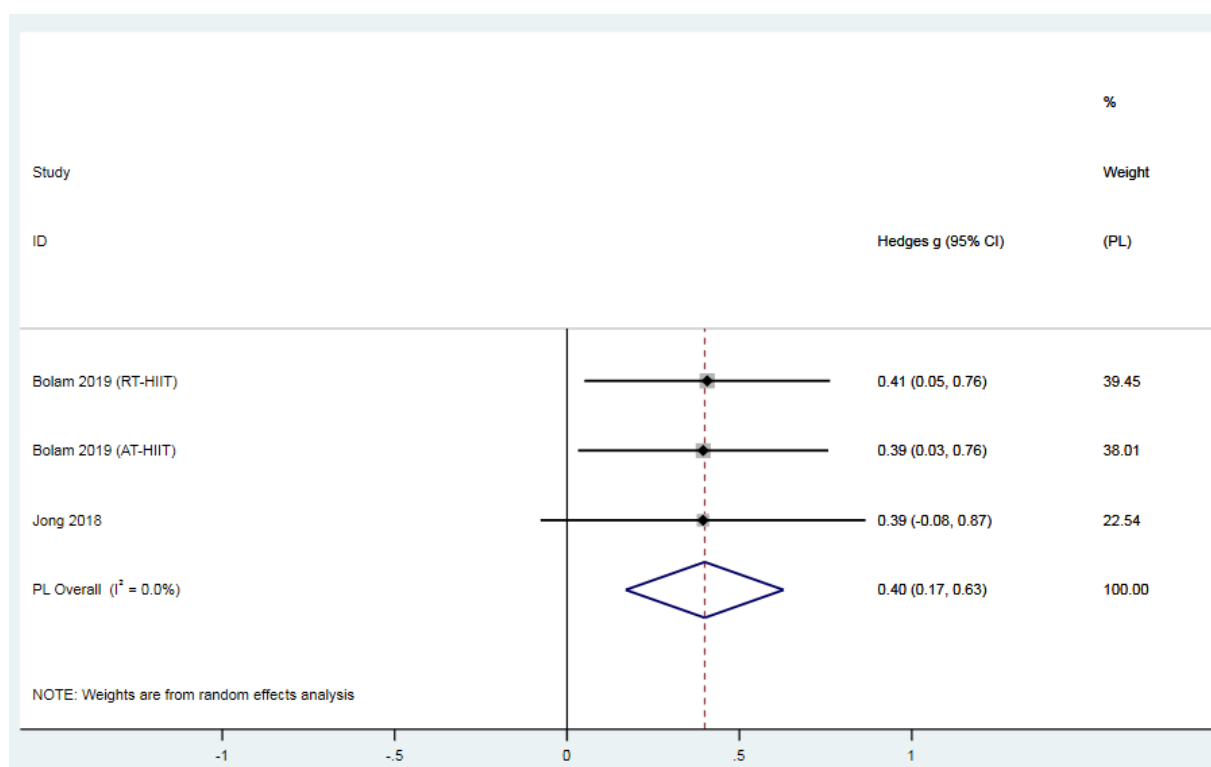


Figure 4.10: Meta-Analysis of Physical Functioning QoL at 3-4 Months (Change in Values from Baseline to 3-4 Months)

Cognition: No statistically significant differences were observed post-intervention between intervention and control groups across any of the three studies which reported cognitive outcomes.

4.3.6.5 Effectiveness of Interventions on other Outcomes – Narrative Synthesis

Physical: Of the seven studies reporting physical outcomes, three reported a statistically significant difference for patient-reported physical outcomes (Bolam et al, 2019; Jong et al, 2018; Rogers et al, 2009). These findings were not always positive, however. Rogers et al (2009) observed greater perceived joint stiffness in the intervention group compared to the control (mean difference = 1.1; 95% CI= 0.1-2.2; $d=0.70$; $p=0.04$). Despite this they also reported statistically significant differences for activity count and hip-to-waist ratio in favour of the intervention group, however it was not the purpose of this current review to explore outcomes other than patient-reported, and work outcomes. Ibrahim et al (2017) was the only intervention study to explore upper limb function, which could be important for women living with and beyond breast cancer,

but there were no statistically significant differences in overall DASH scores. Four studies reported fatigue outcomes, two of which reported statistically significant differences between intervention and control groups (Bolam et al, 2019; Jong et al, 2018). While both effect sizes were small, Bolam et al (2019) reported statistically significant differences between the RT-HIIT intervention group and Usual Care group in total cancer-related fatigue (-1.37(95% CI -2.70, -0.04) ($p<0.05$) (ES -0.06) and in Cognitive cancer-related fatigue (-1.47 (95% CI -2.75, -0.18) ($p<0.05$) (ES -0.28). While there were no statistically significant differences in the domain scores of both MFI and FQL in the Jong et al (2018) study, they did report a statistically significantly higher percentage of women in the intervention group (51%) experiencing fatigue reduction when compared to the control group (19%) at 3-months ($p<0.001$).

Psychological: Of the six studies which reported psychological outcomes, only two studies (Jong et al, 2018; Maguire et al, 1983) demonstrated statistically significant results. Jong et al (2018) found that while both intervention and control groups differed significantly at baseline with respect to anxiety and depression (where the intervention group scored more poorly), there were statistically significant improvements in anxiety in the intervention group at three ($p=0.011$) and six ($p=0.014$) months, compared to baseline. Despite this, there were no significant differences between the intervention and control groups at either three- or six-month timepoint. ANCOVA highlighted a significant difference for depression between both groups at the three-month timepoint, in favour of the intervention (yoga). Maguire et al (1983), on the other hand, found that participants in the control group were statistically significantly more dissatisfied with their prosthesis, in comparison to the intervention group. A recalculation of the chi square test based on data in the provided table indicated that the $X^2 = 6.66$ and $p=0.001$. Although there were no statistically significant differences between groups in Maunsell et al's (1996) study, both groups experienced reduced levels of psychologic distress between baseline and three months that reached statistical significance.

Quality of Life: Of the four studies reporting quality of life outcomes, three reported some improvements in quality of life, or components of QoL outcomes (Hubbard et al, 2013; Jong et al, 2018; Rogers et al, 2009). While there were no reported statistically significant differences between groups in the total scores of the EORTC-QLQ-C30 ($p=0.333$), Hubbard et al (2013) identified statistically significant differences between

groups on the Breast Cancer Subscale at six-months, in favour of the intervention group (intervention: 26.4 [SD = 4.65], control: 20.2 [SD = 4.68], $p=0.020$). Differences however were not sustained at the 12-month timepoint. Jong et al (2018) identified a statistically significant improvement in nausea and vomiting (an EORTC-QLQ-C30 item) for the intervention group at six-months ($p=0.003$), however no other items of the QoL measure met statistical significance. Finally, Rogers et al (2009) observed statistically significant improvements in social wellbeing for the intervention group compared to control, with a large effect size ($d=0.76$; $p=0.03$). Bolam et al (2019) were the fourth study to explore QoL outcomes, as measured by the EORTC-QLQ-C30, however did not find any statistically significant differences.

4.4 DISCUSSION

The objective of this review was to determine efficacy of rehabilitation interventions on work outcomes for women living with and beyond breast cancer, identify core elements of these interventions, and suitable measurement tools. Following review of the evidence-base, nine studies were identified that measured a work outcome, only three of which had a work component as part of the intervention. While there was some evidence of improvements in quality of life and physical sequelae across interventions, only one study (Mourgues et al, 2014) observed statistically significant differences for work outcomes. Outcome measures varied considerably across studies. Study heterogeneity limited meta-analysis within this review. Future research in developing and evaluating work-specific interventions for women living with and beyond breast cancer appears warranted.

4.4.1 Effectiveness and Cost-Effectiveness of Interventions in supporting Work and Health-Related Quality of Life Outcomes

Only one study observed statistically significant differences in work outcomes between intervention, and control groups, observing greater resumption of work and participation in overall work activities at 12-months for the intervention group (Mourgues et al, 2014). The success of this study could be partially explained by its

MDT format providing exercise, psychological and dietary advice or to the sample size which may have been more adequately powered than other studies. A recent Cochrane review identified moderate quality evidence for MDT interventions in enhancing RTW rates across all cancer types, underlining the potential effects of a multicomponent rehabilitative approach (de Boer et al, 2015). Despite this, some aspects of the intervention (e.g., thermal water treatment) may be impractical if applied to informing a work-focused intervention, where thermal water treatment facilities are not widely available in healthcare services. In addition, no work-related content was included in the intervention. Lack of statistically significant impact on work outcomes across the other studies can perhaps be explained by the fact that the majority of interventions did not specifically focus on work in their interventions. Evidence suggests that interventions which are designed to target management of a specific concern, result in significant effects on that specified outcome (Howell et al, 2017). While three studies in this current review included work components in their intervention, the content varied, and no statistically significant results were observed for work outcomes across the three studies (Björneklett et al, 2013; Hubbard et al, 2017; Maguire et al, 1983). This could be because there was insufficient work-specific content in the interventions or that the studies comprised of small sample sizes. For example, despite Hubbard et al. (2017) including work-specific content in their intervention, only 18 women participated. Future RCTs with larger samples may provide further insight into effectiveness using work-directed approaches.

It is well documented that treatment and disease-related symptoms such as cancer-related fatigue, cognitive changes, and anxiety can impact on work ability and could be targeted as part of a RTW intervention (Carlsen et al, 2013; Kamal et al, 2017; Todd et al, 2011). Therefore, physical, psychological and QoL outcomes were also examined in this current review. Outcomes differed widely across studies, with varying results making it challenging to offer definitive recommendations for the content and delivery of interventions to support return to work. Of the four studies measuring fatigue, significant improvements were observed only in a physical intervention (Bolam et al, 2019). Interventions which deliver aerobic exercise have previously been cited in a Cochrane Review as beneficial in reducing cancer-related fatigue (Cramp & Byron-Daniel, 2012). Another Cochrane Review reported limited evidence for psychosocial interventions in reducing fatigue unless specifically targeting fatigue (Goedendorp et al,

2009). An update of evidence is warranted however as the review was conducted more than a decade ago.

In contrast, of the four studies measuring the impact of interventions on QoL, three which reported improvements, delivered both physical and psychosocial interventions. This underlines the importance of a MDT approach in RTW interventions in targeting a holistic range of treatment- and disease-related factors that impact on work for women living with and beyond breast cancer. Interventions targeting QoL have varied considerably in participants, delivery and content making it difficult to arrive at a firm conclusion regarding effectiveness, although a Cochrane review tentatively concluded potential benefit of interventions which are educational and offer supportive attention (Galway et al, 2012). Some specific outcomes of interest that are known to impact on work, were under-reported. For example, financial status, social support and cognitive dysfunction were less commonly reported outcomes, but could be considered, particularly as they can impact on RTW (Islam et al, 2014; Sun et al, 2017). In addition, considering upper limb function could be important for women living with and beyond breast cancer, who are more likely to experience upper limb impairment compared to other cancer groups (Sun et al, 2017). Lymphoedema, for example, is known to compound RTW challenges where there may be restrictions in mobility or heavy lifting, for example (Boyages et al, 2016). A multicomponent approach in rehabilitation may help to address wide-ranging disease and treatment-related side-effects that impact on RTW (Bilodeau, Tremblay & Durand, 2017; Dong et al, 2020; Invernizzi et al, 2020).

There were few studies which reported intervention cost-effectiveness (Björneklett et al, 2013; Mourgues et al, 2014). This gap is important to note as economic evaluation is a key consideration for decision- and policy- makers and is also explicitly outlined as a key pillar for intervention evaluation under the MRC framework for complex interventions (Craig et al, 2008). Two of the nine studies reported cost-effectiveness outcomes for the respective interventions, observing contrasting results. One study found higher costs for the intervention group who typically sought greater use of healthcare services than the control group (Björneklett et al, 2013). This could be explained by education that women in the intervention group received on availability of healthcare professionals and self-management of symptoms. Greater self-awareness of one's own health status could lead to willingness to self-manage health and seek out

appropriate professional services. This could potentially result in reduced or self-managed co-morbidity in the future which could provide a cost-benefit to the intervention.

In contrast, Mourgues et al (2014) observed enhanced work outcomes and reported cost-effectiveness of the intervention at 12 months. It is not clear however if, like Björneklett et al., (2013) consultations with healthcare professionals other than medical professionals were also factored into analysis. Mourgues et al. (2014) did however use two facilitators as part of their intervention, whereas Björneklett et al. (2013) noted seven facilitators from a range of disciplines, which is likely to have impacted on overall cost. While MDT interventions have been identified as impacting RTW rates in cancer care (de Boer et al, 2015), researchers should take into consideration the overall cost impact if embedding a variety of disciplines into an intervention. Future intervention studies could factor in healthcare utilisation into CEA both in the short- and long-term and avoid small sample sizes which are considered a limitation when calculating CEA.

4.4.2 Core Elements and Delivery Format of Work-Related Interventions for Women Living With and Beyond Breast Cancer

Variability in the content and delivery of interventions, and unclear evidence of effectiveness for work outcomes make it challenging to offer definitive recommendations on the content or delivery of interventions that support return to work. Despite work outcomes measured across all studies, only three of the interventions included a specific work component as part of their content. These components included encouragement to return to the workplace (Maguire et al, 1983), an information session on the sick leave and insurance (Björneklett et al, 2013), and a vocational rehabilitation case management intervention which included referrals to other disciplines (Hubbard et al, 2013). Hubbard et al's (2013) was the only intervention to include a work-directed approach within the individualised interventions, when appropriate for the participant. A work-directed approach includes an intervention component 'aimed at the workplace by means of workplace adjustments such as modified work hours, modified work tasks, or modified workplaces and

improved communication with or between managers, colleagues and health professionals.’ (de Boer et al, 2015, p.7). While no statistically significant findings were observed from this intervention, participants within the intervention reported an average of 53 fewer sick days over the first six-months post-surgery compared to the control group. Non statistically significant results could be explained by underpowering of the study where only 18 women participated. Future randomised control trials with larger samples may provide further insight into the effectiveness of this type of intervention using work-directed approaches.

Only one study (Mourgues et al, 2014) reported statistically significant differences in work outcomes. Content in this intervention was MDT nature, including physiotherapy, consultation with a dietitian, thermal water treatment and daily two-hour physical activity. A Cochrane review (de Boer et al, 2015) exploring RTW interventions for all cancer cohorts, favoured MDT interventions where it was found that there was moderate quality evidence to demonstrate that MDT interventions which involved physical, psycho-educational, and/or vocational components led to higher RTW rates than usual care (RR 1.11, 95% CI, 1.03-1.16, $n=450$).

While there is some promise for MDT interventions where there are multiple disciplines involved, it is difficult to draw a conclusion on who should lead or co-facilitate a work-focused intervention. A variety of facilitators across many disciplines delivered the interventions in the included studies and stemmed mostly from a professional healthcare background. As reported in Phase I of this study (Chapter 3, Section 3.3.2), qualitative findings indicated inconsistency amongst healthcare professionals around whose role should lead in vocational assessment and rehabilitation. This is problematic as lack of clarity around whose responsibility it is to implement RTW programmes has been previously cited as a barrier in implementing RTW programmes (Tamminga et al, 2019). Occupational therapists were the only profession to suggest leadership in the role of RTW in Phase I of this research, however this perception stemmed from only two participants. Despite this, occupational therapists are trained to support vocational rehabilitation and have been identified as a key stakeholder in providing this type of rehabilitation (Tan et al, 2012). A stronger evidence-base is required to draw conclusive recommendations on facilitation.

4.4.3 Measuring Impact: What Outcomes are being Measured, and How?

While work outcomes were measured across all studies by self-report, they varied from quantifying number of working days/hours to whether the participant had returned to work (yes/no response). Measuring RTW by binary yes/no could be problematic where the definition of RTW is blurred. As Lamore et al. (2019) highlighted, RTW does not necessarily indicate that a previous lifestyle is completely restored, and there needs to be clarity as to the definition of RTW. Researchers could consider if work outcomes imply return to full-time work, part-time work, or perhaps a perceived satisfaction that the individual is satisfied with the outcome. While work outcomes were the primary outcome for this systematic review, they were considered the primary outcome in only three studies (Björneklett et al, 2013; Hubbard et al, 2013; Mourgues et al, 2014). One study (Ibrahim et al, 2014) did report work outcomes as a main outcome in the title of the paper but focused on upper limb function as a whole.

Variability in Patient Reported Outcome Measures (PROMs) across all studies, make it difficult to offer a recommendation on best practice in measuring other HRQoL outcomes. On only two occasions, did studies overlap in use of an outcome measure. The European Organisation for Research and Cancer Treatment Quality of Life Questionnaire (EORTC-QLQ-C30) was used by both Bolam et al (2019) and Jong et al (2018). The Functional Assessment of Cancer Therapy-Breast (FACT-B) was used by Rogers et al (2009) and Hubbard et al (2013), both measuring quality of life. Other outcomes which were most frequently reported included physical (e.g., fatigue, upper limb disability) and psychological sequelae (e.g., psychological distress) all of which are key components that could affect work performance or readiness to return to work. Financial status and social support were less commonly reported outcomes, but could also be key factors to consider, particularly as they can impact on the RTW process (Islam et al, 2014; Sun et al, 2017).

4.4.4 Theoretical Frameworks underpinning Rehabilitation Interventions

On reviewing health behaviour change theory underlying study interventions, no clear conclusions on a preferred or most effective model can be drawn. Of the nine studies, only three reported using a theoretical framework, all of which varied. This gap has been previously echoed for other rehabilitation interventions for those with cancer (Désiron et al, 2013; Lamore et al, 2019; Sun et al, 2017) and is noteworthy as incorporating insights from theory is recommended as a key consideration when developing complex interventions (Craig et al, 2008). In this current review, none of the theories reported in the three studies were specific to work rehabilitation. For example, Social Cognitive Theory (Bandura, 1986) which is often used in behaviour change interventions, was reported in one study (Rogers et al, 2009). This theory holds promise for understanding RTW motivations, expectations of efficacy, and predicting one's ability to achieve desired outcomes (i.e., work outcomes), but can be vague in operationalisation (Schultz et al, 2007). Similarly, while the Biopsychosocial model reported by Hubbard et al. (2013) is holistic in nature considering biological, psychological and social factors, its generic nature can limit its direct application to work rehabilitation research and practice (Engel, 1977; Schultz et al, 2007). With this in mind, the evidence base beyond this current review can be explored for more specific models to occupational rehabilitation. A Cancer and Work Model was developed by Feuerstein et al., for all cancer cohorts, it includes factors that can be addressed by healthcare professionals, individuals living with or beyond cancer, and employers, and could be considered in intervention development (Feuerstein et al, 2010).

4.4.5 Increasing Rigour in Study Designs

This systematic review provides an update on previous literature exploring the topic (Hoving et al, 2009) where only one of four studies identified was controlled. In contrast, all nine studies in this review were RCT in design, three of which were pilots, potentially reducing selection bias. This is a promising indication that more rigorous methods are being employed in intervention evaluation. Furthermore, several protocols for upcoming RCTs in the area have been published (de Groef et al, 2019; Sheppard et al, 2019; Stevens et al, 2020), and it is likely that there will be an increased evidence

base for researchers to further explore the feasibility and effectiveness of such work-related interventions in the future.

In addition, there are ongoing limitations in programme development, where there is a lack of piloting and feasibility studies. Several models of intervention development (Craig et al, 2008; Czajkowski et al, 2015) advocate for pilot testing of interventions. Despite this, only three out of the nine studies reported were pilots, and the six remaining RCTs did not report prior pilots to the full trial. While recruitment, adherence and attendance rates were referred to briefly in four papers (Björneklett et al, 2013; Bolam et al, 2019; Ibrahim et al, 2014; Maunsell et al, 1996), feasibility was only explicitly reported in two (Hubbard et al, 2013; Rogers et al, 2009). The RE-AIM Feasibility framework (Dzewaltowski et al, 2004) was used to capture feasibility in the former study. Lack of piloting and exploring of feasibility, can lead to issues at a later stage. For example, Jong et al (2018) did not report any pilots or exploration of feasibility or acceptability and noted marked issues in recruitment. They estimated it would take two years to recruit their sample of 104 women, however only achieved 50% of this at the two-year mark. Despite adding an additional recruitment site, rates remained a challenge. The piloting and feasibility of interventions should be considered in future studies.

4.4.6 Strengths and Limitations

There are a lack of studies specifically examining return to work interventions. This review offers a collective insight into current evidence available in the area. A systematic search process was applied with no restriction to year. Backwards (screening of references cited at the end a text) and forwards (screening of citations of a text) chaining was also completed on any relevant texts to ensure a complete overview of RTW interventions for women living with and beyond breast cancer. The search strategy was also reapplied in April 2021, to verify that there were no additional texts to add. Where a study was deemed overall either ‘high’ or ‘unclear’ risk, attempts were made to contact corresponding authors (e.g., via corresponding email or ResearchGate) for supplementary information, however with no success. While it could be argued that blinding is not feasible due to the nature of the complex interventions reported in the

included studies, and should therefore not be considered a weakness, it remains the case that lack of blinding can cause a bias, even if that blinding is not feasible.

Limitations also exist, however. First, heterogeneity of the interventions precluded meta-analysis for many outcomes which may have offered a statistical measure of the impact of interventions for women living with and beyond breast cancer. Despite this, there was limited meta-analysis completed where possible however it is acknowledged that results need to be taken with great caution where only two studies could be pooled. There are numerous arguments for and against the meta-analysis of few studies. Valentine, Pigott & Rothstein (2010) argue however that given the need for a conclusion, at least two studies are required for meta-analysis as all other synthesis techniques are less transparent. Second, a limit was applied to eligibility criteria for English-test only. This was for practical reasons. However, this may have restricted other potential texts from being included in the final review. Third, no PPI input was sought for this phase which could have provided valuable inputs including (but not limited to) the initial stages of the review (e.g., forming the research question) or supporting the interpretation of findings. Finally, only nine studies were included in the final review, of which only three included a work-related component to the intervention. As such, findings should be interpreted with caution.

4.4.7 Recommendations for Future Research: Further research in the development and evaluation of interventions that support the return to work for women living with and beyond breast cancer is warranted. Despite enhanced rigour in the design of studies over the past decade, there remains a paucity in piloting and testing feasibility of interventions. Future research could incorporate a model of intervention development into the study design. Furthermore, sufficient sample sizes to ensure an adequately powered study are necessary to make definitive recommendations on the content and delivery of work interventions for women living with and beyond breast cancer.

4.4.8 Recommendations for Clinical Practice: In the absence of a sufficient evidence-base and the ability to make definitive recommendations, clinicians could consider MDT interventions to support women living with and beyond breast cancer to return to

work. A Cochrane review (de Boer et al, 2015), identified moderate quality evidence in enhancing RTW rates across all cancer types using a MDT approach. While interventions which did include a work component to their intervention did not observe any statistically significant results, the value of work components cannot be ruled out, particularly where the only study to use a work-directed approach (e.g., work accommodations and modifications) was underpowered (Hubbard et al, 2013).

4.4.9 Conclusion

This systematic review has identified that studies reporting interventions to support women living with and beyond breast cancer to return to, or remain at, work remain scarce. Of interventions that do exist, variability in content, and lack of evidence of the effectiveness on work outcomes, make it challenging to offer definitive recommendations for delivery of work-focused interventions. Despite this, studies of higher quality have emerged in the past decade with promising potential for an expanded evidence base in the future. Future research in developing and evaluating work-related interventions for women living with and beyond breast cancer is therefore warranted.

CHAPTER FIVE: CONSENSUS STUDY

PHASE III STUDY: Prioritising the content, format and delivery of a work-focused intervention for women living with and beyond breast cancer using the nominal group technique online

5.1 INTRODUCTION

Key findings from the qualitative-descriptive study (Phase I) of this research identified potential work-focused content for a RTW intervention, however there were mixed perceptions on intervention delivery. In addition, key findings from the systematic review (Phase II) identified that studies reporting interventions to support women living with and beyond breast cancer to return to, or remain at, work remain scarce, and that for interventions that do exist, variability in content, and lack of evidence of the effectiveness on work outcomes, make it challenging to offer definitive recommendations for delivery of work-focused interventions. It is acknowledged under the MRC framework, that a “series of studies may be required to progressively refine the intervention before embarking on a full-scale evaluation” (Craig et al, 2008 p.2). Therefore, an additional phase (Phase III) was included to prioritise both intervention content and delivery among key stakeholders for a RTW intervention that would be tested in the final phase of this research.

The aim of this study was to seek consensus among key stakeholders on the content and delivery of a work-focused intervention for women living with and beyond breast cancer.

Research questions:

1. What is the preferred content for a work-focused intervention to support work outcomes in women living with and beyond breast cancer?
2. What format should the work-focused intervention take? (e.g., group-based, one-to-one, or blended)?

3. How should the work-focused intervention be delivered? (e.g., online, face-to-face, blended)?
4. If face-to-face, where should the work-focused intervention be delivered?
5. If online, where should the work-focused intervention be delivered?
6. What length should each individual session of the work-focused intervention be?
7. What overall length should the work-focused intervention be?

5.2 METHODS

5.2.1 Study Design: As part of this intervention development process, a consensus-building study using the Nominal Group Technique (NGT) was conducted. The reporting of this study draws on but largely extends on an accepted paper for publication in *WORK* (Algeo, Bennett & Connolly, in press-b). The NGT is an adaptable consensus method that seeks consensus in groups of individuals through four steps; (i) idea generation, (ii) sharing of ideas, (iii) refining ideas, and (iv) ranking preference for ideas through anonymised voting (Delbecq, Van de Ven & Gustafson, 1975):

- (1) *Idea generation:* During idea generation, a question is posed and participants are provided a silent time period in which they can reflect on their responses. During this period, participants are asked to write down as many items in response to that question. A pre-defined number of questions are provided to participants prior to data collection.
- (2) *Round robin discussion (sharing of ideas):* The facilitator of the group then asks one participant at a time to provide a single idea to the group in a ‘round robin’ fashion. This is repeated across the group until all ideas are exhausted. Participants may think of additional ideas during the round robin discussion but wait their turn before sharing with the wider group. Each item is recorded via a shared Microsoft® Word document.

- (3) *Refining ideas*: Once ideas are exhausted, all recorded items are clarified and refined. Where there is agreement among the group, similar ideas are grouped together into themes. Discussion is important during this step to ensure that all participants interpret each refined idea in the same way.
- (4) *Ranking preference through anonymised voting*: Once topics/themes were refined, participants then prioritised items by ranking them anonymously using the Mentimeter platform, a third-party platform specialising in online interactive voting and ranking. The number of items that participants rank depended on the topic, with ranking of five topics common in the literature (Delbecq, Van de Ven & Gustafson, 1975; McMillan et al, 2014).

While the design is typically conducted face-to-face, the study was adapted to an online format due to public health restrictions of Covid-19. The NGT can be a valuable approach in developing a work-focused intervention as it facilitates key stakeholders to express views on key components of the intervention, as well as how to best approach implementation. Limitations exist with the method however, where it is thought that the Delphi consensus method may offer a clearer numerical description of level of agreement, determined in advance (McMillan, King & Tully, 2016). Despite this, it was chosen over the Delphi Consensus technique for pragmatic reasons; results were captured in real-time, and the research team were able to use results to inform the intervention immediately, where highest ranked items were deemed acceptable. Full ethical approval was granted on the 7th June 2020 by the Faculty of Health Sciences Research Ethics Committee [REF 2020403] (See Appendix L).

5.2.2 Participants and Sampling: Key stakeholders including (i) women living with and beyond breast cancer who have direct experience in RTW post-diagnosis, (ii) occupational therapists with experience in supporting RTW post-cancer and/or clinical oncology experience, (iii) occupational therapy managers with experience in resource allocation in an Irish setting, (iv) directors/co-ordinators of cancer support centres with experience in survivorship interventions, and (v) policy informers who are involved with developing Irish policy, were invited to participate in the online discussion conducted in August 2020 (Table 5.1). These stakeholders were chosen as they either

had (i) direct experience in RTW post-cancer diagnosis or (ii) had an influence in how survivorship interventions are facilitated, resourced and/or implemented. All participants were required to be able to attend a group-based online discussion. Purposive sampling was used in participant selection and involves choosing a sample based on similar or identical traits; in this case, key stakeholders who have experience (across different perspectives) in RTW during and after cancer.

Table 5.1: Inclusion Criteria

Women living with and beyond breast cancer	Occupational therapists	Occupational therapy managers	Directors of cancer support centres	Policy informers in cancer survivorship
Age 18-66 years (working age)	Have clinical experience in providing vocational rehabilitation interventions to individuals with cancer and/or have clinical experience in oncology.	Work in a health-related service providing occupational therapy services to individuals with cancer and have responsibility for occupational resource allocation in oncology services in any Irish setting.	Have experience in overseeing/co-ordinating a variety of cancer survivorship programmes (1:1, group, mixed)	Have experience in developing and/or influencing cancer-related policy in Ireland.

5.2.3 Sample Size: While NGTs typically vary between two to 14 members (McMillan, King & Tully, 2016), a maximum of seven is recommended (McMillan et al, 2014). However, because a range of stakeholders were required at this workshop, up to three of each key stakeholder were recruited via social media (Twitter). This was to account for any potential attrition while still ensuring

representation of each cohort. Due to pragmatic reasons, one workshop was facilitated, however greater representation would have been possible had multiple workshops been facilitated, each hosting one cohort.

5.2.4 Study Procedure: The study was advertised via social media in July 2020, where retweeting was encouraged. Potential participants were invited to contact the researcher by email or telephone to express interest in the study. The researcher then issued the PIL (Appendix M), consent form (Appendix N), and participant pack (Appendix O) for the potential participant to consider. The participant pack included the agenda for the consensus workshop, as well as questions to be posed during the workshop, for the participant to reflect on prior to attending the workshop. Signed consent forms were returned via email. The consensus workshop was hosted using the Microsoft® Teams platform and voting/ranking conducted using the MentiMeter platform (www.mentimeter.com). MentiMeter is a third-party platform specialising in online interactive voting and ranking. Seven questions were posed throughout the workshop. Once a question was posed, participants were invited to complete a ‘silent generation of ideas’, where they wrote down ideas to address the question posed. Once complete, the facilitator completed a ‘Round Robin’, asking the group to share their ideas, until all ideas were exhausted. All ideas were written up onto a Microsoft® Word document and shared with participants in real-time online. Participants were then asked to group items together into more targeted themes on which they could vote. Once topics/themes were refined, participants then prioritised items by ranking them anonymously using the MentiMeter platform. The number of items that participants rank depends on the topic, with ranking of five topics commonly recommended (Delbecq, Van de Ven & Gustafson, 1975; McMillan et al, 2014) however, this can be increased. Results were available in real-time, where the participants could view the results to each question posed.

5.2.5 Data Collection: An online workshop using the NGT was conducted. As part of the process, participants were posed a question, asking them to generate ideas around a particular topic, share and refine them, and then rank in relation to preference.

Questions posed included:

- What content should be included and prioritised for a work-focused intervention?
- What format should the intervention adopt? (e.g., Group-based, one-to-one etc)
- How should a work-focused intervention be delivered? (e.g., Online, face-to-face, telephone, etc)
- If face-to-face, in what service setting should the intervention be delivered?
- If online, where would the intervention be best set?
- What length should each individual session be?
- What overall length should the intervention be?

5.2.6 Data Analysis: Voting responses were captured by MentiMeter and automatically populated onto an Excel spreadsheet which weighted and ranked each item. Higher scores indicate higher preference (McMillan, King & Tully, 2016). For example, for six items, the most important item scores six, and the least preferred item, scores one point. Individual rank scores were added for each item and ranked based on total scores.

5.3 RESULTS

Twelve key stakeholders participated in the workshop; two women living with and beyond breast cancer who had returned to work, three directors of cancer support centres, three occupational therapists, three policy informers in cancer survivorship services in Ireland, and one occupational therapy manager. Participants voted only on items that they perceived as suitable. For example, if a participant did not feel that an acute hospital was a suitable setting for a face-to-face delivery of the intervention, they could choose not to include it in any ranking. As such, on some occasions, not all items were voted on by all participants. The workshop took place over two hours and 45 minutes in August 2020.

Content: Several categories for content were generated by participants and refined into six superordinate categories following discussion (Appendix P). Six topics were generated by participants as core components for a work-focused intervention (Table 5.2).

Table 5.2: Ranked Preferences for Intervention Content

Content	Individual rank scores	No. of votes	Total group rank scores
Developing an RTW plan: A personal roadmap	6,6,6,6,5,5,5,5,4,2,1,1	12	52
Employment legislation, rights, and entitlements	6,6,6,6,6,4,4,4,3,3,2,1	12	51
Managing psychological side-effects in the workplace	6,5,5,5,4,4,4,3,3,3,2,2	12	46
Managing cancer-related fatigue and cognition in the workplace	6,6,5,5,3,3,3,3,2,2,2,1	12	41
Communicating with employers and colleagues	5,5,5,4,4,4,3,2,2,1,1,1	12	37
Managing physical side-effects in the workplace	4,4,3,3,2,2,2,1,1,1,1	11	24

Highest ranked preference = 6 points, second highest ranked preference = 5 points, etc.

Format and delivery: Participants were posed two NGT questions; the format and delivery of an intervention. The highest-ranking preference was for a blended format (group-based with an individual one-to-one component) with nine first preference votes (Table 5.3). The second highest preference was for a group-based intervention, followed by an individual (one-to-one) intervention which had no first preference votes. Most participants opted for a blended approach to the intervention delivery i.e., face-to-face and online (Table 5.4). This was followed by face-to-face, online, and via telephone, as second, third and fourth preference, respectively. Nine of the 12 participants voted a blended approach as their first preference for delivery. Every participant ranked the use of a telephone as their lowest preference. Face-to-face format received three first preferences and eight second preferences, whereas an online format received one second preference and 11 third preferences.

Table 5.3: Ranked Preferences for Intervention Format

Format	Individual rank scores	No. of votes	Total group rank scores
Group and individual	3,3,3,3,3,3,3,3,2,2,2	12	33
Group	3,3,3,2,2,2,2,2,2,1,1	11	23
Individual	2,2,1,1,1,1,1,1,1,1	10	12

Highest ranked preference = 3 points, second highest ranked preference = 2 points, etc.

Table 5.4: Ranked Preferences for Intervention Delivery

Delivery	Individual rank scores	No. of votes	Total group rank scores
Face-to-face and online	4,4,4,4,4,4,4,4,3,3,3	12	45
Face-to-face	4,4,4,3,3,3,3,3,3,3,2	12	38
Online	3,2,2,2,2,2,2,2,2,2,2	12	25
Telephone	1,1,1,1,1,1,1,1,1,1,1	12	12

Highest ranked preference = 4 points, second highest ranked preference = 3 points, etc.

Setting: Participants discussed the setting where the intervention should be delivered. Both face-to-face and online settings were explored. For a face-to-face setting, a ‘blended setting’ received the highest ranking with seven first preference votes and was defined by participants as a mix of at least two settings (e.g., Cancer Support Centre and Local Community Hall) to provide greater reach (Table 5.5). Cancer Support Centres were the second highest ranked setting for face-to-face interventions, receiving five first preference votes, and six second preference votes.

Table 5.5: Ranked Preferences for Intervention Setting (Face-to-Face)

Setting (face-to-face)	Individual rank scores	No. of votes	Total group rank scores
Blended (>2 settings)	5,5,5,5,5,5,5,4,4,4,3	12	54
Cancer support centre	5,5,5,5,5,4,4,4,4,4,2	12	51
Community centre/parish hall	4,4,3,3,3,3,2,2,2,1,1	12	29
Primary care centre	3,3,3,3,3,3,2,2,2,2	10	26
Acute hospital	3,2,2,2,1,1,1,1,1,1	10	15

Highest ranked preference = 5 points, second highest ranked preference = 4 points, etc.

For an online delivery, participants generated six platforms on which to vote (Table 5.6). Zoom Video Communications, Inc. was ranked highest. Google Meet and Microsoft® Teams earned equal points and equal first preferences, however as Google Meet scored higher second preferences in total, it was considered second ranked preference. The Attend Anywhere platform (used by Ireland's national health service) was the lowest ranked platform.

Table 5.6: Ranked Preference for Intervention Setting (Online)

Setting (online)	Individual rank scores	No. of votes	Total group rank scores
Zoom Video Communications, Inc.	6,6,6,6,6,6,4,4,4,3,1	12	56
Google Meet	6,6,5,5,5,4,4,3,3,2,2,1	12	46
Microsoft® Teams	6,6,5,5,4,4,4,3,3,2,2,2	12	46
WebEx	6,5,5,5,5,4,3,3,2,2,2,1	12	43
Skype	5,5,4,3,3,3,3,2,2,1,1,1	12	33
Attend Anywhere	6,5,4,3,2,2,1,1,1,1,1,1	12	28

Highest ranked preference = 6 points, second highest ranked preference = 5 points, etc.

Intervention and session length: Participants discussed and voted on two temporal aspects of the intervention. First, the overall length of the intervention was discussed. Following brainstorming, only two options were generated for voting: four or six weeks duration. Following voting, six weeks was prioritised for overall length of delivery with eight first preferences votes (Table 5.7). Second, the overall length of each session was discussed. Following brainstorming, three options for the length of each session were identified and voted on: (1) 90-120 minutes (with tea break before or after), (2) 60-90 minutes (with tea break before or after), (3) 120-150 minutes (with tea break during the session) (Table 5.8).

Table 5.7: Ranked Preferences for Intervention Length

Overall length	Individual rank scores	No. of votes	Total group rank scores
Six weeks	2,2,2,2,2,2,2,2,1,1	10	18
Four weeks	2,2,2,2,1,1,1,1,1,1,1	12	16

Highest ranked preference = 2 points, second highest ranked preference = 1 point

Table 5.8: Ranked Preferences for Session Length

Session length	Individual rank scores	No. of votes	Total group rank scores
90-120 minutes (tea break before/after)	3,3,3,2,2,2,2,2,2,2	11	25
60-90 minutes (tea break before/after)	3,3,3,3,3,2,1,1,1,1	11	24
120-150 minutes (tea break in between)	3,3,3,2,1,1,1,1,1	9	16

Highest ranked preference = 3 points, second highest ranked preference = 2 points, etc.

5.4 DISCUSSION

From the NGT consensus workshop, a six-week group-based intervention with a single individual session was prioritised. Sessions lasting 90-120 minutes were preferred and consensus on content included a personalised RTW plan, employment rights and benefits, and managing common treatment side-effects. Community-based settings were the preferred delivery site over the acute setting for face-to-face interventions, with Zoom Video Communications, Inc. ranked the preferred online platform.

5.4.1 Content and Blended Approaches in Format

All suggested content discussed by participants was work-specific. Despite employment and cancer being advocated as a key area for research, a Cochrane review observed that there are no specific work-focused interventions across any cancer cohort, citing the finding as “remarkable” (de Boer et al, 2015, p.20). Instead, interventions are typically aimed at reducing physical or psychosocial sequelae and only sometimes include a work component as part of the overall content. Evidence suggests that interventions which are designed to target management of a specific concern, such as work, result in significant effects on that specified outcome (Howell et al, 2017). Much of the content prioritised in this study was related to education on self-management of treatment- or disease-related symptoms, within the context of work. For example, cancer-related fatigue was prioritised as a topic, but content included recommendations for a phased

RTW, work-life balance, and prioritising work tasks. Fatigue, cognitive changes, physical and psychological side-effects have all been shown to impact negatively on RTW yet are amenable to change and could be targeted in a work-focused intervention to enhance work outcomes (Carlsen et al, 2013; Sun et al, 2017; Todd et al, 2011). Where there is lack of evidence for work-focused interventions, future studies can explore the impact and acceptability of such content on enhancing work outcomes.

Findings of this study also indicated a higher preference for blended approaches in format (individual and group sessions) and hosting (face-to-face vs. online) of a work-focused programme. However, O'Connor et al (2019) reported that, there is no one-size-fits-all approach to the delivery of survivorship programmes and therefore perhaps a blended approach may have been ranked highest by participants in this study out of uncertainty. Despite this, use of the NGT offers insight into subsequent preferences, where a group format with face-to-face delivery were favoured by participants. There are potential advantages in delivering a work-focused intervention in a blended format. It is widely acknowledged that group-based interventions can provide a platform for peer-support and learning (Hu et al, 2019), whereas adding an additional individual session to the intervention could overcome the complexities of specific job roles. While tested interventions have typically been either group-based or individual, the testing of blended approaches is warranted.

5.4.2 Face to Face and Online Settings

In this study, community-based settings were the preferred location for delivery of a face-to-face intervention over a hospital setting. This is not always reflected in practice, where often previous interventions have been facilitated in the clinical setting. A Cochrane Review exploring the impact of interventions on work outcomes among all cancer cohorts, reported that 13 of 15 interventions were based in hospitals (de Boer et al, 2015). The impact and implementation of community-based cancer survivorship interventions has been previously successful, demonstrating potential promise for delivery of work-focused interventions in the community setting (Boland et al, 2019; Gibbons et al, 2020). In recent times, however, the Covid-19 pandemic has necessitated health-related care to be delivered virtually. For this reason, participants in this study were also asked to consider preference for an online platform in which Zoom Video

Communications, Inc. was the highest ranked. Zoom Video Communications, Inc., a cloud-based platform for video and audio conferencing, is relatively novel and has observed exceptional growth since the pandemic (Tilley, 2020). Because of the novelty of adopting Zoom Video Communications, Inc. as a telehealth platform, there is limited evidence into its acceptability and usability. Despite this, emerging evidence suggests promise for the implementation of cancer survivorship programmes using Zoom Video Communications, Inc. One study observed a surge in participation having converted an interdisciplinary cancer survivorship wellness group programme to telehealth using Zoom Video Communications, Inc., however, did not report participant perceptions of Zoom Video Communications, Inc. itself (Jhaveri et al, 2020). Future studies for web-based interventions could consider the acceptability and usability of cloud-based platforms used.

5.4.3 Temporal Factors of a Work-Focused Intervention

The overall length of time for an intervention and sessions is also important to consider. Findings of this study indicated a preference for a six-week intervention with weekly sessions of 90-120 minutes each. In general, intervention and session length vary widely across cancer survivorship interventions and while overall programme length is regularly reported, specific sessions lengths can be underreported. Timeframes of sessions could be adapted depending on an in-person or online intervention. For example, there are several successful survivorship programmes hosted face-to-face over two and a half hours, but this could potentially be fatiguing if hosted in an online format (Boland et al, 2019; Gibbons et al, 2020). Online interventions, on the other hand, are typically shorter per session varying from 30 minutes to 1-2 hours (Bantum et al, 2014; Grimmer et al, 2013; van den Berg, 2015). The timing of programmes should be carefully considered based on the context in which they are hosted. Participant perceptions could also be captured to determine feasibility of session length online.

5.4.4 Strengths and Limitations

This study offers a novel insight into stakeholder perspectives when informing a future work-focused intervention. To the best of knowledge, the NGT has not been used as a method to prioritise a work-focused intervention for cancer until now. The NGT can offer several strengths; It increases the likelihood of equal participation for all groups members and limits researcher bias in analysis. Limitations were also identified. For practical reasons, one workshop was hosted to determine priorities for a work-focused intervention across five cohorts. However, it may have added value to conduct independent workshops for each cohort which could have highlighted comparison of priorities between groups and could have provided a wider perspective with a larger number of participants. Furthermore, additional topics could have been explored such preference for MDT input however were not included due to time constraints. Finally, no other healthcare professionals beyond occupational therapists were sought to be included in the sample. This is a potential limitation as other disciplines may have offered valuable insights for intervention prioritisation. Despite this, several cancer support centre and policy informer participants stemmed from a nursing background, and previous research (Phase I) sought perceptions and experiences from a variety of healthcare disciplines to inform the intervention.

5.4.5 Impact on Future Research

Recommendations for future research include pilot and feasibility testing of a work-focused intervention for women living with and beyond breast cancer. According to the MRC framework, following the development stages of an intervention, the next stage should be feasibility and piloting (Craig et al, 2008). In this case, testing procedures, estimating recruitment and retention, and determining acceptability prior to evaluation and implementation of an intervention.

While the NGT design is traditionally conducted in a face-to-face format (Delbecq et al, 1975), there may be promise in conducting the NGT online in future consensus studies. Conducting this Phase III research online enabled a diverse range of stakeholders nationwide, attend the once-off meeting which might not have been possible to co-ordinate in a face-to-face format. Contextual factors such as commute time and

parking/accessibility to location have previously been cited as barriers in face-to-face research participation and were negated in this instance (Boland et al, 2018; Risendal et al, 2013). Further research exploring in-depth the use of the online NGT as a methodology is warranted. The use of online workshops using the NGT for group decision-making for research is promising and could be considered for other cancer cohorts in the future.

5.4.6 Impact on Clinical Practice

This study adds clarity on preferences amongst key stakeholders in Ireland towards a work-focused intervention for women living with and beyond breast cancer. Clinicians interested in addressing work outcomes could consider work-specific content in the areas of fatigue, cognition, physical and psychological side-effects, education around employment rights and benefits, and communication strategies to manage employers and colleagues. Zoom Video Communications, Inc. could be offered as a telehealth platform, pending local policies, due to overall familiarity with the medium. Community-based locations could be more conducive to survivorship programmes than the acute setting although the acute setting is imperative in co-ordinating a clear survivorship pathway for those living with and beyond cancer.

5.4.7 Conclusion

The focus of this online NGT meeting was to prioritise the preferred content and delivery of a work-focused intervention for women living with and beyond breast cancer. A six-week predominantly group-based programme was co-designed with key stakeholders. Content prioritised included managing physical and psychological side-effects in the workplace, with particular attention to cancer-related fatigue and cognition, employer-employee communication, and employment legislation, rights and entitlements. While a blended format (face-to-face and online) was prioritised, the potential necessity for an online intervention was acknowledged, and Zoom Video Communications, Inc was the preferred the platform of choice for online delivery. A pilot of the proposed intervention will be conducted to test for feasibility and acceptability.

CHAPTER SIX: SINGLE-ARM FEASIBILITY AND QUALITATIVE- DESCRIPTIVE DESIGN

PHASE IV STUDY: Evaluating the feasibility of a self-management intervention to support return to work for women living with and beyond breast cancer: A single-arm feasibility study and qualitative-descriptive design

6.1 INTRODUCTION

Findings of Phases I, II and III of this research informed the *Work and Cancer* intervention (Figure 6.1) as per the MRC Framework for the development of complex interventions (Chapter 1, Section 1.2). Findings from the qualitative-descriptive study (Phase I) underlined the importance of addressing physical and psychological sequelae of breast cancer and its treatment, where frequently discussed symptoms included cancer-related fatigue, cognitive dysfunction, psychological distress, and physical sequelae such as lymphoedema, hot flushes, and sensory changes. Effective employer-employee communication and awareness of employment rights and entitlements in the RTW process also informed intervention content (Algeo, Bennett & Connolly, in press-a). Findings also indicated mixed perceptions on how a RTW intervention should be delivered. For example, there were varied preferences for group and individual formats, as well as session length from one hour to half a day.

Phase II was a systematic review to determine efficacy of rehabilitation interventions on work outcomes for women living with and beyond breast cancer, identify core elements of these interventions, and suitable measurement tools. Findings of the review identified no standardised work-specific outcome measures used to measure work outcomes, and a variability in PROMs across all studies. Findings also underlined the scarcity of work-focused interventions for women living with and beyond breast cancer and highlighted

variability in the content and delivery of RTW interventions (Algeo, Bennett & Connolly, 2021).

Therefore, a consensus study (Phase III) was undertaken to prioritise the content and delivery of the *Work and Cancer* intervention among key stakeholders in Ireland (Algeo, Bennett & Connolly, in press-b). A six-week predominantly group-based intervention was co-designed with key stakeholders. Content prioritised included managing physical and psychological sequelae of cancer and its treatment in the workplace, with particular attention to cancer-related fatigue and cognition, mental and physical health, employer-employee communication, and employment legislation, rights and entitlements. While a blended format (face-to-face and online) was prioritised, the potential necessity for an online intervention was acknowledged, and Zoom Video Communications, Inc was the preferred platform of choice for online delivery.

Typically, a developed intervention can be further refined through exploratory methods such as a feasibility study (Craig et al, 2008). Under the MRC framework, a feasibility study prior to a definitive trial is recommended. This will identify potential problems which could undermine acceptability and delivery of an intervention such as issues with recruitment, adherence, retention, or acceptability of the intervention (O’Cathain et al, 2015). Therefore, the *Work and Cancer* intervention was tested for feasibility in this Phase IV study. This chapter presents the findings from a single-arm feasibility study and qualitative-descriptive design.

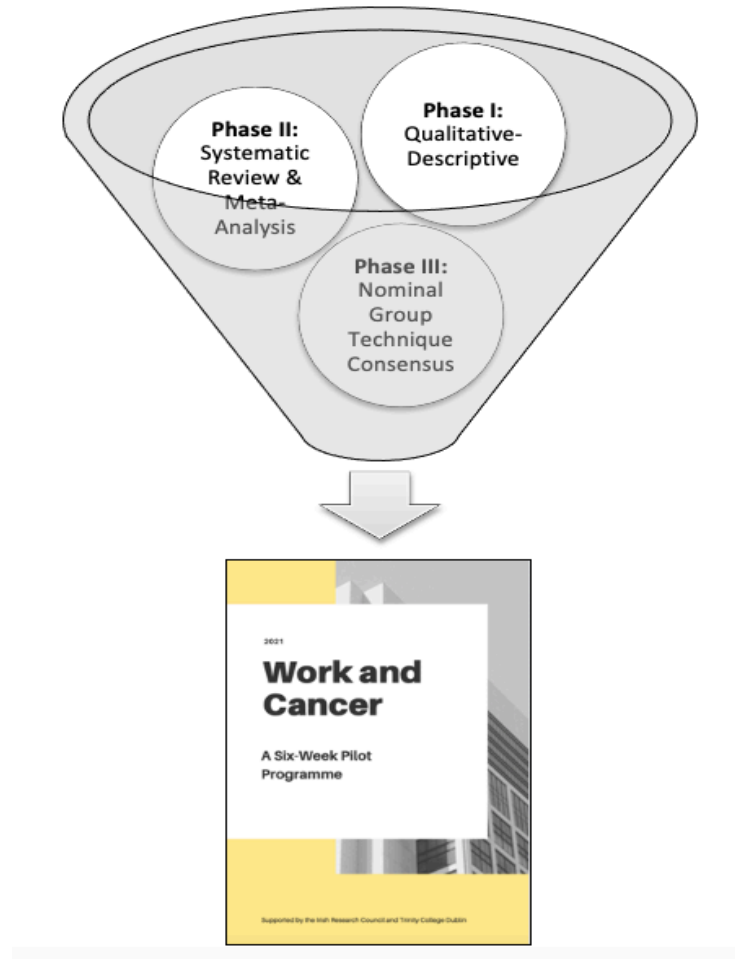


Figure 6.1: The Development of the Work and Cancer Intervention

The overall aim of this study was to establish the feasibility of a work-focused intervention for women living with and beyond breast cancer. Study objectives included:

1. To establish the feasibility of recruitment including length of time required to complete participant recruitment and reasons for declining participation.
2. To assess adherence to and completion (retention) of the intervention.
3. To assess acceptability of the intervention for women living with and beyond breast cancer.
4. To identify barriers and facilitators in completion of the intervention through qualitative-descriptive design
5. To identify suitable outcome measures for a RTW intervention for women living with and beyond breast cancer.

6.2 METHODS

A parallel mixed design consisting of a single-arm feasibility study and qualitative-descriptive design was conducted. Reporting of the qualitative-descriptive design was guided by the COREQ checklist (Tong, Sainsbury & Craig, 2007) (Appendix Q).

6.2.1 Intervention

The *Work and Cancer* intervention is described as per the Reporting of Intervention Description and Replication (TIDieR) checklist criteria (Hoffmann et al, 2014) (Appendix R) and delivered over a six-week period. It is a six-week online intervention underpinned by self-management theory that aims to support women living with and beyond breast cancer in managing their RTW following diagnosis (Table 6.1). Aims of the intervention include to develop strategies to self-manage physical and psychological sequelae of breast cancer and its treatment in the workplace, to increase knowledge of employment rights and entitlements, and to enhance confidence in negotiating and communicating around work with employers.

6.2.1.1 Content: All content of the intervention was work-focused, addressing an identified gap in rehabilitation interventions from the systematic review of this research (Algeo, Bennett & Connolly, 2021). Content was informed by Phases I, II, and III of this study, and is presented in Table 6.1. The six sessions included:

- Week 1: Introduction to the Programme
- Week 2: Employment Rights and Entitlements after Cancer
- Week 3: Managing Cancer-Related Fatigue and Cognitive Changes in the Workplace
- Week 4: Communicating Effectively with your Employer, Colleagues and Family
- Week 5: Managing your Mental Health and Physical Side-Effects in the Workplace
- Week 6: Developing a Return-to-Work Plan (Individual session)

Each group-based session commenced with an overview of the topic, a review on the previous session (if applicable), followed by an educational presentation on the topic. Comments, questions and reflections were welcome at any point throughout the presentation, as interaction was encouraged. At the end of each educational component for the week, SMART goal-setting was encouraged, and every participant reflected on short term goals related to the topic where applicable.

The purpose of the sixth and final session was to apply learning from the previous five weeks to inform a Work Plan in collaboration with a registered occupational therapist. This one-to-one session was guided by an occupational analysis checklist that was included in the intervention handbook (Appendix S). A letter of tailored recommended accommodations was also offered to participants (Appendix T). This was issued to the participant in soft-copy format via email, and a signed hard-copy posted to them for their convenience.

6.2.1.2 Self-Management Theory and Self-Efficacy: It is recommended, within the MRC framework, to identify or develop theory that can act as a mechanism in driving a complex intervention (Craig et al, 2008). In the systematic review (Phase II) of this research, theoretical frameworks underpinning interventions were underreported in the included intervention studies identified (Algeo ,Bennett & Connolly, 2021). In the absence of a definitive conclusion for best practice theoretical frameworks for work-focused interventions, evidence for effective cancer survivorship interventions in general was examined, where self-management theory was identified as a frequently used mechanism underpinning survivorship interventions. Self-management interventions underpinned by self-management theory have previously been found to be effective in health behaviour change (Bantum et al, 2014; Garvey et al, 2015). While definitions of self-management across chronic conditions vary (Barlow et al, 2002; Lorig & Holman, 2003), self-management in the context of cancer survivorship has been defined as “awareness and active participation by the person with cancer in their recovery, recuperation and rehabilitation, to minimize the consequences of treatment, promote survival, and health and well-being” (National Cancer Survivorship Initiative, 2009, as cited in Davies & Batehup, 2010, p. 6).

Self-efficacy is a factor that can influence an individual’s self-management. Based on Social Cognitive Theory (Bandura, 1986), self-efficacy is the belief or confidence that

individuals have that they can perform a required behaviour to produce a desired outcome (Bandura, 1997). Greater levels of self-efficacy can lead to greater levels of perceived control over one's actions and behaviours. The four key components which can influence self-efficacy were embedded into the *Work and Cancer* intervention to support self-management (Lorig & Holman, 2003) as follows:

- **Modelling:** Observing peers engaging in behaviour change and acting as models can increase learning and personal self-efficacy (Bandura, 1997). Throughout the *Work and Cancer* intervention, participants discussed how they applied information learned to change behaviours.
- **Performance mastery:** As part of action planning, goal setting using Specific, Measurable, Achievable/Attainable, Relevant/Realistic, and Time-specific (SMART) goals can increase likelihood of achieving desired behaviours (Bailey, 2017). Where there is increased self-efficacy in achieving goals, there is a greater likelihood of behaviour change (Foster & Fenlon, 2011). SMART goal setting was embedded at the end of each session of the *Work and Cancer* intervention.
- **Verbal/Social persuasion:** Support and positive feedback from peers as well as the presence of others can encourage changes in behaviour (Mukhtar et al, 2012). Discussion among the group was encouraged throughout the group-based sessions.
- **Physiological feedback/Interpreting symptoms:** Individuals living with and beyond cancer can be empowered with education to understand the causes and mechanisms of their symptoms. Greater knowledge can lead to a more targeted approach in self-managing symptoms which could potentially impact on work (Howell et al, 2017). Each session of the intervention included education on specific topics such as cancer-related fatigue, cognitive dysfunction, and physical and psychological sequelae. Education was combined with strategies to address self-management of these symptoms. Participants could then consider trialling and applying these strategies in their own lives and in the workplace.

6.2.1.3 Facilitators: The intervention was facilitated by a registered occupational therapist with a clinical and research background in oncology. This facilitation was supplemented by MDT input for two of the five group-based sessions (Table 6.1). MDT

input was embedded into the intervention as there is moderate quality evidence to suggest that MDT input can enhance RTW outcomes (de Boer et al, 2015). The community welfare officer (Session 2) had experience in working in cancer support centres, whereas the physiotherapist (Session 5) had both a research and clinical background in oncology. While no formal training was provided to the facilitators at this stage in the intervention development, an informal meeting was arranged with each MDT member to discuss the context, content and delivery of the intervention prior to co-facilitation.

6.2.1.4 Setting: The intervention was hosted online using the Zoom Video Communications Inc. platform (Table 6.1). While Phase III NGT findings indicated a preference for a blended (face-to-face and online) delivery of the intervention in a community-based setting, the setting was adapted in response to public health restrictions during the Covid-19 pandemic. Phase III NGT findings identified a preference for the Zoom Video Communications Inc. platform, should the intervention be delivered online.

6.2.1.5 Intervention and Session Length: The intervention was six weeks in total, as per the preferred timeframe identified in Phase III NGT findings. Group-based sessions were 90 minutes in total. This was to reflect the preference of 90-120 minutes indicated in Phase III, but to also allow for any potential fatigue with online delivery.

Table 6.1: Content and Delivery of the *Work and Cancer* Intervention

Week	Title	Content	Facilitator(s)	Format	Length	Setting
Week 1	Introduction to the Programme	• Outline of Programme • Introductions • Introduction to SMART goal setting	Occupational Therapist			
Week 2	Employment Rights and Entitlements after Cancer	• Employment Rights • Entitlements • Grants • SMART goal-setting	Occupational Therapist and Community Welfare Officer			
Week 3	Managing Cancer-Related Fatigue and Cognitive Changes in the Workplace	• Understanding Cancer-Related Fatigue • 4 Ps of Energy Management and Application to the Workplace • Understanding Cognitive Changes • Cognitive Strategies to apply to the Workplace • SMART goal-setting	Occupational Therapist			
				Group	90 minutes	Online via Zoom Communications Inc.
Week 4	Communicating Effectively with your Employer, Colleagues and Family	• Re-engaging with your Workplace • Taking Control of your Return to Work • Disclosing your Diagnosis • Negotiating a Return-to-Work/Work-Maintenance Plan with your Employer • Navigating Unwanted Conversations with Colleagues • Discussing Work with Family • SMART goal-setting	Occupational Therapist			

Week 5	Managing your Mental Health and Physical Side-Effects in the Workplace	• Managing Stress and Anxiety in the Workplace • Ergonomics – Adapting your Workspace • How to Manage Physical Side-Effects at Work such as Pain, Fatigue, Breathlessness, Hair Loss, and Changes in Sensation. • SMART goal-setting	Occupational Therapist and Physiotherapist		
Week 6	Developing a Return-to-Work Plan	• Occupational Analysis exploring Job Role. • A Return-to-Work Plan tailored for you by a registered Occupational Therapist • A Letter with Recommended Accommodations • Assessing Readiness to Return to Work • SMART goal-setting	Occupational Therapist	Individual	~60 minutes

6.2.2 Study design

A parallel mixed design was chosen to address the aim and objectives of this study, using a single-arm feasibility study with qualitative-descriptive design. It is acknowledged, under the MRC framework, that both quantitative and qualitative data can offer important understandings of intervention functioning at the feasibility stage (Moore et al, 2015). Parallel mixed designs involve two or more parallel quantitative and qualitative components conducted either simultaneously or with minimal time lapse. (Creswell & Plano Clark, 2011). Findings from both strands inform the overall interpretation of this study.

Single-Arm Feasibility Study: Following the development of a complex intervention, it is recommended to explore intervention feasibility prior to full-scale evaluation (Craig et al, 2008). Therefore, a single-arm feasibility study with qualitative-descriptive design established intervention feasibility. In general, a feasibility study “asks whether something can be done, should we proceed with it, and if so, how?” (Eldridge et al, 2016, p.8) and is iterative, formative and adaptive (Bowen et al, 2009).

Qualitative-Descriptive Design: A qualitative-descriptive design was also conducted within the study to establish intervention acceptability. Intervention acceptability is a distinctive feature of feasibility studies, informing overall feasibility (Orsmond & Cohn, 2015). The study design has been described elsewhere (Chapter 3, Section 3.2.1). There is growing recognition that qualitative methods play an important role in optimising interventions and the design of RCTs, exploring any key uncertainties prior to a future trial (O’Cathain et al, 2015). For example, if problems with recruitment, adherence or retention arise, qualitative data can be used to explore reasoning for this. A qualitative-descriptive approach was integrated into the study through the facilitation of individual semi-structured interviews, approximately one-week post-intervention.

6.2.3 Participant Selection

The aim of the *Work and Cancer* intervention was to support work outcomes for women living with and beyond breast cancer. Therefore the PhD Candidate sought to recruit a specific cohort of participants. Purposive sampling, a type of non-probability sampling (Marshall, 1996), was used in participant selection and involves choosing a sample based on similar or identical traits, as per inclusion criteria:

- (i) Women living with and beyond breast cancer of working age (18-66 years old – current adult employment age in Ireland)
- (ii) Employed at time of diagnosis
- (iii) Had either returned to work (within any time-frame) and self-report to be struggling *or* were aiming to return to work within six months from recruitment.

All participants required an internet-enabled device that could support the Zoom Video Communications Inc. platform, the preferred platform indicated in Phase III findings.

Sample Size: It was aimed to recruit up to ten participants into the feasibility study. Similar studies exploring online psycho-social interventions have recruited up to eight participants per group to manage group dynamics in an online format (Lemma & Fonagy, 2013; Muscara et al, 2020). Therefore, it was aimed to recruit up to ten participants to account for potential attrition which has been commonly estimated at 20% for digital interventions (Foster et al, 2016; Howarth et al, 2018; Willems et al, 2017). As this was a feasibility study in design, a sample size calculation was not conducted. Sample sizes in feasibility studies are typically small and vary depending on the aims and objectives of the study (Lewis et al, 2021). While data saturation for the qualitative-descriptive design could also be considered where it has been recommended (Bowen, 2008) to interview a sample of ten cases followed by at least a further three cases to determine if any new themes emerge, the overall aim of this study was to establish the feasibility of a work-focused intervention, and therefore sample size criteria for a feasibility study was prioritised.

6.2.4 Recruitment

Following full ethical approval, a gatekeeper at a single cancer support centre searched their database for potentially eligible participants. Potentially eligible participants were contacted by the gatekeeper via telephone and were emailed the PIL (Appendix U) (which outlined role of the researcher) and consent form (Appendix V) if interested in the research. If the potentially eligible participant declined participation, reasons for non-participation were recorded. Those interested in taking part were then invited to contact the researcher to express interest in participation if they wished to proceed with the study. Therefore, no relationship had been established with participants and the researcher prior to study commencement. Once in contact, the researcher provided participants with study questionnaires via email to complete prior to the intervention commencing. Once a consent form was received by the researcher, every participant was sent (by post) the *'Work and Cancer'* handbook (in hard-copy format) which provided presentation slides for each session, supplementary information on each session topic, and additional pen-and-paper reflective exercises (Appendix W).

6.2.5 Quantitative Data Collection and Analysis

Baseline data were collected one week pre-intervention, and outcome measures repeated within one-week post-intervention. Outcome measures were sent to participants via e-mail, although participants could request hard-copy questionnaires via post if preferred. While one participant requested this pre-intervention, nine out of ten requested the postal option, post-intervention.

Establishing effectiveness was not the aim of this study as this does not align with the objectives of a feasibility study. Despite this, exploring changes in pre- and post-intervention scores can provide useful descriptive information and has been explored in other self-management interventions for women living with and beyond breast cancer (Newman et al, 2019). Data collection and analysis of each of the outcome measures are described below.

Demographics: Several demographic details of participants were collected including work and participant demographics. Work demographics included job role, sector (e.g.

public, private), working hours pre- and post-diagnosis, if the participant had returned to work (yes/no), and length of sick leave. In addition, participant demographics including age, highest level of education, and relationship status were recorded. Data were collected one week pre-intervention using a questionnaire which had been informed by employment outcomes identified in the systematic review (Phase II) (Algeo, Bennett & Connolly, 2021) (Appendix X). For those who had yet to RTW, they were asked pre- and post-intervention to describe their 'readiness' to RTW ('Do you feel ready to RTW? Yes/Partially/No). Demographic characteristics of the study population were summarised using the appropriate descriptive statistics (e.g., frequencies and percentages for categorical variables, and means and SDs for continuous variables) with IBM SPSS Statistics for Mac, Version 23 (UK).

Work Outcomes: The ability to manage work demands amongst participants who had returned to work was assessed pre- and post-intervention. This included outcomes such as work scheduling & output demands, physical demands, mental & social demands, and flexibility demands, which were measured using the Work Role Functioning Questionnaire 2.0 (WRFQ) (Appendix Y) (Abma, van der Klink & Bültmann, 2013). The WRFQ is a widely used tool for the assessment of health-related work functioning (Abma et al, 2018), and has been found to be a reliable and valid instrument in working individuals living with and beyond cancer (Dorland et al, 2021). While no validated outcome measure for work outcomes had been identified during the systematic review (Phase II) (Algeo, Bennett & Connolly, 2021), it was chosen as it aligned with work outcomes of interest (i.e. to assess if the intervention increased ability to manage work demands), and was validated for a cancer population using a heterogeneous sample of individuals with cancer with different cancer sites and treatments, where a large sample was diagnosed with breast cancer (Dorland et al, 2021).

The WRFQ consists of 27 items, and is divided into four domains; work scheduling & output demands (10 items), physical demands (5 items), mental & social demands (7 items) and flexibility demands (5 items). Participants respond to each item using a five-point scale where 0 = difficult all the time, 1 = difficult most of the time, 2 = difficult half of the time, 3 = difficult some of the time, 4 = difficult none of the time. An additional response, 'Does not apply to my job', can also be selected but is recorded as a missing value for the purposes of scoring (Abma et al, 2018). Overall WRFQ scores

were transformed into percentages, where summed scores were divided by the number of non-missing items and multiplied by 25 to obtain a percentage between 0-100%. Where > 20% of items in a subscale were not answered, the scale score was recorded as missing. Higher scores indicate higher work function (Dorland et al, 2021). Wilcoxon signed-rank tests using pre- and post-scores were conducted to explore any changes in scores. The test was chosen as a non-parametric alternative to paired *t*-tests where the data are not normally distributed. Data were reported as medians and interquartile range (IQR).

Quality of Life Outcomes: It is well documented that there are associations between employment status and QoL, where increased work ability is positively associated with increased QoL (Timperi, et al, 2013). Therefore, QoL and breast cancer specific QoL outcomes were also assessed. QoL was assessed using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ-C30) Version 3.0 (Aaronson et al, 1993) (Appendix Z). The EORTC-QLQ-C30 is an internationally recognised tool which is both reliable and valid for assessing cancer-specific QoL in those living with and beyond cancer (Aaronson et al, 1993). It was used in conjunction with the Breast Cancer Subscale (Appendix AA). Both questionnaires were chosen as QoL measures as they had previously featured in two studies identified in the systematic review (Phase II) (Algeo, Bennett & Connolly, 2021).

The EORTC-QLQ-C30 includes 30 items embedded over nine scales: five functional scales (physical, role, cognitive, emotional, and social functioning), three symptom scales (fatigue, pain, nausea and vomiting), and a global health status QoL scale. Six single-items that assess additional symptoms commonly reported by those living with and beyond cancer are also included (dyspnoea, insomnia, appetite loss, constipation, diarrhoea) as well as financial difficulties. Participants respond to each item using a four-point scale where responses include ‘Not at all’, ‘A little’, ‘Quite a bit’, and ‘Very much’. Scores are linearly transformed onto a 0-100 scale as per the scoring manual (Fayers et al, 2001). Higher scores for functional scales and global health status, indicate higher levels of function and QoL, respectively. Higher scores for symptom scale indicated higher levels of symptomatology/problems.

The EORTC-QLQ-C30 summary score is calculated as the mean of the combined 13 QLQ-C30 scale and item scores (excluding global QoL and financial difficulties),

where a higher summary score indicates a higher HRQoL (Giesinger et al, 2016). Individual item scores of the EORTC-QLQ-C30 were calculated using Wilcoxon signed-rank tests, as previously described. Data were reported as medians and interquartile range (IQR). Where sample size was >6 for the EORTC-QLQ-C30, a One-Sample Kolmogorov-Smirnov normality test was conducted to test if each individual item followed a normal distribution. Where $p < 0.05$, is used to reject the null hypothesis of a normal distribution.

Breast cancer specific QoL was assessed using the Breast Cancer Subscale (QLQ-BR23) (Sprangers et al, 1996). The QLQ-BR23 is a breast cancer specific module of the EORTC QLQ-C30 and has been widely tested for its reliability and validity cross-culturally (Sprangers et al, 1996). It is recommended that the QLQ-BR23 be administered in combination with the EORTC-QLQ, and therefore can be lengthier than other breast-specific QoL subscales (Kanas et al, 2012).

The questionnaire comprises of 23-items and is categorised into functional scales and symptom scales. Functional scales include items on body image, sexual functioning, sexual enjoyment, and future perspective. Future perspective explores the extent to which a participant is worried about their health in the future (Fayers et al, 2001). Symptom scales include systemic side-effects, breast symptoms, arm symptoms, and hair loss. Participants respond to each item using a four-point scale where responses include 'Not at all', 'A little', 'Quite a bit', and 'Very much', and scores are linearly transformed onto a 0-100 scale (Fayers et al, 2001). Higher scores for functional scales indicate higher levels of function and QoL, respectively. Higher scores for symptom scale indicated higher levels of symptomatology/problems. Individual item scores of the QLQ-BR23 were calculated using Wilcoxon signed-rank tests, as previously described. Data were reported as medians and interquartile range (IQR). Where sample size was >6 for the QLQ-BR23, a One-Sample Kolmogorov-Smirnov normality test was conducted to test if each individual item followed a normal distribution. Where $p < 0.05$, is used to reject the null hypothesis of a normal distribution.

Feasibility: Feasibility involves exploring features such as recruitment, adherence and retention to an intervention as well as intervention acceptability (Orsmond & Cohn, 2015). Descriptive statistics regarding participant recruitment, adherence, retention and completion of study and intervention procedures were tracked throughout the

intervention and recorded on a Microsoft® Excel spreadsheet, and presented in the form of frequencies, percentages and means (SD), where appropriate. Progression criteria are often under-reported in feasibility studies leading to variations in the interpretation of findings (Mbuagbaw et al, 2019). In the absence of formal guidance, progression criteria in this study were determined based on a feasibility study of a similar online cancer survivorship intervention (O'Neill et al, 2021). Feasibility to proceed to a definitive evaluation of the *Work and Cancer* intervention was determined by the acceptability by women living with and beyond breast cancer as well as the following progression criteria: $\geq 50\%$ of eligible participants recruited, mean of $\geq 80\%$ adherence to the online intervention, and $\geq 83\%$ retention at post-intervention assessment. Sessions which were partially attended were considered adhered to if $>50\%$ of the session was attended. Reasons for non-participation in sessions were recorded when provided by participants.

6.2.6 Qualitative Data Collection and Analysis

The acceptability of the intervention and participant perceptions on intervention content and delivery was explored using semi-structured interviews. Semi-structured interviews involve a dialogue between researcher and participant, guided by a flexible interview guide that includes follow-up questions and probes to prompt discussion on the topic of interest (Hinton & Ryan, 2020). One-to-one interviews were preferred over focus groups as this enabled a deeper exploration of the experiences of participants who were at varying stages in their RTW journey, and potentially experienced diverse RTW challenges due to varying cancer treatment regimens and job roles (Silverman, 2016).

Once-off semi-structured interviews were conducted one week post-intervention over Zoom Video Communications Inc., platform and audio-recorded by Dictaphone with each participant. No one other than the PhD Candidate and participant, was present during interviews. An interview guide with open-ended questions was used to guide the focus of interviews which developed over time as interviews progressed with new insights (Appendix BB). Example questions that guided the one-to-one interview included:

- What motivated you to participate in this study?
- What motivated you to stay in the programme?
- What are your overall thoughts on the programme?
- What would you change about the programme?
- What helped you to be able to complete the programme?
- Was there anything that made it difficult for you to complete the programme?

Fieldnotes were made during each interview to document any contextual data such as the use of nonverbal cues and situational background (Hinton & Ryan, 2020). The PhD Candidate independently completed all transcription work rather than outsource to transcription services as this stage of data processing is a research activity that involves the close, repeated listening to audio-recording that can often reveal previously un-noted recurring features (Atkinson & Heritage, 1984). All transcripts were pseudonymised and uploaded onto Nvivo (Version 12) for data analysis. Qualitative data were analysed using the six-step thematic analysis (Braun & Clarke, 2006) which has been described previously in detail in Chapter 3 (Section 3.2.7).

6.2.7 Pursuing Quality in Qualitative Research

A series of techniques were used throughout the conduct of the qualitative-descriptive design to enhance the trustworthiness of the research. Trustworthiness involves four factors: credibility, transferability, dependability, and confirmability (Lincoln & Guba, 1985) (Figure 6.2).

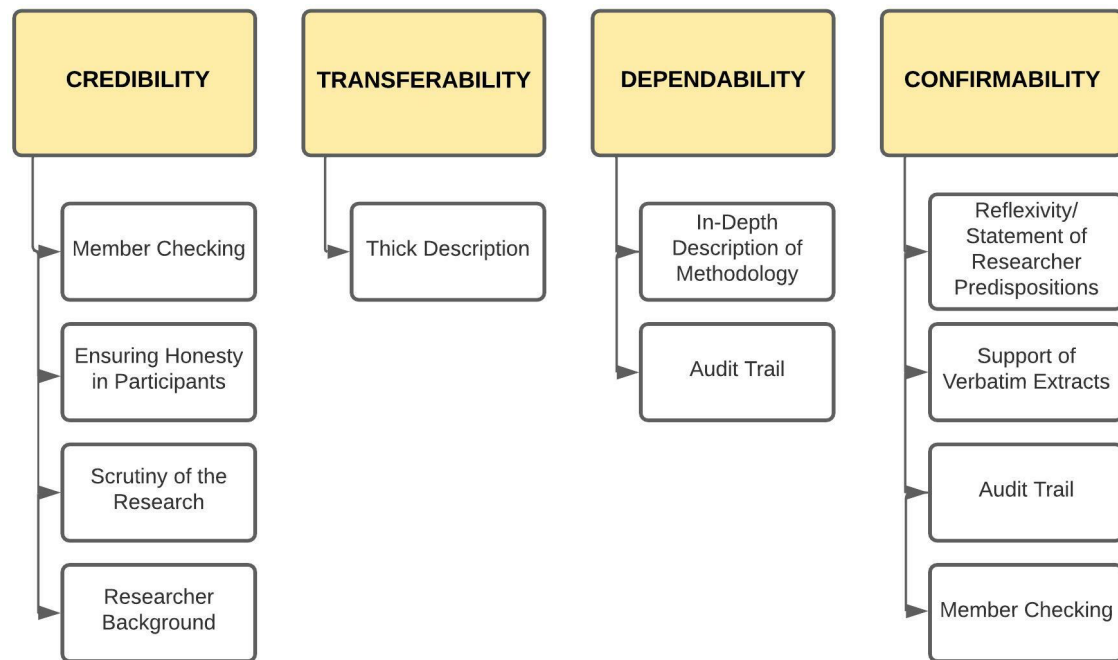


Figure 6.2: Strategies used to enhance Trustworthiness during Qualitative-Descriptive Design (Lincoln & Guba, 1985)

Credibility: Credibility involves confidence in the ‘truth’ of results, i.e., whether findings of the study are to be believed. Several strategies were used to enhance credibility of findings including member-checking, encouraging honesty, scrutiny of the research, and the researcher background. Member-checking, considered a common structure for addressing potential researcher bias and enhancing a study’s credibility, was facilitated (Doyle, 2007; Lincoln & Guba, 1985). Each participant was provided with their interview transcript and a summary of findings and invited to offer any feedback within two weeks of receipt to verify responses. This helped establish the level of correspondence between the researcher’s interpretation and participant accounts, as part of the process in error reduction. The PhD Candidate who was also the

interventionalist conducted interviews which may have influenced participant responses. To reduce the potential influence of social desirability, participants were reminded that the purpose of the feasibility study was to enhance the intervention, therefore all feedback negative or positive was welcomed, and would have no impact on the PhD Candidate. This was aimed to encourage honesty, and therefore credibility (Shenton, 2004). Peer scrutiny was sought throughout the study through regular supervision with the principal investigator and co-supervisor, and presentation of methods to academic peers (e.g., via peer review on journal submission, at conferences, continuation viva, and journal club). Finally, the credibility of the researcher is important in qualitative research as they act as an instrument in data collection and analysis (Patton, 1990). The researcher has previous experience in conducting and publishing qualitative methods and holds a taught Master's degree in Clinical Research.

Transferability: Transferability concerns the extent to which the findings of a study can be applied elsewhere (Merriam, 1998). Qualitative inquiry involves exploring unique individuals and groups often in unique contexts, therefore an in-depth account of participants and the study context may provide understandings of relevance to other settings (Carlson, 2010). Inclusion and exclusion criteria of participants, data collection methods and the time period in which data was collection are all outlined in this chapter.

Dependability: Dependability indicates that should the research be repeated, with the same context, methods and participants, that similar findings would be achieved. An in-depth description of the methodology is outlined in this chapter. Furthermore, an audit trail was developed to demonstrate the steps taken from raw data to final results.

Confirmability: Confirmability concerns the extent to which findings are shaped by participants and not that of researcher motivation, bias or interest. A potential bias of the researcher was that they had developed the intervention being tested for feasibility and acceptability and would, therefore, be more likely to be biased towards the intervention. To attempt to overcome this, potential biases were outlined from the outset, and several strategies for trustworthiness were embedded into the study design. As referred to previously, member checking can assist in reducing potential researcher bias as was used as a method in overcoming any bias. Despite this, member-checking cannot guarantee confirmability, where participant's perspectives may alter since the

time of data collection and may not align with experiences captured at that timepoint (Birt et al, 2016). Therefore, additional strategies were incorporated to enhance confirmability; Findings of this study are supported by verbatim extracts and include deviant cases where they were present. In addition, an audit trail mapped how findings were developed. Reflexivity concerns the ways in which the researcher and the research process may have influenced data collection, taking into consideration prior knowledge, experience and assumptions (Pope & Mays, 2020). By outlining potential biases at the outset through a statement of the researcher's disposition, and employing a number of the aforementioned strategies to overcome this bias, the researcher attempted to overcome these (Chapter 1, Section 1.5).

6.2.8 Ethical Considerations

Ethical approval was obtained from the Faculty of Health Sciences, Trinity College Dublin Research Ethics Committee on 4th December 2020 [REF: 20201003] (Appendix CC). Ethical considerations included data protection and participant confidentiality, potential for discomfort, informed consent, coercion, and beneficence and the absence of non-maleficence.

Data protection and confidentiality: Pseudo-anonymised data were used, and all participants were allocated a Study ID to replace any personal information. The codebook with Study IDs was kept in a secure locked cabinet, as per Trinity College Dublin Guidelines for Good Research Practice. While pseudo-anonymisation can act as a security measure in de-identification, the data are still considered personal data which can be re-identified. All participant personal data were kept in a secure locked cabinet in the supervisor's office as per Trinity College Dublin, Guidelines for Good Research Practice. In addition, the Zoom account being used for the intervention was facilitated by TCD IT services and used security features such as password-protected entry and end-to-end encryption.

Potential for discomfort: As the content of the intervention occasionally contained content of a sensitive nature, there was the potential that participants may experience some discomfort during data collection. For example, managing mental health in the workplace was reflected on and discussed. All participants were reminded that they

could cease the intervention at any stage without reason nor penalty. The study was undertaken by a researcher who has undertaken similar research with women living with and beyond breast cancer and is therefore experienced and highly sensitive to the wellbeing of the participants involved.

Coercion: There was a mild possibility that potential participants may have felt obliged to participate as recruitment stemmed for eight out of ten participants from their local cancer support centre. A gatekeeper was in place at all recruitment sources, and consent and participant information leaflets clearly stated that individuals were not obliged to participate that non-participation would not impact on future services or care at the centre.

Beneficence and absence of non-maleficence: Beneficence refers to striving to do good for others while also preventing harm (Beauchamp & Childress, 2001). In this case, the feasibility and acceptability of the *Work and Cancer* intervention was determined with a view that the intervention could be refined and implemented for others in the future. Non-maleficence refers to the protection from or minimisation of harm when striving to reach a beneficial outcome, or simply to do no harm (Morrison, 2009). The conduct of this research was considered low risk however there was a small possibility that participants could experience emotional distress when discussing topics such as mental health in the workplace. All participants were informed of support services such as Aware and encouraged to access their local cancer support centre for counselling support, if required.

6.3 RESULTS

Ten participants (mean age 47.6 years; SD: 5.06) were recruited into the study over a three-week period. Mean working hours pre-diagnosis was 34.75 hours (SD: 8.9) and mean length of sick leave was 15.73 months (SD: 6.33). For the five participants who had yet to RTW at baseline (pre-intervention), the mean length of time that they expected to RTW was 2.6 months (Range 1-5 months). For the five participants who had returned to work at baseline, mean time since RTW was 16.75 months (Range 0.25-40 months). Participant demographics are presented in Table 6.2.

Table 6.2: Demographic Characteristics of Participants (pre-intervention)

Characteristic		Frequency (%)
Highest level of education	Secondary Level Education	2 (20%)
	Third Level Education	8 (80%)
Relationship status	Married/Civil Partnership	9 (90%)
	Co-Habiting	1 (10%)
Stage	I	2 (20%)
	II	6 (60%)
	III	1 (10%)
	Unknown	1 (10%)
Treatment	Surgery	10 (100%)
	Chemotherapy	7 (70%)
	Radiation Therapy	10 (100%)
	Herceptin	3 (30%)
	Hormone Therapy	9 (90%)
Work Sector	Public	6 (60%)
	Private	4 (40%)
Returned to work	Yes	5 (50%)
	No	5 (50%)
Occupational Group ¹	Clerical & Office Workers	3 (30%)
	Social Work & Related Occupations	2 (20%)
	Business & Commerce	2 (20%)
	Health & Related Workers	1 (10%)
	Teachers	1 (10%)
	Managers & Executives	1 (10%)
RTW Readiness (For those yet to RTW)	Partially	4 (80%)
	No	1 (20%)

¹Occupational Group is structured as per Central Statistics Office (CSO) Occupational Groups definitions

6.3.1 Quantitative Results

Changes in outcomes of the intervention were explored using findings from the WRFQ, EORTC-QLQ-C30, and QLQ-BR23. While there were no statistically significant changes in any items, changes in scores are reported for descriptive purposes. Wilcoxon signed-rank data using medians and IQR are presented. Compliance with using these outcome measures was also examined.

Work outcomes

WRFQ: Findings from the WRFQ are presented in Table 6.3. Data were available from five participants who had returned to work with the exception of output and physical demands where four participants fully answered the domain, and social demands where only three participants answered the domain pre- and post-intervention. While Wilcoxon signed-rank test indicated that the six week intervention did not elicit any statistically significant changes in work outcomes, there were reported increases in median scores in work scheduling demands, physical demands, social demands. There were observed decreases in scores in output, mental and overall demands.

Table 6.3: Wilcoxon Signed-Rank Test Comparison of WRFQ Pre- and Post-Intervention Median Values (IQR), and P-Values.

Outcome	Median (IQR)		<i>Z</i>	<i>p</i> -value
	Pre-Intervention (<i>n</i> =5)	Post-Intervention (<i>n</i> =5)		
Work Scheduling Demands	75 (42.5, 97.5)	85 (52.5, 90.0)	0.27	0.79
Output Demands	87.5 (53.5, 100.0)	80.4 (66.1, 94.6)	1.10	0.27
Physical Demands	60.4 (27.1, 90.0)	87.5 (62.5, 90.8)	1.46	0.14
Mental Demands	87.5 (31.3, 89.6)	83.3 (54.2, 86.3)	0.41	0.68
Social Demands	87.5 (56.3, 100.0)	95.8 (72.9, 100.0)	0.45	0.66
Overall	90 (44.0, 94.9)	86.4 (61.3, 90.8)	0.41	0.69

Higher scores indicate higher work function.

Completion of the WRFQ was considered good with only 1.48% missing items (Table 6.4). Pre-intervention there were missing data for physical demands and social demands. Post-intervention there were missing data for output demands and social demands.

Table 6.4: Compliance of WRFQ

Compliance	Pre-Intervention	Post-Intervention
Number of questionnaires expected	5	5
Number of questionnaires received	5	5
Number of questions per questionnaire	27	27
Number of missing items	2	2
% missing items per questionnaire	1.48%	1.48%

Quality of Life Outcomes

EORTC-QLQ-C30: Data were available from all participants ($n=10$). Category scores from the EORTC-QLQ-C30 are presented in Table 6.5. Every category score improved (Summary, Functional and Symptom scores), with the exception of Global Health Status where there was a decrease in post-intervention score.

Table 6.5: Comparison of Changes in Median Values (IQR) of EORTC-QLQ-C30 Category Scores Pre-and Post-Intervention

	Pre- Intervention (n=10) Median (IQR)	Post- Intervention (n=10) Median (IQR)	Change in Median	p-value
Global Health Status Scores	62.5 (47.9, 77.1)	54.17 (50.0, 77.1)	8.33	0.93
Functional Scores	62.23 (55.6, 85.0)	70.09 (58.9, 75.0)	7.86	0.58
Symptoms Scores	26.93 (10.3, 37.2)	25.64 (16.7, 37.8)	1.29	0.36
Summary Scores	62.5 (57.1, 90.9)	63.3 (55.2, 87.5)	0.80	0.13

Higher scores for global health status and functional scores indicate higher level of functioning. However, higher scores of symptom scales indicate higher levels of issues. Higher summary score indicates higher QoL. P-values calculated using Wilcoxon signed-rank test.

Examining EORTC-QLQ-C30 functional scales, Wilcoxon signed-rank tests indicated higher emotional and cognitive functioning, no changes in physical or social functioning, and a decrease in role functioning (Table 6.6). Examining symptoms scales, Wilcoxon signed-rank tests indicated higher levels of nausea and vomiting, and fatigue. On investigating individual scores, two of the participants who recorded higher fatigue scores post-intervention, had returned to work during the intervention which may have impacted on scores. Lower levels of pain were observed post-intervention. While there were no observed changes in dyspnoea, diarrhoea, constipation, appetite loss, or financial difficulties, there were higher levels of issues for insomnia, observed. Finally, global health status scores reduced post-intervention. One-Sample Kolmogorov-Smirnov Tests indicated skewed distributions for 8 of the 15 items, where

$p < 0.05$, indicating that the difference scores are not normally distributed for most items.

Table 6.6: Wilcoxon Signed-Rank Test Comparison of EORTC-QLQ-C30 Pre- and Post-Intervention Median Values (IQR), and P-Values

Outcomes		Median (IQR)		Z	p-value
		Pre-Intervention (n=10)	Post-Intervention (n=10)		
Functional scales	Physical Functioning	80 (66.7, 81.7)	80 (71.7, 86.7)	-0.71	0.94
	Role Functioning	66.7 (25.0, 83.3)	50.0 (41.7, 91.7)	-0.51	0.61
	Social Functioning	58.3 (29.2, 100.0)	58.3 (45.8, 87.5)	-0.11	0.92
	Emotional Functioning	58.3 (45.8, 83.3)	70.8 (39.6, 83.3)	0.00	1.00
	Cognitive Functioning	50.0 (45.8, 70.8)	58.3 (29.2, 66.7)	-1.27	0.22
Global Health Status	Global Health Status	62.5 (47.9, 77.1)	54.2 (50.0, 77.1)	-0.85	0.93
Symptom scales	Fatigue	33.3 (22.3, 58.4)	44.3 (22.3, 69.4)	-1.34	0.18
	Nausea and Vomiting	0.0 (0.0, 16.7)	8.3 (0.0, 16.7)	-1.13	0.26
	Pain	50.0 (25.0, 75.0)	41.7 (29.2, 50.0)	-1.21	0.23
Single Items	Dyspnoea	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	-0.38	0.71
	Insomnia	50.0 (25.0, 100.0)	66.7 (33.3, 75.0)	-1.13	0.26
	Appetite Loss	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	-1.00	0.32
	Constipation	0.0 (0.0, 75.0)	0.0 (0.0, 41.7)	-0.82	0.41
	Diarrhoea	0.0 (0.0, 0.0)	0.0 (0.0, 8.3)	-1.41	0.16
	Financial Difficulties	33.3 (0.0, 66.7)	33.3 (0.0, 33.3)	-1.63	0.10

Higher scores for functional scales and global health status indicate higher level of functioning. However, high scores of symptom scales and single items indicate higher levels of issues.

QLQ- BR23: Examining QLQ-BR23 data, higher function was observed in every scale (body image, sexual functioning, systemic therapy side-effects, and breast symptoms), except future perspective and arm symptoms which did not change (Table 6.7). One-Sample Kolmogorov-Smirnov Tests indicated skewed distributions for 4 of the 6 items, where $p < 0.05$, indicating that the difference scores are not normally distributed for most items.

Table 6.7: Wilcoxon Signed-Rank Test Comparison of QLQ-BR23 Pre- and Post-Intervention Median Values (IQR), and P-Values

	Outcome	Median (IQR)		Z	p-value
		Pre-Intervention (n=10)	Post-Intervention (n=10)		
Functional scales	Body Image	37.5 (8.3, 77.1)	41.7 (6.2, 66.7)	-0.95	0.34
	Sexual Functioning	8.3 (0.0, 20.8)	16.7 (0.0, 37.5)	-0.92	0.36
	Future Perspective	83.3 (58.3, 83.3)	83.3 (66.7, 83.3)	-0.41	0.68
Symptom scales	Systemic Therapy Side-Effects	23.8 (14.3, 36.9)	19.0 (11.9, 23.4)	-1.40	0.16
	Breast Symptoms	41.7 (16.7, 52.1)	29.2 (14.6, 37.5)	-1.56	0.12
	Arm Symptoms	33.3 (19.5, 55.7)	33.3 (22.3, 55.7)	-0.21	0.83

Higher scores for functional scales indicate higher level of functioning. However, higher scores of symptom scales indicate higher levels of issues

Compliance with EORTC-QLQ-C30 completion was considered good with two missing items for role functioning and pain scales in total (Table 6.8). There were no missing items in the QLQ-BR23. Out of a potential 530 questions posed (EORTC-QLQ-C30 and QLQ-BR23 across the ten participants in total), only one question was missing pre-intervention, and one question post-intervention, indicating 0.19% missing items.

Table 6.8: Compliance of EORTC-QLQ-C30 + QLQ-BR23

Compliance	Pre-Intervention	Post-Intervention
Number of questionnaires expected	10	10
Number of questionnaires received	10	10
Number of questions per questionnaire	53	53
Number of missing items	1	1
% missing items	0.19%	0.19%

Feasibility

The feasibility of the intervention was established by measuring recruitment, adherence and retention rates, and acceptability further explored through qualitative-descriptive design (Section 6.3.2).

Recruitment: Ten women living with and beyond breast cancer participated in this study. Eight participants were recruited into the intervention over a three-week period between January and February 2021 via a gatekeeper at a cancer support centre (Figure 6.3). Two additional participants learned about the intervention via word of mouth and approached the researcher directly within that three week period. Two participants declined. Reasons for non-participation included clashing with part-time work and feeling that the intervention was not relevant to them. The recruitment rate was 83.3%.

Adherence: The mean attendance of the intervention was 90% (range 67-100%) (Figure 6.3). Half of participants attended every session. Of the six sessions in total missed, reasons for non-attendance were medical appointments ($n=3$), clashed with work ($n=2$), and bereavement ($n=1$). One participant attended 67% of sessions due to work commitments.

Retention: Every participant completed all study procedures of completing the intervention, and pre- and post- intervention questionnaires (100%, $n=10$) (Figure 6.3).

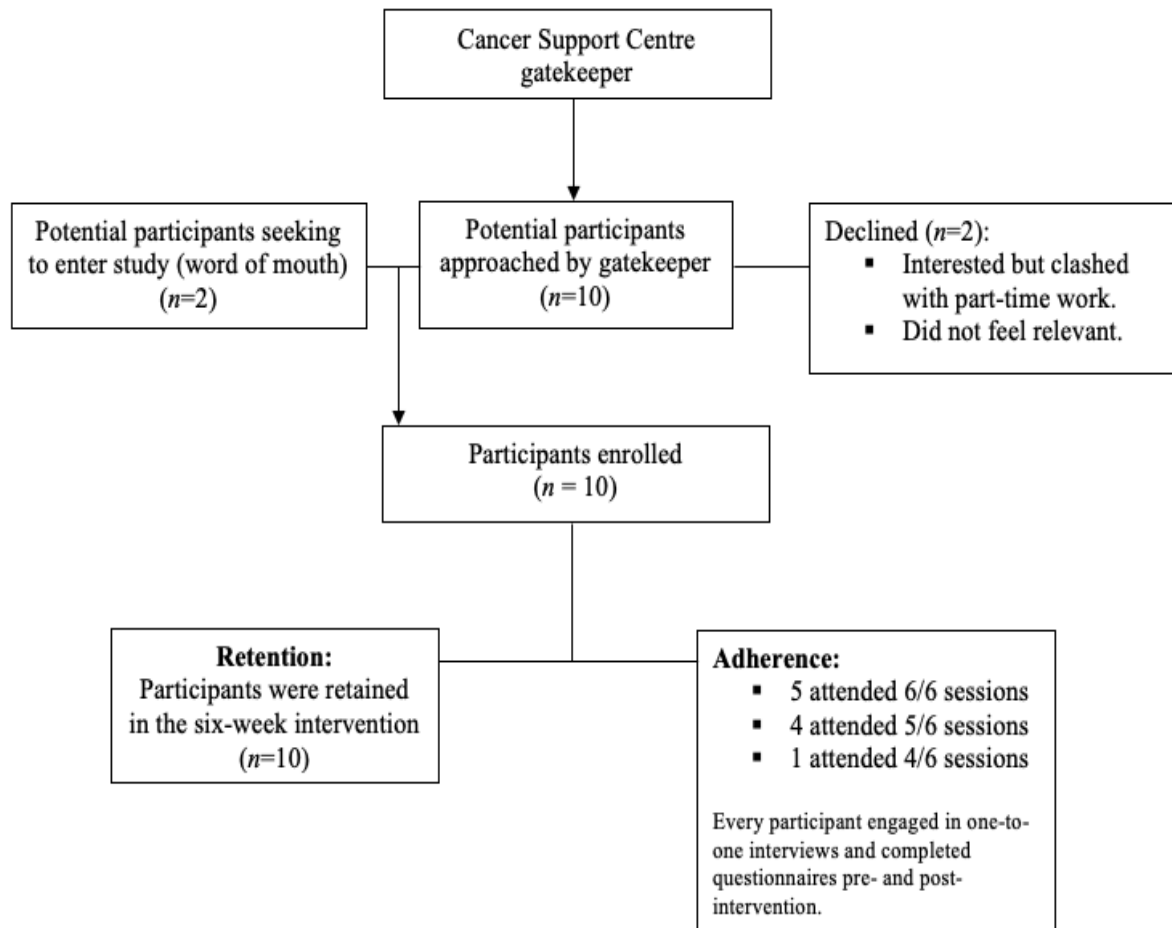


Figure 6.3: Participant Recruitment, Adherence, and Retention Flowchart

6.3.2 Qualitative Findings

Participant demographics are previously outlined in Table 6.2, however additional information is provided in Table 6.9 to provide context for qualitative findings.

Table 6.9: Demographic Characteristics of Participants

	Age	Occupational Group ¹	Working Hours pre-diagnosis	RTW (pre-intervention)	Sick Leave ²
P1	48	Managers and Executives	50	No	>11 months
P2	54	Social Work and Related Occupations	37	Yes	23 months
P3	50	Clerical and Office Workers	22	No	>14 months
P4	43	Business and Commerce	35	Yes	22 months
P5	54	Teachers	27.5	Yes	11 months
P6	45	Business and Commerce	45	No	>6 months
P7	37	Clerical and Office Workers	37	No	>25 months
P8	48	Health and Related Workers	26	No	>20 months
P9	49	Clerical and Office Workers	28	Yes	8 months
P10	48	Social Work and Related Occupations	40	Yes	16 months

¹Occupational group is structured as per Central Statistics Office (CSO) Occupation Groups definitions (CSO, 2002). ²Where a participant had not yet returned to work pre-intervention, sick leave was recorded with '>' to recognise sick leave period at that time.

6.3.2.1 Key Themes and Sub-Themes

Three key-themes emerged from data analysis and comprised several sub-themes (Figure 6.4). An introduction into each key-theme will be provided, followed by a brief explanation of each sub-theme, illustrated by verbatim extracts. The mean length of interview was 56 minutes (Range: 26-84 minutes). While it appeared that data saturation may have been achieved, where no new themes emerged in the final two interviews, it cannot be confirmed as at least 13 interviews are recommended (Bowen, 2008).

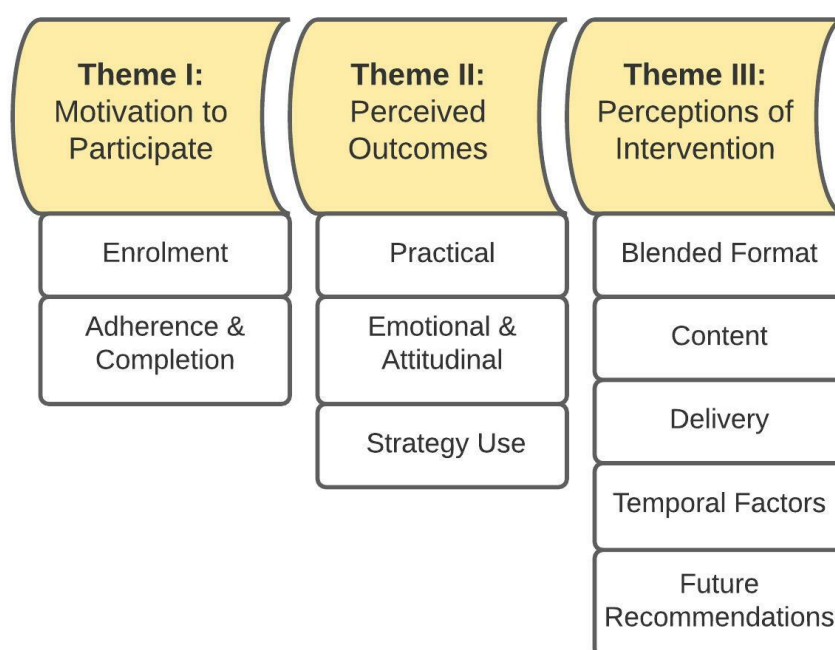


Figure 6.4 Key Themes and Sub-Themes

THEME I – MOTIVATION TO PARTICIPATE

Motivations for enrolment into and completion of the intervention were discussed by participants, and were largely similar across cohorts who had returned to work, and those yet to RTW.

Sub-Theme I: Enrolment

Motivations for enrolling into the intervention included interest and curiosity in the area as well as seeking RTW support. Two participants, at different stages of RTW, reflected on the desire to access support to help navigate their RTW.

“I had done the Thriving and Surviving [intervention] last year and that was very beneficial...I was really glad to have another opportunity to garner support and move forward and get back to work.” (P2)

“It was literally the time when I was starting to think about the return to work. So, like, it was tailor made for me. It literally said it on the tin, you know?” (P1)

Others discussed curiosity around the intervention in their motivation to join. This applied to both those who had already returned to work or had yet to.

“I suppose, curiosity, nosiness. I’m not sure.” (P5)

“I said yes because I was really curious to see what it is that you were offering.” (P6)

Another participant, who had yet to RTW, reflected on a gap in post-acute care, highlighting the intervention as an opportunity to ask questions in the area.

“I found the concept really interesting. I thought this is a really worthwhile thing to look at because I suppose what I was going through there are constant questioning once you’ve finished the regular hospital appointments, you’ve nobody really to ask” (P8)

Sub-Theme II: Adherence and Completion

Motivation to continue to participate and complete the intervention included interest in the topic and peer support. Two participants who had returned to work at the time of the intervention reflected on this.

“It was very interesting, so I suppose that was my motivation to stay on every week, you know?...you weren’t thinking ‘Oh God, is this ever going to end?’ and most of the time you were thinking, ‘Gosh, is the time up already?’. It just seemed to fly by.” (P9)

“I liked being part of the group...I enjoyed, you know, hearing other people’s stories as well...The feeling that you’re not alone in all of this, that you’re not the only one that has gone through this whole process.” (P5)

Several participants reflected on the social persuasion in the group, often finding themselves motivated on listening to other group members’ experiences.

“I [found the group motivating] because I wanted to get on that train. When they were saying ‘Oh I did this’, you were kind of questioning yourself like, ‘I should be doing this. I’m going to ask her how she did that’” (P3)

“I found it motivating actually...What I enjoyed was when people give you those tips and tricks and what works for them...so I’ve always taken notes throughout the course, and I’ll always try a lot of what people recommend.” (P4)

One participant who had yet to RTW, reflected on wanting to continue with the intervention while she worked through a thought process around her RTW.

“I was just starting the thought process [around work] and so I was working through a process as I was working through the programme... it’s a very tricky time and I think that that is when the support is needed and so, the programme being a support and helping you and creating a framework to bringing you through the process of thinking is very very useful.” (P1)

THEME II – PERCEIVED OUTCOMES

Participants described a range of perceived outcomes from the intervention, including (i) practical outcomes, (ii) emotional and attitudinal changes, and (iii) increased strategy use to self-manage their condition in the workplace.

Sub-Theme I: Practical

Practical outcomes refer to when information/theory learned through the intervention is applied in a real-life context. Several practical outcomes of the intervention were described by participants including the letter to employer and RTW plan, ergonomic changes, and application for financial entitlements.

Eight of the ten participants requested a letter for their employer outlining tailored reasonable accommodations. Reasons for non-request included autonomy in role and feeling that it had been too long post-RTW. Words used to describe the letter included “powerful” (P2), “it just gives you that peace of mind” (P6), and “supportive” (P8). One participant described the letter as an empowering tool that instilled confidence in them to advocate for themselves.

“It’s offered me a bit of support, I suppose. Just someone sort of advocating on my side just to...it’s nice to have that in letter to hand over to the employer, and they can take away, have a read of it and kind of say ‘Okay we can implement these strategies. This is how we go about it’, you know? So, I found it very good.” (P4)

Participants who had yet to RTW or had already returned to work, received a RTW Plan or Work Maintenance Plan, respectively. Words used to describe the reports included “worthwhile” (P2), “clear” (P7), “invaluable” (P9), and “really helpful” (P8). Several participants discussed the importance of having information in writing, that they could refer to in the future.

“I think that’s helpful, not least because as I say I’m going to go back to all of this info in August and, you know, it’s really good to have it all written down and reminders and the references to the information ... reminding me to do some job practice, job simulation and all of those kind of things” (P1)

“It’s really really lovely that I have six things that I know will help me in my return to work and there they are in black and white. You know, I can refer to them because we all know I’m going to forget some of them [laughs]” (P8)

Participants also discussed how increased knowledge of ergonomics led to environmental changes in their workplace. One participant who had returned to work, found benefit from learning about ergonomics and reflected on how she could adapt her workplace.

“I have begun to look carefully around me. Even the layout of how my stuff is organised and where I store things on shelves and on my desk. You know, even the logistics of getting my books and equipment and resources to and from school.” (P5)

Another participant reflected on increased knowledge around reasonable accommodations and entitlements.

“I didn’t know about the reasonable accommodations and I didn’t know about the financial supports [before the intervention]...now I mightn’t be successful in getting them but at least I’ve applied...nothing ventured, nothing gained. So those were the two things I suppose that really helped me to feel in more control in kind of planning and managing my return to work” (P8)

Several participants also discussed new knowledge on financial entitlements and grants that they were not aware of prior to the intervention.

“It’s good, you know, for somebody who is just starting out and is looking for benefits and entitlements because I wasn’t aware of the partial capacity, you know? And for the employer too, like that [Workplace Equipment Adaptation] Grant” (P9)

“The fact that I was told about the invalidity [benefit] has lifted a huge weight off of my shoulders because I was forcing myself to be ready by a certain time, by a certain date. Whereas now, I don’t have that pressure. So, now when I actually go back to work, it’s because I will be physically and emotionally ready which is amazing” (P7)

Sub-Theme II: Emotional and Attitudinal

Participants reflected on several perceived emotional and attitudinal changes including a new sense of empowerment, reduced feelings of anxiety around RTW, and validation of their RTW experiences. Several participants reflected on feelings of empowerment in self-managing their condition.

“I have to say the biggest takeaway for me has been the feeling of ‘I can manage this’ ...I got, what I called a nugget or a gem from every session that I thought ‘I can do something with this’ ...So, the practicality of it was instrumental in changing my perception of my return to work which was negative” (P8)

“The course encouraged me and the others to get help with pain and I’ve taken that on board and going through that. I had blood tests this morning.” (P2)

“I just feel, I suppose, a bit more empowered...I feel I’m more in control of me going back into work, whereas, you know, before, like I was saying I would have said, ‘Ok well I’m back to work, they can do whatever they want with me’.” (P9)

This was often encouraged through the educational components of the intervention, providing information on treatment and disease related side-effects which increased their awareness of their symptoms.

“Information is power, isn’t it?” (P9)

“As well as the content, there’s the kind of framing of things that helps, and I think there was a nice blend of content as in hard and fast information, ‘the legislation says this’, ‘your entitlements are this’, to how you feel about, you know, how you’re doing, or how you’re going to communicate.” (P1)

One participant discussed how the intervention and peer feedback increased awareness of their condition and caused an attitudinal shift in how they viewed their RTW.

“Only by talking to you guys, and others in the group, that I realised, ‘Well listen, a phased return – it does not mean six weeks’, you know? It can be longer. So, the

programme has definitely broadened my perspective, and actually made me acutely aware that, you know, I need to think of myself.” (P6)

For women who had yet to RTW, the most reported perceived outcome from the intervention was reduced anxiety navigating the RTW process often enabled through increased confidence and knowledge.

“I suppose I’m not as psyched up about it. I’m not as nervous about it. I have more confidence. I’m a bit more stronger I suppose. You know, getting the help through the course.” (P3)

“I don’t feel as anxious...it’s like, “I’m going to go back to work and I have no expectations of myself for the first two, three weeks until I find my feet’. And I suppose it wouldn’t have dawned on me before that that was ok.” (P8)

For participants who had returned to work for greater than a year, the intervention provided validation of their experiences as well as reflection on the journey that they had been through.

“For me, it’s knowing that the thoughts I had, that other people have had them. That just helps me, to be honest with you. I kind of feel like...That I’m not being difficult. That other people have experienced this. It really does help.” (P10)

“I suppose even just reflecting on where I am now kind of thing, and how far I’ve come.” (P5)

Sub-Theme III: Strategy Use

Finally, participants discussed how the intervention influenced self-management of their treatment- and disease-related side-effects, using strategies. In particular, participants discussed using strategies and reflective exercises to self-manage their fatigue and cognitive changes. Participants discussed using strategies such as the four P’s of energy conservation, in self-managing their fatigue or using tools such as the energy diary to track their energy levels.

“The aspects on fatigue was really useful, learning the four Ps. Very practical, very relevant, and very good. That’s something we’ll all use for a very long time” (P2)

“I’m still actually doing that energy diary...when I’m working I use a notepad and in the back I’ll kind of write how I’m feeling that morning and how I’m feeling by the end of the work day just giving me an idea of trying to gauge how I am on those days.” (P4)

Participants also reflected on the use of strategies in managing their cognitive function. Two participants reflected on planning ahead their work tasks to ensure they were not too cognitively heavy, following the intervention.

“If there was talk of assigning me work, I was very mindful to say, ‘Listen, start me off with something that’s well defined and not as cognitively taxing so I can see how I how I can accommodate it’...It just made me very conscious that I needed to control my return and that if I took control that I’d lessened my own stress.” (P6)

“I used that Lumosity App and I also did the traffic light system. I found that good to help me with my work days...Because everything I do is so cognitively heavy. It just made me aware I suppose...like I can’t continue to do that many tasks in one day because it just does take too much out. And if some of them need to be lighter. But I did find that very useful.” (P4)

THEME III: PERCEPTIONS OF INTERVENTION

Every participant used positive terminology to describe overall impressions of the intervention. Words such as “supportive” (P3), “very comprehensive” (P5), “really special” (P8), “empowering” (P7), and “hugely beneficial” (P2) were used to describe the six-week intervention. One participant reflected on the intervention being unique in that it pulls information on work and cancer together.

“There’s a lot written about [work and cancer] but there’s nothing that pulls it all together in a one-stop shop package like this.” (P8)

Participants reflected on various aspects of the intervention including the format, content, delivery, temporal factors and future of the intervention.

Sub-Theme I: Blended Format

Every participant reported preference for the blended format of both group-based and individual sessions, suggesting several advantages. Participants reflected on *“the benefit of learning from each other”* (P1), the acknowledgement that *“you’re not alone”* (P2), and *“interaction”* (P9) as key benefits to the group-based sessions. Participants reflecting on modelling, where they learned from other’s experiences.

“Just listening to the other women and their experiences of going back to work was a bit mind-blowing really about how much we’re entitled to that we’re not aware of.”
(P8)

“I love hearing people’s stories as well, you know? I think... you’ll pick up information from hearing other’s telling their stories.” (P9)

Emphasis was placed on the tailored component of the one-to-one session which was described by participants as *“personalised”* (P1), and an opportunity for *“individual support”* (P4). One participant underlined this importance of personal context, also underlining the opportunity for those less vocal in the group to have a platform in the one-to-one session.

“While there’s huge overlap in people’s experience, not everybody’s context is the same. And I think it also probably, coming as it did at the end, provided a bit of an opportunity to provide those people who weren’t saying things in the group, having an opportunity to follow up and ask advice on things or ask for help on something, you know?” (P1)

One participant echoed this, reporting to feel more open in the one-to-one session, outside of the group.

“There are things maybe that I would be comfortable with that one-to-one situation that I wouldn’t say to the group.” (P5)

Participants also reflected on the group size. Most participants felt that this number was *“just right”* (P1), *“just perfect”* (P3), *“a good mix”* (P4), and *“not too small, not too*

big” (P7). Reasons for this preference of group size included the ability to be able to contribute to the group, and to be able to view every group member on the screen.

“I don’t feel that the ten in the group took away from anything. We were all, everyone had lots to say and we were all able to do that.” (P10)

“They all fit in a screen and they’re still reasonable size so you could see. And you could see people’s reaction so it allowed for chat and it allowed I think – I think it allowed you to engage with everybody.” (P1)

One participant considered the doubling of group size suggesting that resources available would not be impacted.

“I think you could probably double that number because we weren’t interfering with one other in any way. There wasn’t any lessening of resources available to the 10 of us if there had been 20.” (P2)

Sub-Theme II: Content

The content of the intervention was described as “very practical” (P10), and “very relevant” (P2). Every participant reported content to be relevant in the context of work, with applicability to all job roles.

“There [were] women from different walks of life...It’s all applicable, regardless of what you do. This isn’t just applicable to predominately an office or a desk job, you know, this is [an intervention] you follow regardless of what job you’re in.” (P6)

Perceptions varied around what was the most important content, with every topic referenced at one point among the participants. The session on Employment Rights and Entitlements after Cancer was the most discussed session, however, with eight participants offering reflection on the session.

“I think that people should be told about the illness benefit, the partial capacity benefit. If I had known those things before [the intervention], I would have had a lot of stress taken off my shoulders and I’m a public servant.” (P7)

“And even just to be aware of the legislation that you were entitled, that you’re entitled to have accommodations at work, that your employer has to make accommodations for you. That is interesting. I didn’t consider that before, I really hadn’t. That is useful into the future I think.” (P5)

Most participants did not report any missing content however two participants did suggest additions to Session 4 on Communication. One participant suggested adding management of conversations with family and friends around when they were going back to work.

“I found that our friends [were] constantly asking, ‘When are you going back to work?’, ‘Why aren’t you back at work? ...they’re not really aware that it doesn’t end when the active treatment phase ends...That you’re not finished.” (P4)

Another participant suggested further guidance on managing conversations when full-time hours aren’t sustainable, even when a phased RTW is initially put in place.

“If you’re in work and you can’t, you can’t maintain the level you did before or you can’t make the mark, I suppose, what discussions are had then? Or how do you approach those discussions? So, I suppose that piece is missing, I suppose, from the programme.” (P6)

In addition, tools and activities in the handbook to support the intervention were commonly discussed by participants.

“The very quick tools whether it be the energy diary for managing fatigue, or thinking about things in a slightly different way...I thought that all of those were really useful” (P1)

“With the book, the letter and the action plan, you physically gave us the tools to help us.” (P7)

Participants also discussed goal-setting as a component of the intervention. Examples of goals set included (but was not limited to) initiating contact with an employer or colleague, rearranging working days to non-consecutive days during a phased return to manage fatigue, and applying for entitlements (e.g., partial capacity benefit). Some participants described an initial apprehension in goal-setting, however found benefit to the goal-setting content over time.

“I suppose I didn’t really take [goal-setting] too seriously in the beginning...But then that changed when I knew that I was in work and I said, ‘Okay well I need to do this because it will be a benefit for me in a conversation I know is coming with my manager the next day’ ...So the goals benefited me.” (P6)

Another participant described goal-setting as motivating which encouraged them to complete a task.

“It definitively did motivate me when I said I would do it. Do you know the way? Because I know if I say I’ll do it, if I tell you I’ll do it, I will do it. Whereas if I tell myself I’m going to do it, it might never happen. If I say to you I will, I will definitely do it. Do you know?” (P9)

Sub-Theme III: Delivery

Participants reflected on how the intervention was delivered, including perceptions on the online setting and facilitators. Every participant reported the online delivery of the intervention acceptable, describing it as “very easy” (P1), “so much more flexible” (P7) and “second nature” (P6). Reasons for acceptability included the ability to use online features (e.g., raise hand function and mute) to minimise interruption, being able to complete the intervention in the comfort of one’s own home, and eliminating commuting. One participant reflected on the smooth delivery of the intervention with little interruption.

“I have to say, it did work out very well for an online programme...because people would ask a question or raise their hand. Nobody was talking over anyone.” (P4)

Another participant described comfort in her own home and reflected on commuting to interventions as barriers.

“Now, I liked online because I can be in the comfort of my own house...There’s no dragging myself to Dublin or wherever. Planes, trains and automobiles...the stress of all of that...So, in terms of that, I think the online suited me a lot.” (P5)

This was echoed by another participant who also used the word ‘stress’ when discussing commuting to face-to-face interventions.

“I can’t drive far. When you’re sitting behind the computer, you obviously have to make the time. But you don’t have to add time with a commute. You don’t have to add stress to park.” (P7)

One participant also discussed the online format as enhancing confidence behind the screen.

“It actually gives you a little bit of an extra confidence, right? If you’re in a face-to-face, I would probably hesitate more to input. Don’t ask me why...I don’t know what it is about the online. It just makes you shake off your shackles and just give you a little bit of confidence.” (P6)

Two participants reflected that their acceptability of online platforms had changed since the onset of the pandemic.

“If it’s because of the pandemic, I’m not sure. But just being used to doing everything online, shopping, more confidence with doing it online compared to two years ago.” (P3)

“I think before [the pandemic] I would have said face-to-face, but [now] I think online because it requires less commitment from everybody if they have children at home or

difficulty travelling or stuff like that or for [the external speakers] to pop in and out, it's easier isn't it?" (P2)

Despite indicating acceptability of online delivery, there were mixed feelings towards the future delivery of the intervention. Six participants indicated a preference for an online format, with the remaining four choosing the face-to-face as their preference. Several participants reflected on *"the social aspect"* (P3) that comes with face-to-face delivery where *"you could sit around the big table and chat it out"* (P9). One participant discussed the ability to read other group member's body language in a face-to-face group.

"I much prefer everything face-to-face, to be honest with you because I think you can read a person. You can read people's body language, what they're not saying." (P4)

Every participant indicated acceptability of Zoom as an online platform for intervention delivery. It was described as *"hassle-free"* (P10), *"much more straightforward"* (P2), *"mostly fool-proof"* (P7), and *"very easy to use"* (P9). Other platforms such as Microsoft® Teams, Skype and WebEx were discussed, however barriers such as technical difficulties were highlighted.

"I find Zoom very good. My work uses Skype, and it breaks down frequently and there's problems and people struggling to get in" (P2)

If the intervention were to be hosted face-to-face in the future, every participant indicated preference for community-based settings. Specifically, cancer support centres were suggested by eight of the participants who used words such as *"relaxed"* (P6) *"feels more like home"* (P7) and *"comforting"* (P10) with the setting. In addition, participants cited access to kitchen facilities as an enabler to the cancer support centre setting.

"I do think a more relaxed setting kind of thing where you can make your cup of tea and coffee and, you know, you have maybe more beautiful surroundings." (P5)

The acute setting, on the other hand, was associated with unwanted memories of treatment.

“I don’t know if a hospital setting might be too triggering for some people, you know? If you’re finished your treatment, you may not want to darken the door of a hospital for as long as you live, so I think a community setting would be more open, you know?”

(P8)

Participants’ understanding of the role of occupational therapy varied, however three participants familiar with the role, underlined the appropriateness of the intervention being occupational therapy-led which was described as “well-placed” (P8), “perfect” (P5) and “extremely appropriate” (P7).

“I think [occupational therapy] is perfect...It’s everything that you need for your occupation, so from the terms of the physical to how to cope when you are there... You know, rather than that very medical model, led by a nurse or a physio or somebody who’s just focused on the medical thing.” (P5)

“I thought it was extremely appropriate for an occupational therapist to do this because you got it. You’re able to understand our symptoms, our side-effects, what we’ve been through and why we’re like this. In addition to that, you’re able to tell ‘this is how you can improve. This is what I recommend to you’.” (P7)

Every participant welcomed MDT input of the intervention reporting it as “really helpful” (P8), and something that “worked really well” (P6). One participant reflected on the complex nature of cancer and that it requires a MDT approach.

“This is a multidisciplinary problem, so I think the expectation and seeing and getting each particular expertise to contribute at the right time is a really great idea.” (P1)

In particular, participants emphasized the inclusion of the community welfare officer whose input was described as “an eye-opener” (P3), “absolutely wonderful” (P7) and “really significant” (P8).

“Please, please, please keep [the community welfare officer]...the physiotherapist was desirable whereas with [the community welfare officer], that was essential.” (P7)

Participants valued the physiotherapy input but acknowledged that it was challenging to offer tailored advice.

“I suppose it was hard for [the physiotherapist] to give exact instructions on what to do...unless they’re dealing with you one-to-one, it’s hard for them to say, ‘You should do this or you should do that’.” (P9)

Despite this, participants valued the input, and considered other ways in which physiotherapy could be embedded into the intervention such as pre-recorded video input.

“If you add a handout to the handbook. If it was pre-recorded to have that ready, it would reduce the amount of time.” (P7)

There would be certain exercises that apply to everybody, do you know what I mean?... I think [video input] would help [instead], you know what I mean? (P4)

Sub-Theme IV: Temporal Factors

Participants discussed their perceptions on overall length of the intervention (six weeks), and session length (90 minutes). Most participants reported that the intervention length of six weeks was ‘just right’. One participant reflected that six-weeks enabled them to go through a thought process around their RTW, whereas another participant commented that the intervention length was just right for the content presented.

“I think [the intervention length is] just about right. I think any shorter and we may not have come on the journey, or it might have been a bit more magpie-ish so different participants homing in on different pieces but not getting the whole framework and not being brought through a process of thinking.” (P1)

“It wasn’t too long for sure. It flew by for us. For me anyway. No, I think it was probably just right because everything that was in it was relevant and I can’t think of any topic that you didn’t cover that could have been in there.” (P2)

There were mixed feelings on session length, although no participant suggested decreasing length. Most participants stated an amendment to session length could be increased by 15-30 minutes online to allow for a short break in between, and provide further opportunities to socially interact,

“It’s hard to sit still for too long and you don’t want to make it go on too long but I do think that [sessions] were short as in we were often rushed towards the end and that was really when people were getting going and that was really when people were sort of sharing stories, experiences and opinions.” (P4)

“I’d probably have said is it might be a good idea to stretch the time period for the sessions and give a break in the middle...I think that probably doing a two-hour, but saying ‘Ok, after an hour’...have a break and then start the next topic” (P1)

The remaining participants, however, cited the session length as ‘perfect’ (P8), ‘just enough’ (P6) or ‘okay’ (P5). If the intervention was to transition to a face-to-face format however, participants typically felt that sessions would be extended, particularly where there could be increased social interaction.

“I think if it was face-to-face, it would naturally run longer because people are going to be telling stories and I think that that’s one thing that you do less, that I’ve noticed that you do less online.” (P8)

“I think if it was face-to-face, it would extend, do you know? Because people chat more when they’re together.” (P9)

Finally the timing of the intervention was reflected on, where the most discussed barrier to completing the intervention was the potential that it would clash with work and/or treatment.

“Personally, I think if I had just returned to work and I was asking to complete the programme. I might get a little bit of kickback.” (P6)

“The fact that I’m job sharing. The fact that I had the time on my week off...that I could dedicate the hour and a half or whatever it was. I think if you’re back at work it’s impossible to do the programme. If I was at work full-time, I just couldn’t have signed up.” (P5)

Despite this, participants who had returned to work reported benefit from the intervention which is discussed further in Section 6.3.2.3.

Sub-Theme V: Future Recommendations

Participants reflected on a positive outlook for future implementation as well as considerations for future research.

Every participant indicated a desire for the intervention to be rolled out nationally in the future. The potential for future roll-out of the Work and Cancer intervention was described as “*so necessary*” (P1), “*very important*” (P10), and “*so beneficial*” (P8) in the context of what was described as “*an under-resourced area*” (P8) where “*there really wasn’t anything*” (P1). Several participants suggested the extent of the roll-out of the intervention should mirror that of the Thriving and Surviving intervention (Gibbons et al, 2020), which is rolled out nationally through cancer support centres.

“It’s a great body of work. It’s a great course and that it should be permanently available to everyone as much as Thriving and Surviving is. I would really like to see that happen. I really think it should happen.” (P2)

“To be honest, the Thriving and Surviving has rolled out everywhere so I think that this one should be as well because there’s a lot of people I’ve met on my cancer journey going back into the workforce” (P4)

Several participants also reflected on the potential social and economic impact of rolling out the intervention in the future, in conjunction with health benefits.

“We all need to work and pay the bills and whatever and for those who have the purse-strings, I think it’s valuable money and money saved rather than paying out disability

pensions or, you know, social welfare pensions or whatever it is. For people's health and well-being I think it's money well spent.” (P5)

“Splash the cash!...It's a no brainer because you're getting people back out [to work]. It's of benefit to the economy with more people working.” (P3)

Participants also discussed considerations for future research, including amendments to be made to the research design.

Several amendments were suggested to embed into future research of the intervention, including outcome measures, and how documents such as the consent forms and outcome measures would be issued to participants. On discussing the employment demographic questionnaire, EORTC-QLQ-C30, QLQ-BR23, and WRFQ, most participants reported the data collection tools as user-friendly with words used to describe them as “easy” (P7), “easy to understand” (P9) and “there was nothing difficult about it” (P2). Despite this, there were some minor amendments suggested. For the employment demographic questionnaire, participants discussed removing the word ‘fully’ from the question ‘Do you feel fully ready to return to work?’ as well as to provide more options in answering that question. For example, to include a “*between partially and yes*” (P3).

“Do you feel fully ready to return? Partially is a bit grey...Partially, well what do you mean partially? I could be ready but I'm not yet...you could have a scale of, ‘On a scale of 1-5, how ready do you feel to return to work?’. 0 being not at all, 5 being very much so. (P7)

Other participants queried the necessity of some of the demographic questions, including education level and relationship status, posed. One participant suggested that it would be helpful if the purpose of these questions was outlined.

“When you ask somebody their background, their highest level of education. I'm not sure if that would be off putting for some people...It's hard to see how it's relevant.” (P4)

“If it’s [being asked] to see, ‘Ok, it’s actually single people who need it the most because they have no one at home’ then fair enough. So, if it is a purpose rather than just demographics.” (P7)

One participant reflected on the QLQ-BR23 QoL outcome measure which posed questions on sexual activity which caused discomfort when completing the questionnaire.

“The only thing I would say is that the questionnaire is a little bit intimate, and I just wondered why that you needed to know that? I felt very awkward answering those questions. If it was a whole broad spectrum of cancer on your overall life sector but in the context of work, I don’t know.” (P6)

Most participants discussed preference for the postage of hard-copy materials such as questionnaires and consent forms over email for a variety of reasons including ease of use, increased attention, and time to reflect on the hard-copy documents.

“I like to get post. It’s so rare these days and I pay more attention to it when it comes in the post. I have a bit more respect for it, I think.” (P2)

“I have to say I probably do have a preference for handwritten. I like to re-read it again and kind of go over it and go do I still think of that?” (P8)

The use of an online survey tool where participants did not need to navigate scanners, Adobe software or printers was also suggested by several participants. One participant suggested the use of online data collection tools such as SurveyMonkey to collect the data.

“Something like SurveyMonkey might be a good idea. But it has to be something fairly secure in terms of data transfer...So, just to find something that is more online portal based.” (P1)

Another participant echoed the convenience of an online survey tool which could negate the need for tools and software such as Adobe, scanners, etc.

“Well, if you had all the gadgets then email, but the post I found beneficial as my scanner is on the blink. If you could straightforward click your answers there, then perfect.” (P3)

Finally, participants reflected on the eligibility criteria for the intervention, suggesting that the group should be expanded to all cancer cohorts in the future.

“I do think that it would be very useful for many people with different types of cancer too.” (P5)

“I would personally think it would serve better if it was to [all cancer cohorts] because why exclude?” (P7)

6.4 DISCUSSION

The objective of this feasibility study was to evaluate a work-focused intervention for feasibility and acceptability among women living with and beyond breast cancer. The findings indicate that the intervention was accepted by participants and that it is feasible to recruit and retain participants in the six-week online intervention. Therefore, a large-scale evaluation is warranted to determine intervention effectiveness on work and health-related outcomes.

6.4.1 Participant Profiles

In this research study, women living with and beyond breast cancer who participated in the intervention were at varying stages of their RTW trajectory. Of those who had returned to work pre-intervention, this ranged from one week since RTW to over three years. In addition, mean length of sick leave was over 15 months. This supports research that indicates that impaired work ability can persist for many months and years post-breast cancer treatment (Boelhouwer, Vermeer & van Vuuren 2021; van Maarschalkerweerd et al, 2020). In particular, treatment type can be a predictor of impaired work ability (Islam et al, 2014). In this study, at least 70% of women living with and beyond breast cancer had received a combination of surgery, chemotherapy, radiation therapy, and/or hormone therapy, all of which have been cited as predictors to impaired work ability (Carlsen et al, 2013; Munir et al, 2010). This suggests that those who seek out support in their RTW, may be in receipt of more complex treatment regimens, and experiencing subsequent physical and psychological side-effects which were also outlined as significant barriers in RTW in Phase I findings. In addition, it suggests that eligibility criteria for this type of intervention should be left open to both women who have returned to the workplace, and those yet to RTW. Keeping eligibility broad for a work-focused intervention was considered in Phase I findings which suggested no time specific criteria, as well as in perceptions of participants of this feasibility study who welcomed keeping criteria open. This can also have positive benefits for the intervention where peer learning from others experiences can enhance perceived outcomes (Bandura, 1997).

6.4.2. Impact on Work and QoL Scores

Establishing effectiveness was not an outcome of this study, as this did not align with the methodology used. Despite this, outcomes were explored for descriptive purposes. The intended aim of the *Work and Cancer* intervention was to support work outcomes for women living with and beyond breast cancer. There were mixed results observed in every domain of the WRFQ as well as role functioning (EORTC-QLQ-C30), although there were observed increases in scores in work scheduling, physical and social demands at work. The greatest changes in scores observed in the WRFQ was that of managing physical demands at work, however there were no changes in physical functioning scores in the EORTC. This could be explained by intervention content targeting physical side-effects in the context of work and not necessarily general physical function. As previously outlined, evidence suggests that interventions which are designed to target management of a specific concern, such as work, result in significant effects on that specified outcome (Howell et al, 2017). Two aspects of the intervention addressed physical demands in the context of work and may have influenced this change in WRFQ scores; content on cancer-related fatigue (Session 3), and managing physical side-effects at work (Session 5).

Examining category scores of the EORTC, functional status and overall summary scores improved and symptom burden reduced post-intervention. Despite this, there were mixed findings across individual QoL outcomes. For example, there were higher median fatigue scores post-intervention. This could be perhaps explained by several factors. First, two of the participants who reported higher levels of fatigue post-intervention, returned to work during the intervention period and this initial increase in activity may have contributed to fatigue levels. Second, higher levels of insomnia were also noted and this is likely to have impacted on fatigue levels, where they are widely accepted to be reciprocally related (Zee & Ancoli-Israel, 2009). On the other hand, there were increases in median scores across cognitive and emotional functioning. Participants frequently discussed an emotional and attitudinal shift in their approach to RTW during semi-structured interviews, as well as self-managing any cognitive impairment through strategy-use. Strategy-use for cancer-related cognitive impairments are commonly used (Klaver et al, 2020) and promising results have been observed for compensatory strategy training (Fernandes, Richard & Edelstein, 2019). Despite this, a

large scale evaluation of the *Work and Cancer* intervention is warranted to determine effectiveness in this context and for all outcomes.

6.4.3 Feasibility

Adherence to the intervention and retention were considered high at 90% and 100%, respectively, although this is not unusual for women living with and beyond breast cancer. A Cochrane review exploring home-based multidimensional survivorship interventions for women living with and beyond breast cancer, found adherence ranged from 58-100% (Cheng et al, 2017), with four of the eight studies recording adherence, reporting >90% attendance. There may be several reasons for this. Group-based interventions have previously been recommended in increasing adherence due to enhanced motivation and peer support (Michael et al, 2021) and may have been a factor of the intervention which encouraged adherence. This was echoed by qualitative findings which indicated a preference for a group format, and has been observed as a preference over one-to-one interventions in other studies for those living with and beyond cancer (Oswald, Victorson & Fox, 2021; Rabin et al, 2013).

The intervention also took place during a significant restriction period in public health in response to the Covid-19 pandemic, and this could have encouraged adherence, where there were fewer competing activities. Despite this, intervention feedback was consistently positive, with participants citing interest in the topic and feeling part of a group as motivators in completing the intervention. Women living with and beyond breast cancer typically seek out and utilise healthcare services more frequently than other cancer cohorts however (Boland, 2018; Treanor et al, 2013) and therefore there is the potential that feasibility may not be generalisable to other cancer cohorts. Future studies could explore the feasibility of the intervention with other cancer cohorts. Potential advantages would be providing value in enabling equal access to work-focused interventions for all as well as potentially higher accessibility in recruitment when drawing from a larger population. Despite this, consideration on amending some aspects of the intervention would likely need to be made e.g., including management of feeding for an oesophageal cohort or higher emphasis on breathlessness management for those living with and beyond lung cancer.

In addition, research could explore the feasibility of a face-to-face format, particularly in a landscape post-pandemic. Promising feasibility findings however support the potential implementation of the *Work and Cancer* intervention online, pending outcomes of effectiveness in a definitive trial.

Finally, overcoming barriers to the intervention should be considered in future implementation. Quantitative findings highlighted partial adherence to the intervention (67%) from one participant, due to work commitments. The juggling of work roles was widely cited by participants in qualitative findings as a potential barrier in completing the intervention and is to be expected. Previous studies exploring supportive interventions for those living with and beyond cancer, cited work commitments as a barrier in attending a cancer survivorship intervention (Boland, 2018; Rabin et al, 2013). Despite this, the inclusion of those who have returned to work and self-report to be struggling is important. Evidence suggests that treatment and disease related side-effects can be chronic (Bodai & Tusso, 2015; Mokhatri-Hesari & Montazeri, 2020), and support is warranted for this cohort. As such, flexibility of intervention delivery outside of working hours might be considered, such as in the evening or at weekends if possible, as suggested by Lyons et al (2015). No other barriers were discussed, and instead emphasis placed on the online format as a facilitator to intervention completion.

6.4.4 Outcome Measures: Feasibility, Suitability and Distribution

Beyond the intervention, completion of instruments pre- and post-intervention was also deemed to be feasible where participants reported measures to be easily understood and completed each relevant outcome measure, with 1.48% and 0.19% overall missing items for the WRFQ, and EORTC-QLQ-C30/QLQ-BR23, respectively. This has been considered feasible in the past; While missing responses for items for the WRFQ are infrequently reported, some studies which do cite missing items have previously ranged from 2-3.5% (Ramada et al, 2014a; Ramada et al, 2014b). Missing items using the EORTC-QLQ-C30 range from 0-8.6% (Apolone et al, 1998; Davda et al, 2021; Waldmann, Schubert & Katalinic, 2013). In general, qualitative findings supported the use of instruments as acceptable. Therefore, use of both WRFQ, EORTC-QLQ-C30 and QLQ-BR23 could be considered feasible in future research in this context. Despite this, other outcome measures could be explored, where the appropriate selection of outcome

measurements for an intervention can be challenging where close attention is paid to what outcome should be measured as well as how it should be measured (Coster, 2013).

An objective of this study was to identify suitable outcome measures for a RTW intervention for women living with and beyond breast cancer. While the EORTC-QLQ-C30, QLQ-BR23, and WRFQ had high compliance rates and were perceived as acceptable by women living with and beyond breast cancer, qualitative findings suggested some potential gaps in outcome measurement that may be of importance. For example, qualitative findings highlighted perceived changes in self-efficacy, where women discussed a new sense of empowerment and attitudinal changes towards their RTW. This could be important to measure as higher job self-efficacy is related to an earlier RTW, as well as a stronger predictor for a full RTW than work ability (Wolters et al, 2018). The PROMIS® Self-Efficacy for Managing Chronic Conditions is one outcome measure that has demonstrated internal consistency and cross-sectional validity (Gruber-Baldini et al, 2017), and could be applied to a cancer population. More specifically, work self-efficacy could be examined using an outcome measure such as the 19-item Return-to-Work Self-Efficacy Questionnaire (RTWSE) which has demonstrated reliability and adequate validity in a cancer population (Rosbjerg et al, 2021). This could be of particular use to participants who have yet to return to the workplace and were not in a position to complete the more detailed WRFQ for work outcomes.

Finally, qualitative-descriptive findings highlighted a preference for hard-copy documents/outcome measures over email distribution, over ease of use, perceived increased attention when completing, and time for reflection. There is some literature exploring response rates for email and postal questionnaire, however it is mostly outdated (Kaplowitz, Hadlock & Levine, 2004; Sheehan, 2001), where digital literacy may have since progressed. Despite this, one study based in Ireland, did observe a response rate for posted questionnaires almost twice of that for the email equivalent, although at a higher financial cost (James, 2007). Further work into documentation distribution could be explored as a study within a trial (SWAT) as part of the large-scale evaluation.

6.4.5 Acceptability of the *Work and Cancer* intervention: Content and Delivery

The content and delivery of the *Work and Cancer* intervention was perceived as acceptable by participants who reflected on several core aspects to the intervention. First, all content, which was work-focused, based on self-management theory and personalised through a one-to-one session, was described as relevant by participants. There are similarities to this with a work-focused intervention reported by Hubbard et al (2013), which offered a tailored approach with MDT input. It is difficult, however, to compare intervention content where there is a paucity of work-focused interventions for this cohort, as identified by Algeo, Bennett & Connolly (2021). Indeed, a Cochrane review cited it ‘remarkable’ that there remains a paucity of work-focused interventions in cancer care (de Boer et al, 2015, p.20). Further research into interventions of this kind, will provide clarity on effectiveness and conclusive recommendations on key content. Furthermore, it is challenging to ascertain what intervention content ‘worked’ and what didn’t, in the absence of definitive conclusions for effectiveness. Despite this, qualitative findings highlighted no irrelevant content, and emphasis was placed in particular on employment rights and entitlements, which was also prominently discussed in Phase I (Algeo, Bennett & Connolly, in press-a). Qualitative-descriptive findings also highlighted the letter to the employer and RTW Plan as useful resources to apply in the RTW process. Letters with tailored accommodations for the workplace were previously highlighted as facilitators in the RTW process in Phase I findings, and can advocate for an individual living with and beyond cancer where there can be reduced awareness of rights (National Disability Authority, 2019).

The online delivery of the intervention via the Zoom Video Communications Inc. platform was deemed acceptable by participants and often cited as an enabler in adherence in qualitative findings. Of interest, several participants reported a paradigm shift in their perceptions towards online delivery since the onset of the pandemic. It is likely that further insights into the acceptability of online self-management interventions will emerge over time, as suggested by several study protocols (Nohra et al, 2020; Price & Brunet, 2020; Wright et al, 2020). Considering online platforms in the future could overcome traditional barriers to face-to-face interventions such as caregiving and work responsibilities, lack of time or inadequate transportation (Ades et al, 2017). Furthermore, while some self-management interventions may transition back

to face-to-faces format post-pandemic, there may be opportunities to host interventions completely or partially online to cater for those with the digital preference. Despite this, there is no ‘one-size-fits-all’ approach in intervention delivery (O’Connor et al, 2019), where poor digital literacy has previously been cited as a barrier to participation in online cancer support groups (Klemm et al, 2003; Lepore et al, 2019) . In addition, while online delivery of interventions may overcome barriers for some cohorts, they can conversely present barriers to others (Annaswamy, Verduzco-Gutierrez & Frieden, 2020). For example, those living with and beyond cancer who are socio-disadvantaged may experience barriers in accessibility where strong WiFi and an internet-enabled device is required.

This study explored the feasibility of the *Work and Cancer* intervention delivered online, but there may be a place to explore feasibility of a face-to-face delivery in the future, where four out of ten participants in this study reported a preference for the face-to-face format had they the choice. While there is an increasing evidence-base exploring the transition of traditionally face-to-face interventions to online platforms in recent years (O’Neill et al, 2021; Smith et al, 2020; Wu et al, 2021), there is limited evidence exploring the transition of online interventions to a face-to-face format. Despite this, evidence that is available suggests that transferability of online cancer interventions to the face-to-face setting is feasible (Akard et al, 2020; Gibbons et al, 2020), although further research is required on this topic.

Findings of this feasibility study also indicated a preference for community-based settings, should the intervention be delivered face-to-face in the future. Preference for the community setting could be partially explained by the recruitment strategy of this study. Most participants were recruited via a gatekeeper in a cancer support centre which may have influenced preference for community-based cancer support centres. Despite this, several survivorship interventions have been facilitated in the community setting and have observed effectiveness in QoL outcomes (Gibbons et al, 2020; Gifford et al, 2021). This contrasts with Phase II systematic review findings where the majority of the nine intervention studies identified were set in the hospital setting (Algeo, Bennett & Connolly, 2021). Despite this, most interventions identified in the systematic review were not work-specific, and the one intervention that did explore employment, was set between an outpatient hospital setting and the community.

The combination of both group and individual sessions was acceptable to participants. While self-management interventions for those living with and beyond cancer are typically in self-guided or group formats (Boland, 2018; Gibbons et al, 2020), the use of hybrid interventions is less common. Despite this, there is emerging evidence indicating promise for this format. For example, women living with and beyond breast cancer engaging in an occupation-focused cognitive self-management programme found both the group format and one-to-one contact with an occupational therapist highly beneficial (Newman et al, 2019). There are several reasons why the hybrid approach may be acceptable. First, group formats enable peer support which was widely reported by participants in qualitative findings as a motivator in intervention adherence. Group formats have also been recommended elsewhere (Michael et al, 2021) to enhance motivation and peer support amongst participants. Second, individual sessions include content that is tailored to specific work challenges, and greater flexibility in scheduling individual appointments (Bernstein et al, 2018). An evolving body of research into hybrid intervention models is warranted to further explore potential benefits.

Finally, temporal factors of the intervention were considered, where the six-week intervention length was deemed acceptable by participants, but session length deemed too short at 90 minutes. Six-week self-management interventions for those living with and beyond cancer have been implemented into practice in Ireland (Bantum et al, 2014; Boland et al, 2019). Session length in self-management survivorship interventions, however, can vary widely (Bantum et al, 2014; Grimm et al, 2013; van den Berg, 2015), and has been discussed in further detail in Chapter 5 (Section 5.4.3). Further refinement of the intervention could include amending session length by 15-30 minutes.

6.4.6 Future Implementation

Findings from this feasibility study indicated a strong desire by participants for an online intervention of this kind to be implemented nationwide. The necessity of this is echoed in a recent Irish Cancer Society report (2021a, p.4) which recommends that “The Government should introduce a state-run pilot programme on reintegration into the workplace for cancer patients and survivors out of work at the time of their diagnosis or after their diagnosis”. As indicated in the systematic review (Algeo, Bennett & Connolly, 2021), there are no dedicated work-focused interventions for women living with and beyond breast cancer and this intervention may address the

current gap in Ireland and internationally, should future evaluation indicate effectiveness. As the intervention is deemed both feasible and acceptable, testing the effectiveness in relation to work and quality of life outcomes is indicated, taking into consideration amendments suggested during the qualitative-descriptive design. For example, session length may be increased from 90 minutes to two hours. While 90-120 minutes was prioritised as the preferred session length in the NGT study, 90 minutes was initially chosen for the feasibility study where there was a concern that excess screen time may be fatiguing.

6.4.7 Implications for Future Research: Findings from this feasibility study indicate that the *Work and Cancer* intervention is feasible to implement, and acceptable to women living with and beyond breast cancer. Therefore, a large-scale RCT evaluation is warranted to determine intervention effectiveness on work and health-related outcomes. Elements of the intervention to be retained in future research studies include the work-focused content, six-week duration, and hybrid delivery of group-based sessions and one-to-one occupational therapy input. Factors that will be modified include the increase of session length and distribution of questionnaires, in the future development and testing of the *Work and Cancer* intervention. As the intervention was tested for feasibility using the online platform, there may be benefit in piloting the intervention face-to-face, in addition to the online format. It is becoming increasingly clear, as healthcare professionals and patients continue to navigate the pandemic, that variety in service delivery may be necessitated and needs to be evaluated.

The sample size was small in this feasibility study ($n=10$), therefore future piloting of the intervention is warranted to increase sample size to more accurately estimate a standard deviation for a sample size calculation for large-scale evaluation. Typically, an overall sample size of 30 is recommended as a ‘general rule of thumb’ for good practice (Lancaster, Dodd & Williamson, 2004, p.308). Determining the primary outcome measure prior to sample size calculation is also required. In this Phase IV study, a potential gap in outcomes to be measured was identified, where qualitative findings highlighted the importance of self-efficacy in ability to RTW or maintain work which was an outcome not explored previously.

6.4.8 Implications for Clinical Practice: The *Work and Cancer* intervention is a six-week self-management programme that aims to support work ability of women living with and beyond breast cancer. Occupational therapists are well-placed to deliver the online intervention and, as suggested by participants in this study, eligibility of the intervention could be expanded to other cancer cohorts once evaluated. While MDT input was welcomed, strategic delivery of such input could be considered from a pragmatic implementation perspective. For example, it may be difficult to co-ordinate an occupational therapist in leading the intervention, alongside a community welfare officer and physiotherapist. Therefore, based on participant feedback, recorded video input could be considered from a physiotherapy perspective, where it may be otherwise difficult to offer personalised advice without formal assessment. Video education has been found to be feasible for a breast cancer cohort, although this was not physiotherapy-specific (Sulakvelidze et al, 2019). Despite this, there is emerging evidence exploring physiotherapy-specific video education for women living with and beyond cancer (Guloglu et al, 2021).

6.4.9 Strengths and Limitations

This study offers an insight into the feasibility and acceptability of the '*Work and Cancer*' intervention in Ireland. The study design is strengthened with the use of mixed methodology prior to a larger evaluation which could potentially optimise the intervention itself as well as the conduct of a future trial. There are also several limitations. Data were collected by the interventionalist which may have influenced participant responses. Furthermore, participants were mostly recruited from a single cancer support centre which may have influenced findings for preferred intervention face-to-face setting. While this study explored the feasibility of an online iteration of the *Work and Cancer* intervention, it cannot be concluded that a face-to-face version would also be feasible. Despite this, there were mixed feelings among the group for format preference in the future, with four of the ten participants indicating preference for a face-to-face intervention.

6.4.10 Conclusion

Quantitative and qualitative findings suggest a positive impact on both work and QoL outcomes. This study has shown it is feasible to recruit and retain participants to the six-

week intervention which was widely accepted by women living with and beyond breast cancer navigating return to work, or work maintenance. This study builds on the limited research available in work-focused interventions for women living with and beyond breast cancer, as shown by the systematic review completed (Algeo, Bennett & Connolly, 2021), and findings support the necessity for further testing of an intervention of this kind. Minor amendments such as increasing session length and offering outcome measures in other formats such as post and/or online survey will be made. A large-scale evaluation is warranted to determine intervention effectiveness on work and QoL outcomes.

CHAPTER SEVEN: CONCLUSION

7.1 Introduction

The overall aim of this research was to develop and evaluate the feasibility of a self-management intervention to support work outcomes for women living with and beyond breast cancer. Four separate studies were undertaken as part of this research. This chapter will provide an overall conclusion. A diverse range of facilitators and barriers in RTW for women living with and beyond breast cancer in an Irish context were explored using a qualitative-descriptive approach. A systematic review and meta-analysis of rehabilitation interventions that support women living with and beyond breast cancer in RTW highlighted a lack of effective and methodologically rigorous intervention studies for this cohort. In response to inconclusive recommendations for the content and delivery of a work-focused intervention, a consensus study using the NGT was conducted, prioritising the development of the six-week *Work and Cancer* intervention delivered across five group-based sessions and one individual session with an occupational therapist. Findings from a single-arm feasibility study and qualitative-descriptive design indicated that the *Work and Cancer* intervention is both feasible and acceptable to women living with and beyond breast cancer.

7.2 Persisting symptoms, employment rights, and employer-employee communication: Core factors in return to work after breast cancer in Ireland

Throughout the course of this research, persisting symptoms, employment rights, and employer-employee communication emerged as common factors impacting on RTW post-breast cancer diagnosis. Phase I findings observed these factors as either facilitators and barriers in RTW for women living with and beyond breast cancer that could be amenable to change through rehabilitation. Ways in which to address these factors, amongst others, were discussed and prioritised in Phase III findings to inform core content for the proposed *Work and Cancer* intervention (Algeo, Bennett & Connolly, in press-b). Since the onset of this research, the Irish Cancer Society (2021a)

has recommended raising awareness of work-related supports and rights for employees and employers in Ireland for all living with and beyond a cancer diagnosis, as well as ensuring appropriate employer-employee communication (frequency and method of contact tailored to the employee). This is in addition to the importance of psychological and physical readiness in RTW, which is widely cited internationally (Islam et al, 2014; Tan et al, 2012).

Of note, however, no included interventions from the Phase II systematic review specified employment rights or employee-employer communication as part of intervention content (Algeo, Bennett & Connolly, 2021), although one study did explore finance (Björneklett et al, 2013). This is echoed in findings by de Boer and colleagues in their 2015 Cochrane Review, which explored RTW interventions across all cancer types. While several interventions in their review included focus on management and rehabilitation of physical and psychological sequelae, there were no identified interventions which explored employee-employer communication or employment rights, which feature in the *Work and Cancer* intervention. There is promise, however, for a work-focused intervention to address these factors. A similar intervention encompassing both employment legislation and effective employer-employee communication observed significant improvements in work ability, although this was targeted towards individuals with rheumatic disease (McCormack et al, 2018). While these factors emerged as areas of importance in this research, large scale evaluation is warranted to understand if an intervention embedding these factors, such as the *Work and Cancer* intervention, enhances work outcomes.

7.3 The development of work-focused interventions for women living with and beyond breast cancer

The development and feasibility of the *Work and Cancer* intervention was informed by the MRC Framework for complex interventions (Craig et al, 2008). As outlined previously, intervention development and evaluation is a dynamic process, and not necessarily a linear pursuit, as highlighted over the course of this research. For example, where findings from Phases I and II did not conclude definitive recommendations for the content and delivery of a work-focused intervention, a consensus study was conducted (Phase III). This is reflective of MRC framework guidance, where learning

from one or more actions in intervention development, can influence plans for other actions (O’Cathain et al, 2019).

The conduct of an additional phase was not the only challenge encountered during intervention development, however. In response to public health measures in place at the time of planning Phase IV, the *Work and Cancer* intervention was evaluated for feasibility online. This was despite no conclusive recommendations for an online or face-to-face delivery in Phases I and II, and an overall preference for face-to-face delivery prioritised in Phase III. It was accepted, however, that the risk-benefit ratio of research needed to be considered throughout the pandemic to inform whether it should proceed (Padala et al, 2020). Challenges to the conduct of research during this period have been well documented. In Ireland, both clinical care and research in cancer were significantly impacted by the COVID-19 pandemic (Department of Health, 2020; Irish Cancer Society, 2021g). For example, recruitment into cancer trials in Ireland fell by 45% when comparing Q1 2020 and Q1 2021 figures (Cancer Trials Ireland, 2021). Had the feasibility of the intervention been tested in a face-to-face setting, it is possible that there may have been different findings. The shift to hybrid and online intervention delivery has prompted, however, the consideration of developing future hybrid and/or online rehabilitation interventions.

7.4 Recommendations for Future Research

Several recommendations for future research are presented (Table 7.1), many of which have been discussed in further detail elsewhere (Sections 3.4.2, 4.4.7, 5.4.5 & 6.4.6). Findings from this feasibility study indicate that the *Work and Cancer* intervention is feasible to implement, and acceptable to women living with and beyond breast cancer in Ireland. Elements of the intervention to be retained include the work-focused content, six week duration, and hybrid delivery of group-based sessions and one-to-one occupational therapy input. Factors that will be modified include increased session length, alternative distribution of questionnaires, and minor additions to Session 4 (Communication) content in the future development and testing of the *Work and Cancer* intervention.

Table 7.1 Key Recommendations for Future Research

Key Recommendations	
1.	Future research into the development of employer education in legal issues protecting employees with health problems such as cancer is warranted.
2.	A greater body of evidence of work-focused intervention studies, incorporating a model of intervention development into the study design and with sufficient sample sizes, for women living with and beyond breast cancer is required.
3.	Further research exploring in-depth the use of the online NGT as a methodology is warranted.
4.	Further research into hybrid delivery of interventions is warranted.
5.	Future piloting of the <i>Work and Cancer</i> intervention is warranted in both online and face-to-face formats.
6.	Feasibility and piloting of the <i>Work and Cancer</i> intervention for all cancer cohorts is warranted.
7.	PPI input should be embedded throughout all stages of intervention development

7.4.1 Beyond Development and Feasibility: Progressing the Work and Cancer intervention

A large-scale evaluation is warranted to determine intervention effectiveness on work and health-related outcomes. Findings from Phase IV also indicated an acceptability by women living with and beyond breast cancer for the intervention to be expanded to other cancer cohorts in the future as well as keeping criteria open to both those who have yet to RTW, and those who have returned to work but self-report to be struggling. This is important as it is recognised that treatment and disease related side-effects can be cumulative and long-lasting, impacting on employment (Short et al, 2005).

Where an intervention is considered feasible, the intervention development and evaluation process can be progressed to the next stage, as per the MRC framework for development of complex interventions (Craig et al, 2008). As outlined previously (Section 1.2), intervention development and evaluation is a dynamic process, and not necessarily a linear pursuit (Craig et al, 2008). While a substantial component of the intervention development phase may have been conducted in this PhD research, in reality the intervention can be further refined during further evaluation and implementation phases (O’Cathain et al, 2019). In addition, subsequent stages to progress the intervention would include determining sample size for future definitive trials, before progressing to an evaluation stage in which a large-scale RCT would be

conducted (Craig et al, 2008). As discussed in Chapter 6 (Section 6.4.6), the sample size was small in Phase IV ($n=10$), therefore future piloting of the intervention is warranted to increase sample size to more accurately estimate a standard deviation for a sample size calculation for large-scale evaluation. Determining the primary outcome measure prior to sample size calculation is also required.

Finally, a close relationship was formed with PPI members during the development stages of the *Work and Cancer* intervention (Section 3.2.3), and it is envisaged that these links not only be maintained, but expanded on where PPI could be embedded in partnership through all research phases. Consistency in this PPI input is warranted, where there were opportunities missed to involve PPI members (Section 4.5). RCTs have been considered particularly likely to benefit from PPI input (Gamble et al, 2014) with some examples of input including (i) precision and co-production of a research question, (ii) outcomes to be measured, (iii) intervention schedules and settings, (iv) methods of data collection, and (v) recruitment and consent procedures (Staniszewska et al, 2007).

7.5 Implications for Policy and Practice

In recent years, there has been greater emphasis placed on the importance of reintegration into the workplace after cancer in Ireland. This is evident through the embedding of key recommendations and commitments made in national policy and strategy in Ireland (Department of Health, 2017; Irish Cancer Society 2020; Marie Keating Foundation, 2020). For example, RTW has been referenced to as part of the ten ‘Big Commitments’ of the *Irish Cancer Society 2020-2025 Strategy* (Irish Cancer Society, 2020). In the *National Cancer Strategy 2017-2026*, “assimilation back into the workforce” is recognised as a key area in optimising quality of life (Department of Health, 2017, p.109). Proposed actions have recently been recommended at national level to introduce a State-run pilot programme on reintegration into the workplace (Irish Cancer Society, 2021a). The development of the *Work and Cancer* intervention is therefore timely and relevant, having been developed within an Irish context, and could potentially address the policy gap outlined. Research can impact policy in several ways. Weiss (1998) identified four key mechanisms of influence including instrumental use, mobilisation of support, conceptual use, and redefining/wider influence. This research

offers mobilisation of support, where research findings offer persuasive evidence to support recent policy and strategy described. It could also potentially influence instrumental use where “research findings directly drive or define policy” (Kuruvilla et al, 2006, p.10). Once all publications have been made public, a policy brief with summary of findings and recommendations will be drawn up and published as recommended by Arnautu and Dagenais (2021).

Equipped with a unique skillset in activity analysis and analysing occupational performance, occupational therapists are well placed to develop and implement work-focused interventions (Baxter et al, 2017). Despite this, the evidence-base in occupational therapy rehabilitation and cancer care is limited, although evolving (Hunter et al, 2017). Strengthening the evidence-base through subsequent research is required. Occupational therapists could consider small-scale research projects exploring occupation-based survivorship interventions in the clinical setting or consider forging alliances with higher education institutions in joint clinical-academic partnerships to strengthen both the evidence-base and service development (Bennett, 2014).

7.6 Strengths and Limitations

This study is the first of its kind internationally to explore the development and feasibility of a work-focused intervention for those living with and beyond breast cancer. The importance of feasibility methods is underlined as an important step to incorporate in intervention development. A paucity in piloting and feasibility studies in this field was identified by Phase II findings, despite several models of intervention development advocating for testing prior to any evaluation (Craig et al, 2008; Czajkowski et al, 2015). This research addresses this gap, promoting more comprehensive intervention development and refinement. A patient-centred approach was also embedded into several aspects of the research, including PPI input in Phase I, dissemination of Phases I and II to a lay audience, the input of key stakeholders in forming the final intervention in Phase III. Despite this, there were further opportunities where PPI consultation could have been embedded however were not, due to time constraints. For example, PPI input could have been embedded into the design of Phase II, providing valuable input including (but not limited to) the initial stages of the review (e.g., forming the research question) or supporting the interpretation of findings.

Finally, transparent and accurate reporting of the research was promoted through use of robust reporting guidelines such as COREQ, PRISMA and TIDiER. Reporting guidelines can reduce reporting bias, inform clinical decision-making, and inform future research (Chan et al, 2014).

Limitations also existed. Semi-structured interviews as part of the Phase IV qualitative-descriptive design were also conducted online, via the Zoom Video Communications Inc. platform. This platform was the highest ranked online platform identified in Phase III and has previously been used for qualitative data collection pre-pandemic (Archibald et al, 2019; Daniels et al, 2019). There are strengths and limitations to this format of data collection. Early literature identified research interviews online as a novel scientific process of inquiry (Bertrand et al, 2010), that offers several advantages including affordability (unlimited one-to-one interviewing at no cost), convenience, and accessibility for some cohorts. Accessibility, however, may not be equitable across all cohorts where there is the potential for technical difficulty, and accessibility concerns for those with a socio-disadvantaged background or in the older adult population (Foley, 2021). In addition, challenges may arise if the security of data is compromised, adding additional ethical considerations for confidentiality and privacy (Lobe et al, 2020). Despite this, video-based online interviews are emerging as a promising substitute to face-to-face interviewing and will likely feature considerably in study designs from here on.

The sample size for the single-arm feasibility study was also small. This minimum number was selected for practical reasons but may have implications on calculating sample size for a future definitive trial. Therefore, further piloting of the intervention with larger samples is warranted. In addition, both the intervention and semi-structured interviews were led by the researcher and this may have led to bias in social desirability. Nonetheless, adherence and retention rates suggest that there is promise for an intervention of this kind.

7.7 Conclusion

The overall aim of this PhD research was to develop and evaluate the feasibility of a work-focused occupational therapy-led intervention to support return to work for women living with and beyond breast cancer. Persisting symptoms, employment rights and employer-employee communication emerged as key factors influencing the RTW process throughout this research. Despite this, rehabilitation interventions that impact on work outcomes for this cohort are lacking, and of those which do exist, lack methodological rigour. This PhD research identified key barriers and enablers in RTW for women living with and beyond breast cancer in Ireland, explored perceptions around what a RTW intervention could look like, and prioritised content and delivery of such a RTW intervention. While effectiveness of the *Work and Cancer* intervention could not be determined due to the design of the study, the intervention was deemed to be both feasible and acceptable to women living with and beyond breast cancer. In line with the dynamic and iterative nature of intervention development, minor amendments will be made to the intervention prior to proceeding to a larger-scale investigation. Future research is required to evaluate the effectiveness and sustainability of the *Work and Cancer* intervention which could be considered in both online and face-to-face formats.

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APPENDICES

APPENDIX A: COREQ CHECKLIST (PHASE I)

Topic	Item No.	Description	Reported on:
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/ Facilitator	1	Which author(s) conducted the interview or focus group?	37
Credentials	2	What were the researcher's credentials? E.g., PhD	37 (MRes, BScOT)
Occupation	3	What was their occupation at the time of the study?	37
Gender	4	Was the researcher male or female?	37 (refers to 'she')
Experience and training	5	What experience or training did the researcher have?	37
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	36
Participant knowledge of the interviewer	7	What did the participants know about the researcher? E.g., reasons for doing the research	36
Interviewer characteristics	8	What characteristics were reported about the interviewer? E.g., bias, assumptions, reasons and interest in the research topic	8-9
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, content analysis.	32-33
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, snowball.	33
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email.	34-35; 36
Sample size	12	How many participants were in the study?	35; 43
Non-participation	13	How many people refused to participate or dropped out? Reasons?	37
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g., home, workplace, etc.	37
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	37
Description of sample	16	What are the important characteristics of the sample? e.g., demographic data, date	43-46
<i>Data collection</i>			

Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	37 + Appendix D
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	37 ('once-off')
Audio/visual recording	19	Did the research use audio or video recording to collect data?	37 (audio)
Field notes	20	Were field notes made during and/or after the interview or focus group?	37 (Yes)
Duration	21	What was the duration of the interviews or focus group?	37
Data saturation	22	Was data saturation discussed?	47; 79
Transcripts returned	23	Were transcripts returned to participants for comment and/or correction?	38
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	38 (Two coders)
Description of the coding tree	25	Did authors provide a description of the coding tree?	40 Codes were managed using NVivo. No coding tree.
Derivation of themes	26	Were themes identified in advance or derived from the data?	38
Software	27	What software, if applicable, was used to manage the data?	38
Participant checking	28	Did participants provide feedback on the findings?	39 (checking did not feature)
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quote identified? e.g., participant number	48-68
Data and findings consistent	30	Was there consistency between the data presented and the findings?	47-72
Clarity of major themes	31	Were major themes clearly presented in the findings?	47-68
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	47-72. (In particular, minor items added 68-72)

APPENDIX B: PARTICIPANT INFORMATION LEAFLETS (PHASE I)



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Participant Information Leaflet: Women Living With and Beyond Breast Cancer

Thank you for taking time to read this participant information leaflet. You are being invited to take part in a research study led by Ms Naomi Algeo (PhD Candidate) and Dr Deirdre Connolly (Principle Investigator), Discipline of Occupational Therapy, Trinity College Dublin.

Title of study: *BReast cAnCer surVivors and Employment (BRAVE): Facilitators and barriers in returning to and staying at work in Ireland*

Introduction:

Cancer survivorship is increasing. In 2015, there were over 148,000 cancer survivors in Ireland. Breast cancer is common, affecting over 30% of newly-diagnosed women. Women often report experiencing many difficulties including fatigue, pain, fogginess in their thinking, and physical limitations (e.g. reaching above shoulder level). This can have an impact on their ability to work. Recent figures indicate that around 84% of women in Ireland stop working after breast cancer diagnosis but often return some time after treatment.

We would like to explore the following:

- What are the experiences women with breast cancer in staying at or returning to work during/post-treatment?
- What helps or hinders women with breast cancer who return to work?
- What factors support or limit effective work performance in women with breast cancer?
- What could be put in place for the future to support women with breast cancer in staying on at work or returning to their previous role?

To answer these questions, we are inviting women living with and beyond breast cancer, who have completed treatment in the past 24 months, and have either stayed at or returned to work since then, to take part in a research study. This will involve a once-off interview between March and July 2019.

Procedures: Who are we looking to speak with?

We are looking to speak with women living with and beyond breast cancer who meet the following criteria:

- Women living with and beyond breast cancer (primary diagnosis breast cancer) who have completed their cancer treatment in the past 24 months and have since either stayed at work or returned to work.
- Aged 18-66 years old (current retirement age in Ireland)
- In employment at time of diagnosis

If you choose to take part in the study, you will be invited to attend a once-off face-to-face interview at Trinity Centre for Health Sciences or another predetermined setting between March and July 2019. Interviews should last no more than 75 minutes and will be recorded using a digital recorder, with your consent.

Benefits: Are there any benefits from my participation?

There is no benefit for research participants.

Risks: Are there any risks or disadvantages involved in participating?

There is a possibility that you may become upset during interview. Talking about your diagnosis, treatment, and life following this, can be a sensitive subject to talk about. If you do become upset, you are reminded that you can stop the interview at any time. All participants are reminded that they can access support services such as the Irish Cancer Society and ARC Cancer Support Centres should they wish to seek any support services.

It is recognised that participation in the study may cause mild inconvenience.

Therefore, we will try to arrange all interviews at a day and time are most convenient to you. While Trinity Centre for Health Sciences will be the main interview location, there is flexibility in where the interview will take place. It can be arranged to meet in a location that is closer to your home or more convenient.

Exclusion from participation: Is there any reason why I wouldn't be able to participate?

You will not be able to participate in this study if you completed your breast cancer treatment more than 24 months ago.

There is also the potential that the study may become over-subscribed. We are aiming to recruit up to 13 women living with and beyond breast cancer. If interest exceeds this number, we will select participants based on certain characteristics so that we interview as wide a range of women as possible. These characteristics will include type of work, stayed at work vs. returned to work, type of treatment and time since diagnosis. If you are not selected for interview, we will notify you by your preferred contact detail.

Confidentiality and Data Protection: Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study group. Personal information collected from this study (for example: your name, and contact details on the consent form) will be kept in a locked cabinet with access restricted only to the research team.

Each participant will receive a Study ID number. If you would like a copy of your transcript, please contact the researcher with your unique Study ID number. All computerised data (such as audio recordings and transcripts) will be stored on a password-protected computer. Please note that Study IDs are used to pseudo-anonymise your data. This means that personal details e.g. your name, are coded which acts as a measure to protect your confidentiality. A document (called a code-book) will link your name and Study ID. This code book will be stored securely and separately from other data such as consent forms etc.

The research team aim to present and publish results of this study at conferences and in scientific journals in the future, however no identifiable personal data will be published. In addition, no information that could lead to your identification will be disclosed in any reports on the project, or to any other party. All data will be stored for the duration of the study i.e. until results have been fully reported and then kept in a locked cabinet for five years. All data collected (including consent forms, audio-recordings, Study ID Code-Book) will then be deleted securely at the end of this five year period. This material will not be used in future unrelated studies without further specific permission being obtained. Identifiable information will not be shared with any other organisation. Your data will be processed for the legitimate interest of health research (Article 6;1(f), General Data Protection Regulation, 2016) and scientific research purposes (Article 9;2(j), General Data Protection Regulation, 2016).

Compensation: This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation: If you decide to volunteer to participate in this study, you may withdraw at any time (up until the point that your data have been analysed and reported) without giving a reason. If you decide not to participate, or if you withdraw, you will not be penalised in any way and there will be no implications on your regular treatment plan. If you have already completed interview and would like to withdraw your data, you can contact the research team and provide them with your unique ID number. It is aimed that all data will analysed and written up by February 2020.

Stopping the study: Your Principal Investigator may stop your participation in the study at any time without your consent.

Permission: This study was approved by the Faculty of Health Sciences Research Ethics Committee on the 12th March 2019.

Further Information: You can get more information or pose questions about the study, your participation in the study, and your rights, to Ms Naomi Algeo who can be telephoned at 083-053-0777 or e-mailed at nalgeo@tcd.ie. If your Principal Investigator learns of important new information that might affect your desire to remain in the study, she will tell you.

Ms Naomi Algeo

PhD Candidate

Trinity College Dublin

Discipline of Occupational Therapy

Trinity Centre for Health Sciences

James Street

Dublin 8

Participant Information Leaflet: Healthcare Professionals

Thank you for taking time to read this participant information leaflet. You are being invited to take part in a research study led by Ms Naomi Algeo (PhD Candidate) and Dr Deirdre Connolly (Principle Investigator), Discipline of Occupational Therapy, Trinity College Dublin.

Title of study: *BReast cAnCer surVivors and Employment (BRAVE): Facilitators and barriers in returning to and staying at work in Ireland*

Introduction:

Cancer survivorship is increasing. In 2015, there were over 148,000 individuals living with and beyond cancer in Ireland. Breast cancer is common, affecting over 30% of newly-diagnosed women. Women often report experiencing many difficulties including fatigue, pain, foggy thinking, and physical limitations (e.g. reaching above shoulder level). This can have an impact on their ability to work. Recent figures indicate that around 84% of women in Ireland stop working after breast cancer diagnosis but often return some time after treatment. We would like to explore the following:

- From a healthcare professional perspective, what challenges do women with breast cancer present with in staying at or returning to work during/post-treatment?
- What helps or hinders women living with and beyond breast cancer who return to work?
- What factors support or limit effective work performance in women living with and beyond breast cancer?
- What could be put in place for the future to support women living with and beyond breast cancer in staying on at work or returning to their previous role?

To answer these questions, we are inviting healthcare professionals who work with women with breast cancer to take part in a research study. This will involve a once-off interview between March and July 2019.

Procedures: Who are we looking to speak with?

We are looking to speak with healthcare professionals who meet the following criteria:

- Healthcare professionals who work directly with women living with and beyond breast cancer.
- Address employment as *part* of their assessment and/or intervention with women living with and beyond breast cancer.

If you choose to take part in the study, you will be invited to attend a once-off face-to-face interview at Trinity Centre for Health Sciences or another predetermined

setting, between March and July 2019. Interviews should last no more than 75 minutes and will be recorded using a digital recorder, with your consent.

Benefits: Are there any benefits from my participation?

There is no benefit for research participants.

Risks: Are there any risks or disadvantages involved in participating?

It is recognised that participation in the study may cause mild inconvenience. Therefore, we will try to arrange all interviews at a day and time are most convenient to you. While Trinity Centre for Health Sciences will be the main interview location, there is flexibility in where the interview will take place. It can be arranged to meet in a location that is closer to your workplace or more convenient.

Exclusion from participation: Is there any reason why I wouldn't be able to participate?

There are no exclusion criteria for this study.

Confidentiality: Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study group. Personal information collected from this study (for example: your name, and contact details on the consent form) will be kept in a locked cabinet with access restricted only to the research team.

Each participant will receive a Study ID number. If you would like a copy of your transcript, please contact the researcher with your unique Study ID number. All computerised data (such as audio recordings and transcripts) will be stored on a password-protected computer. Please note that Study IDs are used to pseudo-anonymise your data. This means that personal details e.g. your name, are coded which acts as a measure to protect your confidentiality. A document (called a code-book) will link your name and Study ID. This code book will be stored securely and separately from other data such as consent forms etc.

The research team aim to present and publish results of this study at conferences and in scientific journals in the future, however no identifiable personal data will be published. In addition, no information that could lead to your identification will be disclosed in any reports on the project, or to any other party. All data will be stored for the duration of the study i.e. until results have been fully reported and then kept in a locked cabinet for five years. All data collected (including consent forms, audio-recordings, Study ID Code-Book) will then be deleted securely at the end of this five year period. This material will not be used in future unrelated studies without further specific permission being obtained. Identifiable information will not be shared with any other organisation.

Compensation: This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation: If you decide to volunteer to participate in this study, you may withdraw at any time (up until the point that your data have been analysed and

reported) without giving a reason. If you decide not to participate, or if you withdraw, you will not be penalised in any way and there will be no implications on your regular treatment plan. If you have already completed interview and would like to withdraw your data, you can contact the research team and provide them with your unique ID number. It is aimed that all data will be analysed and written up by February 2020.

Stopping the study: Your Principal Investigator may stop your participation in the study at any time without your consent.

Permission: This study was approved by the Faculty of Health Sciences Research Ethics Committee on the 12th March 2019.

Further Information: You can get more information or pose questions about the study, your participation in the study, and your rights, to Ms Naomi Algeo who can be telephoned at 083-053-0777 / 01-896-3222 or e-mailed at nalgeo@tcd.ie. If your Principal Investigator learns of important new information that might affect your desire to remain in the study, she will tell you.

Ms Naomi Algeo
PhD Candidate
Trinity College Dublin
Discipline of Occupational Therapy
Trinity Centre for Health Sciences
James Street
Dublin 8

Participant Information Leaflet: Employers

Thank you for taking time to read this participant information leaflet. You are being invited to take part in a research study led by Ms Naomi Algeo (PhD Candidate) and Dr Deirdre Connolly (Principle Investigator), Discipline of Occupational Therapy, Trinity College Dublin.

Title of study: *BReast cAncer surVivors and Employment (BRAVE): Facilitators and barriers in returning to and staying at work in Ireland*

Introduction:

Cancer survivorship is increasing. In 2015, there were over 148,000 individuals living with and beyond cancer in Ireland. Breast cancer is common, affecting over 30% of newly-diagnosed women. Women often report experiencing many difficulties including fatigue, pain, fogginess in their thinking, and physical limitations (e.g. reaching above shoulder level). This can have an impact on their ability to work. Recent figures indicate that around 84% of women in Ireland stop working after breast cancer diagnosis but often return some time after treatment. We would like to explore the following:

- From an employer perspective, what challenges do individuals living with and beyond cancer present with in staying at or returning to work during/post-treatment?
- What supports, if any, does your organisation offer to individuals living with and beyond cancer?
- What is your knowledge of employment rights in Ireland?
- Work modifications that employers have needed to put in place for employees who have had cancer.
- What benefits are available to individuals living with and beyond cancer, if any?

To answer these questions, we are inviting employers to take part in a research study. This will involve a once-off interview between May and October 2019.

Procedures: Who are we looking to speak with?

We are looking to speak with employers who meet the following criteria:

- Employers and/or their departments which oversee employees such as managers, supervisors, occupational health or human resource staff members.
- As part of your role, have addressed sick leave and/or work modifications.
- Small, medium *or* large organisation
- Public *or* private organisation

If you choose to take part in the study, you will be invited to attend a once-off face-to-face interview or another predetermined setting, between May and October

2019. Interviews should last no more than 60 minutes and will be recorded using a digital recorder, with your consent.

Benefits: Are there any benefits from my participation?

There is no benefit for research participants.

Risks: Are there any risks or disadvantages involved in participating?

It is recognised that participation in the study may cause mild inconvenience. Therefore, we will try to arrange all interviews at a day and time are most convenient to you. While Trinity Centre for Health Sciences will be the main interview location, there is flexibility in where the interview will take place. It can be arranged to meet in a location that is closer to your workplace or more convenient. Alternatively, a telephone interview can be arranged.

Exclusion from participation: Is there any reason why I wouldn't be able to participate?

There are no exclusion criteria for this study.

Confidentiality: Your identity and the identity of your company will remain confidential. Your name and company will not be published and will not be disclosed to anyone outside the study group. Personal information collected from this study (for example: your name, and contact details on the consent form) will be kept in a locked cabinet with access restricted only to the research team.

Each participant will receive a Study ID number. If you would like a copy of your transcript, please contact the researcher with your unique Study ID number. All computerised data (such as audio recordings and transcripts) will be stored on a password-protected computer. Please note that Study IDs are used to pseudo-anonymise your data. This means that personal details e.g. your name, are coded which acts as a measure to protect your confidentiality. A document (called a code-book) will link your name and Study ID. This code book will be stored securely and separately from other data such as consent forms etc.

The research team aim to present and publish results of this study at conferences and in scientific journals in the future, however no identifiable personal data will be published. In addition, no information that could lead to your identification will be disclosed in any reports on the project, or to any other party. All data will be stored for the duration of the study i.e. until results have been fully reported and then kept in a locked cabinet for five years. All data collected (including consent forms, audio-recordings, Study ID Code-Book) will then be deleted securely at the end of this five year period. This material will not be used in future unrelated studies without further specific permission being obtained. Identifiable information will not be shared with any other organisation.

Compensation: This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation: If you decide to volunteer to participate in this study, you may withdraw at any time (up until the point that your data have been analysed and reported) without giving a reason. If you decide not to participate, or if you withdraw, you will not be penalised in any way and there will be no implications on

your regular treatment plan. If you have already completed interview and would like to withdraw your data, you can contact the research team and provide them with your unique ID number. It is aimed that all data will analysed and written up by February 2020.

Stopping the study: Your Principal Investigator may stop your participation in the study at any time without your consent.

Permission: This study was approved by the Faculty of Health Sciences Research Ethics Committee on the 31st May 2019.

Further Information: You can get more information or pose questions about the study, your participation in the study, and your rights, to Ms Naomi Algeo who can be telephoned at 083-053-0777 / 01-896-3222 or e-mailed at nalgeo@tcd.ie. If your Principal Investigator learns of important new information that might affect your desire to remain in the study, she will tell you.

Ms Naomi Algeo

PhD Candidate

Trinity College Dublin

Discipline of Occupational Therapy

Trinity Centre for Health Sciences

James Street

Dublin 8

APPENDIX C: CONSENT FORM (PHASE I)



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin



IRISH RESEARCH COUNCIL
An Chomhairle um Thaighde in Éirinn

CONSENT FORM: Women Living With and Beyond Breast Cancer

PROJECT TITLE: *BReast cAncer surVivors and Employment (BRAVE): Facilitators and barriers in returning to and staying at work in Ireland*

Research team: Ms. Naomi Algeo and Dr. Deirdre Connolly

Background:

- I consent to taking part in this study and understand that agreeing to take part means that I am willing to:
 - Take part in a once-off interview with the researcher to gather my experiences in returning to or staying at work following my breast cancer diagnosis. This interview will last no more than 75 minutes.
- I understand that the interview will be audiotaped and fully transcribed and that I may view the transcript at any time.
- I am aware that any information provided is confidential and no information that could lead to my identification will be disclosed in any reports on the project, or to any other party. No identifiable personal data will be published. The identifiable data will not be shared with any other organization.
- I am aware that data will be kept securely in a locked cabinet for up to five years following completion of the study. All personal data collected will then be deleted securely at the end of this five year period. I understand that this information will not be used for any other reasons without my permission.
- I understand that my participation is entirely voluntary and that I can withdraw at any stage of the study without being penalized or disadvantaged in any way.

DECLARATION:

I have read, or had read to me, the information leaflet for this project and I understand the contents. I have had the opportunity to discuss the study and ask questions which have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I understand that I may withdraw from the study at any time and I have received a copy of this agreement.

PARTICIPANT'S NAME.....

CONTACT DETAILS:.....

PARTICIPANT'S SIGNATURE:.....

Date:.....

Statement of Investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

INVESTIGATOR'S NAME.....

INVESTIGATOR'S SIGNATURE:.....

Date:.....



CONSENT FORM: Healthcare Professionals

PROJECT TITLE: *BReast cAnCer surVivors and Employment (BRAVE): Facilitators and barriers in returning to and staying at work in Ireland*

Research Team: Ms. Naomi Algeo and Dr. Deirdre Connolly

Background:

- I consent to taking part in this study and understand that agreeing to take part means that I am willing to:
 - Take part in a once-off interview with the researcher to gather my experiences working with women with breast cancer in supporting them in returning to or staying at work following their breast cancer diagnosis. This interview will last no more than 75 minutes.
- I understand that the interview will be audiotaped and fully transcribed and that I may view the transcript at any time.
- I am aware that any information provided is confidential and no information that could lead to my identification will be disclosed in any reports on the project, or to any other party. No identifiable personal data will be published. The identifiable data will not be shared with any other organization.
- I am aware that data will be kept securely in a locked cabinet for up to five years following completion of the study. All personal data collected will then be deleted securely at the end of this five year period. I understand that this information will not be used for any other reasons without my permission.
- I understand that my participation is entirely voluntary and that I can withdraw at any stage of the study without being penalized or disadvantaged in any way.

DECLARATION:

I have read, or had read to me, the information leaflet for this project and I understand the contents. I have had the opportunity to discuss the study and ask questions which have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I understand that I may withdraw from the study at any time and I have received a copy of this agreement.

PARTICIPANT'S NAME.....

CONTACT DETAILS:.....

PARTICIPANT'S SIGNATURE:.....

Date:.....

Statement of Investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

INVESTIGATOR'S NAME.....

INVESTIGATOR'S SIGNATURE:.....

Date:.....



CONSENT FORM: Employers

PROJECT TITLE: *BReast cAnCer surVivors and Employment (BRAVE): Facilitators and barriers in returning to and staying at work in Ireland*

Research Team: Ms. Naomi Algeo and Dr. Deirdre Connolly

Background:

- I consent to taking part in this study and understand that agreeing to take part means that I am willing to:
 - Take part in a once-off interview with the researcher to gather my experiences in addressing sick leave and/or work modifications with those living with and beyond cancer. This interview will last no more than 60 minutes.
- I understand that the interview will be audiotaped and fully transcribed and that I may view the transcript at any time.
- I am aware that any information provided is confidential and no information that could lead to my identification will be disclosed in any reports on the project, or to any other party. No identifiable personal data will be published. The identifiable data will not be shared with any other organization.
- I am aware that data will be kept securely in a locked cabinet for up to five years following completion of the study. All personal data collected will then be deleted securely at the end of this five-year period. I understand that this information will not be used for any other reasons without my permission.
- I understand that my participation is entirely voluntary and that I can withdraw at any stage of the study without being penalized or disadvantaged in any way.

DECLARATION:

I have read, or had read to me, the information leaflet for this project and I understand the contents. I have had the opportunity to discuss the study and ask questions which have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I understand that I may withdraw from the study at any time and I have received a copy of this agreement.

PARTICIPANT'S NAME.....

CONTACT DETAILS:.....

PARTICIPANT'S SIGNATURE:.....

Date:.....

Statement of Investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

INVESTIGATOR'S NAME.....

INVESTIGATOR'S SIGNATURE:.....

Date:.....

APPENDIX D: INTERVIEW GUIDES (PHASE I)

INTERVIEW GUIDE (Participants who stayed at work)

Setting the scene
Can you tell me about your cancer diagnosis and treatment? <i>Prompt: When did you receive diagnosis, how you felt, what treatment you underwent?</i> What does your job role involve? What does a typical day look like? What does your job mean to you? Tell me about your decision to stay at work? What factors influenced your decision?
Experiences
How did you feel at work during diagnosis / treatment? How did you find working during treatment?
Facilitators and Support Systems
What helped you be able to work? Who has provided support for you to work? Did you get as much support as you wanted or needed? What supports had you available? Is there anything that would have helped that wasn't available to you in your workplace? Can you tell me what strategies you used to keep working during active treatment?
Barriers
How did cancer diagnosis or treatment affect your work? What difficulties do/did you have at work? <i>Prompt: Ask about Physical, Cognitive, Psychological difficulties</i> How did they impact on your ability to work? <i>Prompt: How did Physical, Cognitive, Psychological difficulties impact?</i> Have you made any changes to your job? <i>Prompt: Hours, type of work or duties, schedule</i> Are there any other things that affected you being able to work during active treatment?
Reflection
What is your understanding of employment legislation in Ireland in relation to cancer diagnoses? What advice would you give to other women with breast cancer who are considering staying in work during treatment? If you could change anything now in relation to staying at work, what would it be? We are hoping to develop a RTW support for women to help them go back to work, but we don't know what that looks like yet, what are your thoughts on that? <i>Prompts: (i) Format (ii) length (iii) timing (iv) content</i>

INTERVIEW GUIDE (Participants who returned to work)

Setting the scene

Can you tell me about your cancer diagnosis and treatment?

Prompt: When did you receive it, what treatment you underwent, how long did it last?

What stage did you return to work post treatment?

What does your job role involve? What does a typical day look like?

What does your job mean to you?

Tell me about your decision to return to work? What factors influenced your decision?

Experiences

If you needed time off for the treatment/recovery, was there flexibility around this?

How did you feel when you initially returned to work?

How do you think your return to work went?

When you returned, had any changes been made to your role?

Facilitators and Support Systems

What helped you be able to return to work? Who has provided support for you to work?

Did you get as much support as you wanted or needed? What supports had you available?

Is there anything that would have helped that wasn't available to you in your workplace?

Barriers

What difficulties do/did you have at work?

Prompt: Ask about Physical, Cognitive, Psychological difficulties

How did they impact on your ability to work?

Prompt: How did Physical, Cognitive, Psychological difficulties impact?

Have you made any changes to your job?

Prompt: Hours, type of work or duties, schedule

Reflection

What is your understanding of employment legislation in Ireland in relation to cancer diagnoses?

What advice would you give to other women with breast cancer, exploring return to work?

If you could change anything now in relation to returning to work, what would it be?

Anything else?

We are hoping to develop a RTW support for women to help them go back to work, but we don't know what that looks like yet, what are your thoughts on that?

Prompts: (i) Format (ii) length (iii) timing (iv) content

INTERVIEW GUIDE (Healthcare Professionals)

Setting the scene
What is your role in supporting women with breast cancer in returning to work? <i>Prompt: How long have you had this role? What is typical pathway like with each patient/client?</i>
Facilitators and Support Systems
What do you think helps women with breast cancer return to or stay at work? <i>Prompt: Strategies, social support systems</i> What supports are available for women returning to work or staying at work? <i>Prompt: At national level, organisational level.</i>
Barriers
What difficulties do women living with and beyond breast cancer present with at work? <i>Prompt: Ask about Physical, Cognitive, Psychological difficulties</i> What recommendations or modifications have you recommended in the past to women living with and beyond breast cancer in returning to or staying at work? <i>Prompt: Hours, type of work or duties, schedule</i>
Reflection
Do you think there is enough being done to support women living with and beyond breast cancer in returning to / staying at work? Why/Why not? What do you think needs to be put in place to support this cohort of women in returning to or staying at work? We are hoping to develop a RTW support for women to help them go back to work, but we don't know what that looks like yet, what are your thoughts on that? <i>Prompts: (i) Format (ii) length (iii) timing (iv) content</i>

INTERVIEW GUIDE (Employers)

Setting the scene
What is your current role in your organisation? <i>Prompt: Role type (e.g. Manager etc), Size of organisation (approx no. Employees) , area of work (e.g. healthcare, education), sector (public/private)</i>
Facilitators and Support Systems
What have you experienced that helps individuals living with and beyond cancer return to or stay at work? <i>Prompt: Strategies, social support systems, any particular experiences relating to breast cancer?</i> What supports are available in your workplace for those living with and beyond cancer returning to work or staying at work? <i>Prompt: Services (e.g. Occ Health), work modifications, etc.</i> What modifications if any, have you made in the past for those living with and beyond cancer in returning to or staying at work? <i>Prompt: Hours, type of work or duties, schedule, any particular experiences relating to breast cancer?</i>
Barriers
What difficulties do those living with and beyond cancer present with at work? <i>Prompt: Ask about Physical, Cognitive, Psychological difficulties, any particular experiences relating to breast cancer?</i> What, if any, structural/organisational barriers are there in your workplace that may limit cancer survivors in returning to work, or optimising their work performance post-treatment?
Reflection
What is your understanding of employment legislation in Ireland with regards to sick leave and return to work following sick leave? Do you think there is enough being done to support those living with and beyond cancer in returning to / staying at work? Why/Why not? What would help you as an employer in supporting this cohort in returning to or staying at work?

APPENDIX E: LETTER OF ETHICAL APPROVAL (PHASE I)



Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin

Ollscoil Átha Cliath | The University of Dublin

Ms Naomi Algeo
Discipline of Occupational Therapy,
Trinity Centre for Health Sciences,
St. James Hospital,
James St.,
Dublin 8

12th March 2019

Ref: 190101

Title of Study: **BReast cAnCer surVivors and Employment (BRAVE): Facilitators and barriers in returning to and staying at work in Ireland**

Dear Naomi,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in January 2019. We are pleased to inform you that the above project has ethical approval to proceed.

As a researcher you must ensure that you comply with other relevant regulations, including DATA PROTECTION and HEALTH AND SAFETY.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Brian O'Connell'.

Prof. Brian O'Connell
Chairperson
Faculty Research Ethics Committee

Dámh na nOllscochtaí 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.healthsciences.tcd.ie

APPENDIX F: LETTER OF ETHICAL APPROVAL WITH ADDENDUM (PHASE I)



Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Naomi Algeo
Discipline of Occupational Therapy,
Trinity Centre for Health Sciences,
St. James' Hospital,
James Street,
Dublin D08 W9RT
Ireland

31st May 2019

Ref: 190101

Title of Study: BREast cAnCer survivors and Employment (BRAVE): Facilitators and barriers in returning to and staying at work in Ireland

Dear Naomi,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in May 2019, we are pleased to inform you that the above project (as amended with the following changes) has ethical approval to proceed.

Women with breast cancer Inclusion criteria:

- *Breast cancer survivors (primary diagnosis breast cancer) who have had treatment been eliagnoseel in the past 24 months of commencement of study and have either stayed on at work or returned to work since then.*
- *Aged 18-66 years old (current retirement age in Ireland).*
- *In employment at time of diagnosis.*

Exclusion criteria:

If treatment of breast cancer was completed greater than 24 months previously.

2. Recruitment of an additional cohort, Employers.

In addition to women who have had breast cancer and healthcare professionals, we would like to recruit a third cohort, employers, to take part in a once off semi-structured interview lasting no more than 60 minutes. This is to gain further insight around what supports are available to women in staying at/ returning to work in Ireland, following breast cancer diagnosis.

Recruitment:

It is aimed to recruit 12-15 employers. Employers will be recruited via the Marie Keating Foundation who have pledged full support and written confirmation of this for the study (See Appendix A). The Marie Keating Foundation are the first cancer charity in Ireland to launch a 'Back to Work after Cancer' booklet for both employees and employers, in partnership with the CIPD (Professional Body for HR and People Development). They work closely with employers, providing workshops and awareness of cancer and return to work, and have a number of industry contacts. They will act as a gatekeeper and provide written information such as the Participant Information Leaflet (Appendix B) and Consent Form (Appendix C) to their industry contacts. This written information will invite employers to contact the researcher directly should they wish to partake.



The researcher (Naomi Algeo) will also highlight the study via her social media channels e.g. Twitter, Linked In (Appendices D and E).

Inclusion Criteria:

- *Employers and/or their staff who are involved in supporting return to work (e.g. Human Resources professional, Occupational Health professional, supervisor or manager)*
- *With experience in managing staff sick leave and/or work modifications due to cancer.*
- *Willing to take part in a face-to-face or telephone interview for no longer than 60 minutes.*
- *Small, medium and/or large organisations*
- *Public or private organisations*

Procedure:

Procedures for data collection will be followed as per other cohorts approved (Women with breast cancer and Healthcare professionals) i.e. potential participants will be invited to participate in the study via Marie Keating Foundation or social media, and can contact the researcher directly via email or telephone provided to express interest in the study. The researcher will then provide the potential participant with the Participant Information Leaflet and Consent form if they do not have this already. The potential participant will be contacted at least seven days following this, to allow time to reflect on the information provided. A day and time will be set for the semi-structured interview (either face-to-face at Trinity Centre for Health Sciences or via telephone). Consent will be received prior to commencing any interviews (in person at face-to-face meeting or via post for telephone interviews). The interview will then last no more than 60 minutes, The Participant Information Leaflet and Consent Forms are based on forms previously approved by REC for breast cancer survivor and healthcare professionals cohorts.

Consent and Confidentiality:

All consent and confidentiality procedures will be followed as per other cohorts approved (Women with breast cancer and healthcare professionals). Once employers have contacted the researcher directly (by email or telephone), they will be sent out further information via preferred method of contact (e-mail or postal address). This will include Participant Information Leaflet and Consent Form. The potential participant will be contacted at least one week after this period, to allow time to reflect on their potential participation. Should the potential participant wish to proceed with the study, they will collaborate with the researcher to organise a time and date convenient to them for interview. At the beginning of the interview, the researcher will read the consent form and provide the participant the opportunity to pose any questions about the study. Should they remain happy to proceed, both the participant and researcher will sign the form. A copy will be available for both researcher and participant for their records. The interview will then proceed with the researcher using an interview schedule to guide the interview (See Appendix F). The Consent form is based on form previously approved by REC for breast cancer survivor and healthcare professionals cohorts (Appendix C), with amendment being made only to



Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin

Ollscoil Átha Cliath | The University of Dublin

Risk, benefit and harm

As per Section 4.1 in previously approved form, all ethical issues considered for both women with breast cancer, and healthcare professionals will be applied to employers.

As a researcher you must ensure that you comply with other relevant regulations, including DATA PROTECTION and HEALTH AND SAFETY.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Prof. Brian O'Connell".

Prof. Brian O'Connell

Chairperson

Faculty Research Ethics Committee

AMENDMENT

APPENDIX G: PRISMA Checklist

Section/topic	#	Checklist item	Reported on page:
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	81
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	See Algeo et al 2021
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	81
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	81-82
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	83 and Appendix H
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	83-85
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	85
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	85-86 and Appendix I
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	86
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	86-87
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	87
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	87-88
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	88

Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis.	88-89

Section/topic	#	Checklist item	Reported on page:
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	89-90 + Appendix J
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	90-102
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	103-105
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	105-108
Synthesis of results	21	Present the main results of the review. If meta-analyses are done, include for each, confidence intervals and measures of consistency	109-119
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	119-128
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	126-127
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	128
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	See Algeo et al 2021

Appendix H: PROSPERO Protocol

PROSPERO
International prospective register of systematic reviews



UNIVERSITY *of York*
Centre for Reviews and Dissemination

Systematic review

1. * Review title.

Give the title of the review in English

Rehabilitation Interventions to support return to work for women with breast cancer: A systematic review and meta-analysis

2. Original language title.

For reviews in languages other than English, give the title in the original language. This will be displayed with the English language title.

3. * Anticipated or actual start date.

Give the date the systematic review started or is expected to start.

24/02/2020

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

24/02/2021

5. * Stage of review at time of this submission.

Tick the boxes to show which review tasks have been started and which have been completed. Update this field each time any amendments are made to a published record.

Reviews that have started data extraction (at the time of initial submission) are not eligible for inclusion in PROSPERO. If there is later evidence that incorrect status and/or completion date has been supplied, the published PROSPERO record will be marked as retracted.

This field uses answers to initial screening questions. It cannot be edited until after registration.

The review has not yet started: No

Review stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	Yes
Risk of bias (quality) assessment	Yes	Yes
Data analysis	Yes	Yes

Provide any other relevant information about the stage of the review here.

6. * Named contact.

The named contact is the guarantor for the accuracy of the information in the register record. This may be any member of the review team.

Naomi Algeo

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

Ms Algeo

7. * Named contact email.

Give the electronic email address of the named contact.

nalgeo@tcd.ie

8. Named contact address

Give the full institutional/organisational postal address for the named contact.

Discipline of Occupational Therapy, Trinity Centre for Health Sciences, St James' Hospital, James' Street,
Dublin.

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

00353830530777

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

Trinity College Dublin

Organisation web address:

<https://www.tcd.ie>

11. * Review team members and their organisational affiliations.

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. NOTE: email and country now MUST be entered for each person, unless you are amending a published record.

Ms Naomi Algeo. Trinity College Dublin
Dr Deirdre Connolly. Trinity College Dublin
Professor Kathleen Bennett. Royal College of Surgeons in Ireland

12. * Funding sources/sponsors.

Details of the individuals, organizations, groups, companies or other legal entities who have funded or sponsored the review.

One of the authors (NA) is funded and supported by the Irish Research Council. This funding is awarded solely for the development of the scholar rather than to inform specific research topics. Any opinions, findings, conclusions or recommendations expressed are those of the author(s) and not necessarily those of the Irish Research Council.

Grant number(s)

State the funder, grant or award number and the date of award

13. * Conflicts of interest.

List actual or perceived conflicts of interest (financial or academic).

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. NOTE: email and country must be completed for each person, unless you are amending a published record.

15. * Review question.

State the review question(s) clearly and precisely. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PICO or similar where relevant.

The objectives of this review are to (i) examine the core elements (content, delivery, effectiveness) of rehabilitation interventions for women with breast cancer on at least one work outcome, and (ii) identify measures used to test the impact of these interventions.

Key questions include:

- (i) What are the core elements (i.e. work-related content, delivery, resources, length, and format) of rehabilitation interventions for women with breast cancer?
- (ii) What measures are used to test the impact of these rehabilitation interventions?
- (iii) How (i) effective and (ii) cost-effective are rehabilitation interventions in enhancing work outcomes?
- (iv) What are the most commonly used theoretical frameworks incorporated in rehabilitation interventions (if

any)?

16. * Searches.

State the sources that will be searched (e.g. Medline). Give the search dates, and any restrictions (e.g. language or publication date). Do NOT enter the full search strategy (it may be provided as a link or attachment below.)

The following databases will be searched: EMBASE, Web of Science, MEDLINE (OVID), CINAHL, PsycINFO and the Cochrane Central Register of Controlled Trials (CENTRAL). Search terms were developed in consultation with a medical librarian and will be applied to the above databases.

Inclusion criteria:

- (i) Experimental designs including Randomised Control Trials (RCTs) and Quasi-Experimental trials, Meta-Analyses and Systematic Reviews.
- (ii) Group, individual and/or online interventions for women with breast cancer
- (iii) Acceptable comparators include participants randomised to standard care or a waiting list control (WLC).
- (iv) Measurement of at least one work-related outcome.

Exclusion criteria:

- (i) Studies that are not an RCT, Quasi-Experimental with a Control group.
- (ii) Studies written up in languages other than English.

No limits will be set on year, setting, intervention length, or intervention facilitators.

Searches will be re-run prior to the final analysis to identify any additional studies for inclusion.

17. URL to search strategy.

Upload a file with your search strategy, or an example of a search strategy for a specific database, (including the keywords) in pdf or word format. In doing so you are consenting to the file being made publicly accessible. Or provide a URL or link to the strategy. Do NOT provide links to your search results.

https://www.crd.york.ac.uk/PROSPEROFILES/142560_STRATEGY_20190730.pdf

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Do not make this file publicly available until the review is complete

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied in your systematic review.

Breast Cancer

19. * Participants/population.

Specify the participants or populations being studied in the review. The preferred format includes details of both inclusion and exclusion criteria.

Women who have had breast cancer (18 years old at time of diagnosis) who were working at time of diagnosis.

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the interventions or the exposures to be reviewed. The preferred format includes details of both inclusion and exclusion criteria.

Rehabilitation Interventions. Can be group-based, individual, and/or online mediums.

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the intervention/exposure will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

Acceptable comparators (if relevant) include participants randomised to standard care or a waiting list control (WLC).

22. * Types of study to be included.

Give details of the study designs (e.g. RCT) that are eligible for inclusion in the review. The preferred format includes both inclusion and exclusion criteria. If there are no restrictions on the types of study, this should be stated.

Experimental designs including Randomised Control Trials (RCTs) and Quasi-Experimental trials

23. Context.

Give summary details of the setting or other relevant characteristics, which help define the inclusion or exclusion criteria.

24. * Main outcome(s).

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

Work-related outcomes (e.g. return to work, hours at work, absenteeism, work disability, sick leave, employment status)

Measures of effect

Please specify the effect measure(s) for you main outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

All time frames and effect measures will be included as relevant.

25. * Additional outcome(s).

List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state 'None' or 'Not applicable' as appropriate to the review

Health-related quality of life outcomes (e.g. fatigue, stress, anxiety, depression, self-efficacy, mood)

Measures of effect

Please specify the effect measure(s) for you additional outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

All time frames and effect measures will be included as relevant.

26. * Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

EndNote will be used to manage all retrieved studies. All studies will be organised using this software into folders divided by database. EndNote will also screen for duplications. Once all references are organised, the EndNote library will be uploaded onto Covidence. Covidence is an online software tool used for ~~following the search strategy~~ screening. Following the search strategy, all retrieved studies will be screened by two reviewers for suitability based on their abstracts and titles, using a checklist. The checklist for screening is based on the PICO criteria and other criteria as outlined above. Where it is clear that the study does not meet the inclusion criteria, it will be excluded. Where lack of clarity remains during screen, the full text of the study will be examined to determine eligibility.

Two of the authors will use a data extraction tool based on the Cochrane Handbook for Systematic Review of Interventions (Higgins & Green, 2011) to independently extract data from each study. Predetermined information to extract includes:

- Author, year of publication
- Participant characteristics including (i) diagnosis/cancer type, (ii) numbers, (iii) setting (e.g. inpatient, community), (iv) country, (v) inclusion/exclusion criteria.
- Intervention characteristics including (i) type (e.g. digital, individual, or group), (ii) duration, (iii) work-related content, (iv) facilitators (e.g. occupational therapists, nurses, etc.), (v) theoretical frameworks incorporated into intervention (if any).
- Comparator (e.g. WLC or standard care, if applicable).
- Outcomes – work-related outcomes and patient reported outcomes, follow-up period.

Should any disagreements occur at any timepoint in the study selection and data extraction periods, a third reviewer will be available to resolve any issues.

27. * Risk of bias (quality) assessment.

State which characteristics of the studies will be assessed and/or any formal risk of bias/quality assessment tools that will be used.

To establish the validity of eligible randomised control trials, two reviewers will independently assess risk of bias using the Cochrane Collaboration Risk of Bias tool [Version 5.1.0] (Higgins & Green, 2011) which assesses bias on random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other sources of bias. Should a disagreement occur between both reviewers, these

will be resolved by discussion and consensus or should this fail, a third reviewer will be consulted. The quality assessment of each study will be used to evaluate the strength of evidence for outcomes and will be considered should a meta-analysis be conducted.

28. * Strategy for data synthesis.

Describe the methods you plan to use to synthesise data. This must not be generic text but should be specific to your review and describe how the proposed approach will be applied to your data. If meta-analysis is planned, describe the models to be used, methods to explore statistical heterogeneity, and software package to be used.

The synthesis of quantitative data in systematic reviews is not recommended when studies have diverse methodologies or where there are issues of quality (Centre for Reviews and Dissemination, 2009). It would be appropriate to complete quantitative data synthesis where there are multiple randomised-controlled trials in the topic area and data are homogenous. However, preliminary literature searches have indicated that this is unlikely to be the case in this review. The Centre for Reviews and Dissemination recommends that the method of data synthesis be decided at the outset of the review (2009). For this review, narrative methods of synthesis will be used to summarise the results. This will firstly consist of a clear descriptive summary of the ~~Descriptive findings of included studies will be~~ structured around core elements of intervention (i.e. work-related content, delivery, resources, length, and format), study design, target population characteristics, type of outcomes, outcome measures used, and theoretical frameworks used (if any).

29. * Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.

None planned.

30. * Type and method of review.

Select the type of review, review method and health area from the lists below.

Type of review

Cost effectiveness

No

Diagnostic

No

Epidemiologic

No

Individual patient data (IPD) meta-analysis

No

Intervention

Yes

Living systematic review

No

Meta-analysis

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No

Methodology

No

Narrative synthesis

No

Network meta-analysis

No

Pre-clinical

No

Prevention

No

Prognostic

No

Prospective meta-analysis (PMA)

No

Review of reviews

No

Service delivery

No

Synthesis of qualitative studies

No

Systematic review

Yes

Other

No

Health area of the review

Alcohol/substance misuse/abuse

No

Blood and immune system

No

Cancer

Yes

Cardiovascular

No

Care of the elderly

No

Child health

No

Complementary therapies

No

COVID-19

No

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Crime and justice
No

Dental
No

Digestive system
No

Ear, nose and throat
No

Education
No

Endocrine and metabolic disorders
No

Eye disorders
No

General interest
No

Genetics
No

Health inequalities/health equity
No

Infections and infestations
No

International development
No

Mental health and behavioural conditions
No

Musculoskeletal
No

Neurological
No

Nursing
No

Obstetrics and gynaecology
No

Oral health
No

Palliative care
No

Perioperative care
No

Physiotherapy
No

Pregnancy and childbirth

No

Public health (including social determinants of health)
No

Rehabilitation
Yes

Respiratory disorders
No

Service delivery
No

Skin disorders
No

Social care
No

Surgery
No

Tropical Medicine
No

Urological
No

Wounds, injuries and accidents
No

Violence and abuse
No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.
English

There is not an English language summary

32. * Country.

Select the country in which the review is being carried out. For multi-national collaborations select all the countries involved.

Ireland

33. Other registration details.

Name any other organisation where the systematic review title or protocol is registered (e.g. Campbell, or The Joanna Briggs Institute) together with any unique identification number assigned by them. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

34. Reference and/or URL for published protocol.

If the protocol for this review is published provide details (authors, title and journal details, preferably in Vancouver format)

Add web link to the published protocol.

Or, upload your published protocol here in pdf format. Note that the upload will be publicly accessible.

No I do not make this file publicly available until the review is complete

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans.

Do you intend to publish the review on completion?

Yes

Give brief details of plans for communicating review findings.?

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords help PROSPERO users find your review (keywords do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

breast cancer; cancer survivorship; employment; return to work

37. Details of any existing review of the same topic by the same authors.

If you are registering an update of an existing review give details of the earlier versions and include a full bibliographic reference, if available.

38. * Current review status.

Update review status when the review is completed and when it is published. New registrations must be ongoing so this field is not editable for initial submission.

Please provide anticipated publication date

Review_Completed_published

39. Any additional information.

Provide any other information relevant to the registration of this review.

40. Details of final report/publication(s) or preprints if available.

Leave empty until publication details are available OR you have a link to a preprint (NOTE: this field is not editable for initial submission). List authors, title and journal details preferably in Vancouver format.

Algeo, N., Bennett, K. & Connolly, D. (2021). Rehabilitation interventions to support return to work for women with breast cancer: a systematic review and meta-analysis. BMC Cancer, 21(895). Available at:

<https://rdcu.be/csBNQ>

Give the link to the published review or preprint.

<https://rdcu.be/csBNQ>

APPENDIX I: SEARCH STRATEGY

EMBASE 635

1. 'breast cancer'/exp
2. (Breast NEAR/3 (cancer OR carcinoma* OR tumo?r* OR neoplasm*)):ti,ab
3. #1 OR #2
4. 'cancer survivor'/exp OR 'cancer survival'/exp
5. Survivor*:ti,ab
6. #4 OR #5
7. 'employability'/exp OR 'career'/exp OR 'career mobility'/exp OR 'career planning'/exp OR 'employment'/exp OR 'job change'/exp OR 'job characteristics'/exp OR 'job finding'/exp OR 'presenteeism'/exp OR 'absenteeism'/exp OR 'work capacity'/exp OR 'job accommodation'/exp OR 'job security'/exp OR 'work'/de
8. ((Work OR job OR employment) NEAR/3 (retention OR return OR retain OR cessation OR continuation OR maintain* OR opportunit* OR quit* OR loss OR non-retention OR resumption OR resume*)):ti,ab
9. (unemploy* OR career* OR employability OR demotion OR absenteeism OR presenteesism OR underemployment OR productivity OR reemployment or re-employment OR 'sickness absence' OR "sick leave"):ti,ab
10. ((work*) Near/3 (Stay* OR remain* OR continu* OR adjustment* OR readiness OR functioning OR limitation* OR participation OR transition* OR capacity OR status)):ti,ab
11. (Workplace Near/3 (intervention* OR discrimination OR accommodation* OR support*)):ti,ab
12. #7 OR #8 OR #9 OR #10 OR #11
13. #3 AND #6 AND #12

Medline (OVID) 252

1. exp Breast Neoplasms/
2. (Breast adj3 (cancer OR carcinoma* OR tumo?r* OR neoplasm*)):ti,ab.
3. or/1-2
4. Survivors/ OR Cancer Survivors/
5. Survivo?r*.ti,ab.
6. or/4-5
7. exp work/ or return to work/ or exp employment/ or unemployment/ or exp occupations/ or workplace/ or Rehabilitation, Vocational/ or Sick Leave/ or Absenteeism/ or Presenteeism/ or Retirement/ or Workers' Compensation/ or Job Satisfaction/ or Employee Grievances/ or Workload/ or Personnel Turnover/ or Work Engagement/ or Work Performance/ or exp Occupational Stress/
8. ((Work OR job OR employment) adj3 (retention OR return OR retain OR cessation OR continuation OR maintain* OR opportunit* OR quit* OR loss OR non-retention OR resumption OR resume*)):ti,ab.
9. (unemploy* OR career* OR employability OR demotion OR absenteeism OR presenteesism OR underemployment OR productivity OR reemployment or re-employment OR sickness absence OR sick leave).ti,ab.

10. ((work*) adj3 (Stay* OR remain* OR continu* OR adjustment* OR readiness OR functioning OR limitation* OR participation OR transition* OR capacity OR status)).ti,ab.
11. (Workplace adj3 (intervention* OR discrimination OR accommodation* OR support*)).ti,ab.
12. or/7-11
13. and/3,6,12

CINAHL 268

1. (MH "Breast Neoplasms+")
2. TI (Breast N6 (cancer* OR neoplasm* OR carcinoma* OR tumo?r*)) OR AB (Breast N6 (cancer* OR neoplasm* OR carcinoma* OR tumo?r*))
3. S1 OR S2
4. (MH "Cancer Survivors") OR (MH "Survivors")
5. TI (survivor*) OR AB (survivor*)
6. S4 OR S5
7. (MH "Employment+") OR (MH "Career Mobility") OR (MH "Promotion and Tenure") OR (MH "Occupations and Professions") OR (MH "Income") OR (MH "Unemployment") OR (MH "Job Satisfaction+") OR (MH "Absenteeism") OR (MH "Adaptation, Occupational") OR (MH "Stress, Occupational") OR (MH "Presenteeism") OR (MH "Productivity") OR (MH "Professional Image") OR (MH "Professional Recognition") OR (MH "Work-Life Balance") OR (MH "Time Management") OR (MH "Work Capacity Evaluation") OR (MH "Work") OR (MH "Work Engagement")
8. TI ((Work OR job OR employment) N3 (retention OR return OR retain OR cessation OR continuation OR maintain* OR opportunit* OR quit* OR loss OR non-retention OR resumption OR resume*)) OR AB((Work OR job OR employment) N3 (retention OR return OR retain OR cessation OR continuation OR maintain* OR opportunit* OR quit* OR loss OR non-retention OR resumption OR resume*))
9. TI (unemploy* OR career* OR employability OR demotion OR absenteeism OR presenteesism OR underemployment OR productivity OR reemployment or re-employment OR "sickness absence" OR "sick leave") OR AB (unemploy* OR career* OR employability OR demotion OR absenteeism OR presenteesism OR underemployment OR productivity OR reemployment or re-employment OR "sickness absence" OR "sick leave")
10. TI ((work*) N3 (Stay* OR remain* OR continu* OR adjustment* OR readiness OR functioning OR limitation* OR participation OR transition* OR capacity OR status)) OR AB ((work*) N3 (Stay* OR remain* OR continu* OR adjustment* OR readiness OR functioning OR limitation* OR participation OR transition* OR capacity OR status))
11. TI (Workplace N3 (intervention* OR discrimination OR accommodation* OR support*)) OR AB (Workplace N3 (intervention* OR discrimination OR accommodation* OR support*))
12. S7 OR S8 OR S9 OR S10 OR S11
13. S3 AND S6 AND S12

PsycINFO 380

1. DE "Breast Neoplasms"

2. TI (Breast N6 (cancer* OR neoplasm* OR carcinoma* OR tumor*)) OR AB (Breast N6 (cancer* OR neoplasm* OR carcinoma* OR tumor*))
3. S1 OR S2
4. DE "Survivors"
5. TI (survivor*) OR AB (survivor*)
6. S4 OR S5
7. DE "Social Support" OR DE "Employee Productivity" OR DE "Occupational Health" OR DE "Reemployment" OR DE "Supervisor Employee Interaction" OR DE "Employment Status" AND DE "Working Conditions" OR DE "Working Women" OR DE "Workplace Intervention" OR DE "Unemployment" OR DE "Lower Income Level" OR DE "Career Development" OR DE "Working Women" OR DE "Occupational Stress" AND DE "Employee Absenteeism" OR DE "Employee Efficiency" OR DE "Employee Engagement" OR DE "Employee Layoffs" OR DE "Employee Motivation" OR DE "Employee Retention"
8. TI ((Work OR job OR employment) N3 (retention OR return OR retain OR cessation OR continuation OR maintain* OR opportunit* OR quit* OR loss OR non-retention OR resumption OR resume*)) OR AB((Work OR job OR employment) N3 (retention OR return OR retain OR cessation OR continuation OR maintain* OR opportunit* OR quit* OR loss OR non-retention OR resumption OR resume*))
9. TI (unemploy* OR career* OR employability OR demotion OR absenteeism OR presenteesism OR underemployment OR productivity OR reemployment or re-employment OR "sickness absence" OR "sick leave") OR AB (unemploy* OR career* OR employability OR demotion OR absenteeism OR presenteesism OR underemployment OR productivity OR reemployment or re-employment OR "sickness absence" OR "sick leave")
10. TI ((work*) N3 (Stay* OR remain* OR continu* OR adjustment* OR readiness OR functioning OR limitation* OR participation OR transition* OR capacity OR status)) OR AB ((work*) N3 (Stay* OR remain* OR continu* OR adjustment* OR readiness OR functioning OR limitation* OR participation OR transition* OR capacity OR status))
11. TI (Workplace N3 (intervention* OR discrimination OR accommodation* OR support*)) OR AB (Workplace N3 (intervention* OR discrimination OR accommodation* OR support*))
12. S7 OR S8 OR S9 OR S10 OR S11
13. S3 AND S6 AND S12

Web of Science 635

TS=((Breast NEAR/3 (cancer OR carcinoma* OR tumor* OR neoplasm*)) AND survivor* AND (((Work OR job OR employment) NEAR/3 (retention OR return OR retain OR cessation OR continuation OR maintain* OR opportunit* OR quit* OR loss OR non-retention OR resumption OR resume*)) OR (unemploy* OR career* OR employability OR demotion OR absenteeism OR presenteesism OR underemployment OR productivity OR reemployment or re-employment OR "sickness absence" OR "sick leave") OR ((work*) NEAR/3 (Stay* OR remain* OR continu* OR adjustment* OR readiness OR functioning OR limitation* OR participation OR transition* OR capacity OR status)) OR (Workplace NEAR/3 (intervention* OR discrimination OR accommodation* OR support*))))

Cochrane Library 34

1. [mh "Breast Neoplasms"]
2. (Breast NEAR/3 (cancer OR carcinoma* OR tumor* OR tumour* OR neoplasm*)):ti,ab,kw
3. #1 OR #2
4. [mh "Survivors"] OR [mh "Cancer Survivors"]
5. (Survivor*):ti,ab,kw
6. #4 OR #5
7. [mh "work"] or [mh "return to work"] or [mh "employment"] or [mh "unemployment"] or [mh "occupations"] or [mh "workplace"] or [mh "Rehabilitation, Vocational"] or [mh "Sick Leave"] or [mh "Absenteeism"] or [mh "Presenteeism"] or [mh "Retirement"] or [mh "Workers' Compensation"] or [mh "Job Satisfaction"] or [mh "Employee Grievances"] or [mh "Workload"] or [mh "Personnel Turnover"] or [mh "Work Engagement"] or [mh "Work Performance"] or [mh "Occupational Stress"]
8. ((Work OR job OR employment) NEAR/3 (retention OR return OR retain OR cessation OR continuation OR maintain* OR opportunit* OR quit* OR loss OR non-retention OR resumption OR resume*)):ti,ab,kw
9. (unemploy* OR career* OR employability OR demotion OR absenteeism OR presenteesism OR underemployment OR productivity OR reemployment or re-employment OR "sickness absence" OR "sick leave"):ti,ab,kw
10. ((work*) NEAR/3 (Stay* OR remain* OR continu* OR adjustment* OR readiness OR functioning OR limitation* OR participation OR transition* OR capacity OR status)):ti,ab,kw
11. (Workplace NEAR/3 (intervention* OR discrimination OR accommodation* OR support*)):ti,ab,kw
12. #7 OR #8 OR #9 OR #10 OR #11
13. #3 AND #6 AND #12

APPENDIX J: PAPERS EXCLUDED FROM FULL-TEXT REVIEW

Author	Reason for Exclusion
Alsobrooks et al. (2010)	No work-related outcomes
Cimprich et al. (2005)	No work-related outcomes
Damkjaer et al. (2011)	Study design other than RCT or quasi-experimental design (with comparator). Cohort design.
Désiron (2010)	No clear reporting of work outcomes
Dietrich et al. (2016)	No work-related outcomes
Hegel et al. (2011)	No work-related outcomes
Hershman (2013)	No work-related outcomes
Hoving, et al. (2009)	Study design other than RCT or quasi-experimental design (with comparator). Systematic Review.
Khan et al. (2012)	No work-related outcomes
Loh et al. (2013)	No work-related outcomes
Lyons et al. (2015)	No work-related outcomes
Meneses et al. (2007)	No work-related outcomes
Meneses et al. (2009)	No work-related outcomes
Meneses et al. (2020)	No work-related outcomes
Newman et al. (2019)	No work-related outcomes
Sandgren et al. (2000)	No work-related outcomes
Schulman-Green et al. (2017)	No work-related outcomes
Thompson et al. (2014)	No work-related outcomes
Winick et al. (1977)	Study design other than RCT or quasi-experimental design (with comparator). Non-controlled.

APPENDIX K: RISK OF BIAS ASSESSMENT RATIONALE

Author		Bias	Judgement	Support for Judgement
<i>Björneklett et al, 2013</i>	Selection Bias	Sequence generation	Low risk	Quote: “Patients were stratified according to adjuvant chemotherapy and randomized in blocks of four by the use of closed envelopes”.
		Allocation concealment	Unclear risk	Comment: Sealed envelopes however does not state if sequentially numbered and/or opaque as per the SNOSE method (Sequentially Numbered, Opaque, Sealed Envelope).
	Performance bias and detection bias	Blinding of participants and personnel	High risk	Comment: Impossible to blind participants due to the nature of the intervention.
		Blinding of outcome assessors	Unclear risk	Comment: Participants were the outcome assessors (as using self-reported questionnaires). It is unclear if knowing which intervention they were randomised to, would have directly influenced the outcomes.
	Attrition bias	Incomplete outcome data	High risk	Comment: Attrition rates outlined however no reasons for dropouts explained or mentioned in the analysis.
	Reporting bias	Selective reporting	Low risk	Comment: Appear to present results for three main outcomes; Sick leave, Health care utilisation and Costs of healthcare.
		Other biases	High risk	Comment: Potential weaknesses identified in the discussion; (i) Self-reported/Subjective outcome measures, which were (ii) not validated. Health status before randomisation unknown.
<i>Bolam et al, 2019</i>	Selection Bias	Sequence generation	Low risk	Comment: Computer-generated randomisation, as per original paper (Wengström et al, 2017)
		Allocation concealment	Unclear risk	Comment: Unclear how concealment occurred.
	Performance bias and detection bias	Blinding of participants and personnel	High risk	Comment: Impossible to blind participants due to the nature of the intervention.
		Blinding of outcome assessors	Unclear risk	Comment: Participants were the outcome assessors (as using self-reported questionnaires). It is unclear if knowing which intervention they were randomised to, would have directly influenced the outcomes.
	Attrition bias	Incomplete outcome data	High risk	Comment: There are multiple timepoints where there is lost to follow-up/dropouts, described in figure. There are many more dropouts in the usual care immediately post-randomisation than other group. Also, not all is clear e.g. from week 16 after usual care (n=182), number approached for 2-year follow-up down to n=179. No allowance for this is made in approach to analysis.
	Reporting bias	Selective reporting	Low risk	Comment: Appears all pre-specified outcomes were reported
		Other biases	Unclear risk	Comment: Potential sources of bias are that information on other activity being conducted by participants outside of the intervention was not complete a

Author	Bias	Judgement	Support for Judgement	
Hubbard et al, 2013	Selection Bias	Sequence generation	Low risk	Comment: Allocation sequence generated from a Bernoulli probability distribution with a specified probability of 0.5, which ensured participants had an equal chance of being in either group.
		Allocation concealment	Low risk	Comment: Allocation sequence concealed from researcher. Administrator who was not involved in process, assigned participants to intervention and usual care groups.
	Performance bias and detection bias	Blinding of participants and personnel	High risk	Comment: Impossible to blind participants due to the nature of the intervention.
		Blinding of outcome assessors	Unclear risk	Comment: Participants were the outcome assessors (as using self-reported questionnaires). It is unclear if knowing which intervention they were randomised to, would have directly influenced the outcomes.
	Attrition bias	Incomplete outcome data	Low risk	Comment: Intervention group was n=7 for final analysis (Down 1 participant from allocation). Control group was n=11 (down 3 participants from allocation). Reasons were provided for attrition. Have explained exclusions, however, could have used imputation methods in sensitivity analysis to determine the impact of missing data on results.
	Reporting bias	Selective reporting	Low risk	Comment: Appears all pre-specified outcomes were reported
		Other biases	High risk	Comment: While demographics and clinical characteristics are outlined for each group, it's not clear if there are any statistically significant differences between groups. Likely due to small sample. Other potential sources of bias identified in the discussion; Low sample size, potentially healthier sample and those with greatest need may be excluded.
Ibrahim et al, 2017	Selection Bias	Sequence generation	Low risk	Comment: Block randomisation used.
		Allocation concealment	Unclear risk	Comment: Unclear who individual was in the allocation process. The treatment assignment was hidden until name entered but not explained how hidden?
	Performance bias and detection bias	Blinding of participants and personnel	High risk	Comment: Impossible to blind participants due to the nature of the intervention.
		Blinding of outcome assessors	Unclear risk	Comment: Participants were the outcome assessors (using self-reported questionnaires). It is unclear if knowing the intervention they were randomised to, would have directly influenced outcomes.
	Attrition bias	Incomplete outcome data	Unclear risk	Comment: Two dropped out and 3 died during the study. No explanation how/if they were included in the analysis. Table 1 showing baseline and follow-up does not provide numbers in final analysis.
	Reporting bias	Selective reporting	Low risk	Comment: Appears all pre-specified outcomes were reported
		Other biases	High risk	Comment: Higher baseline levels of activity in exercise vs control group. Limited time available for intervention, potential for selection bias. Lack of adherence with self-reported logs

Author	Bias		Judgement	Support for Judgement
Jong et al, 2018	Selection Bias	Sequence generation	Low risk	Comment: Described adequately using blocked randomisation
		Allocation concealment	Unclear risk	Comment: While it is reported that the study monitor was blinded for allocation sequence, it is unclear how this achieved i.e. through sequential sealed envelopes, etc.
	Performance bias and detection bias	Blinding of participants and personnel	High risk	Comment: Impossible to blind participants due to the nature of the intervention.
		Blinding of outcome assessors	Unclear risk	Comment: Participants were the outcome assessors (as using self-reported questionnaires). It is unclear if knowing which intervention they were randomised to, would have directly influenced the outcomes.
	Attrition bias	Incomplete outcome data	High risk	Comment: Not all participants who were randomised were accounted for at 3 months since the reasons provided do not add to the total dropping out.
	Reporting bias	Selective reporting	Low risk	Comment: Appears all pre-specified outcomes were reported
		Other biases	High risk	Comment: Intervention group had significantly more participants who had not received hormone therapy. Many outcomes were psychological which may have been impacted by the fact that there was a statistically significant difference between groups by hormone therapy.
Maguire et al, 1983	Selection Bias	Sequence generation	Low risk	Comment: Sequence generated using a random numbers table.
		Allocation concealment	Unclear risk	Comment: Unclear who completed the randomisation.
	Performance bias and detection bias	Blinding of participants and personnel	High risk	Comment: Impossible to blind participants due to the nature of the intervention.
		Blinding of outcome assessors	Unclear risk	Comment: Participants were the outcome assessors (as using self-reported questionnaires). It is unclear if knowing which intervention they were randomised to, would have directly influenced the outcomes.
	Attrition bias	Incomplete outcome data	Low risk	Comment: Reported numbers at each stage, including numbers of drop-outs and reasons for drop out. There were a small number (20/172) of those who were excluded from the analysis for different reasons leaving 152. All 152 were accounted for in the tables presented
	Reporting bias	Selective reporting	Low risk	Comment: Based on the outcomes they appear to describe all outcomes are presented, no evidence of selective reporting
		Other biases	Unclear risk	Comment: Participant characteristic - unclear regarding baseline characteristics and if there were any statistically significant differences between groups. Paper reports that the group 'proved closely matched on variables', but no data reported to support this. As the authors do not present any limitations to the study it is not clear if other sources of bias might exist

Author	Bias		Judgement	Support for Judgement
<i>Maunsell et al, 1996</i>	Selection Bias	Sequence generation	Low risk	Comment: Use of sealed envelopes (prepared using a random numbers table) randomly varied block sizes used.
		Allocation concealment	Low risk	Comment: Nurse was blinded to patient's treatment allocation, where the secretary randomised all patients.
	Performance bias and detection bias	Blinding of participants and personnel	High risk	Comment: Impossible to blind participants due to the nature of the intervention.
		Blinding of outcome assessors	Unclear risk	Comment: Participants were the outcome assessors (as using self-reported questionnaires). It is unclear if knowing which intervention they were randomised to, would have directly influenced the outcomes.
	Attrition bias	Incomplete outcome data	Low risk	Comment: Attrition rates outlined and explanation provided.
	Reporting bias	Selective reporting	Low risk	Comment: Appears all pre-specified outcomes were reported
		Other biases	Unclear risk	Comment: Participant characteristics - No p values available to confirm there were no statistically significant differences between groups. Only one site used so potential bias in that regard.
<i>Mourgues et al, 2014</i>	Selection Bias	Sequence generation	Unclear risk	Comment: While it is reported that randomisation was balanced and stratified, it is unclear as to how this was done.
		Allocation concealment	Unclear risk	Comment: Unclear if allocation was concealed from team members. Randomisation performed by the oncology centre is vague.
	Performance bias and detection bias	Blinding of participants and personnel	High risk	Comment: Impossible to blind participants due to the nature of the intervention.
		Blinding of outcome assessors	Unclear risk	Comment: Participants were the outcome assessors (as using self-reported questionnaires). It is unclear if knowing which intervention they were randomised to, would have directly influenced the outcomes.
	Attrition bias	Incomplete outcome data	Low risk	Comment: While there are no reasons provided for attrition levels of the three analysis timepoints, the authors do account for missing data in the analysis using a mixed model (MRMs).
	Reporting bias	Selective reporting	Low risk	Comment: Appears all pre-specified outcomes were reported
		Other biases	Unclear risk	Comment: Participant characteristics - Statistically significant difference between the two groups (p <0.05) for monthly activities where control group complete 132.8 hours per month vs. intervention group with 99.5 hours. All other variables tested had no statistically significant difference. Unclear if this had influence on outcomes.

Author	Bias		Judgement	Support for Judgement
Rogers et al, 2009	Selection Bias	Sequence generation	Low risk	Quote: “Participants were randomized after completion of all base- line assessments. Randomization was computer generated and kept in sealed envelopes until randomization to prevent bias in group allocation by study personnel.”
		Allocation concealment	Unclear risk	Comment: Randomised allocation kept in sealed envelopes to prevent bias in group allocation by study personnel. However, no mention if envelopes were opaque or sequentially numbered. As per SNOSE technique, envelopes should be Sequentially Numbered, Opaque, Sealed Envelope.
	Performance bias and detection bias	Blinding of participants and personnel	High risk	Comment: Impossible to blind participants due to the nature of the intervention.
		Blinding of outcome assessors	Unclear risk	Comment: Participants were the outcome assessors (as using self-reported questionnaires). It is unclear if knowing which intervention they were randomised to, would have directly influenced the outcomes.
	Attrition bias	Incomplete outcome data	Low risk	Comment: The authors provide an assessment of missing data in the statistical analysis section (for individual items on scales and imputation) and for those lost to follow-up. However, the numbers on each outcome are not provided in the tables so assumed all others were complete or imputed.
	Reporting bias	Selective reporting	Low risk	Comment: Appears all pre-specified outcomes were reported
		Other biases	High risk	Comment: Potentially other sources of bias, including variation in stage/time since diagnosis, short follow-up time. As this is a feasibility study, it is not powered for effects.

APPENDIX L: LETTER OF ETHICAL APPROVAL (PHASE III)



Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Ms. Naomi Algeo
Discipline of Occupational Therapy,
Trinity Centre for Health Sciences,
St. James' Hospital,
James Street,
Dublin D08 W9RT
Ireland

7th July 2020

Ref: 2020403

Title of Study: BREast cAnCer surVivors and Employment (BRAVE): Developing a work-focused intervention using a nominal group technique.

Dear Naomi,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in June 2020, we are pleased to inform you that the above project (as amended with the following changes) has ethical approval to proceed. 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):

Please give specific details of the requested amendment(s):

1. DATA COLLECTION

- a. Data collection method changed: Face-to-face data collection via nominal group technique workshop at Trinity Centre for Health Sciences, St James' Hospital changed to data collection via nominal group technique workshop online via Microsoft Teams.

Original approved Data Collection Method approved	Proposed change in Data Collection Method	Supported by TCD IT Service
Face-to-face nominal group technique.	Online nominal group technique via Microsoft Teams video conferencing.	Yes

Original approved Data Collection Method approved (for Anonymous Voting)	Proposed change in Data Collection Method for Anonymous Voting
Anonymised voting to be completed using anonymous voting cards.	Anonymised voting will be completed using the GDPR compliant online platform, <i>MentiMeter</i> . The research team will not purchase an account for this platform until full approval received from the DPO.

2. INCLUSION CRITERIA

- a. Inclusion criteria for ALL cohorts has changed.

Original approved Inclusion Criteria for ALL cohorts	Proposed change Inclusion Criteria for ALL cohorts



Need to be willing and able to attend a once-off group-based face-to-face discussion based at Trinity Centre for Health Sciences.	Need to be willing and able to attend a once-off group-based online discussion via Microsoft Teams video conferencing. All participants will require an internet connection and a device that supports Microsoft Teams.

3. CONSENT

- a. Consent procedure changed: Discussion with participant around study and signing of consent forms *in person* on day of the workshop changed to discussion via telephone call and consent forms received via email.

Original approved Consent Procedure	Proposed change Consent Procedure
Prior to the workshop, participants would be provided an individual timeslot to discuss with the researcher in person any aspects of the PIL and pose any questions about the workshop. At this point, they sign the consent form if happy to proceed.	Prior to the workshop, the researcher will call the potential participant to discuss any aspects of the PIL and pose any questions about the workshop. At this point, they complete the form and sign it using an e-signature. Saving the form as a PDF, the participant can then email this back to the researcher.

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

APPENDIX M: PARTICIPANT INFORMATION LEAFLET (PHASE III)

Participant Information Leaflet

Name of Study: *BReast cAncer surVivorship and Employment (BRAVE): Developing a work-focused intervention using the nominal group technique.*

Site	Trinity Centre for Health Sciences, St James' Hospital.
Principal Investigator(s) and Co-Investigator(s) (insert names, titles and contact details)	Dr. Deirdre Connolly (Principal Investigator) Ms. Naomi Algeo (Co-Investigator)
Data Controllers	Trinity College Dublin
Data Protection Officer	Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2

You are being invited to take part in a research study that is being carried out within the Discipline of Occupational Therapy by Dr. Deirdre Connolly and Ms. Naomi Algeo, at the Trinity Centre for Health Sciences. Before you decide whether or not you wish to take part, please read this information sheet carefully. Ask Ms. Naomi Algeo or Dr. Deirdre Connolly any questions. Don't feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you.

This leaflet has five main parts:

Part 1 – The Study

Part 2 – Data Protection

Part 3 – Costs, Funding and Approval

Part 4 – Future Research

Part 5 – Further Informatio

Part 1 – The Study

Why is this study being done?

Breast cancer is one of the most common cancers amongst women in Ireland. Increased survival rates have prompted focus on improving quality of life beyond cancer. Employment is important in maintaining well-being however 84% of women with breast cancer in Ireland temporarily or permanently stop working after their diagnosis. There is currently a lack of programmes to support women with breast cancer to transition back into the workplace.

The BReast cAncer surVivorship and Employment (BRAVE) in Ireland study is a four-phase study exploring work and employment in Ireland after a breast cancer diagnosis.

- In Phase I, we interviewed women with breast cancer, healthcare professionals and employers in Ireland to explore what helped and limited women to return to the workplace after their cancer diagnosis.
- In Phase II, we reviewed all the research that's been carried out to find out if there are any support programmes that help women return to work after breast cancer. This type of research in Phase II is known as a *systematic review*.
- This study that we are inviting you to participate in is Phase III. The purpose of this phase is to prioritise different aspects of a work-focused programme for women with breast cancer, with a focus on how it's run, what content is included, where it is run, and how long for. This can then inform a future work-focused programme that will be tested with women who have had breast cancer. This programme will be tested during Phase IV of our research. In order to develop a work-focused programme for women with breast cancer, we would like to prioritise:
 - How we should run the programme – so looking at preference for a group vs. one-to-one vs. combined programme format.
 - Where this programme should be facilitated
 - What content is delivered in the programme.
 - How long the programme should be.

To answer these questions, we are inviting those who we feel can make key contributions to such a programme to take part in a research study. This will involve a once-off meeting online (via Microsoft® Teams) on Tuesday 11th August.

Why have I been invited to take part?

You have been invited to take part as you are considered a key stakeholder who could inform the development of a future work-focused support programme for women who have had breast cancer in Ireland. We are looking to speak with the following:

- **Three women who have had breast cancer** and have had experience in transitioning back into the workplace in Ireland following a breast cancer diagnosis in the past two years.
- **Three occupational therapists** who have experience in addressing return to work after cancer, and/or oncology in practice.
- **Three occupational therapy managers** who have experience in overseeing staff resources in oncology in any Irish setting.
- **Three directors/co-ordinators of cancer support centres** who have experience in overseeing/co-ordinating a variety of cancer survivorship programmes (1:1, group: mixed).
- **Three Policy informers** who have experience in overseeing policy updates in oncology in Ireland.

ALL: Need to be willing and able to attend a once-off group-based online discussion via Microsoft® Teams video conferencing. All participants will require an internet connection and a device that supports Microsoft® Teams.

Do I have to take part? Can I withdraw?

You do not have to take part in this study. It is entirely voluntary. If you decide to volunteer to participate in this study, you may withdraw at any time prior to the workshop without giving a reason. All data (information) collected will be unidentifiable after anonymisation, therefore it will be impossible to withdraw data after this point. Anonymisation is a process that protects your privacy. It means that all data collected (such as your thoughts and opinions) are not linked to you, therefore you cannot be made identifiable through this data. If you decide not to participate, or if you withdraw, you will not be penalised in any way and do not have to give a reason. It is aimed that all data will be analysed and written up by July 2021.

You can change your mind at any time prior to the workshop by contacting Ms. Naomi Algeo (by email: nalgeo@tcd.ie or phone: 083-053-0777). You do not need to give a reason for this.

What happens if I change my mind?

If you decide not to participate, or if you withdraw, you will not be penalised in any way.

How will the study be carried out?

We are looking for up to three of each cohort to attend an online meeting which aims to reach a consensus amongst the attendees in relation to key questions related to developing a work-focused intervention. A once-off workshop using the nominal group technique (NGT) will be used to engage participants in a prioritisation process for a work-focused programme for women with breast cancer. This meeting will take place online using Microsoft® Teams on Tuesday 11th August, subject to participant availability.

What will happen to me if I decide to take part?

If you decide to take part, you can contact the researcher (Ms. Naomi Algeo) by phone or email. Ms. Algeo will then send you copies of the participant letter, consent form, participant information leaflet, and participant pack by email or post (whichever you prefer). Ms. Algeo will then check at least seven days later to see if you are happy to proceed in participating in this workshop, which will take place online using Microsoft® Teams. Before the workshop, you'll be invited to take a look at the participant information pack which includes the timetable for the day, as well as the questions that will be posed to the group. This will allow you time to reflect on ideas and suggestions.

Ms. Algeo will call you prior to the workshop to discuss any questions that you might have about the study. If you are still happy to proceed, you will be asked to sign the consent form using an e-signature and emailing it back to Ms. Algeo. Ms. Algeo will be on hand to offer assistance if you require any help with adding an e-signature.

On Tuesday 11th August, you will take part in the *once-off* online workshop with other key individuals involved in the participation and facilitation of a work-focused programme. The workshop involves four stages:

- (1) Participants individually writing down ideas related to the specific question.
- (2) These ideas are shared and Ms. Algeo will share a screen with all these ideas on a Word document.
- (3) The group will then discuss the ideas and refine/organise into wider themes, if needed.
- (4) Participants will then be invited to rank their preferences for each category discussed (e.g. setting, content, etc.). This will be completed using the interactive online platform, Mentimeter.

This process will be repeated as required and it is hoped that the outcome of the meeting will be agreement on the key questions proposed. On completion of this, the workshop will then end, and you will only be contacted again if you wish to opt-in for future update on publications.

What will happen to my Data?

All ideas expressed by individuals will be typed up onto a Word document and shared with participants via the shared screen feature during the discussion period. Only ideas will be typed; no identifying details will be recorded beside ideas. Ideas may be refined and altered following group discussion and agreement. Finally, you will vote for your preferred options to each question using the online platform MentiMeter. The data you provide in voting will be anonymous. This will then be used for data analysis. After collection of this data, it will be impossible to withdraw your data from the study as cards will be anonymous. All data from the shared screen and MentiMeter voting will be analysed, and anonymised results kept on a Word document on a password protected TCD computer. MentiMeter will store your IP address for 14 days after your use the platform, after which it will be deleted. Your IP address is a unique numerical address which identifies a device connected to the internet. MentiMeter requires your IP address to enable you to vote/provide preference online for each question. For more information on what will happen to your personal data, see Part II of this participant information leaflet (overleaf).

Are there any benefits to taking part in this research?

While there is no direct benefit to you, it is anticipated that the results of this consensus will provide a valuable contribution to the development of a work-focused intervention for women with breast cancer in Ireland.

Are there any risks to me or others if I take part?

While there is no audio recording or recording of identifying information required as part of this process, discussion will take place in a group format where the researcher cannot guarantee confidentiality. However, participants will be reminded to keep any discussion or opinions expressed within the meeting confidential to the group.

Will I be told the outcome of the study?

The results of the study will be reported in scientific journals and disclosed at scientific conferences. No information which reveals your identity will be disclosed. If you would like to be sent a copy of published work relating to this research, you may opt in on your consent form for future communications around this.

Part 2 – Data Protection

What information about me (personal data) will be used as part of this study?

We will collect the following personal data for the purposes of communicating with you:

- Your name
- Your contact details – preferred phone number and email address. In addition to this, we will *only* collect your home address if you wish for documents, such as the participant information pack, to be posted to you.

MentiMedia (the online voting platform) will collect:

- Your IP address.

No other personal data will be collected.

What will happen to my personal data?

- Your data will be used as part of the research, '*BReast cAncer surVivorship and Employment (BRAVE): Developing a work-focused intervention using the nominal group technique*' and will only be processed as necessary to achieve the objective of the health research. It will not be processed in a way that damage or distress will be caused to you.
- Your data is being processed for the purpose of legitimate interest (Article 6;1(f), General Data Protection Regulation, 2016) and for the purpose of scientific research purposes (Article 9;2(j), General Data Protection Regulation, 2016).
- Consent forms with your name will be stored in a locked cabinet in Dr. Deirdre Connolly's office in Trinity Centre of Health Science for 7 years in line with Trinity College Dublin Policy, however your contact details will be destroyed when no longer required, i.e. on the day of the workshop, or else when future publications are communicated to you (if you opt-in for this).
- Measures will be taken to reduce risk when processing the data, however, should a data breach occur, this may cause you harm. This harm will be significantly reduced as your data will not have any identifiable information on it. Instead of your name, a code number will be used. This is called **pseudonymisation**. **In summary, pseudonymisation means that identifiable information is removed from a data record and replaced with another identifier, i.e. a pseudonym. For example, instead of using a name, data could be labelled 'Participant 1'. While this doesn't remove all identifying detail, it reduces the ability to link data to the identity of a person.**
- If necessary, you have the right to lodge a complaint with the Data Protection Commissioner. Their contact details can be found at the top of this document.

- Until data is analysed by the researcher, you have the right to the following;
 - request access to your data and a copy of it
 - to have any inaccurate information about you corrected or deleted
 - to have personal data deleted
- It would be impossible to conduct this research without processing of your data, therefore data processing is necessary. Data processing is any operation which is performed on personal data, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction (Act 4(2), General Data Protection Regulation, 2016).
- Your data will used for this research only and will not be used for any other future research without your explicit consent. All data will be destroyed after seven years maximum.

Who will access and use my personal data as part of this study?

Only Naomi Algeo (Co-Investigator) and Dr. Deirdre Connolly (Principal Investigator) will have access to your personal data. Access to your personal data will only be made for the purposes of communicating to you.

MentiMeter will process and store your IP address for 14 days after you log into their website. They require your IP address to enable you to vote online.

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 will do this:

- Your personal data (name on consent form) will be kept in paper form in a locked cabinet at Trinity Centre for Health Sciences, St. James' Hospital. It will be kept here for seven years, in line with TCD policy. Contact details will be destroyed as soon as no longer required. This will either be on the day of the workshop where no further updates are required about the day *or* contact details will be destroyed when future publications have been sent to you (only if you opt-in for this).
- A Data Protection Impact Assessment has been completed and has been reviewed by the Data Protection Officer, TCD.
- Training in data protection law and practice has been provided to the research team. Naomi Algeo and Dr. Deirdre Connolly have both undertaken the GDPR and Health Research Regulations Workshops in Trinity College Dublin in preparation for the project. Naomi Algeo has also completed the online TCD GDPR training.

Part 3 – Costs, Funding and Approval

- All data that is collected from the Nominal Group Technique process is anonymous. No identifying details are recorded on shared screens during discussion, and voting is completely anonymous.
- Because this data is anonymous, any future presentations or publications in relation to the findings of this research cannot be traced back to participants.
- Naomi Algeo and Dr. Deirdre Connolly are bound by a contractual code of secrecy which protects your confidentiality.
- If something did go wrong and your data was compromised, we would contact you and the Data Protection Officer at Trinity College Dublin.

What is the lawful basis to use my personal data?

By law,¹ we can use your personal information for scientific research² (in the public interest³). 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 (except where it is de-identified)
- 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 Ms. Naomi Algeo (Email: nalgeo@tcd.ie) 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.

¹ The European General Data Protection Regulation (GDPR)

² Article 9(2) (j))

³ (Article 6(1)(e))

Has this study been approved by a research ethics committee?

Yes. This study was approved by the Faculty of Health Science Research Ethics Committee, TCD in July 2020.

Who is organising and funding this study?

While this study is not in receipt of any funding, Ms. Naomi Algeo is funded by the Irish Research Council and Trinity College Dublin to undertake her doctoral studies and is conducting this research for the purposes of obtaining a doctoral qualification.

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. Participation is voluntary.

Part 4 – Future Research

Will my personal data be used in future studies?

No. Your personal data will not be used for any future studies., however you will have the opportunity to opt-in for updates on future publications that stem directly from this research

Part 5 – Further Information

Who should I contact for information or complaints?

If you have any concerns or questions, you can contact:

- Co-Investigator: Ms. Naomi Algeo (nalgeo@tcd.ie or 083-053-0777)
- Principal Investigator: Dr. Deirdre Connolly (CONNOLDM@tcd.ie)
- 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 is complete, you will only be contacted again if you opt-in to hear about future publications.

APPENDIX N: CONSENT FORM (PHASE III)

Consent Form

STUDY NAME: *BReast cAncer surVivorship and Employment (BRAVE): Developing a work-focused intervention using the nominal group technique.*

There are 3 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.

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	Initial
I confirm I have read and understood the Participant 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 I will not be paid for taking part in this study .	
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. I understand that there are no direct benefits to me from participating in this study.	
I understand that MentiMeter, a third-party online platform, will collect my IP address and store it for up to 14 days before destroying. This is to enable me to vote online.	

Data processing	Initial
I understand that personal information about me will be protected in accordance with the General Data Protection Regulation.	
I understand that I cannot withdraw any data collected after the workshop as it will be anonymous.	
I understand that I can stop taking part in this study at any time without giving a reason.	
I understand that my data will not be used in future studies	
I understand that my contact details will only be kept up until the day of the workshop <i>unless</i> I opt in for future correspondence (as below)	

Optional Opt-In	Initial
I would like to be contacted in the future about publications relating to this research.	

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: Naomi Algeo

Title and qualifications: B.Sc. Occupational Therapy; M.Res. Clinical Research

Signature:

Date:

| | |

2 copies to be made: 1 for participant, 1 for PI

APPENDIX O: NGT PARTICIPANT PACK (PHASE III)

PARTICIPANT PACK

BReast cAncer surVivorship and Employment (BRAVE): Developing a work-focused intervention using the nominal group technique.

Tuesday 11th August – Online via Microsoft Teams

Timetable for the day*:

0930-0945hrs: Registration/Log In

0945-1000hrs: Welcome and Introduction to the Nominal Group Technique process

1000-1015hrs: NGT Question 1 [Adapted] *Format of the Intervention*

1015-1030hrs: NGT Question 2 [Adapted] *Hosting of the Intervention*

1030-1045hrs: NGT Question 3 *Setting of a Face-to Face Intervention*

1045-1100hrs: NGT Question 4 *Setting of an Online Intervention*

1100-1115hrs: BREAK

1115-1130hrs: NGT Question 5 *Timing of the Intervention*

1130-1215hrs: NGT Question 6 *Content for the Intervention*

1215-1230hrs: Discussion and Close.

*Please note times are subject to change however the workshop will start at the indicated time, and will conclude by 1230hrs at the latest.

NGT Question 1 [ADAPTED]: What would you consider the preferred format of a work-focused intervention?

This NGT Question is adapted. This means that all participants will go straight to the voting phase. The following options were drawn from Phase I of this study.

- A:** Group
- B:** One-to-one
- C:** Group with a once-off one-to-one session.

NGT Question 2 [ADAPTED]: What would be your preference for attending a work-focused intervention?

This NGT Question is adapted. This means that all participants will go straight to the voting phase. The following options were drawn from Phase I of this study.

- A:** Face-to-face sessions
- B:** Online

NGT Question 3: If the intervention was face-to-face, where would it be best to deliver such an intervention?

Prompts: E.g. cancer support centre, University-based, outpatient hospital setting, community centre etc

NGT Question 4: If the intervention was online, what online platform would be preferred?

Prompts: Zoom, Microsoft Teams, Facebook

NGT Question 5: Over what period of time should an intervention take place?

Prompt: E.g. Over consecutive days? Once a week for how many weeks? A once-off event? Any other periods of time?

NGT Question 6: What are the key areas that need to be addressed as part of a work-focused intervention for women with breast cancer?

Phase I of this research indicated the following areas as important:

- Understanding employment rights and entitlements
- How to effectively communicate between employer-employee
- Managing cancer-related fatigue in the workplace
- Managing mental health in the workplace
- Managing 'chemobrain' in the workplace

Please also add your own ideas below of what else might be helpful.

APPENDIX P: Brainstorming content for a work-focused intervention

Content of Programme – Brainstorming Ideas and Notes:

INTRODUCTION Session:

Setting the scene

Introduction into Vocational Rehabilitation -

Education: What is Vocational Rehabilitation? What can be done to support women with breast cancer back to work? Explaining role of different Healthcare Team Members.

Education Role of Occupational Health Departments.

1. Legislation, Rights and Entitlements [GROUP]

Education re:

An introduction into employment law in the context of cancer, including but not limited to:

- Sick leave and Annual Leave entitlements (including taking time for appointments, using leave to phase back on a part-time basis)
- Rights for the self-employed
- Reasonable Accommodations. What is a reasonable accommodation?
- The definition 'Disability'
- Discrimination and how to manage potential discrimination.
- Employer Duty of Care to Employees
- Who can I contact if my employment rights are not being met?
- The right to Privacy/Confidentiality
- The role of the Union
- Travel insurance
- What are rights when RTW and too soon – not able to fulfil roles?
- Financial supports and benefits – e.g. Partial Capacity Benefit, Illness Benefit, Disability Benefit
- Impact on Pension
- Redundancy

2. Psychological Considerations [GROUP]

Signposting to psychological/psycho-oncology supports

Signposting resources – e.g. Use of Apps (Calm and Headspace),

Managing anxiety

Stress management strategies

Managing expectations – Employees and Employers

Boosting confidence in the workplace.

Enhancing Self-Image; Managing physical changes in the context of work

3. Fatigue Management and Cognition [GROUP]

Fatigue Management:

- Phased Return To Work/Grading Tasks.
- Self-care: Taking breaks, exercise, work-life balance
- 4 Ps; Prioritising, Pacing, Planning,
- Different types of fatigue: Physical, Mental, Emotional, Cognitive.
- Signposting resources – e.g. Cancer-Related Fatigue App (Untire)

Managing your thinking skills:

- Managing Cognitive impacts of treatment, including strategies to enhance memory, attention.
- Cognitive fatigue
- The link between fatigue, stress, and cognitive function.
- Signposting resources – e.g. App (Luminosity)

4. Communication Skills [GROUP]

Communicating with Family, Colleagues, and Employer

Negotiation skills – negotiating ongoing rehabilitation and/or medical needs during RTW.

Re-engaging with the workplace. What you want people to know, or not know.

Addressing family's desire for things to go back to normal. – managing expectation with employer

PT vs FT. What do I want? What is right for me at this time?

Managing colleagues

5. Physical Considerations [GROUP]

Managing physical limitations in the context of work; e.g. lymphoedema, menopausal symptoms, joint pain, wigs, prosthesis.

Self-image. Managing physical changes in context of work.

Pain Management

Impact of ongoing treatment

Ergonomic principles. – seating, desks, managing limitations in lymphoedema, sensation, etc.

Assistive technology.

6. Developing a Return To Work Plan: A Personalised Roadmap: [INDIVIDUAL]

Offering a Once-off Assessment:

- Occupational Analysis – discussion of job role and participation strengths and limitations.
- Assessment of readiness to RTW

Intervention:

- Discussion of RTW options – e.g. considering part time vs full-time, redeployment to other roles, re-training for other roles, exploring other options internally to own organisation or externally, retirement
- Development of RTW plan, personalised to participant. Inclusive of SMART goals, and with summary of practical strategies.
- Highlighting items such as medical clearance, when to link in with occupational health and/or HR, negotiation with employer (negotiation skills will be further refined in Communications session).

CLOSE: - Recap on signposting resources, services, etc.

Education / Signposting

What resources are there available? Signposting.

Community resources – can access in own communities

Psycho-oncology

Cancer information and support centres.

Options for smaller firms.

Self-employed – managing and support.

What supports are in place for me when RTW?

Seeking a mentor / advocate within or outside of the organisation?

APPENDIX Q: COREQ CHECKLIST (PHASE IV)

Topic	Item No.	Description	Reported on:
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/ Facilitator	1	Which author(s) conducted the interview or focus group?	158
Credentials	2	What were the researcher's credentials? E.g., PhD	37
Occupation	3	What was their occupation at the time of the study?	37
Gender	4	Was the researcher male or female?	37
Experience and training	5	What experience or training did the researcher have?	37
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	154
Participant knowledge of the interviewer	7	What did the participants know about the researcher? E.g., reasons for doing the research	153
Interviewer characteristics	8	What characteristics were reported about the interviewer? E.g., bias, assumptions, reasons and interest in the research topic	8-9
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, content analysis.	152
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, snowball.	153
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email.	154
Sample size	12	How many participants were in the study?	153
Non-participation	13	How many people refused to participate or dropped out? Reasons?	154
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g., home, workplace, etc.	158
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	158
Description of sample	16	What are the important characteristics of the sample? e.g., demographic data, date	Table 6.9
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	158-159; Appendix BB

Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	158
Audio/visual recording	19	Did the research use audio or video recording to collect data?	158
Field notes	20	Were field notes made during and/or after the interview or focus group?	159
Duration	21	What was the duration of the interviews or focus group?	176
Data saturation	22	Was data saturation discussed?	153;176
Transcripts returned	23	Were transcripts returned to participants for comment and/or correction?	160
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	38
Description of the coding tree	25	Did authors provide a description of the coding tree?	40 Codes were managed using NVivo. No coding tree.
Derivation of themes	26	Were themes identified in advance or derived from the data?	38
Software	27	What software, if applicable, was used to manage the data?	159
Participant checking	28	Did participants provide feedback on the findings?	160-162
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quote identified? e.g., participant number	176-196
Data and findings consistent	30	Was there consistency between the data presented and the findings?	176-196
Clarity of major themes	31	Were major themes clearly presented in the findings?	176-196
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	176-196

APPENDIX R: TIDIER CHECKLIST

Brief Title: The Work and Cancer Intervention

Why: The aim of the Work and Cancer intervention is for those living with and beyond breast cancer to (i) self-manage common side-effects and apply to the workplace, (ii) make informed decisions around return to work, (iii) co-develop a return to work or work maintenance plan, and (iv) feel supported in sustaining their job role.

As this is a self-management intervention, it is based on self-management theory which incorporates keys aspects into the programme:

- Weekly goal-setting
- Peer support, interaction and feedback
- Enhancing understanding of symptoms in order to effectively self-manage them

What:

Materials:

- The *Work and Cancer* handbook, a 155 page handbook focusing on each session and providing supplementary information and optional exercises for participants to apply new knowledge.
- A licensed Zoom account
- Letter to Employer template
- Work Report template

Procedures:

Week	Title	Content	Facilitator(s)	Format	Length	Setting
1	Introduction to the Programme	• Outline of Programme • Introductions • Introduction to SMART goal setting	Occupational Therapist	Group	90 minutes	Online via Zoom
2	Employment Rights and Entitlements after Cancer	• Employment Rights • Entitlements • Grants	Occupational Therapist and Community Welfare Officer	Group	90 minutes	
3	Managing Cancer-Related Fatigue and Cognitive Changes in the Workplace	• Understanding Cancer-Related Fatigue • 4 Ps of Energy Management • Applying the 4Ps to the Workplace • Understanding Cognitive Changes • Cognitive Strategies to apply to the Workplace	Occupational Therapist	Group	90 minutes	
4	Communicating Effectively with your Employer, Colleagues and Family	• Re-engaging with your Workplace • Taking Control of your Return to Work • Disclosing your Diagnosis • Negotiating a Return-to-Work/Work-Maintenance Plan with your Employer • Navigating Unwanted Conversations with Colleagues • Discussing Work with Family	Occupational Therapist	Group	90 minutes	
5	Managing your Mental Health and Physical Side-Effects in the Workplace	• Managing Stress & Anxiety in the Workplace • Ergonomics – Adapting your Workspace • How to Manage Physical Side-Effects at Work such as Pain, Fatigue, Breathlessness, Hair Loss, and Changes in Sensation.	Occupational Therapist and Physiotherapist	Group	90 minutes	
6	Developing a Return-to-Work Roadmap	• Occupational Analysis exploring Job Role. • A Return-to-Work Plan tailored for you by a registered Occupational Therapist • A Letter with Recommended Accommodations, if required. • Assessing Readiness to Return to Work	Occupational Therapist	Individual	60 minutes	

- Who Provided:* The intervention is occupational therapy-led with MDT input (Session 2 – community welfare officer; Session 5 – physiotherapist).
Occupational therapist: Naomi Algeo (BScOT; MRes) is a registered occupational therapist with clinical background in oncology and vocational rehabilitation. She developed the programme as part of her doctorate in occupational therapy.
Community Welfare Officer: [Name omitted confidentiality] Is a Community Welfare Officer and has lived experience of a cancer diagnosis.
Physiotherapist: [Name omitted confidentiality] (BSc, PhD) is a registered physiotherapist and has both clinical and research experience in cancer rehabilitation.
- How:* The intervention is hosted online using Zoom and is predominantly in a group format (Sessions 1-5 inclusive). Session 6, however, is an individual session in which each participant co-develops a tailored return to work/work maintenance plan online with a registered occupational therapist.
- Where:* Setting: The intervention is set online using the Zoom platform.
- When and How Much:* Six sessions hosted every week. Sessions 1-5 are group-based and an average of 90 minutes. Session 6 is an individual session between the participant and a registered occupational therapist to tailor a return to work/work maintenance plan.
Session 6 is 60 minutes in duration and run with each participant.
Sessions 1-5: 90 minutes x 5 = 450 minutes (7.5 hours)
Session 6: 60 minutes x 10 participants = 600 minutes (10 hours)
Total clinical time:
17.5 hours occupational therapist
1.5 hours physiotherapist
1.5 hours community welfare officer
- Tailoring:* Session 6 is an individual session with each participant and the occupational therapist. A tailored session is provided to develop a personalised roadmap for participants reflecting their personal cancer experience and the diversity of each job role. This session is the last session of the programme and is hosted at this time so that participants are better equipped to apply their learning from Sessions 1-5 to brainstorm with the occupational therapist. The occupational therapist completes an occupational analysis using a checklist assessing the participant's job role. Based on this and an interview with the participant, the occupational therapist writes up a return to work/work maintenance plan/report as well as a letter to the employer outlining recommended accommodations. These two documents are sent to each participant.

Modifications: If applicable, how was the intervention modified? One modification made during sessions 2 and 5 – Additional ten minutes added to end of session.
(What, when, why and how)

How Well: Planned: Intervention ran as planned with the exception of Sessions 2 and 5 where there was an additional ten minutes added to each session. Planned: 90 minutes

Actual: 100 minutes in Sessions 2 and 5.

APPENDIX S: OCCUPATIONAL ANALYSIS CHECKLIST

Interview Questions

During your 1:1 session with the Occupational Therapist, you will be asked questions similar to the below. Have a think about how you answer them - sometimes it can be more difficult to think when you're put on the spot!

Medical History: (Type of cancer and stage (if you remember), Other than your cancer , any other conditions?)

Current health status:

Social Situation (Home situation, family and friend supports):

Current ability and any changes to performance in:

Mobility (do you use any mobility aids e.g. stick or wheelchair, or are you aid-free?):

Community mobility (how you get around in the community e.g. walking, driving, public transport):

Self-care (any difficulties with washing/dressing, eating, sleeping etc):

Leisure (any difficulties in completing any hobbies?) :

Interview Questions:

Other occupational roles (e.g. carer, volunteer, parent, etc.):

Education: (Highest level of education, any training, any future education plans):

Work History: (Past roles, reasons for leaving/changing)

Job at time of diagnosis: (Employer, position, type and sector of work, hours of work, duties and responsibilities,

Commute: (Mode of transport, length of commute)

Reasons why you want to return to work:

Are you satisfied with your job?

Financial: (Salary/Income, any current entitlement payments)

Organisational/Legislation: (What sick leave entitlements do you have/have left (if any)?

APPENDIX T: SAMPLE LETTER OF REASONABLE ACCOMMODATIONS



Discipline of Occupational Therapy
Trinity Centre for Health Sciences
St James's Hospital
James's Street
Dublin 8

3rd April 2021

Re: Reasonable Accommodations Request

Dear Employer,

██████ attended an Occupational Therapy assessment on 1st April 2021 following a period of work absence due to breast cancer. ██████ has warmly welcomed her return to work, and is keen to work with you in reviewing accommodations in the future. To enable ██████ to access equal opportunities in the workplace, the following accommodations are recommended in order to perform essential functions of her role as ██████:

- *Review of working hours:* As ██████ has recently transitioned back into the workplace, a review meeting is recommended to determine if her current working week of four days (one day of which is being supplemented by annual leave) is manageable and sustainable. At present, it is strongly recommended that ██████ work no more than three days/week, secondary to her cancer-related fatigue. Cancer-related fatigue is a chronic side-effect of cancer treatment that can take months-years to subside.
- *Flexibility of working hours:* ██████ would benefit from the option to separate working days where required. For example, to work Monday, Tuesday and Thursday.
- *Working from home:* It is strongly recommended that ██████ continue to work from home. This accommodation is recommended in light of cancer-related fatigue that ██████ experiences as an ongoing chronic side-effect of her cancer treatment.
- *Movement breaks:* ██████ would benefit from frequent movement breaks throughout the day to alleviate any potential joint pain and tension. For example, movement (approximately 30-60 seconds) every 30 minutes from a desk-based role. ██████ may find it useful to use some of her breaktimes to engage in light physical activity, to alleviate joint pain and stiffness which is a side-effect of her ongoing cancer treatment.
- *Assistive technology:* ██████ may benefit from a speech-to-type software such as Nuance Dragon Speech Recognition technology to assist with report writing and documentation, potentially alleviating fatigue.

Thank you for considering the above requests. While I am not in a position to disclose medical information, if you require any additional information regarding the above recommended accommodations, please do not hesitate to contact me.

Best wishes,

Naomi Algeo (MRes; BScOT)
Registered Occupational Therapist (CORU: OT025366)
Email: nalgeo@tcd.ie

APPENDIX U: PARTICIPANT INFORMATION LEAFLET (PHASE IV)

Participant Information Sheet

Name of Study: *An online work-focused intervention to support women with breast cancer to return or stay in the workplace: A single-arm feasibility study and qualitative-descriptive design*

Site	Trinity Centre for Health Sciences, St James's Hospital.
Principal Investigator(s) and Co-Investigator(s) (insert names, titles and contact details)	Dr. Deirdre Connolly (Principal Investigator – CONNOLDM@tcd.ie) Ms. Naomi Algeo (Co-Investigator – nalgeo@tcd.ie)
Data Controllers	Trinity College Dublin
Data Protection Officer	Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2

You are being invited to take part in a research study that is being carried out within the Discipline of Occupational Therapy by Dr. Deirdre Connolly and Ms. Naomi Algeo, at the Trinity Centre for Health Sciences. Before you decide whether or not you wish to take part, please read this information sheet carefully. Ask Ms. Naomi Algeo or Dr. Deirdre Connolly any questions. Don't feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you.

This leaflet has five main parts:

Part 1 – The Study

Part 2 – Data Protection

Part 3 – Costs, Funding and Approval

Part 4 – Future Research

Part 5 – Further Information

Part 1 – The Study

Why is this study being done?

In 2020, there were over 200,000 individuals living with or beyond cancer in Ireland. Breast cancer is common, affecting over 30% of newly diagnosed women. Women often report experiencing many difficulties including fatigue, pain, foggiess in their thinking, and physical limitations (e.g. reaching above shoulder level). This can have an impact on their ability to work. Recent figures indicate that around 84% of women in Ireland stop working after breast cancer diagnosis but often return some time after treatment. At present, there has been little research completed in designing or evaluating programmes that support women in their job role after breast cancer. Since 2018, researchers at Trinity College Dublin have been working on developing a work-focused support programme and would like to trial it to see what works well and if anything needs to be changed.

We would like to explore the following:

- Are women interested in taking part in such a programme?
- If they take part, do they stick with the programme throughout, and do they attend all or most sessions?
- Do they complete all aspects of the programme including self-directed work such as goal-setting?
- Are they satisfied or dissatisfied with any aspect of the programme?
- Is the programme of a good enough quality to be accepted and rolled out in the future?
- Should any changes be made to the (i) content, (ii) length, (iii) facilitation of the programme?
- Are questionnaires easy to understand and use?
- What supported and hindered women to complete the programme?

To answer these questions, we are inviting up to eight women with breast cancer to participate in a research study to take place between the end of February and the start of April. This will involve completing some questionnaires in your own time, taking part in an online support programme once a week for six-weeks, and taking part in a short interview after the programme to discuss what you think about the programme, if anything should be changed, and any other thoughts.

Why have I been invited to take part?

You are being asked to participate because you:

- Are a woman who has experienced breast cancer and treatment
- Were employed at the time of your breast cancer diagnosis
- Have either returned to work in the last 12 months and feel you are struggling.

Or

- Are hoping to return to work within the next six months.

You also need to be willing and able to: (i) complete two questionnaires, (ii) attend an online programme which will run for 90 minutes once a week, for six weeks, and (iii) complete a

once-off interview lasting up to 30 minutes (this can take place online). All participants will require an internet connection and a device that supports Zoom.

Do I have to take part? Can I withdraw?

It is completely up to you if you would like to take part or not. If you decide not to take part, it won't affect your current or future care at Cuisle. You can change your mind about taking part in the study and opt out at any time even if the study has started. If you decide to opt out, it won't affect your current or future care at Cuisle. You don't have to give a reason for not taking part or for opting out. You will be able to opt out up until the time that the information we collect is published. This information will be anonymous. You can read more about this in Part 2 of this document. If you wish to opt out, please contact Naomi Algeo (PhD Researcher and Occupational Therapist – nalgeo@tcd.ie or 083-053-0777) who will be able to facilitate this for you.

What happens if I change my mind?

If you change your mind about participating, you will not be penalised in any way. If you wish to opt out at any stage, please contact Naomi Algeo (PhD Researcher and Occupational Therapist – nalgeo@tcd.ie or 083-053-0777) who will be able to organise this for you.

How will the study be carried out?

We are looking for up to eight women to participate in a six-week online support programme focusing on returning to or staying at work after breast cancer. The programme will take place using the online platform Zoom between February and March, 2021. Before the programme takes place, we will ask you to complete two questionnaires to then email back to us.

Then, we will invite you to participate in a six-week online programme. This will take place once a week for six weeks every Thursday between 10.00-11.30am. The first five sessions will be group based. The final session will be an individual session with an occupational therapist who will work with you to tailor an individualised work plan. One week after the programme is finished, we will contact you for a short interview (approx. 30 minutes) to discuss your thoughts on the programme e.g. what went well, what didn't, what would you change?

What will happen to me if I decide to take part?

If you decide to take part, you can contact the researcher (Ms. Naomi Algeo) by phone or email. Ms. Algeo will then send you copies of the participant letter and consent form by email or post (whichever you prefer). Ms. Algeo will then check at least seven days later to see if you are happy to proceed in participating in this programme which will take place online via Zoom between February and March 2021. If you remain happy to proceed, you will be asked to complete a consent form and send it to Ms. Algeo via email.

Before the programme: Up to one week before the programme, Ms. Algeo will contact you

to complete two questionnaires to email back to her. One questionnaire will ask you about your quality of life and one will ask you about your work situation (for example, how many hours you were working). You will at all times be invited to pose any questions that you might have. If you haven't used Zoom before, Ms. Algeo is happy to help you set it up.

During the programme: Each session will take place via Zoom on Thursday at 10.00-11.30am. As it is online, you may access it wherever you like, but we do encourage that it is in a place where there is a relatively strong internet connection and that is not too noisy. The first five sessions will be group-based. This means that there will be up to seven others joining the group to learn more about the days' topic. You do not have to discuss anything that you do not want to. Each session will have a Powerpoint presentation on an assigned topic. There will always be a comfort break, and then there will be discussion and goal-setting at the end of the session. The goals set will be personal to each individual and based on the topic of the day. While everyone will be encouraged to share their goal, they do not have to. The final session of the programme (Week 6) will be a one-to-one session with Ms. Algeo who is a registered Occupational Therapist (CORU: OT025366). Together, you and Ms Algeo will develop an individual return to work or work maintenance plan tailored to your needs.

Date	Topic	Format
Week 1 (25th February 2021)	Welcome: Introduction to the Programme	Group
Week 2 (4th March 2021)	Legislation, Rights, and Entitlements	Group
Week 3 (11th March 2021)	Psychological and Physical Considerations in the context of Work	Group
Week 4 (18th March 2021)	Fatigue Management and Cognition in the context of Work	Group
Week 5 (25th March 2021)	Communicating with my Employer, Colleagues and Family.	Group
Week 6 (Week commencing 29th March – at time convenient to you)	Individual session with Occupational Therapist: Developing a RTW Plan and Personal Roadmap	Individual
~1-2 weeks after Week 6 - at time convenient to you	Brief 1:1 interview on experiences of the programme (up to 30 minutes max)	Individual

After the programme: You will be invited to take part in a telephone or online interview (approx. 30 minutes) to discuss your thoughts on the programme. This interview will be recorded. However, only audio will be recorded – no video footage. This will be an opportunity for you to share what you thought went well or not so well during the programme.

What will happen to my Data?

We will collect the following personal data for the purposes of communicating with you:

- Your name
- Your contact details – preferred phone number and email address. In addition to this, we will *only* collect your home address if you wish for documents, such as the participant information leaflet, to be posted to you.

No other personal data will be collected. We will not access your medical records, however for the purposes of recruitment, you will have been approached by Ms. Mary Ruddy (Support Manager, Cuisle Cancer Support Centre) to participate in this research. Your records at Cuisle will **not** be accessed for any other reasons in this study, beyond those of recruitment. Your name and contact details will be held on file in a locked cabinet for only as long as required, i.e. up until we send your interview transcript to you for checking and await feedback within the given timeframe.

Are there any benefits to taking part in this research?

This will be the first time to run the work-focused support programme. As it has not been evaluated before, we cannot say for sure if it will be helpful or not for women who want to return to or stay at work. Despite this, your participation will provide a valuable contribution to the development of a work-focused intervention for women with breast cancer in Ireland.

Are there any risks to me or others if I take part?

There is a possibility that you may experience mild discomfort during the programme or during the one-to-one interview. Talking about your diagnosis, treatment, and life following this, can be a sensitive subject to talk about. If you do become upset, you are reminded that you can stop the interview at any time. All participants are reminded that they can access support services such as the Irish Cancer Society and Cuisle Cancer Support Centre should they wish to seek any support services. The study will be undertaken by a researcher (Ms. Algeo) who has undertaken similar research with women with breast cancer and is therefore experienced and highly sensitive to the wellbeing of the participants involved. The research team members are experienced in conducting research of sensitive nature and will use the skills acquired and apply them to this study

Will I be told the outcome of the study?

The results of the study will be reported in scientific journals and disclosed at scientific conferences. No information which reveals your identity will be disclosed. If you would like to learn about updates to the research, you can check online for details on the Twitter page <https://twitter.com/WorkCancerIRL> . You do not need to have a Twitter account to access this.

Part 2 – Data Protection

What information about me (personal data) will be used as part of this study?

We will collect the following personal data for the purposes of communicating with you:

- Your name
- Your contact details – preferred phone number and email address. In addition to this, we will *only* collect your home address if you wish for documents, such as the participant information pack, to be posted to you.

No other personal data will be collected.

What will happen to my personal data?

- Your data will be used as part of the research, '*An online work-focused intervention to support women with breast cancer to return or stay in the workplace: A single-arm feasibility study and qualitative-descriptive design*' and will only be processed as necessary to achieve the objective of the health research. It will not be processed in a way that damage or distress will be caused to you.
- Your data is being processed for the purpose of legitimate interest (Article 6;1(f), General Data Protection Regulation, 2016) and for the purpose of scientific research purposes (Article 9;2(j), General Data Protection Regulation, 2016).
- Consent forms with your name will be stored on a password-protected computer at Trinity Centre for Health Sciences, however your contact details will be destroyed when no longer required, i.e. up until the end of the period for checking interview transcripts is complete.
- Measures will be taken to reduce risk when processing the data, however, should a data breach occur, this may cause you harm. This harm will be significantly reduced as your data will not have any identifiable information on it. Instead of your name, a code number will be used. This is called **pseudonymisation**. **In summary, pseudonymisation means that identifiable information is removed from a data record and replaced with another identifier, i.e. a pseudonym. For example, instead of using a name, data could be labelled 'Participant 1'. While this doesn't remove all identifying detail, it reduces the ability to link data to the identity of a person.**
- If necessary, you have the right to lodge a complaint with the Data Protection Commissioner. Their contact details can be found at the top of this document.
- Until data is analysed by the researcher, you have the right to the following;
 - request access to your data and a copy of it
 - to have any inaccurate information about you corrected or deleted
 - to have personal data deleted

Part 3 – Costs, Funding and Approval

- It would be impossible to conduct this research without processing of your data, therefore data processing is necessary. Data processing is any operation which is performed on personal data, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction (Act 4(2), General Data Protection Regulation, 2016).
- Your data will be used for this research only and will not be used for any other future research without your explicit consent. All data will be destroyed as soon as interview transcripts have been checked by participants within the timeframe provided.

Who will access and use my personal data as part of this study?

Only Naomi Algeo (Co-Investigator) and Dr. Deirdre Connolly (Principal Investigator) will have access to your data. Access to your data will be made only to communicate with you.

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 will do this:

- Your personal data will be kept in soft copy format on a password-protected computer at Trinity Centre for Health Sciences. Contact details will be destroyed as soon as no longer required. This will be after transcripts have been sent to you for feedback
- A Data Protection Impact Assessment has been reviewed by the Data Protection Officer, TCD.
- Training in data protection law and practice has been provided to the research team. Naomi Algeo and Dr. Deirdre Connolly have both undertaken the GDPR and Health Research Regulations Workshops in Trinity College Dublin in preparation for the project. Naomi Algeo has also completed the online TCD GDPR training.
- Your questionnaire data and transcripts from your interview will be pseudonymized, this means they will be tagged with a specific Study ID to your name and your personal details will not be recorded on the files. This makes it harder to trace back data to you.
- Naomi Algeo and Dr. Deirdre Connolly are bound by a contractual code of secrecy which protects your confidentiality.
- If something did go wrong and your data was compromised, we would contact you and the Data Protection Officer at Trinity College Dublin.

What is the lawful basis to use my personal data?

By law,⁴ we can use your personal information for scientific research⁵ (in the public interest⁶). 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 (except where it is de-identified)
- 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 Ms. Naomi Algeo (Email: nalgeo@tcd.ie) 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.

Has this study been approved by a research ethics committee?

Yes. This study was approved by the Faculty of Health Science Research Ethics Committee, TCD in December 2020.

Who is organising and funding this study?

While this study is not in receipt of any funding, Ms. Naomi Algeo is funded by the Irish Research Council and Trinity College Dublin to undertake her doctoral studies and is conducting this research for the purposes of obtaining a doctoral qualification.

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. Participation is voluntary.

⁴ The European General Data Protection Regulation (GDPR)

⁵ Article 9(2) (j))

⁶ (Article 6(1)(e))

Part 4 – Future Research

Will my personal data be used in future studies?

No. Your personal data will not be used for any future studies., however you will have the opportunity to check for research updates online at the following link:
<https://twitter.com/WorkCancerIRL>

Part 5 – Further Information

Who should I contact for information or complaints?

If you have any concerns or questions, you can contact:

- Co-Investigator: Ms. Naomi Algeo (nalgeo@tcd.ie or 083-053-0777)
- Principal Investigator: Dr. Deirdre Connolly (CONNOLDM@tcd.ie)
- 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.

APPENDIX V: CONSENT FORM (PHASE IV)

Consent Form

STUDY NAME: *An online work-focused intervention to support women with breast cancer in Ireland: A single-arm feasibility study and qualitative-descriptive design.*

- There are 3 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. - Thank you for participating. Please <u>Initial</u> the box if you agree with the statement. Please feel free to ask questions if there is something you do not understand.	
General	Initial
I confirm I have read and understood the Participant 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 any future care or medical services.	
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.	
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. I understand that there are no direct benefits to me from participating in this study.	
Data processing	Initial
I understand that personal information about me will be protected in accordance with the General Data Protection Regulation.	
I understand that I will have the opportunity to review my data (in the questionnaires and transcript) and will can amend or withdraw it up until the point that it has been analysed, at which point it will become anonymous.	
I understand that I can stop taking part in this study at any time without giving a reason.	
I understand that my data will not be used in future studies	
I understand that the Questionnaires and Transcripts (which are marked by my Study ID number <i>not</i> my name) will be destroyed once publication is complete. This is estimated to be January 2022.	
I understand that my consent form will be deleted as soon as I have had the opportunity to provide feedback on my transcript.	
I understand that my contact details will only be kept up until period for checking interview transcripts is complete.	

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

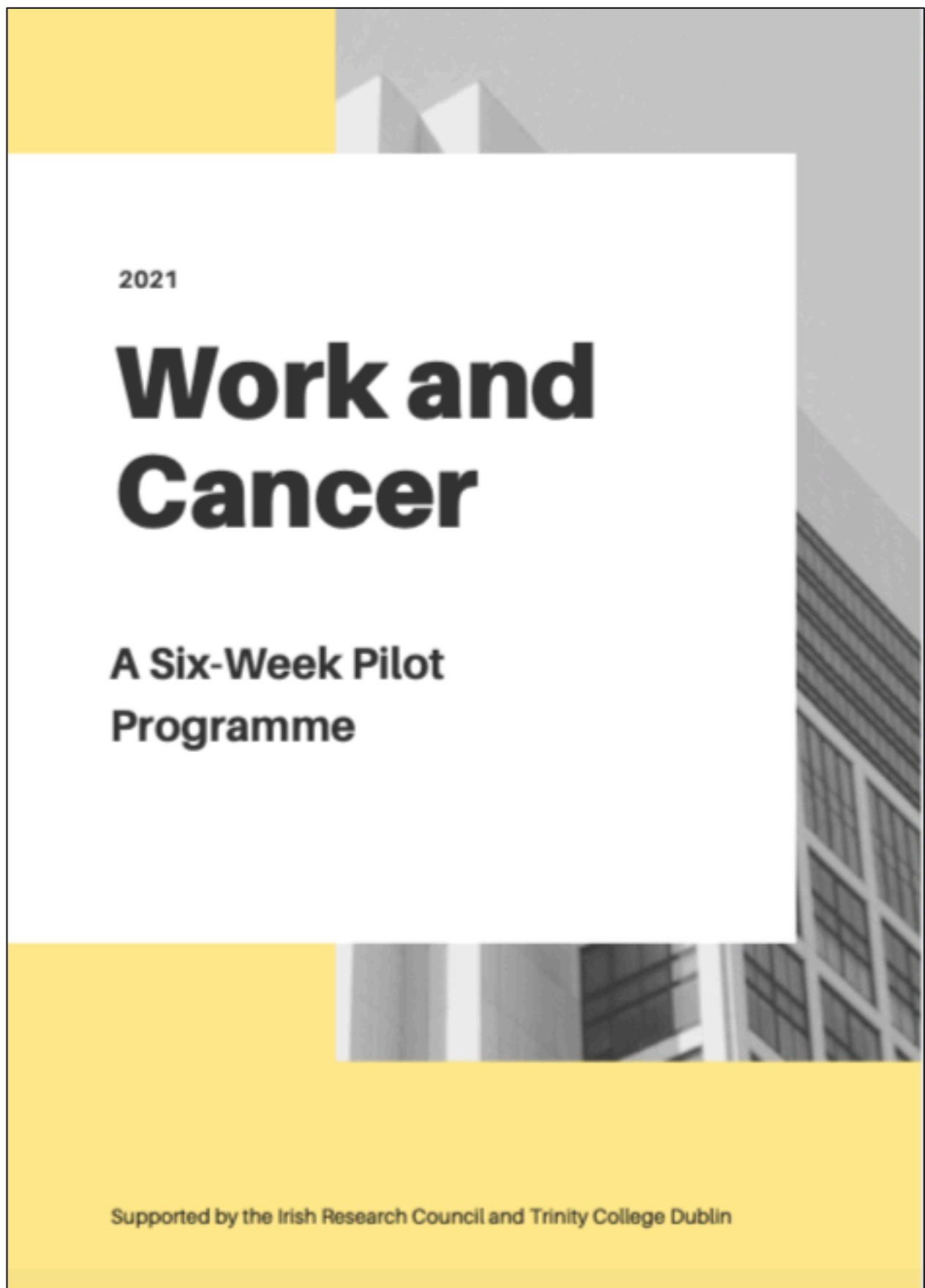
Researcher name: Naomi Algeo

Title and qualifications: B.Sc. Occupational Therapy; M.Res. Clinical Research

Signature:

Date: _____

2 copies to be made: 1 for participant, 1 for PI



Week 3: Managing Cancer-Related Fatigue and Cognitive Changes in the Workplace



This session will cover:

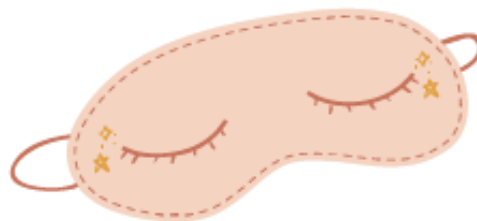
- What is Cancer-Related Fatigue?
- How to Manage Cancer-Related Fatigue in the Workplace
- What is Cognition?
- How to Manage Cognitive changes in the Workplace

What is cancer-related fatigue?

Cancer-related fatigue is a very common symptom experienced during and after cancer. It is different from general fatigue in that it doesn't improve with rest or sleep. It can be caused by treatment, the cancer itself, a lack of iron, some medications or supplements, inactivity, poor diet or changes in sleep. While it typically improves over time, in some small instances it can become chronic (lasting months or years). There are ways in which cancer-related fatigue can be managed however.

During treatment, a pattern of fatigue can be predicted. For example, during **chemotherapy**, people generally experience high levels of fatigue a day or two after their chemotherapy cycle. The fatigue then eases until the next time there is a chemotherapy cycle. With **radiation therapy**, on the other hand, the fatigue typically builds as the radiation therapy goes on. The same predictability can't be said for after treatment. It's unclear why some people continue to experience fatigue, and others don't. It typically will get better over time though.

You will be guided throughout this session on what fatigue is, principles of **energy management**, and how you can apply these principles in the workplace. Remember, some strategies will work for some and not for others. It can be very individual. Have a go at trialling some strategies and seeing what works best for you. You may need to try some strategies a few times before you see any benefit.



What are the principles of energy management?

Often, occupational therapists guide those living with or beyond cancer in energy management principles. These can be known as the **4 Ps**. So, what are they?

Pacing: This means still carrying out activities, but ensuring that you 'pace' yourself, taking short rest periods between activities, and not pushing yourself to a level of exhaustion. Sometimes it can be easy to try to 'fight' the fatigue and push through. Instead, when you pace yourself, you are monitoring your energy levels and taking a break before you become too tired.

Planning: This involves looking into your upcoming days and weeks, and spreading out tasks to make it manageable. For example, if you have a big work event on one day, planning ahead to ensure you have very little on the next day. Try using the Activity Diaries on the following pages to try to identify what a typical day looks like. Taking a step back and looking at it might give you an extra insight in how to plan your day and week.



Prioritising: This involves looking at what activities you need to do, asking yourself what is most important, and prioritising these. Sometimes this might mean delegating a job that is less important to you to someone else.

Posture/Position: Excess bending, reaching, and lifting can contribute to fatigue. Poor posture in sitting and standing can actually impact energy levels negatively. Being mindful of posture and the position of items within good reach, can save energy.

Activity Diaries

EXERCISE: Record your activities throughout one day and rate them with regards to energy expenditure. Remember, a task could be either physically, mentally and/or cognitively demanding. Rate the energy expenditure overall for the activity.

Day: _____

Activity	High	Medium	Low
<i>Example: Prepared breakfast for me and the kids</i>		X	

Applying the 4 Ps to work: some strategies

Planning

- Planning your work day? Switch between physical and cognitive tasks. For example, a nurse might write some notes or a report (cognitive task) and then help a patient out of bed (physical task)
- Plan your most difficult task when you know you'll have most energy.
- Know that you'll have a particularly busy day at work one day? Plan to do very little the next day.
- Planning and Pacing often go hand-in-hand. Use weekly calendars to timetable your working day while also ensuring you pace your activities.
- Research shows that most people will take time off during treatment. For the few who are able to stay on at work, it is possible to predict fatigue to a degree which means work days can be planned. For example, if you are undergoing chemotherapy, it is likely that fatigue will be highest the day or two after your chemotherapy cycle. You might find that you could plan not to work then and instead the days after.

Planning your graded return to work: The way you plan the sequence of your part-time days might be important to consider. Imagine a work day is an energy-draining 'RED' day. If you plan to work these 'RED' days all in a row, you might feel too exhausted to do anything else on your days off.



Instead, could you plan your work days to have a day off in between? Everyone is different so do what feels right for you.



Week 3: SMART Goal Setting



EXERCISE: Choose a SMART goal for this week. It should be related to this week's session.

This week I will:

Don't forget

To specify:

(i) **how much** you want to do

(ii) **when** you will do it and (iii) **how many** days a week you will do it.

The steps required to achieve this goal are:

- 1.
- 2.
- 3.
- 4.
- 5.

What will help me achieve this goal:



What might stop me from achieving this goal:



APPENDIX X: LOCALLY DEVELOPED EMPLOYMENT QUESTIONNAIRE

BACKGROUND

Age: _____

Highest level of education:

Some Primary School ☐
Primary School or Equivalent ☐
Junior/Intermediate Certificate/GCSE or equivalent: ☐
Leaving Certificate/A-Level or equivalent: ☐
Diploma/Certificate: ☐
Technical/Trade Training ☐
Undergraduate Degree: ☐
Postgraduate Degree: ☐
Other: (Please specify): _____ ☐

Relationship Status:

Single ☐
Co-habiting ☐
Married/in a Civil Partnership ☐
Separated/Divorced ☐
Widowed ☐

Job Title: _____

What sector do you work in?

Public ☐ Private ☐ Semi-State ☐ Self-Employed ☐ Other ☐ *please specify* _____

BEFORE YOUR DIAGNOSIS

Before your diagnosis, how many hours were you working/week? _____

WORKING STATUS AT PRESENT

Have you returned to work? Yes ☐ No ☐

If you have not yet returned to work:

How long have you been on sick leave (approximately): __year(s) __month(s) __week(s)

Approximately, when do you plan to return? _____Month _____Year

Do you feel fully ready to return? Yes ☐ No ☐ Partially ☐

If you have returned to work:

If yes, how many hours are you working/week at present? _____

How long had you been on sick leave (approx): __year(s) __month(s) __week(s) N/A ☐

APPENDIX Y: WORK ROLE FUNCTIONING QUESTIONNAIRE (WRFQ)

Work Role Functioning Questionnaire		Difficult all the time	Difficult most of the time	Difficult half of the time	Difficult some of the time	Difficult none of the time	Does not apply to my job
WORK SCHEDULING DEMANDS							
1	Work the required number of hours						
2	Get going easily at the beginning of the workday						
3	Start on your job as soon as you arrived at work						
4	Do your work without stopping to take extra breaks or rests						
5	Stick to a routine or schedule						
OUTPUT DEMANDS							
6	Handle the workload						
7	Work fast enough						
8	Finish work on time						
9	Do your work without making mistakes						
10	Satisfy the people who judge your work						
11	Feel a sense of accomplishment in your work						
12	Feel you have done what you are capable of doing‡						
PHYSICAL DEMANDS							
13	Walk or move around different work locations (for example, go to meetings)						
14	Lift, carry, or move objects at work weighing more than 10 pounds‡						
15	Sit, stand, or stay in one position for longer than 15 minutes while working						
16	Repeat the same motions over and over again while working						
17	Bend, twist, or reach while working						
18	Use hand-held tools or equipment (for example, a phone, pen, keyboard, computer mouse, drill, hairdryer or sander)						
MENTAL DEMANDS							
19	Keep your mind on your work						
20	Think clearly when working						
21	Do work carefully						
22	Concentrate on your work						
23	Work without losing your train of thought						
24	Easily read or use your eyes when working						
SOCIAL DEMANDS							
25	Speak with people in-person, in meetings or on the phone						
26	Control your temper around people when working						
27	Help other people to get work done						

APPENDIX Z: EUROPEAN ORGANISATION FOR RESEARCH AND TREATMENT OF CANCER QUALITY OF LIFE QUESTIONNAIRE (EORTC-QLQ-C30)

ENGLISH



EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:

Your birthdate (Day, Month, Year):

Today's date (Day, Month, Year):

31									

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a <u>long</u> walk?	1	2	3	4
3. Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:

	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:	Not at All	A Little	Quite a Bit	Very Much
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1 2 3 4 5 6 7

Very poor

Excellent

30. How would you rate your overall quality of life during the past week?

1 2 3 4 5 6 7

Very poor

Excellent

APPENDIX AA: BREAST CANCER SUBSCALE 23 (BR23)

ENGLISH



EORTC QLQ - BR23

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week.

During the past week:	Not at All	A Little	Quite a Bit	Very Much
31. Did you have a dry mouth?	1	2	3	4
32. Did food and drink taste different than usual?	1	2	3	4
33. Were your eyes painful, irritated or watery?	1	2	3	4
34. Have you lost any hair?	1	2	3	4
35. Answer this question only if you had any hair loss: Were you upset by the loss of your hair?	1	2	3	4
36. Did you feel ill or unwell?	1	2	3	4
37. Did you have hot flushes?	1	2	3	4
38. Did you have headaches?	1	2	3	4
39. Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
40. Have you been feeling less feminine as a result of your disease or treatment?	1	2	3	4
41. Did you find it difficult to look at yourself naked?	1	2	3	4
42. Have you been dissatisfied with your body?	1	2	3	4
43. Were you worried about your health in the future?	1	2	3	4
During the past <u>four</u> weeks:	Not at All	A Little	Quite a Bit	Very Much
44. To what extent were you interested in sex?	1	2	3	4
45. To what extent were you sexually active? (with or without intercourse)	1	2	3	4
46. Answer this question only if you have been sexually active: To what extent was sex enjoyable for you?	1	2	3	4

Please go on to the next page

During the past week:		Not at All	A Little	Quite a Bit	Very Much
47.	Did you have any pain in your arm or shoulder?	1	2	3	4
48.	Did you have a swollen arm or hand?	1	2	3	4
49.	Was it difficult to raise your arm or to move it sideways?	1	2	3	4
50.	Have you had any pain in the area of your affected breast?	1	2	3	4
51.	Was the area of your affected breast swollen?	1	2	3	4
52.	Was the area of your affected breast oversensitive?	1	2	3	4
53.	Have you had skin problems on or in the area of your affected breast (e.g., itchy, dry, flaky)?	1	2	3	4

APPENDIX BB: INTERVIEW GUIDE (PHASE IV)



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

INTERVIEW GUIDE

General

What were your overall thoughts of the programme?

Prompt: What did you like/dislike? What would you change about the programme? What motivated you to participate and stay on in the programme?

Acceptability of the Intervention

Format:

- This was an online programme. What are your thoughts on this type of format? Would you have preferred face-to-face? Why? Why not?

Hosting: This programme had a blended format in that it was both group-based with an individual component. What did you think about this format?

Timing:

- You have [not yet returned to work/returned to work]. When do you think would be the best time to offer this type of programme?
- *If applicable:* There were some participants who had already returned to work. Did you find the mix useful or should the programme be more focused to those who have yet to return?
- Sessions were 90 minutes online. Was this too long, too short or just right? Why?
- The programme was 6 weeks in length. Was this too long, too short or just right? Why?

Setting:

- This programme was hosted online using Zoom. What do you think of this platform? Would you have preferred to use a different online platform? Why? Why not?
- If this programme was to be hosted face-to-face, where would it be best set?

Content:

- Was there any content that you felt was missing? What was it?
- Was there any content that you felt was irrelevant? What was it?
- What content of the programme did you think was most important?
- What did you think about the order in which the modules were presented?

- What were your thoughts on the letter to the employer?
- What were your thoughts on the return-to-work/work maintenance plan report?

MDT Facilitators: This programme was OT-led with multidisciplinary team input from a community welfare officer and physiotherapist. What did you think of this format?

Theory: What were your thoughts on the goal-setting aspect? Did you find having others in the group motivating or unmotivating for you? Why? Why not?

Acceptability of Outcome Measures

**Show questionnaires up on screen to prompt participant*

Thinking about the EORTC QOL questionnaire, did you think this was: (i) easy or difficult to understand? (ii) covered most/all aspects of quality of life?

Thinking about the Employment questionnaire, did you think this was: (i) easy or difficult to understand? (ii) covered most/all aspects of your working status?

Any other comments about the questionnaires?

Facilitators and Barriers to completing the Intervention

Facilitators: What helped you to be able to complete the programme?

Barriers: Was there anything that made it difficult for you to complete the programme?

Reflection

- Has your approach to your return to work changed at all since starting the programme? If so, how?
- Moving forward, what are your thoughts about this programme being potentially rolled out further in the future?
- Any final thoughts about the programme, or anything that you wanted to mention but haven't had the opportunity yet?

APPENDIX CC: LETTER OF ETHICAL APPROVAL (PHASE IV)



Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Ms. Naomi Algeo
Discipline of Occupational Therapy,
Trinity Centre for Health Sciences,
St. James Hospital,
James St.,
Dublin 8

4th December 2020

Ref: 20201003

Title of Study: An online work-focused intervention to support women with breast cancer in Ireland: A single-arm feasibility study and qualitative process evaluation.

Dear Naomi,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in November 2020. We are pleased to inform you that the above project has ethical approval to proceed.

This study has been ethically approved. We would advise you to seek review and comments on your DPIA from the DPO if required prior to study commencement'

As a researcher you must ensure that you comply with other relevant regulations, including DATA PROTECTION and HEALTH AND SAFETY.

Yours sincerely,

A handwritten signature in dark ink, reading 'Jacintha O'Sullivan'.

Prof. Jacintha O'Sullivan
Chairperson
Faculty Research Ethics Committee

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