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Identifying and addressing uncertainties regarding the tapering of psychiatric medications

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Declaration

I declare that this thesis has not been submitted as an exercise for a degree at this or any other university and it is entirely my own work.

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Summary

Background: There is a cohort of individuals looking to discontinue use of psychiatric medication. Tapering is the recommended approach for reducing and/or stopping the use of psychiatric medication. This involves gradually reducing the dose of the medication over time to minimise the potential for withdrawal symptoms. However, many uncertainties exist regarding the process of reducing and stopping psychiatric medication. The main aim of this thesis was to contribute to the evidence base by developing a body of knowledge that would advance the evidence-base relating to the safe and appropriate tapering of psychiatric medication.

Methods: This thesis comprises four key studies comprising: a Priority Setting Partnership (PSP) Study to identify the Top 10 priorities for future research on reducing and stopping psychiatric medication in collaboration with three key stakeholder groups (i.e., people with lived experience of taking and/or stopping psychiatric medication, family members/friends/carers/supporters, and healthcare professionals) (Study 1); a qualitative descriptive analysis of free-text responses submitted to one of the PSP surveys to explore stakeholders' views and experiences of reducing and stopping psychiatric medication (Study 2); a qualitative descriptive study involving interviews with stakeholders who had participated in Study 1 to explore their views on the PSP methodology as a priority setting exercise (Study 3); and a scoping review to examine the content, underpinning evidence base, and impact of mobile phone apps and app-based interventions that focused on supporting the tapering of psychiatric medication (Study 4). This final study sought to address one of the priorities identified in Study 1 that focused on tapering supports.

Results: Study 1 co-produced the Top 10 list of research priorities on reducing and stopping psychiatric medication. The most highly ranked questions focused on the optimal tapering methods and supports and educating healthcare professionals about reducing/stopping psychiatric medication. Study 2 reported on stakeholders' views and experiences of various points of the withdrawal process, including their motivations for wanting to reduce/stop psychiatric medication, the challenges, and adverse effects they faced upon and after stopping the medication. Data were grouped into eight major

themes. Study 3 captured stakeholders' thoughts on multi-stakeholder involvement, how the PSP study achieved authentic collaboration between the three stakeholder groups, and challenges to their participation. Four major themes were identified across the interview data. Study 4 identified a limited number of commercially available apps targeting individuals looking to taper psychiatric medication, as well as a deficit of studies evaluating any such apps in the literature.

Conclusion: The main contribution of this thesis to the existing literature was through the development of a list of research questions and uncertainties about reducing and stopping psychiatric medication that will help guide future research and deliver responsive and strategic allocation of research resources. Other contributions include the insights into stakeholders' experience of stopping psychiatric medication captured by Study 2 which will encourage reflection on the role of these medications in mental illness, and the findings from the qualitative interviews with key stakeholders in Study 3 which will inform the methodology of future PSP studies. Finally, the findings from the scoping review in Study 4 which will guide the development of apps to support the tapering of psychiatric medication.

List of Abbreviations

AH	Agnes Higgins
BCT	Behaviour Change Technique
BCTTv1	Behaviour Change Technique Taxonomy version 1
BZD	Benzodiazepine
BZRA	Benzodiazepine receptor agonist
CBT	Cognitive behavioural therapy
CC	Cathal Cadogan
COREQ	Consolidated criteria for reporting qualitative research
DSM	Diagnostic and Statistical Manual of Mental Disorders
GP	General Practitioner
GS	Greg Sheaf
HRB	Health Research Board
JBI	Joanna Briggs Institute
JLA	James Lind Alliance
MAOI	Monoamine Oxidase Inhibitors
MB	Miriam Boland
NGT	Nominal Group Technique
NICE	National Institute for Health and Care Excellence
PICO(S)	Population-Intervention-Comparison-Outcome-(Studies)
PIL	Participant Information Leaflet
PPI	Patient and Public Involvement

PRISMA-ScR	Preferred Reporting Items for Systematic Reviews extension for Scoping Reviews
PSP	Priority Setting Partnership
REPRISE	REporting guideline for PRIority SEtting of health research
SNRI	Serotonin and Norepinephrine Reuptake Inhibitor
SSRI	Selective Serotonin Reuptake Inhibitors
SWiM	Synthesis Without Meta-analysis
TAG	Toto Anne Gronlund
TCA	Tricyclic Antidepressant
TCD	Trinity College Dublin
UK	United Kingdom
WHO	World Health Organization

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Publications & Presentations

Peer-reviewed publications from this thesis

Boland M, Higgins A, Beecher C, Bracken P, Burn W, Cody A, Framer A, Gronlund T, Horowitz M, Huff C, Jayacodi S, Keating D, Kessler D, Konradsson-Geuken A, Lamberson N, Montagu L, Smith R, Cadogan C. Identifying priorities for future research on reducing and stopping psychiatric medication: results of a James Lind Alliance priority-setting partnership. BMJ Open. 2024;14:e088266. DOI: 10.1136/bmjopen-2024-088266

Boland M, Higgins A, Beecher C, Bracken P, Burn W, Cody A, Framer A, Gronlund T, Horowitz M, Huff C, Jayacodi S, Keating D, Kessler D, Konradsson-Geuken A, Lamberson N, Montagu L, Osborne B, Smith R, Cadogan C. Priorities for future research on reducing and stopping psychiatric medicines using a James Lind Alliance priority setting partnership: The PROTECT study protocol. HRB Open Research. 2022; 5:72 DOI: 10.12688/hrbopenres.13649.1

Boland M, Higgins A, Doherty G, Sheaf G, Framer A, Cadogan C. Mobile phone applications to support psychotropic tapering: a scoping review protocol. HRB Open Research. 2022; 5:18. DOI: 10.12688/hrbopenres.13501.2.

Other peer-reviewed publications

Boland M. Book review of Antidepressed: A breakthrough examination of epidemic antidepressant harm and dependence by Beverley Thomson (2022). Research in Social and Administrative Pharmacy. 2022; 18(8): 3467-68DOI: 10.1016/j.sapharm.2022.03.001.

Cadogan CA, Murphy M, Boland M, Bennett K, McLean S, Hughes C. Prescribing practices, patterns, and potential harms in patients receiving palliative care: A systematic scoping review. Exploratory Research in Clinical & Social Pharmacy. 2021;23;3:100050. DOI: 10.1016/j.rcsop.2021.100050

Presentations

Oral presentation at the 42nd All Ireland Schools of Pharmacy Conference, Queen's University Belfast, Ireland, 30th to 31st August 2023

Boland M, Higgins A, Beecher C, Bracken P, Burn W, Cody A, Framer A, Gronlund T, Horowitz M, Huff C, Jayacodi S, Keating D, Kessler D, Konradsson-Geuken A, Lamberson N, Montagu L, Osborne B, Smith R, Cadogan C. The co-creation of research priorities on tapering psychiatric medicines.

Oral presentation at the 52nd European Society of Clinical Pharmacy Symposium on Clinical Pharmacy, Krakow, Poland, 21st to 23rd October 2024

Boland M, Higgins A, Beecher C, Bracken P, Burn W, Cody A, Framer A, Gronlund T, Horowitz M, Huff C, Jayacodi S, Keating D, Kessler D, Konradsson-Geuken A, Lamberson N, Montagu L, Smith R, Cadogan C. Identifying priorities for future research through inclusion of patients, carers, and healthcare professionals.

Workshop session at the 52nd European Society of Clinical Pharmacy Symposium on Clinical Pharmacy, Krakow, Poland, 21st to 23rd October 2024

Boland M, Higgins A, Cadogan C. Identifying research priorities on tapering psychiatric medication using a priority setting partnership.

Submitted Abstracts for upcoming conferences

Boland M, Higgins A, Cadogan C. Identifying research priorities on tapering psychiatric medication using a priority setting partnership.

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Provisional titles for future publications

- An analysis of individuals' experiences of taking and discontinuing psychiatric medication. Target journal: Health Expectations
- Exploring stakeholders' views on the Priority Setting Partnership methodology as a priority-setting exercise in mental health research. Target journal: Journal of Mental Health
- Mobile phone applications to support tapering of psychiatric medication: a scoping review. Target journal: British Journal of Clinical Pharmacology

- Lessons and insights learnt from conducting a Priority Setting Partnership study on reducing and stopping psychiatric medication. Target journal: BMC Medical Research Methodology

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Dedication

I would like to dedicate my PhD to Christy Huff, MD. Christy was one of the Steering Group members in Study 1. Christy was a cardiologist by training, but it was her lived experience of taking and stopping benzodiazepines that led to her involvement in Study 1. Christy was also the Director of the Benzodiazepine Information Coalition, a not-for-profit organisation dedicated to raising awareness about safe and appropriate benzodiazepine use. Christy sadly died in 2024. She is deeply missed.

Chapter 1: An Introduction to the Thesis

1.1 Background to the Thesis

The total global consumption of psychiatric medication (e.g., antidepressants, antipsychotics, and benzodiazepine receptor agonists) has increased by 4% annually over an 11-year period spanning 2008–2019 (1). Psychiatric medications are central to all treatment guidelines for mental illness (2). Over time, the prescribing and discontinuation of psychiatric medication has become a contested space, where polarised discourse is common. For example, the safety and efficacy of psychiatric medication is increasingly being debated, particularly in terms of the extent of any clinically significant improvements in symptoms when compared to placebo, the potential for adverse effects and withdrawal symptoms, and the duration of treatment (3, 4). These conflicting views and opinions around the use and discontinuation of psychiatric medication make it difficult for both healthcare professionals and people with lived experience to interpret and determine which information is most accurate and evidence based.

There is a cohort of individuals looking to reduce and/or discontinue the long-term use of psychiatric medication. There are many reported motivations for discontinuing psychiatric medication, such as adverse effects and inability of medication to manage the individuals' symptoms (5). Tapering is the approach that is typically employed by individuals attempting to discontinue psychiatric medication. Tapering involves a gradual dose reduction of the medication over a prolonged period (6). To date, there is no standard approach on how best to taper which thereby creates many uncertainties regarding the process of reducing and stopping psychiatric medication (7).

Rather than identifying and addressing a specific research question about a single aspect of tapering, this thesis took a broader approach. The main aim of this thesis is to develop a body of knowledge that will advance the evidence-base relating to the safe and appropriate tapering of psychiatric medication. The aim and objectives of this thesis are outlined in Section 1.3.

1.2 Personal Journey to the Research Topic

As a qualified pharmacist who has worked in community pharmacy for several years, three of my core responsibilities involve dispensing medication, educating individuals on their appropriate use, and answering medication-related queries. Psychiatric medications are one group of medications that I frequently encounter in community pharmacy in terms of dispensing and answering queries concerning their use and discontinuation. The lack of clear and evidence-based guidelines makes it very difficult to provide concrete answers to these queries. Prescribers are faced with the same challenges. I also have witnessed several individuals taking matters into their own hands and stopping their psychiatric medication without professional support. While some of these individuals managed to stop the medication without too many ill-effects, others experienced severe withdrawal symptoms (e.g., tremor and insomnia) that necessitated the medication to be restarted.

My desire to contribute to the evidence base in a way that would meaningfully support individuals who are discontinuing their psychiatric medication paired with my desire for learning is what motivated me to undertake a PhD on this topic. My background as a community pharmacist brought a clinical, real-world perspective to my PhD. While recognising the challenge and potential for my personal bias to influence the work, I endeavoured to enter the PhD from a neutral stance in relation to the prescribing and use of psychiatric medications.

1.3 Aims and Objectives of the Thesis

The aim of this thesis was to develop a body of knowledge that would advance the evidence-base relating to the safe and appropriate tapering of psychiatric medication.

This thesis had four key objectives. These were to:

1. Determine the Top 10 priorities for future research on reducing and stopping psychiatric medication in collaboration with the three key stakeholder groups: people with lived experience of taking and/or stopping psychiatric medication, family members/friends/carers/supporters, and healthcare professionals (Study 1).

2. Explore stakeholders' views and experiences of reducing and stopping psychiatric medication use by analysing the responses submitted to Section 4 of the Round 1 survey conducted as part of Study 1 (Study 2)
3. Explore stakeholders' views on the PSP methodology as a priority setting exercise by conducting semi-structured interviews with individuals who had participated in Study 1 (Study 3).
4. Based on one of the priorities identified in Study 1 which focused on tapering supports, the final objective was to examine the content, underpinning evidence base, and impact of mobile phone apps and app-based interventions that focused on supporting the tapering of psychiatric medication (Study 4).

1.4 How Mental Health Research has shifted

Traditionally, mental health research was solely conducted by the "experts" i.e., the mainstream researchers and healthcare professionals. This consumerist approach is now regarded by many as a form of "epistemic injustice", one in which individuals diagnosed with mental illness were discredited and wronged in their capacity as knower by having their knowledge and expertise devalued in the knowledge production process (8-10). An individual's psychiatric diagnosis should not dictate their decision-making capacity. This was recognised by Patricia Deegan, an American disability-rights advocate with lived experience of mental illness, psychologist, and researcher who said, *"decision incapacity is the exception rather than the rule, even among people with psychotic conditions"* (11 p.1487).

More recently, there has been a shift in mental health research towards a more participatory and collaborative model. The new model gives greater primacy to the voice of lived experience at all stages of the research process, from idea generation to translation, advocating for a framework which combines experiential knowledge with clinical knowledge to inform treatment, research, and policymaking processes (12, 13). In 2023, a guidance document was jointly published by the World Health Organization (WHO) and the United Nations which foregrounded this collaborative vision whereby individuals with mental illness could fully engage in their own recovery and participate in all areas of mental health, including mental health research (14). This guidance document

recognised the importance of human rights in mental health research. Another form of collaborative research practice that has gained momentum recently in mental health research is Patient and Public Involvement (PPI). PPI also recognises the rights of individuals with lived experience to have an input in research and sees patients and members of the public as active partners in the design, delivery, and dissemination of research (12). PPI is further discussed in Chapter 3.

This thesis aligned with the more contemporary, human rights focused approach to mental health research that values the democratisation of knowledge production and supports the involvement of individuals with lived experience in the research process (15). The justification for choosing each of the research methodologies is outlined in the individual study chapters.

1.5 The Methodological Framework

A research paradigm is a *"framework comprised of a set of beliefs and values which guides how research is conducted and knowledge constructed"* (16 p.39). This thesis is positioned within pragmatism (16), which is one of the most common research paradigms. Other paradigms include positivism/post-positivism, interpretivism, and critical theory. Pragmatism arose in the late 19th and early 20th century from a desire to solve practical real-world problems through inquiry. John Dewey was one of its key founders who acknowledged the need for human experience involvement in the research process. By placing a focus on social justice and joint problem solving, in the context of my thesis, pragmatism makes a strong argument for the involvement of people with lived experience throughout the research process. Patient-oriented research is one of its engagement strategy which incorporates people with lived experience across all stages of the research process with the goal of conducting research that aligns with patient-identified priorities. By acknowledging the value of experiential knowledge, pragmatism is an appropriate philosophical stance to adopt when conducting patient-oriented research (16).

Pragmatism comprises several key principles which include problem solving, democracy and collaboration. In terms of democracy, pragmatism engages multiple stakeholder groups in a way that enables individuals to share their perspectives whilst minimising the power imbalances. It acknowledges and accepts competing interests and provides a sense

of plurality, making it an appropriate paradigm when addressing complex social issues, such as tapering psychiatric medication. Democracy is closely linked to collaboration demonstrated by the shared responsibility of stakeholders for problem solving, flexible negotiation and open dialogue in the pursuit of social justice. Pragmatism is regarded as a tool for action, one in which people with lived experience can come together with researchers to co-construct knowledge (17-19).

The research design is the plan or approach that aligns the research paradigm with the methods to answer the research question (20). This thesis employed a number of research designs to answer the research questions, including the PSP methodology (Study 1), qualitative descriptive studies (Study 2 and Study 3), and the scoping review (Study 4). Surveys and interviews were used to collect data from a range of stakeholders.

1.6 A Note on Terminology in the Thesis

Some terms in the mental health space have been contested by mental health practitioners and individuals with lived experience alike. This section outlines three terms that were agreed by the researcher and supervisory team and utilised throughout this thesis to maintain consistency and minimise ambiguity between the different studies.

Firstly, the term 'mental illness' is utilised in this thesis in favour of 'mental disorder', 'mental health challenge', and 'mental health problem'. Although aligned with the medical model, the term mental illness is still popular as it is considered by many individuals as less stigmatising compared to other terms such as 'disorder', 'disturbance or 'disease' (21) although some people with lived experience favour mental distress. The terms 'mental illness' and 'mental disorder' are defined in Chapter 2.

Secondly, the terms 'person with lived experience' and 'service user' are used in this thesis in favour of 'patient', 'client', 'consumer', and 'survivor'. The humanistic terms 'individual' and 'person with lived experience' were recently endorsed by a study involving individuals with mental illness who considered both terms empowering, and recovery focused (22). In mental healthcare, there has been a shift towards calling individuals in mental healthcare 'service users' instead of 'patients' (23). Despite some psychiatrists arguing that 'patients' is the better term (23), 'service user' is used in guidelines published by the

National Institute for Health and Care Excellence (NICE) (24) and other official documents published by Mental Health Reform in Ireland (25).

Finally, the term 'discontinuation' is purposefully used over the term 'deprescribing'. Deprescribing has been defined as "*the process of withdrawal of an inappropriate medication, supervised by healthcare professionals with the goal of managing polypharmacy and improving outcomes"* (26 p.1254). Discontinuation was chosen as a more inclusive term given the cohort of individuals who stop psychiatric medication without any support or oversight of any healthcare professional (27). Also, in some cases, an individual may wish to stop medication that appear appropriate which does not align with the above definition.

1.7 Structure of the Thesis

This thesis is comprised of four distinct studies as outlined in Table 1.1

Table 1.1: An overview of the PhD thesis structure (Studies 1-4)

Study Number	Description
Study 1	Priority Setting Partnership (PSP) Study to identify the Top 10 priorities for future research on reducing and stopping psychiatric medication in collaboration with the three key stakeholder groups: people with lived experience of taking and/or stopping psychiatric medication, family members/friends/carers/supporters, and healthcare professionals.
Study 2	Qualitative descriptive analysis of free-text responses submitted to one of the PSP surveys to explore stakeholders' views and experiences of reducing and stopping psychiatric medication.
Study 3	Qualitative descriptive study involving semi-structured interviews with stakeholders who had participated in the PSP study to explore their views on the PSP methodology as a priority setting exercise.
Study 4	Scoping review to examine the content, underpinning evidence base, and impact of mobile phone apps and app-based interventions that focused on supporting the tapering of psychiatric medication.

This thesis is divided into **nine chapters** starting with this introductory chapter. **Chapter 2** provides an overview of relevant literature on the prescribing and discontinuation of psychiatric medication. **Chapter 3** provides a background to the concept of PPI in research and presents the PSP methodology in a general context. **Chapter 4** reports on Study 1 which involved a PSP study. The PSP study was conducted in line with the James Lind Alliance (JLA) guidance to identify the Top 10 priorities for future research on reducing and stopping psychiatric medication. **Chapter 5** reports on the findings of Study 1 which addressed the first objective of the thesis. **Chapter 6** reports on Study 2 which involved analysing the free-text responses submitted to one of the surveys conducted as part of the PSP study to explore stakeholders' views and experiences of reducing/stopping psychiatric medication. Study 2 addressed the second objective of the thesis. **Chapter 7** reports on Study 3 which involved semi-structured interviews with stakeholders who had participated in the PSP study to explore their views on the PSP methodology as a priority setting exercise. Study 3 addressed the third objective of the thesis. **Chapter 8** reports on Study 4 which involved a scoping review to examine the content, underpinning evidence base, and impact on mobile phone apps and app-based interventions that focused on supporting the tapering of psychiatric medication. This study addressed the fourth objective of the thesis. **Chapter 9** discusses the overall findings of this thesis, its strengths and limitations, and the potential impact of the research on clinical research, policy, and practice.

Chapter 2: Setting the thesis in context

2.1 Introduction to Chapter 2

Chapter 2 focuses on providing an overview of relevant literature on the prescribing and discontinuation of psychiatric medication to set the thesis and its individual chapters in context of empirical work, theory, and policy. The chapter starts by exploring the classification of mental distress as an illness and outlining a number of proposed definitions of mental health, mental disorder, and mental illness. This is followed by an overview of the development of the individual classes of psychiatric medication, their proposed mechanisms of action, their clinical indications, and the benefits and risks associated with their use. With reference to the current research, the reasons people may want to reduce/stop psychiatric medication, and the common strategies to do so are also discussed. None of the issues pertaining to the prescribing and discontinuation of psychiatric medication are straightforward, and many issues are debated and contested. This chapter addresses some of this debate to set the thesis in context.

2.2 Mental illness

2.2.1 Definitions of mental health, mental disorder & mental illness

The definitions of mental health, mental disorder, and mental illness have been debated with a number of models put forward for each. The term mental health has been defined by the World Health Organization (WHO) as "*a state of mental well-being that enables people to cope with the stresses of life, realise their abilities, learn well and work well, and contribute to their community"* (28). Mental health is considered to be integral to human well-being, determined by a complex interplay of different factors and stresses (28). Some critics have raised concerns that the above definition of mental health creates the potential for misunderstanding by identifying positive feelings and positive functioning as key factors for mental health (21).

The definition of mental disorder has undergone several iterations (29). Wakefield proposed that a mental disorder involved harm, in the form of distress and/or impairment, that is due to the failure of a psychological mechanism to perform its evolved function (29). Additional definitions have been put forward by the WHO and the American

Psychiatric Association, the creator of the Diagnostic and Statistical Manual of Mental Disorders (DSM). The DSM is explained in more detail in Section 2.2.5. The WHO define a mental disorder as *"a clinically significant disturbance in an individual's cognition, emotional regulation, or behaviour…usually associated with distress and impairment in normal functioning"* (28). This definition shares similarities with that in the fifth edition of the DSM (DSM-V) which defines it as a *"syndrome characterised by a clinically significant disturbance in an individual's cognition, emotion regulation, or behaviour that reflects a dysfunction in the psychological, biological, or developmental processes underlying mental functioning. Mental disorders are usually associated with significant distress or disability in social, occupational, or other important activities"* (30, 31 p.540). The DSM definition also specifies that social deviance or conflicts with society are not mental disorders unless they *"result from a dysfunction in the individual"* (31 p.538). Some critics have challenged these definitions, particularly the dysfunction element, and argue that mental disorder is a concept that cannot be easily defined (29). Mental disorders cover a range of conditions which include anxiety disorders, affective disorders, and psychotic disorders (28).

While the official psychiatric classifications such as the DSM and the International Classification of Disease employ the term mental disorder, several generic terms are also used (21). These include mental illness, mental health challenges, psychiatric conditions, and mental health problems. The term mental illness is still used at the expense of the other terms. According to the National Institute of Mental Health, any mental illness is defined as *"a mental, behavioural, or emotional disorder, varying in impact, ranging from no impairment to mild, moderate, and even severe impairment*" (32). Some individuals prefer this term because, to them, it acknowledges the potential severity of conditions experienced by people, while others prefer mental health problem because they see it as less stigmatising (21). As outlined in Chapter 1, the term 'mental illness' is utilised in this thesis.

2.2.2 Prevalence of mental illness

In 2019, the WHO estimated that one in eight every people had a mental illness (28). The impact of the COVID-19 pandemic on the prevalence of mental illness is discussed in Section 2.2.4. Between 1990 and 2019, the global number of disability-adjusted life-years

due to mental illness increased from 80·8 million to 125·3 million (33). The disability-adjusted life-year metric is a measure of the overall disease burden, expressed as the number of years lost to disability or early death (34). As the prevalence of mental illness increases on a global scale (33), it has become one of the leading causes of global health-related burdens. In 2021, depressive disorders carried the highest health burden, followed by anxiety disorders (35).

Despite the rising prevalence of mental illness, it is unclear as to whether these figures present an accurate reflection of the global mental health status (36). Some critics argue that while there may be potential reluctance to seek help/support from healthcare professionals and as a result, individuals who are experiencing symptoms indicative of a mental illness may not receive a diagnosis, other individuals may receive a wrongful diagnosis, contributing to the ongoing diagnostic inflation (36). Questions have been raised as to whether the expansion of the DSM and the potential overdiagnosis of mental illness may have contributed to the ongoing diagnostic inflation (36, 37), the medicalisation of everyday life issues, such as grief and the increase in uses of medications. This is discussed further in Section 2.2.5.

2.2.3 Risk factors for mental illness

The prevalence of mental illness is shaped to a great extent by an individual's social, physical, and economic environments (38). Risk factors are the attributes, characteristics, and exposures of an individual that pose a threat to their mental health (38). The greater an individual's exposure and vulnerability to risk factors, the higher their risk of developing a mental illness (39). In 2012, the WHO categorised risk factors into three domains: (1) individual attributes and behaviours; (2) social and economic circumstances; and (3) environmental factors (40).

Individual attributes and behaviours include gender, age, and ethnicity (39, 41). According to a national survey conducted in the United States in 2021, a higher prevalence of any mental illness was linked to the female gender and young adults aged 18-25 years compared to other individual attributes (32). Individual medical factors (e.g., substance use, genetics) are also thought to impact an individual's vulnerability to developing mental illness (42).

Social and economic circumstances include education, social networks, employment status, and housing (43, 44). Low levels of education and literacy are considered risk factors for mental illness whereas strong family structure, marital satisfaction, and employment function are protective factors (45). The social stress theory regards social disadvantages generated from the social structure as chronic stressors associated with distress and mental illness (46). In line with this theory, mental illness is distributed according to a gradient of economic disadvantage across society with the highest levels of mental illness typically found in the most deprived areas (46).

Environmental factors include injustice and discrimination. Discrimination is targeted by one of the key Sustainable Development Goals (Goal 10) which seeks to *"Reduce inequality within and among countries"* (47). National surveys conducted in the United States, Africa, and other countries have found a link between discrimination and an increased susceptibility of developing psychological disorders including depression, anxiety, and substance use disorders (41). Other environmental factors include climate change, war, and traumas such as adverse childhood experiences. Adverse childhood experiences include child abuse, child neglect, and household dysfunction, and have been recognised as a major risk factor for mental illness. The level of trauma experienced has been shown to affect the severity of mental illness (48).

2.2.4 Impact of COVID-19 pandemic on mental health

The impact of the COVID-19 pandemic on mental health has been evaluated by several studies (49). According to one systematic review, the global pooled prevalence estimates of depression and anxiety between January 2020 to June 2020 were 28.0% and 26.9%, respectively (50). These estimates were significantly higher than the figures previously reported by the WHO's Global Health Estimates in 2015 which found the global estimates of depression and anxiety to be 4.4% and 3.6%, respectively (50). This would suggest that the COVID-19 pandemic worsened global mental health and increased the pooled prevalence of mental illness (50). In a separate report published by the WHO, the COVID-19 pandemic was estimated to have increased the prevalence of anxiety and depression worldwide by 25% (51).

In an attempt to control the spread of the COVID-19 virus, many countries adopted public health measures which included lockdowns, social distancing, and self-isolation. It has been postulated that these measures exacerbated pre-existing social determinants of mental ill health by disrupting social networks and increasing unemployment rates, increasing the prevalence of mental illness (52). It has been suggested that the COVID-19 pandemic had varying effects on different population subgroups. For example, individuals with pre-existing physical health conditions such as obesity and asthma were associated with higher rates of depression and anxiety (53). Whereas individuals with pre-established mental illness were more vulnerable to relapse, exacerbation of symptoms and impaired functioning (53). Young people aged between 15-25 were another population subgroup that was particularly affected by the psychological toll of the pandemic (53).

2.2.5 Debate around diagnostic criteria

There are several contested issues surrounding the prescribing and discontinuation of psychiatric medication (36). This section will address one major point of contention which relates to diagnostic criteria and diagnostic inflation. The DSM is a medical framework comprised of sets of 'fact-based' criteria and/or sets of 'value-based' criteria (31). Most DSM revisions are paired with diagnostic expansion as demonstrated by the 300% increase in the number of diagnoses between the first and fourth editions of the DSM, published in 1952 and 1994, respectively (54). A pivotal moment in the history of psychiatric nosology was the declassification of homosexuality as a mental disorder in 1973 (55) which questioned the validity of the diagnostic criteria (56). This changing opinion drew attention to potential validity issues that exist within the DSM, and the gaps between policy, practice, and evidence (36).

While some support this model, others oppose it and argue that the DSM's diagnostic criteria are not scientifically robust (36). Unlike physical health conditions, there are no clear parameters that can be measured and support the diagnosis. On one hand, there are positive elements to a broader range of mental illness being recognised; individuals typically receive medication whereas in the pre-medication era, individuals were labelled as "mad" and removed from society by being placed in asylums (57). On the other hand, the rise in diagnostic labels has led to criticisms over how the diagnostic criteria are

produced, and the potential for medicalisation of everyday life events and emotions, such as grief. Medicalisation occurs when a diversity of behaviours, feelings, conditions, or health problems are treated as medical problems (58).

Following a psychiatric diagnosis, an individual is typically prescribed one or more psychiatric medications, in line with the clinical treatment guidelines (2). This has led some critics to believing that the ever-expanding list of psychiatric diagnoses favours the pharmaceutical industry, not the service user (59). For decades, neurotransmitter imbalances or deficiencies were cited as rationales to support the use of psychiatric medication in the treatment of mental illness (60). For example, it was previously hypothesised that depression arose due to abnormal serotonin levels in the brain. However, this hypothesis has now been widely discredited due to a lack of empirical evidence (60). While psychiatric medications have demonstrated many clinical advantages, there is a paucity of evidence to support claims of neurotransmitter activity (60). The proposed mechanism of actions of key psychiatric medications is outlined in Section 2.4.

2.3 Development & introduction of psychiatric medication

2.3.1 Antidepressants

The clinical introduction of the first two antidepressants, iproniazid and imipramine, took place in the 1950s when they were approved by the United States Food and Drug Administration for use in major depressive disorder (61, 62). Many antidepressants have been discovered since. There are five major classes of antidepressants which comprise Monoamine Oxidase Inhibitors (MAOIs), Tricyclic Antidepressants (TCAs), Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs), and Noradrenergic and Specific Serotonergic Antidepressants, also known as atypical antidepressants. The discovery of the first three classes of antidepressants is outlined below. Their proposed mechanism of action is further discussed in Section 2.4.1.

Iproniazid was the first MAOI to be discovered (61, 62). Its precursor isoniazid was an antitubercular agent. Iproniazid was first trialled in patients with tuberculosis but after observing its psychological changes the drug was then trialled in patients with depression. Iproniazid (Marsilid®) was the first licensed pharmacological treatment for major

depressive disorder. Following safety concerns (e.g., the “cheese reaction”), Iproniazid was removed from the market in the United States in 1961. The “cheese reaction” appeared upon the co-administration of MAOIs with tyramine-rich foods (e.g., cheese, other dairy products) which caused tachycardia and hypertension by increasing tyramine and noradrenaline concentrations. Iproniazid is a non-selective irreversible MAOI. Years later, the first reversible and selective Monoamine Oxidase isoenzyme A (MAO_A) inhibitor was discovered, moclobemide (Manerix®) which was also used in the treatment of major depressive disorder. While more selective MAOIs have a better safety profile compared to the first MAOIs in terms of fewer adverse effects, their use in clinical practice has largely been replaced by newer antidepressants (63).

Imipramine was the first TCA to be discovered following a modification to the antipsychotic promethazine (61). Imipramine was trialled in individuals with a diagnosis of schizophrenia. Despite what appeared to be low levels of effectiveness in treating people with this diagnosis, imipramine demonstrated antidepressant properties in individuals with depressive psychosis. Another important trial finding was the lack of so-called ‘serious side effects’ in contrast to MAOIs. Imipramine (Tofranil®) was first marketed in 1957 and approved in 1959 for the treatment of major depressive disorder. The second TCA, amitriptyline, was introduced to the market in 1961.

The introduction of the first SSRI, fluoxetine (Prozac®), to the market took place in the late 1980s. Following its launch, the pharmaceutical industry began branding depression as an imbalance of serotonin in the brain (64, 65). As a result, the “serotonin hypothesis” quickly became embedded in professional and popular psyche (60), despite a lack of evidence for this theory.

2.3.2 Antipsychotics

Antipsychotics were discovered serendipitously during a search for anti-malarial drugs (66). As part of the initial search, the phenothiazine derivative, methylene blue, was synthesised. Upon discovering its antimalarial effects, further derivatives were synthesised and used as malaria treatments (66). Years later, amino alkyl phenothiazines were synthesised which possessed significant antihistaminergic activity (66). One example was promethazine which produced a more pronounced sedation compared to other

antihistamines and potentiated the activity of other anaesthetic agents, hence its later use in clinical anaesthesia (66). In the 1950s, the antipsychotic activity of chlorpromazine was discovered upon testing the drug in people with a psychiatric diagnosis. Following the launch of chlorpromazine (Largactil®, later renamed to Thorazine®) to the market, a widespread search for other antipsychotics was initiated. Between 1954-1975, forty antipsychotics were developed around the world (e.g., haloperidol and trifluoperazine). This class of antipsychotics is classified as the "first-generation" or "typical" antipsychotics (67).

The discovery of clozapine in the 1960's saw the beginning of the "second-generation" or "atypical" antipsychotic era (66). This class of antipsychotics was developed in response to the emerging side effect profile of "first-generation" antipsychotics, particularly the extrapyramidal symptoms. The adverse effects associated with antipsychotic use are further discussed in Section 2.5.2. Clozapine was marketed but quickly withdrawn due to safety concerns after reports of agranulocytosis, a potentially life-threatening adverse effect that causes a significant reduction in neutrophils and consequently increases an individual's susceptibility to infection (66). In 1990, its withdrawal was revoked, and it was relaunched on the market in the United States (66). Risperidone was approved for use in 1994, followed by olanzapine in 1996.

2.3.3 Benzodiazepine receptor agonists

Benzodiazepine receptor agonists (BZRAs) encompass benzodiazepines and Z-drugs. Benzodiazepines were discovered by Dr Leo Sternbach (68). In 1956, the first benzodiazepine was synthesised by combining the Gamma-aminobutyric acid A ($GABA_A$) receptor binding compound, meprobamate (Miltown®), with another compound to create a white crystalline powder, 'Ro 5–0690.' Animal drug trials detected a tranquilising effect with no apparent side effects. This compound was named methaminodiazepoxide, which later became known as chlordiazepoxide (Librium®). Librium was approved for use in 1960. Three years later, the second benzodiazepine, diazepam (Valium®) was marketed. In the years that followed, Sternbach developed several other benzodiazepines including flurazepam, flunitrazepam and clonazepam (68).

As evidence started to emerge about the potential risks and adverse effects associated with the use of benzodiazepines, efforts were targeted to developing safer alternatives. Z-drugs, also known as benzodiazepine-like medications, were discovered in the 1980s (69). There are only four Z-drugs commercially available: zaleplon, zolpidem, zopiclone and the s-enantiomer of zopiclone, eszopiclone. Zopiclone and eszopiclone have the longest half-lives.

2.3.4 Other psychiatric medication

In this thesis, "other psychiatric medication" refers to gabapentinoids, mood stabilisers, and stimulants. Gabapentinoids include gabapentin and pregabalin. In the 1970s, there was a push to discover treatments for neurological disorders such as epilepsy. Gamma-aminobutyric acid (GABA) is the primary inhibitory neurotransmitter in the central nervous system that plays an important role in seizure control and thus became the logical target. In search of a new drug molecule, lipophilic groups were added to GABA to increase its bioavailability and ability to penetrate the blood-brain barrier and act on neurotransmitters (70). These alterations to GABA led to the discovery of gabapentin, a GABA receptor agonist and potent anticonvulsant. Pregabalin (Lyrica®) was discovered following the analysis of 3-alkyl-4-aminobutyric acids, a group of acids essential for the synthesis of GABA (71).

The mood stabiliser lithium carbonate was traditionally used to treat gout, a painful form of arthritis. Lithium was discovered based on the theory that mania was caused by hyperuricaemia, an excessive level of the protein metabolite urea in the bloodstream (72). In 1949, an Australian psychiatrist John Cade discovered its mood-altering effects. According to Cade's theory, lithium reduced manic symptoms by increasing the excretion of urea (73). All experiments were abandoned following the death of a patient from lithium poisoning until years later when they were revisited by two psychiatrists, Mogens Schou and Poul Baastrup (73). While lithium demonstrated effectiveness in the treatment of bipolar disorder, it quickly became clear that the level of lithium must be carefully controlled to reduce the risks of adverse effects and toxicity. The introduction of the photometer in 1958 made it possible to measure blood drug concentrations, permitting lithium use in clinical psychiatry (73).

With respect to stimulants, only amphetamines and methylphenidate are discussed in this thesis as they are most relevant to mental illness. Amphetamine, also known as racemic α-methylphenethylamine, was first discovered in 1910 by two scientists George Barger and Henry Dale (74). In 1935, the racemic compound was launched on the market (Benzedrine®). Two years later, the more potent isomer, d-amphetamine, was marketed (Dexedrin®). The less potent isomer, l-amphetamine (Cydril®) was also tested and showed positive results, specifically in children with attention-deficit hyperactivity disorder. Both versions of the isomers are still used in the mixed salts/mixed enantiomers amphetamine (Adderall®) which is available in immediate and prolonged release forms. Methylphenidate was first approved for medical use in 1955 and marketed as Ritalin® (74). In 2000, regulatory approval was granted for an extended-release form of the medication (Concerta®). In 2007, the amphetamine prodrug, lisdexamfetamine dimesylate, was approved by the United States Food and Drug Administration and was launched on the market (Vyvanse®, Tyvense®).

2.4 Pharmacology of psychiatric medication

2.4.1 Antidepressants

Antidepressants were the first licensed pharmacological treatment for major depressive disorder (2). For decades, the underlying pathophysiology of depression was explained by the monoamine hypothesis, also known as the chemical imbalance theory (61, 75). Although contested, this theory proposed that depression was caused by an imbalance of three monoamine neurotransmitters: serotonin, noradrenaline, and dopamine. A neurotransmitter is an agent which transmits messages from one brain cell (neuron) to another, which can be excitatory or inhibitory in nature (76). This theory was strengthened by the scientific observation involving reserpine's effects on monoamines. Reserpine is a plant derivative that depletes the brain's levels of monoamines. Its administration precipitated depression in human studies, and its removal reversed depression. It was subsequently proposed that antidepressants exert their anti-depressant like effects by increasing the levels of monoamines in the synaptic space, correcting the "chemical imbalance" (77). The proposed pharmacology of MAOIs, TCAs, and SSRIs is outlined below.

MAOIs exert their pharmacological action by inhibiting Monoamine Oxidase (MAO) (61). MAO is an enzyme distributed throughout the whole body. MAO has two isoenzymes, MAO_A and MAO_B. MAO_A is responsible for the breakdown of the monoamine's serotonin, noradrenaline and adrenaline, and melatonin (76). Melatonin regulates circadian rhythm and sleep patterns (78). MAO_B is responsible for the breakdown of two isoenzymes, phenethylamine, and benzylamine which control the breakdown of dopamine, tyramine, and tryptamine. The inhibition of MAO_A increases the levels of monoamine neurotransmitters in the presynaptic terminal so that they are readily available for release when action potentials reach the nerve terminal (61). Therefore, the inhibition of MAO_A is thought to be responsible for the antidepressant effects of MAOIs. MAOIs are classified according to which of the isoenzymes they inhibit, and the type of inhibition, whether it is irreversible or reversible. Iproniazid is a non-selective irreversible MAO inhibitor, inhibiting the two isoenzymes, MAO_A and MAO_B, whereas moclobemide is a reversible MAO_A inhibitor (76).

TCAs exert their pharmacological action at two reuptake transporters and three receptor proteins. By blocking presynaptic norepinephrine and serotonin reuptake transporters and postsynaptic adrenergic α_1 and α_2, muscarinic and Histamine H_1 receptors, TCAs inhibit monoamine reuptake, increasing the levels of monoamines in the synaptic cleft (61, 77). TCAs' actions on additional, off-target postsynaptic receptors account for their adverse effect profile (76). For example, antagonism of adrenergic and histaminergic receptors causes dizziness and drowsiness, respectively. The TCA family of antidepressants are classified by their three-benzene ring core as opposed to their mechanism of action.

SSRIs selectively block the reuptake of serotonin at serotonin transporters, increasing serotonin concentrations within the synaptic cleft, and further stimulating postsynaptic serotonin receptors (61, 76). Variations in receptor binding affinity for postsynaptic serotonin (5-HT) receptors (e.g., 5-HT_{1A}, 5-HT_{2A}, and 5-HT_{2c}), and other postsynaptic receptors (e.g., alpha-1-adrenergic ($\alpha_{1,}$), alpha-2-adrenergic (α_2), and beta-adrenergic (β) receptors, Histamine H_1, muscarinic, and Dopamine D_2 receptors have been demonstrated amongst the individual drugs. These variations are responsible for differences in the individual drug's clinical and adverse effect profiles.

While the previously proposed hypothesis that depression is caused by a chemical imbalance in the brain has continued to inform the development of new antidepressants, there is a paucity of evidence to suggest that antidepressants work by addressing an underlying abnormality (79). A recent systematic umbrella review of the evidence on the serotonin theory in depression found a lack of consistent evidence to support the hypothesis that depression is caused by low levels of serotonin activity or concentrations. However, it did find limited evidence to suggest that long-term antidepressant use may reduce serotonin concentration (60). No consensus has been reached on the exact pharmacology of antidepressants (60).

2.4.2 Antipsychotics

Antipsychotics were initially developed to treat schizophrenia (80). The dopamine theory has been put forward to explain the underlying pathophysiology of schizophrenia (81). Dopamine is a catecholamine neurotransmitter that acts at several receptors (76). The original dopamine theory proposed that schizophrenia was caused by an excess of dopamine, and antipsychotics worked by reducing the level of dopamine. Following revisions to the theory, schizophrenia is now thought to be caused by dopamine abnormalities in several brain regions resulting in hypoactive, hyperactive, and dysregulated dopamine transmission (81).

First-generation antipsychotics act primarily on the dopaminergic system (67). By blocking the action of dopamine at the Dopamine D_2 receptors, they produce anti-dopaminergic effects (82). First-generation antipsychotics primarily target the positive symptoms of schizophrenia (e.g., hallucinations, delusions) which are thought to be caused by an excess of dopamine (82). Second-generation antipsychotics have additional target receptors including serotoninergic, histaminergic, and adrenergic α_2 receptors. They can also alter synaptic plasticity (82, 83). Their multi-receptor effects allow second-generation antipsychotics to target the three types of symptoms of schizophrenia: positive symptoms, negative symptoms (e.g., apathy, anhedonia), and cognitive symptoms (e.g., cognitive difficulties) (81, 82).

It has been proposed that their anti-dopaminergic activity is also responsible for their adverse effects given that dopaminergic receptors are not exclusive to the brain (76). The

variable affinity of the first- and second-generation antipsychotics for the different receptors, and subtypes of receptors, is thought to account for the differences in the adverse effect profile of the individual drugs. For example, activity at serotoninergic 5-HT_{2C} receptors and histaminergic receptors is associated with weight gain and sedation, respectively (76, 82). More information on the adverse effects associated with antipsychotic use is provided in Section 2.5.2.

2.4.3 Benzodiazepine receptor agonists

Benzodiazepines have a unique chemical structure, comprised of benzene and diazepine rings (84, 85). These rings allow benzodiazepines to bind to their target receptor, GABA, and exert their clinical effects. GABA signalling involves the transfer of negatively charged particles (chloride ions) to the neuron to make it less responsive to excitatory neurotransmitters. Upon binding to the $GABA_A$ receptor, benzodiazepines change the shape of the receptor, boosting the transfer of these chloride ions into the neurons, and potentiating GABA transmission. As a result, the brain's output of excitatory neurotransmitters (i.e., noradrenaline, serotonin, acetyl choline and dopamine) is reduced. Excitatory neurotransmitters are responsible for many normal bodily functions which include normal alertness, memory, muscle tone and co-ordination, and endocrine gland secretions (85).

There are several subtypes of benzodiazepine receptors. While benzodiazepines combine to a varying degree with all the receptor subtypes, the main subtype that benzodiazepines bind to dictate the type of action that the drug will have. For example, adrenergic α_1 is responsible for the sedative effects, and adrenergic α_2 is associated with the anti-anxiety effects. Benzodiazepines exert five major effects which include anxiolytic, hypnotic, myorelaxant, anticonvulsant and amnesic effects (85). However, individual drugs exert these effects to varying degrees.

Z-drugs are a chemically heterogenous group. Despite the absence of both benzene and diazepine rings, Z-drugs bind to the same binding site as benzodiazepines, enhancing the inhibitory effects of GABA. As a result, Z-drugs produce similar clinical effects to benzodiazepines. The increased selectivity of Z-drugs for a particular subunit, adrenergic α_1, of the $GABA_A$ receptor, enhances their hypnotic effects. Like benzodiazepines, the

differential binding of z-drugs to the various $GABA_A$ receptor isoforms accounts for the variations in clinical effects (86).

2.4.4 Other psychiatric medication

Gabapentin is a modified version of the GABA molecule but despite its inherent similarities with the chemical structures of GABA, gabapentin does not bind to the GABA receptors, nor does it alter GABA transmission (76). Gabapentin has demonstrated a high affinity for binding sites in the brain that contain voltage-gated calcium channels (e.g., alpha-2-delta-1) which inhibit the release of excitatory neurotransmitters in the presynaptic area which participate in epileptogenesis. Epileptogenesis is the process by which the brain becomes more susceptible to seizures (87). The exact mechanism of action of gabapentin remains unknown.

Pregabalin is an antagonist of the voltage gated calcium channels (71). Pregabalin binds to the alpha-2-delta subunit to produce antiepileptic and analgesic actions, blocking the calcium channels and stopping the influx of calcium (76). As a result, the release of excitatory neurotransmitters, glutamate, and sensory neuropeptides (substance P and Calcitonin gene-related peptide antibodies) is reduced, and synaptic transmission is inhibited. By increasing the activity of excitatory amino acid transporters, pregabalin further decreases glutamate levels and inhibits the activation of N-methyl-D-aspartate. The N-methyl-D-aspartate receptor is a receptor of glutamate, the primary excitatory neurotransmitter in the human brain. Pregabalin also modulates potassium channel activation in a way that further inhibits neuronal excitation. These inhibitory effects of pregabalin on neurotransmission account for the anticonvulsant and analgesic properties of pregabalin.

While lithium was discovered based on a theory that was later discredited (see Section 2.3.4), lithium remains an important treatment option for bipolar disorder. It has been hypothesised that bipolar disorder is a degenerative process in which disease-related stressors lead to apoptosis (i.e., cell death) and brain atrophy (i.e., loss of neurons in the brain). On a macroscopic level, lithium would appear neuroprotective by stopping apoptosis, promoting neuroproliferation (i.e., generation of new cells), and blocking the cascade of neurotoxic processes that contribute to the brain alterations (72). On a

microscopic level, lithium appears to modulate neuronal function by interfering with cellular and molecular processes, decreasing excitatory neurotransmission through glutamate and dopamine, and increasing inhibitory neurotransmission via GABA and interferes with neurotransmission by altering the levels of second messenger systems (72). Despite the existence of these theories, the evidence to explain the underlying pathophysiology of bipolar disorder is lacking. As a result, the mechanisms by which lithium exerts its mood stabilising effects are largely unknown (72).

Amphetamines exert their pharmacological action through the induction of noradrenaline and dopamine. By increasing the levels of these catecholamines, amphetamines increase energy levels, create euphoria (i.e., feeling of intense happiness), and improve cognition (88). Methylphenidate also increases catecholamine levels by blocking their reuptake at the dopamine and noradrenaline transporters (76).

2.5 Clinical indications, evidence of effectiveness & adverse effects

2.5.1 Antidepressants

Antidepressants are approved for several conditions which include major depressive disorder and panic disorder (2, 89). While there is evidence to support their use in depression (90) and generalised anxiety disorder (91), several issues of concern have been raised with the existing evidence. This has created uncertainty over whether antidepressants provide any clinically significant benefits over placebo response (92). Firstly, the difficulty interpreting changes in the rating scales and lack of reliable biomarkers of mental illness make it challenging to assess the safety and efficacy of antidepressants (92). The second issue relates to the fact that most trials of antidepressants have been relatively short-lived, lasting approximately four to eight weeks (93) which in turn has created challenges when assessing their long-term effects (93). In addition, there are issues surrounding how trials are conducted, in particular the potential for bias. Withdrawal confounding bias is the misdiagnosis of withdrawal symptoms as an emergence or recurrence of a mental illness, also known as relapse (94). It has been postulated that withdrawal confounding bias may have contributed to the greater likelihood of relapse in trials that stopped antidepressants abruptly in individuals

with remitted depression who had prior exposure to antidepressants (94). Another type of bias that has been highlighted with the clinical evidence relating to antidepressants is reporting bias which refers to the selective reporting of trial findings i.e., negative results being withheld (95). Reporting bias creates challenges when assessing the true risk: benefit profile of the medication. Continued efforts are needed to further improve transparency in the scientific literature (95).

The use of antidepressants is associated with several potential risks and adverse effects on a continuum of mild to more severe. It has been hypothesised that adverse effects associated with antidepressant use are caused by the neurophysiologic readjustments that take place in the presence of the drug (96). Common adverse effects include weight gain, insomnia, and post-selective serotonin reuptake inhibitor sexual dysfunction which is a debilitating and distressing condition that adversely affects the quality of life of the affected individual (97). In terms of risks, antidepressants can cause physiological dependence and tolerance, both of which are thought to be caused by neuroadaptive changes. In cases of physiological dependence, the drug is necessary to function at a level that was previously reachable without any drug (98), and once established, withdrawal symptoms may occur upon reducing, stopping, or switching the drug (98, 99). Withdrawal symptoms and other barriers to discontinuation are discussed in more detail in Section 2.7.4. Tolerance occurs where the response to the same dose of a drug decreases overtime such that a higher dose of a drug is required to achieve the original level of response (98). Tolerance was found to occur in 9 to 57% of individuals being treated with antidepressants in trials (100). It is characterised by the return of depressive symptoms during maintenance antidepressant treatment.

2.5.2 Antipsychotics

Antipsychotics are the first-line pharmacological treatment for people with a diagnosis of schizophrenia (80). Schizophrenia is a condition that can cause psychosis, a collection of symptoms which is defined as “losing touch with reality” (76). Other licensed indications include acute mania, major depressive disorder with psychotic features, and borderline personality disorder (2, 101). Following their discovery, long-term treatment with

antipsychotics (i.e., >3 years) quickly became common practice in the management of people experiencing schizophrenia and other psychotic disorders (102).

While there is high-level evidence to support the use of antipsychotics in schizophrenia, particularly second-generation antipsychotics (103, 104) and in acute mania (105), similar issues of concern have been raised with existing evidence on their safety and efficacy (106). Most trials were relatively short-lived (i.e., less than a year), and compared maintenance treatment with abrupt discontinuation of antipsychotics (107). However, the Research into Antipsychotic Discontinuation and Reduction (RADAR) study involved a randomised controlled trial comparing a gradual strategy of antipsychotic reduction (with discontinuation where possible) with maintenance treatment in people who had experienced recurrent psychotic episodes or been diagnosed with schizophrenia (107). The study demonstrated lower risk of relapse associated with maintenance treatment compared to reducing or stopping antipsychotic treatment over a two-year follow-up period (107).

Antipsychotic use is also associated with a range of potential risks and adverse effects. Adverse effects include weight gain, metabolic disturbances, and sedation (108). Extrapyramidal side effects are a common type of adverse effects associated with antipsychotics and other antidopaminergic agents, but particularly first-generation antipsychotics. Extrapyramidal side effects manifest as drug-induced movement disorders. Tardive dyskinesia is the most challenging extrapyramidal side effects associated with (109, 110). Tardive dyskinesia is a movement disorder associated with irreversible, involuntary, repetitive body movements associated with a significant impairment of functioning and quality of life and an increase in medical morbidity and mortality (109). Other examples of extrapyramidal side effects include parkinsonism, dystonia, and akathisia (76). Antipsychotics are also dependence and tolerance forming drugs. Antipsychotic tolerance was demonstrated by trials comparing the effectiveness of antipsychotics in chronic users versus first-episode schizophrenia patients (naïve users) which showed that the latter group responded to lower doses of antipsychotics, were more sensitive to side effects, and had comparatively higher response rates than patients with an established history of schizophrenia and antipsychotic use (111).

2.5.3 Benzodiazepine receptor agonists

Benzodiazepines are licensed for several clinical indications which include anxiety disorders and insomnia (112). The British National Formulary divides benzodiazepines into two major classes, anxiolytics, and hypnotics, depending on their clinical properties (i.e., half-lives) (68). The half-life of a drug is the time it takes for the initial concentration of a drug in the body to reduce by half (68). Typically, benzodiazepines with shorter half-lives are classified as anxiolytics, used to alleviate anxiety states (e.g., alprazolam, chlordiazepoxide). Whereas those with longer half-lives are classified as hypnotics, used for the short-term treatment of insomnia (e.g., flurazepam, nitrazepam). Diazepam is licensed for insomnia and anxiety. The British National Formulary also lists Z-drugs as hypnotics.

Despite the existing evidence to support the use of benzodiazepines in generalised anxiety disorder, similar concerns have been raised over clinical trial evidence, in particular the limited duration of the trials (113). As a result, BZRAs are only recommended for short-term use (i.e., ≤4 weeks) for the symptoms of anxiety. While there is moderate-quality evidence from meta-analyses to show that benzodiazepines, Z-drugs, and some antidepressants are effective short-term treatments in insomnia (114), there is a lack of evidence to support their use in panic disorders (115).

Benzodiazepine use is associated with a range of adverse effects, particularly long-term use (i.e., >90 days) (68, 116). Adverse effects include cognitive impairment and psychomotor disturbance, both of which increase the risk for falls and fractures (68, 117). Benzodiazepines also have the potential to cause psychological and physical dependence and tolerance within a few weeks or months of regular or repeated use (85, 118). It has been proposed that their dependence potential is linked to their affinity for the GABA receptors (119). Previous studies have shown that drugs with a strong affinity for GABA, and fast clinical onset of action, are correlated with a higher risk of dependence and abuse respectively (119). Whereas tolerance is thought to be related to the compensatory changes that occur in the GABA and benzodiazepine receptors which become less responsive, so that the inhibitory actions of GABA and benzodiazepines are decreased (85). Similar risks and adverse effects are associated with Z-drugs (118).

2.5.4 Other psychiatric medication

Gabapentin has been approved as a muscle relaxant, anti-spasmodic, and anticonvulsant (76). Other licensed indications include postherpetic neuralgia, adjunctive therapy in the treatment of partial seizures, and moderate to severe restless leg syndrome. Pregabalin is licensed for neuropathic pain associated with diabetic peripheral neuropathy, spinal cord injury, postherpetic neuralgia, fibromyalgia, and as an adjunct therapy for partial-onset seizures in adults with epilepsy (71). While there is high-level evidence to support the use of gabapentinoids in neuropathic pain (120), the evidence to support their use in anxiety disorders is limited (91). Both gabapentinoids also have several off-label uses which include bipolar disorder and anxiety disorders (121) despite the lack of clinical trials testing their efficacy in these conditions.

Gabapentinoids are associated with a range of adverse events which include dizziness, somnolence, confusion, and euphoria (120). Similar to benzodiazepines, gabapentinoids also have the potential to cause dependence and abuse. It has been proposed that their abuse potential can be attributed to by the euphoric effects that result from their use, particularly pregabalin which takes less time to achieve peak plasma concentration. That said, a systematic review was unable to confirm this abuse potential (120).

Mood stabilisers are typically used in the treatment of bipolar disorder. Bipolar disorder as a condition in which a person's mood changes from a depressed feeling to a high "manic" feeling or vice versa (76). Mood stabilisers help reduce mood swings and prevent manic and depressive episodes. Lithium is approved for bipolar disorder and for the prophylactic treatment of mania (80, 121). The findings of a systematic review demonstrate lithium's superiority over the placebo at reducing the risk of relapse of manic episodes in individuals with bipolar disorders. That said, its efficacy was significantly lower at reducing relapse rate of depressive episodes (122). Despite the evidence base lacking, lithium has also been used off-label as adjunctive therapy in major depressive disorder when the response to antidepressant monotherapy is inadequate, and in the treatment of bipolar disorder without a history of mania. Lithium is associated range of adverse events (76). These include neurological (i.e., hand tremors), endocrinological (i.e., thyroid dysfunction), and renal (i.e., increased urination) manifestations (123). The risk of adverse

effects and toxicity can be controlled by monitoring the level of lithium and maintaining it within the therapeutic index (80) .

Stimulants are typically used to treat attention-deficit hyperactivity disorder and narcolepsy (i.e., uncontrollable episodes of deep sleep) by increasing alertness, attention, and energy (124). According to a Cochrane review on the efficacy of methylphenidate in attention-deficit hyperactivity disorder (125), methylphenidate was reported to be superior to placebo or no intervention in terms of improving teacher-rated attention-deficit hyperactivity disorder symptoms and general behaviour in children and adolescents with attention-deficit hyperactivity disorder. Methylphenidate is associated with range of non-serious and serious adverse effects (125). Non-serious adverse events include headache, sleep difficulties, and decreased appetite. Serious adverse events such as psychosis, mood disorders, and serious cardiovascular events. The risk of serious events with the use of methylphenidate has been reported as low (125).

2.6 Prescribing & use of psychiatric medication

2.6.1 Legal classification of psychiatric medication in Ireland

The prescribing and supply of medication in Ireland is governed by the Medicinal Products (Prescription and Control of Supply) Regulations 2020 (126). The supply of all psychiatric medication is subject to a medical prescription (126). Most psychiatric medications are classified as Schedule 1(A), or “non-renewable”, meaning that a supply of the medication can only be repeated if the prescriber indicates this on the prescription (127). This includes antidepressants, antipsychotics, lithium and pregabalin.

The supply of BZRAs and stimulants is also governed by the Misuse of Drugs Regulations 2017 (128). The Regulations divide controlled drugs into five schedules according to their abuse potential and therapeutic value; Schedule I has the most restrictions, while Schedule V has the least. Stimulants are classified as Schedule II controlled drugs whereas most benzodiazepines and Z-drugs are classified as Schedule IV controlled drugs. There are additional requirements that need to be met for prescriptions involving drugs substances in Schedule II, III and IV. Drug substances Schedule II and Schedule III must be

stored a safe in the pharmacy and all supplies of Schedule II drugs must be recorded in the pharmacy's controlled drugs register.

2.6.2 Treatment guidelines

Psychiatric medications are used in several conditions relating to mental and physical health. The treatment guidelines vary depending on the indication. The guidelines for four common mental illness (i.e., depression, generalised anxiety disorder, insomnia, and psychosis) are outlined below. A number of treatment guidelines are available for each indication (2, 89, 112). This section was mostly informed by the NICE treatment guidelines developed in the United Kingdom; however, comparisons with other guidelines were also made. The evidence base for the use of psychiatric medications has previously been outlined in Sections 2.5.1-2.5.4.

2.6.2.1 Depression

The treatment guidelines for depression vary depending on the severity of the illness (2). For a new episode of less severe depression, there are several non-pharmacological first-line options which include guided self-help (e.g., individual and group cognitive behavioural therapy (CBT), mindfulness or meditation, and psychotherapy. The evidence base for psychological interventions is further discussed in Section 2.7.2.2. Antidepressants are not considered first-line treatment but can be used. For a new episode of more severe depression, guidelines recommend a combination CBT and an antidepressant such as a SSRI or SNRI. The recommended duration of antidepressant treatment is typically determined by the length of time required to achieve remission (i.e., relief from depressive symptoms and return of normal functioning) (129). Several guidelines advocate for a minimum of six months of antidepressant treatment after remission (129). According to a recent meta-analysis, antidepressant maintenance treatment should be continued for at least six months after remission to prevent relapse (130).

2.6.2.2 Generalised anxiety disorder

The NICE guidelines for generalised anxiety disorder recommend a stepped-care model which involves (1) active monitoring and information; (2) low-intensity psychological interventions (e.g., individual non-facilitated and guided self-help); (3) high-intensity

psychological intervention (i.e., CBT) or a drug treatment; (4) highly specialist treatment, such as complex drug and/or psychological treatment regimens (89). In terms of drug treatment, SSRIs are the first line option. If SSRIs are ineffective or not tolerated, an alternative SSRI, SNRI or pregabalin should be considered. The guidelines recommend that the drug treatment if the drug treatment is "effective" in terms of managing the individual's symptoms, it should be continued for at least a year as the likelihood of relapse is high (91). Benzodiazepines and antipsychotics are not recommended for the treatment of generalised anxiety disorder recommended in primary care.

2.6.2.3 Insomnia

Insomnia is described as a *"disturbance of normal sleep patterns commonly characterised by difficulty in initiating sleep (sleep onset latency) and/or difficulty maintaining sleep (sleep maintenance)"* (112). Given the deviations in individuals' sleep patterns, insomnia can be highly subjective. Hypnotics (i.e., drugs that induce sleep) are typically recommended to relieve the symptoms of insomnia; however, they do not treat the underlying cause. BZRAs are the main class of hypnotics licensed for insomnia (112). Following safety concerns over their use, the Committee on Safety of Medicines has recommended that they should be restricted to severe insomnia and that treatment should be at the lowest dose possible and not be continued beyond four weeks (112). This recommendation was also made by a European guideline for the diagnosis and treatment of insomnia that was developed by the European Sleep Research Society (114) which based their recommendations on a number of meta-analyses. Treatment guidelines also suggest that non-pharmacological treatments (e.g., avoiding stimulants and regular sleeping hours) could replace some of the current prescribing of hypnotics (112).

2.6.2.4 Psychosis

Psychosis is a symptom that presents as a break with consensual reality or what some might term 'losing touch with reality' (76). It may be symptom of a mental illness, such as schizophrenia, bipolar disorder, or severe depression (76). For first episode psychosis, guidelines recommend an oral antipsychotic medication in conjunction with psychological interventions (e.g., family intervention, individual CBT) (101). The choice of antipsychotic depends on the service user and healthcare professional. The full benefit and side effect

profile should be considered. Clozapine is recommended for individuals with treatment-resistant schizophrenia i.e., those whose illness has not responded adequately to treatment with at least two different antipsychotics (101). Despite the use of antipsychotics in schizophrenia for decades, the optimum duration of antipsychotic treatment is not known (131). That said, several clinical guidelines recommend individuals with first episode of psychosis continue taking the antipsychotic for at least one year after remission of psychotic symptoms (101, 132).

2.6.3 Prevalence of use & prescribing trends of psychiatric medication

The global consumption of psychiatric medication is increasing (133). Over an 11-year period spanning 2008–2019, the total global consumption of psychiatric medication increased by 4% annually (134). The highest rate of absolute growth was observed in high-income countries (1). As the role of psychiatric medication, particularly over extended or indefinite periods, is being called into question, these rising prescription trends have been flagged as a concern given the limited available evidence on long-term outcomes for psychiatric medication (133, 135, 136). The growth in the use of psychiatric medication feeds back into the ongoing debate which questions the appropriateness of prescribing and duration of use, as well as the medications' efficacy (135, 136).

2.6.3.1 Antidepressants

Between 2008–2019, the total global consumption of antidepressants increased by 3.5% annually (1). In England, prescriptions for antidepressants almost doubled over the 12-year period spanning 2011 to 2022-23, rising from 47.3 million to 85.6 million (136). In the United States, over the decade between 2009–2010 and 2017–2018, antidepressant use increased from 10.6% to 13.8% (137). It has been postulated that the increases observed in antidepressant prescribing have been driven by increases in the average duration of medication consumption (138). Recent figures in the United Kingdom and the United States show the median duration of antidepressant use have exceeded two years and five years, respectively (138). In England, the median duration of treatment with antidepressants doubled between the mid-2000s and 2017 with around half of individuals taking antidepressants are classed as long-term users (i.e., >12 months) (136, 139).

2.6.3.2 Antipsychotics

Between 2008–2019, the total global consumption of antipsychotics increased by almost 2.5% per year (1). In England, antipsychotic prescriptions increased by 5.1% annually between 1998 and 2010 (133). Despite a lack of more up to date data, the findings demonstrate an overall increase in antipsychotic consumption. That said, the prevalence of antipsychotic use appears to be decreasing in some countries (e.g., Taiwan, Japan) (140). According to one study, second-generation antipsychotics accounted for almost 80% of total antipsychotics prescribed in 2014 (141). Another study that included the same countries showed that this growth continued until the last recorded data point in December 2019 (1).

Two proposed explanations for the observed increases in antipsychotic use include expanded regulatory approval and growing off-label use (140). Off-label use refers to the prescribing of a medication for conditions outside of its licensed indications (142). One review estimated that 40–75% of all antipsychotic prescriptions were off-label, with mood disorders, anxiety disorders, insomnia and agitation being the leading indications of such prescribing (143). Similar figures were reported in Belgium where 30% of antipsychotic prescriptions were for psychotic disorders, suggesting high levels of off-label use (144). In the United States, a national survey estimated the global 12-month prevalence of antipsychotic use to be 1.7%, four times higher than the prevalence of psychosis, also suggesting growing off-label use (145).

2.6.3.3 Benzodiazepine receptor agonists

Over the same 11-year period spanning 2008–2019, there was a modest decrease in the average annual change in BZRA consumption in high-income countries (1). In Ireland, between 2005 to 2015, benzodiazepine prescribing rates significantly decreased from 225.92 per 1000 population to 166.07 per 1000 population, while Z-drug prescribing rates significantly increased from 95.36 per 1000 population to 109.11per 1000 population (116). Whereas in the United States, the prevalence of benzodiazepine use would appear to be growing. Between 1996 and 2013, there was a 4% increase in the number of adults filling a benzodiazepine prescription (146).

One potential explanation for the observed changes in BZRA prescribing is growing Z-drug use. In several countries declining trends in benzodiazepine use which have been offset to an extent by increases in Z-drug use (1). These trends were evident in Ireland and the United Kingdom, as previously outlined (116, 133, 147). Initially, Z-drugs were promoted as safer alternatives to benzodiazepines despite the lack of compelling evidence to support these claims (68). Another explanation for the observed changes is the growing awareness of potential for dependence, withdrawal symptoms, and other risks associated with benzodiazepine use (1).

While BZRA prescribing trends may be declining, there is still a significant number of people taking benzodiazepines. Despite a paucity of evidence to support the use of benzodiazepines over extended periods in the treatment of anxiety and insomnia, long-term use (i.e., >90 days) is common (116). This goes against clinical guidelines which recommend limiting prescriptions to short-term use (i.e., <4weeks) (118). It was estimated that more than a quarter of a million people in the United Kingdom are taking a hypnotic medication for durations exceeding the recommended time scales (118). In Ireland, long-term prescriptions were reported in one-third of individuals dispensed either benzodiazepines or Z-drugs on the main public health scheme (116). Given their potential for adverse effects, this represents a serious public health problem (118).

2.6.3.4 Other psychiatric medication

Over the ten-year period spanning 2008-2018, gabapentinoid consumption increased by 17.2% annually, with the highest consumption rate in high-income countries (148). Similar to antipsychotics, it has been suggested that expanded regulatory approval and growing off-label use are responsible for a significant proportion of their increased consumption. New licensed indications include neuropathic pain, fibromyalgia, and restless legs syndrome (148). Despite a lack of evidence to support their use in non-neuropathic pain and other off-label indications, off-label prescriptions accounted for 52.0% of gabapentin and 54.8% of pregabalin prescriptions with an identified indication in the England in 2017 (70).

With respect to lithium, its prescription has consistently declined internationally over recent decades (149). In the United States, between 1997–2016, the use of lithium in

patients diagnosed with bipolar I disorder more than halved, from over 30% of patients to below 15% (149). The decrease in lithium prescriptions is a global phenomenon including countries in Europe and Asia (149). It has been purported that these declining trends in lithium use have been offset to an extent by increases in antipsychotics (e.g., lamotrigine and quetiapine) and antidepressants (149).

Finally, stimulant prescriptions increased by 250% in the United States over the ten-year period spanning 2006-2016 (150). This aligned with another report published in the United States which showed an increase in stimulant consumption during 2016–2021, particularly during 2020–2021 (151). Increased stimulant prescribing in children specifically was also reported in England (152) One potential explanation for the observed changes in stimulant prescribing is the increased awareness of attention-deficit hyperactivity disorder (150).

2.7 Discontinuation of psychiatric medication

2.7.1 Reasons for discontinuing psychiatric medication

While it is difficult to quantify the number of individuals looking to discontinue psychiatric medication, the growth of peer support forums and online communities (99), such as SurvivingAntidepressants.org, highlights a sizeable cohort of individuals wanting to discontinue their use of psychiatric medication. Thousands of online peer support groups have been developed to raise awareness and provide support to millions of individuals who want to stop their medication (153).

A major motivation for discontinuing psychiatric medication is the adverse effects associated with their use (154, 155). Examples of adverse effects specific to each class of medication are previously outlined above in Sections 2.5.1-2.5.4. One study involving individuals who had taken psychiatric medication for more than nine months found that the decision to discontinue medication for 74% of respondents (n=185/250) was prompted by concerns over the long and short-term effects of the medication (156). Concerns over the long-term effects of psychiatric medication on physical health such as the risk of dependence was another common theme amongst studies (5, 157). Other motivations for discontinuing psychiatric medication include the desire to recapture lost personal autonomy, to live a life free of medication and, in some cases, the medication

may have failed to manage the person's distressing experience and symptoms (5, 158). Some individuals may have recovered on the medication and wish to see if they can stop it without relapsing (5).

While several systematic reviews of qualitive studies have sought to explore individuals' motivations for discounting psychiatric medication, most have focused on antidepressants (27) or antipsychotics (155). More studies involving individuals taking other classes of psychiatric medication (i.e., BZRAs, gabapentinoids, and stimulants), and multiple classes of medications, are needed to fully understand the reasons why individuals discontinue psychiatric medication.

2.7.2 Methods of discontinuation

2.7.2.1 Gradual dose reduction (tapering)

Tapering is the recommended approach for discontinuing psychiatric medication (99). Tapering involves gradually reducing the dose of the medication over a prolonged period (6, 99). Tapering approaches vary in terms of the frequency and magnitude of dose reductions, i.e., the size and percentage of the reduction (99). The two main approaches are fixed dose tapering and hyperbolic tapering.

Fixed dose tapering, also known as linear tapering, recommends linear dose reductions in which the magnitude of the dose reduction remains the same throughout the tapering process, as outlined in Figure 2.1 (159). During a fixed dose taper, there is a constant reduction of the original dose in which the individual reduces the dose in equal amounts (e.g., 10% of the original dose) (159). Given that it only involves a limited number of tapering steps, it is typically completed over a short period of time. This approach was endorsed by several clinical guidelines which recommended short tapering periods of between two to four weeks with linear dose reductions down to minimum therapeutic doses, or half that, before complete cessation to avoid withdrawal symptoms (160).

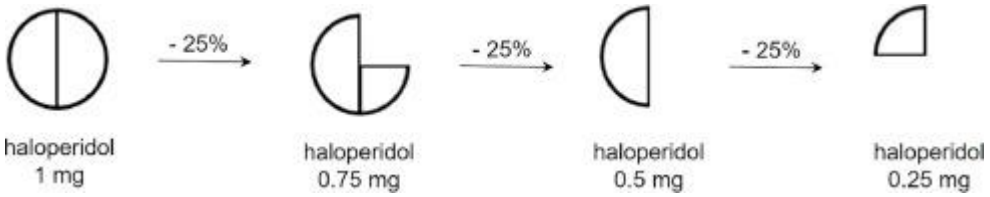

Figure 2.1: An example of a fixed dose tapering regime for the antipsychotic haloperidol. The figure shows the reduction of 1mg antipsychotic haloperidol at a constant dose reduction rate of 25% of the original dose. The first doses were 1mg, 0.75mg, 0.5mg, 0.25mg and 0mg. [source: Eserian et al. 2023 (159)

Hyperbolic tapering involves dose reductions that follow a hyperbolic curve whereby the magnitude of dose reduction becomes smaller and smaller (159, 160), as outlined in Figure 2.2. During a hyperbolic taper, the medication dose is reduced exponentially at a constant rate based on the last current dose as opposed to the original dose of the medication i.e., the magnitude of the dose reductions is bigger at the start of the taper and then become smaller. Hyperbolic tapering regimens typically involve more tapering steps compared to fixed dose tapering regimens and consequently take longer to complete.

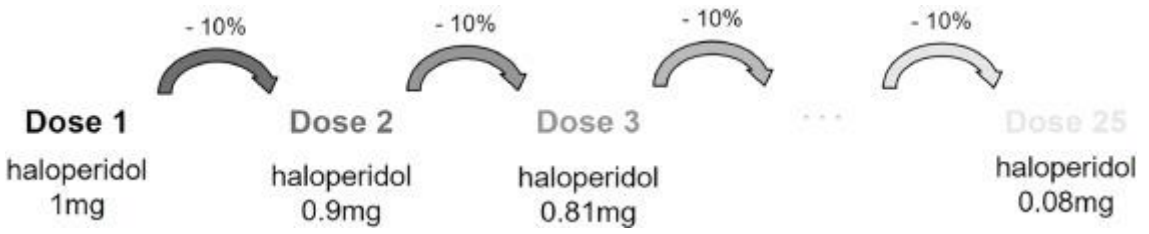

Figure 2.2: An example of hyperbolic tapering of the antipsychotic haloperidol. The figure shows the hyperbolic tapering of antipsychotic haloperidol at a rate of 10% of the last current dose. The first three doses were 1mg, 0.9mg, 0.81mg. [source: Eserian et al. 2023 (159)]

The concept of the hyperbolic taper proposed by Taylor and Horowitz was informed by the law of mass action and the hyperbolic dose-response that exists between drugs and

receptors (160). With linear tapering plans, whereby the dose of the psychiatric medication is reduced by fixed amounts (see Figure 2.3A), even relatively small dosage reductions can have large effects on receptor occupancy, particularly at lower doses, as shown by positron emission tomography (PET) imaging studies (160, 161). In order to mitigate against this, hyperbolic tapering plans have been proposed to achieve a linear reduction in pharmacological effect. This type of tapering plan involves reducing the dose of the psychiatric medication according to fixed intervals of biological effect based on receptor occupancy as opposed to fixed dosage amounts (see Figure 2.3B).

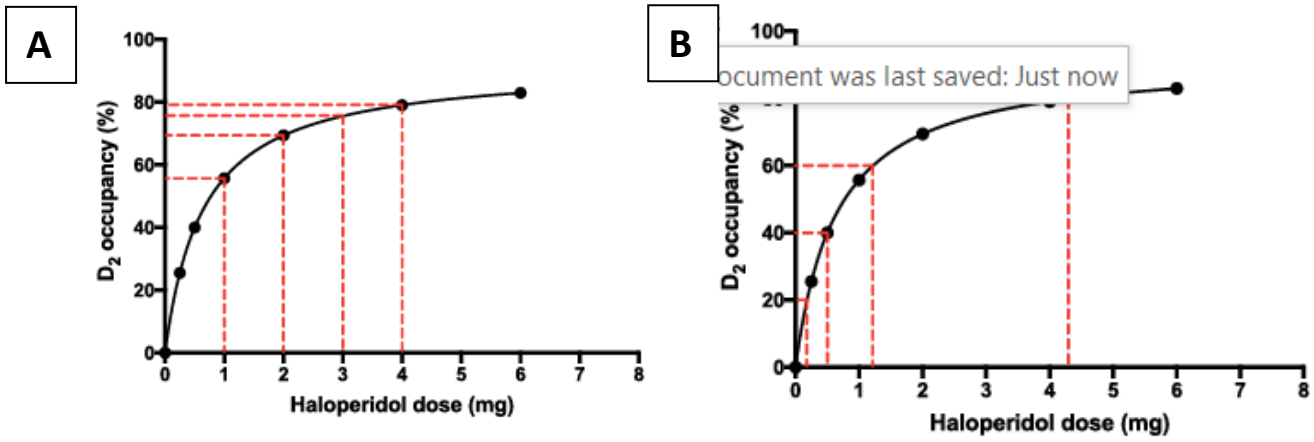

Figure 2.3: The effect of linear and hyperbolic dose reductions of the antipsychotic haloperidol on D_2 receptor occupancy. In Figure (A), linear dose reductions produce increasing changes in D_2 receptor occupancy. In Figure (B), hyperbolic dose reductions produce linear reductions in D_2 receptor occupancy. In this example, each dose reduction is followed by a 20% decrease in D_2 receptor occupancy. [source: Horowitz et al. 2021 (162)]

Tapering schedules that involve reducing the dose by 10% of the most recent dose every two to four weeks has been reported as tolerable for a wide variety of psychiatric medications by online peer support forums, including SurvivingAntidepressants.org (99, 163). This reduction rate was adopted from the tapering guidelines published by the Royal College of Psychiatrists, as outlined in Figure 2.4 (164).

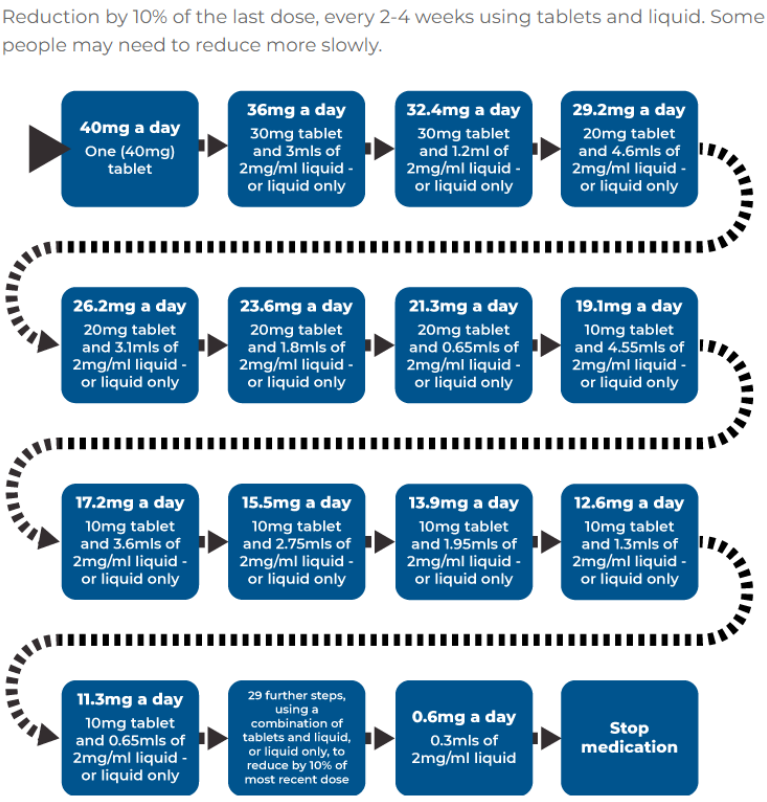

Figure 2.4: A hyperbolic tapering regimen for withdrawing the antidepressant paroxetine. The figure shows the hyperbolic tapering of antidepressant paroxetine at a rate of 10% of the last current dose every 2-4 weeks. [source: Royal College of Psychiatrists (164)]

These studies suggest that hyperbolic dose reductions produce linear reductions in receptor occupancy (159), as opposed to linear dose reductions which produce increasingly large reductions in receptor occupancy. It has been proposed that linear dose reductions may elicit severe withdrawal symptoms (160). In line with this hypothesis, the potential to cause withdrawal symptoms can be reduced by adopting hyperbolic tapering approaches which achieve linear reduction in receptor occupancy and allow adequate time for neuroadaptations between dose changes (159). More studies, involving additional classes of psychiatric medication, are required to test this hypothesis.

2.7.2.2 Psychological interventions

A range of psychological interventions have been investigated in terms of supporting the process of discontinuing psychiatric medication. These include CBT, mindfulness-based cognitive therapy, psychotherapy, and relaxation therapy. Mindfulness-based cognitive therapy is similar to CBT but contains an additional mindfulness-based stress reduction element (165).

The level of empirical evidence to support the use of psychological interventions when discontinuing psychiatric medication is limited. With respect to antidepressants, a Cochrane review found very low certainty evidence to demonstrate superiority of preventive cognitive therapy or mindfulness-based cognitive therapy combined with tapering over tapering alone in terms of achieving higher antidepressant discontinuation rates alone (166). The same review also found "low-certainty evidence" to suggest that discontinuation combined with psychological intervention influences relapse compared to continuation of antidepressants (166). In terms of benzodiazepines, a Cochrane review found CBT plus taper effective in reducing benzodiazepine use in the short term (i.e., three-month period), however, this was not sustained at six months (167). The review did not specify the type of taper used (167). According to another systematic review, cognitive behavioural therapy for insomnia, in which individuals with insomnia were provided with non-pharmacological techniques for managing their insomnia, plus tapering was considered more effective than gradual tapering alone for discontinuation of benzodiazepine hypnotic drugs in the short-term but there was no difference in long-term efficacy of cognitive behavioural therapy for insomnia at 12 months (168). The review also found insufficient evidence to support approaches (e.g., motivational interviewing, relaxation techniques) when discontinuing benzodiazepines (167).

It has been suggested that psychological interventions support the process of withdrawal by helping individuals manage their fears of withdrawal and relapse, and when used in combination with pharmacological interventions, they can reduce the individual's need for the medication over time, which reduces the risk of relapse upon its withdrawal (138). However, additional studies on other classes of psychiatric medication (e.g., antipsychotics, stimulants are needed before any concrete conclusions can be made

surrounding the usefulness of psychological interventions when discontinuing psychiatric medication.

2.7.2.3 Pharmacological substitution

Pharmacological substitution involves the use of an adjunctive medication to support the discontinuation of another medication. A Cochrane review assessed a number of medications including pregabalin, carbamazepine, and antidepressants on benzodiazepine discontinuation and withdrawal symptoms (169). This review was unable to draw any firm conclusions on the efficacy of pharmacological substitution for discontinuing long-term benzodiazepine use given the low quality of the evidence for the reported outcomes, and the small number of trials identified (169). Additional reviews on other classes of psychiatric medication (i.e., antidepressants, antipsychotics) are needed. Pharmacological substitution is not endorsed by clinical guidelines. According to the NICE guidance on safe prescribing and withdrawal management of dependence-forming drugs (i.e., opioid, benzodiazepine, gabapentinoid, Z- drug or antidepressant) published in 2022, withdrawal symptoms should not be treated with another dependence-forming drug. Additionally, sodium valproate or buspirone should not be used to aid withdrawal from a benzodiazepine (170). In the clinical guidelines for stopping antidepressants published by the Royal College of Psychiatrists, no reference was made to pharmacological substitution (164). More randomised controlled trials are required to determine the true effectiveness of pharmacological substitution when discontinuing psychiatric medication.

2.7.3 Guidelines for discontinuing psychiatric medication

Guideline recommendations on the discontinuation of psychiatric medications have evolved over time. Until recently, guidelines recommended relatively rapid tapering of antidepressants over two to four weeks (160). This approach was often not tolerated well by individuals with many reporting withdrawal symptoms, especially when stopping drugs with shorter half-lives. Withdrawal symptoms are further discussed described in Section 2.7.4.1. The most recent guideline published by the NICE in 2022 entitled “Medicines associated with dependence or withdrawal symptoms: safe prescribing and withdrawal management for adults” (170) covers the general principles for prescribing and managing withdrawal from opioids, benzodiazepines, gabapentinoids, Z-drugs and antidepressants

in primary and secondary care. This guideline recommends that when withdrawing from an opioid, benzodiazepine, z-drug, or antidepressant, *"a slow, stepwise rate of reduction proportionate to the existing dose, so that decrements become smaller as the dose is lowered, unless clinical risk is such that rapid withdrawal is needed"* (170 p.19). With respect to gabapentinoid withdrawal, the guideline suggests that the dose is reduced by a fixed amount at each decrement. The slow, stepwise rate of reduction proportionate to the existing dose so that decrements become smaller as the dose is lowered aligns with the principles of hyperbolic tapering, which is further discussed in Section 2.7.2.1. Hyperbolic tapering was also endorsed by the British Journal of General Practice in an article they published to guide prescribers when withdrawing antidepressants in primary care settings (171) and the discontinuation guidelines published by the Royal College of Psychiatrists in 2020 (164).

While it has been shown for some classes of psychiatric medication that gradual reduction is favourable to abrupt discontinuation, what is less well known is exactly what the best approach is to reducing and stopping psychiatric medication (159). The variations in tapering schedules pose challenges both for individuals who are withdrawing these medications and those involved in their supply or administration in terms of deciding which schedule is most appropriate for the individual to follow (7, 159). As a result, the rate of taper is usually based on the clinical experience of the prescriber as opposed to good empirical evidence (7). This thesis was undertaken with the aim of contributing to the evidence base.

2.7.4 Barriers/challenges to discontinuation

There are several barriers to discontinuing psychiatric medication. As previously outlined in this chapter, there are many uncertainties about what constitutes the optimal tapering approach and which interventions best support individuals discontinuing psychiatric medication (7, 138). This lack of robust evidence to inform guidance acts as a barrier to discontinuing psychiatric medication. Three additional barriers to discontinuing psychiatric medication (i.e., withdrawal symptoms, relapse, and availability of pharmaceutical dosage forms) are outlined below.

2.7.4.1 Withdrawal symptoms

Withdrawal symptoms are the main barrier to discontinuing psychiatric medication, as reported by service users (172) and one of the contributing factors to the increases in long-term use of psychiatric medication (138, 173). It has been proposed that neurophysiologic readjustments take place in the body in the absence of these medications and induce withdrawal symptoms (174). In line with this theory, reducing or stopping the medication lowers the levels of neurotransmitters, creating a deficiency of neural activity. The duration of withdrawal symptoms is thought to be affected by how long it takes the brain to return to its normal level of sensitivity. Guidelines recommend slow, stepwise discontinuation to minimise the potential for withdrawal symptoms by giving the body time to adapt between dose reductions, as previously outlined in Section 2.7.3. Withdrawal symptoms are not exclusive to psychiatric medication. Drugs acting on the cardiovascular system also have potential to cause withdrawal symptoms if stopped abruptly (e.g., aspirin, β-adrenergic receptor antagonists, and statins) (162, 174). While the withdrawal symptoms associated with antidepressants, antipsychotics and benzodiazepines (175, 176) are reasonably well understood, less is known about those associated with other classes of psychiatric medication (e.g., gabapentinoids, mood stabilisers) (177, 178).

The list of withdrawal symptoms associated with psychiatric medication is extensive, ranging on a continuum of mild to severe. Common withdrawal symptoms include anxiety, tremors, lethargy, mania, and delirium (99, 172). Withdrawal symptoms can vary depending on the class of psychiatric medication. For example, nausea, fatigue, anxiety, and insomnia are associated with discontinuation of antidepressants (179).

Prevalence rates of withdrawal symptoms vary between studies and classes of psychiatric medication. According to one systematic review, more than 50% of individuals experience withdrawal symptoms upon stopping antidepressants (175). Higher rates were reported by studies involving individuals withdrawing antipsychotics and benzodiazepines, 72% (n=421/585 people) and 78% (n=545/697 people) respectively (180, 181). It has been postulated that their rate of occurrence is more common than reported due to the potential for misdiagnosis as relapse (175). Withdrawal symptoms are not synonymous with the terms relapse or addiction (99). The confusion in diagnosis may be partly

attributable to guidelines which previously characterised withdrawal symptoms as "*mild and self-limiting",* unlikely to persist for longer than one to two weeks (175, 179). Withdrawal symptoms have the potential to form part of a withdrawal syndrome which can be acute or persistent in nature (182). When withdrawal symptoms persist for months or years after reducing or stopping the medication, acute withdrawal transitions into a protracted withdrawal syndrome (182).

2.7.4.2 Relapse

Fear of relapse is another major barrier to discontinuing psychiatric medication (183). In a study involving individuals taking antipsychotics, 70% (n=92/132) of those who did not want to discontinue antipsychotics gave the reason fear of relapse (154). Relapse is defined as the recurrence of a mental illness after a period of improvement (184). Relapse presents in different ways depending on the underlying condition. For example, in schizophrenia it may present as an acute psychotic exacerbation (184), whereas in depression it may present as another depressive episode (185).

Relapse can be withdrawal-associated or endogenous. Withdrawal-associated relapse is typically characterised by early onset of symptoms presenting in the weeks or months following drug cessation (162). This was demonstrated by one study involving individuals withdrawing from antipsychotics in which the relapse rate in the first year after discontinuation was roughly double that after the second year (162). The risk of relapse was highest in the first twelve months after withdrawing antipsychotics compared to longer follow up assessments (162). Withdrawal-associated relapse supports the theory that a causal relationship exists between stopping the medication and relapse. In line with this theory, the neuroadaptations causing relapse can take years to resolve following discontinuation of the medication (162). However, relapse is not restricted to discontinuation of medication; it has also been observed during maintenance treatment. This is considered endogenous relapse whereby the individual's symptoms re-emerge despite ongoing pharmacological treatment. This was demonstrated by a meta-analysis of clinical trials which found that while the relapse rate was lower in individuals who continued antidepressants compared to those who discontinued, the risk was not zero (186).

It has been hypothesised that the process of withdrawal can affect the relapse rate (186). One study involving individuals discontinuing benzodiazepines found a lower relapse rate in those who had tapered alone (30.8%, n=15/47) or in combination with psychological interventions (33.3%, n=16/47) compared to those who had only used psychological interventions and did not taper (69.2%, n=33/47) (187). Similar findings were published by a study involving individuals stopping antipsychotics (162). More gradual dose changes have been purported to lower the relapse rate by allowing more time for neuroadaptations (162). Other factors that may affect the relapse rate include the class of psychiatric medication, dosing schedule, and the duration of treatment (186).

Several trials have sought to compare the relapse rate in individuals who continued taking psychiatric medication versus those who discontinued treatment. One trial involving individuals taking antidepressants found a higher relapse rate of 56% (n=267/478) in individuals who had stopped antidepressants compared to those who continued their medication at 39% (n=187/478) (188). A study involving individuals taking antipsychotics reported similar findings; the relapse rate of 52% (n=2270/4365) was higher in those who stopped treatment compared to 16% (n=699) in those who had continued treatment (184). With respect to benzodiazepines, studies have reported relapse rates exceeding 50% in individuals who stopped benzodiazepines at follow-ups (187). One clinical trial reported a relapse rate of 43% (n=20/47 patients) during a two-year follow up (187). Despite the portrayal of maintenance treatment as a protective factor against relapse, most of these trials have been contested due to similar concerns and inconsistencies raised in Section 2.5.1., particularly trial duration. Most trials stop the medication over a number of weeks which contradicts the clinical guidelines. As outlined in Section 2.7.3, guidelines recommend the slow discontinuation of psychiatric medication over months or years (159). These inconsistencies pose challenges in determining the true prevalence of relapse. While there is potential for relapse upon taking and discontinuing psychiatric medication, fear of relapse should not be the only reason an individual takes psychiatric medication long term.

2.7.4.3 Availability of pharmaceutical dosage forms

The lack of suitable pharmaceutical dosage forms is a major practical challenge that individuals face when trying to taper psychiatric medication (138). As previously discussed

in Section 2.7.2.1., tapering involves gradual dose reductions requiring small incremental dose adjustments. Given that most psychiatric medications are only commercially available in solid dosage forms (i.e., capsules and tablets) that are not specifically designed to facilitate tapering, this has created challenges in making accurate dose reductions and alterations (161).

Individuals have employed different approaches to overcome this major practical issue. Some individuals switched to similar drugs within the same medication class with longer half-lives and are available in liquid form to enable slower tapering (138, 147). Given that drugs with longer half-lives take longer to leave the body, it has been proposed that they reduce the potential for withdrawal symptoms by allowing more time for neuroadaptations between dose reductions (159). For example, an individual tapering an antidepressant may switch to fluoxetine or citalopram with their longer half-lives and availability in liquid form. Similarly, an individual tapering a benzodiazepine may switch to diazepam (147). While the evidence base to support these switches is limited (138), it was recommended by the NICE guidelines published in 2022 (170). Other individuals are attempting do-it-yourself tapering methods, manipulating pharmaceutical dosage forms themselves by splitting or crushing tables, or making up liquid formulations to achieve the doses required to taper (138). These dose alterations require many dose calculations and conversions which can become complicated. While a number of dose calculators and conversion scales are available on websites such as BenzoBuddies and survivingantidepressant.org, none of these have not been validated. Tapering strips have also been developed to try and overcome some of these challenges (189). Tapering strips contain fixed doses of the psychiatric medication in tablet form packaged into daily pouches of incrementally decreasing strength (138). While tapering strips would appear to offer a simple and straightforward method of achieving a gradual dosage reduction, their availability is limited to a small number of countries and the evidence to support their use is limited to observational studies (138).

2.8 Summary

Chapter 2 provided a general overview of relevant literature on the prescribing and discontinuation of psychiatric medication to give context to the thesis and its individual

chapters. The next chapter discusses the concept of Public and Patient Involvement (PPI) in research and outlines the steps involved in the Priority Setting Partnership (PSP) methodology conducted as part of Study 1.

Chapter 3: An overview of the Priority Setting Partnership Methodology

3.1 Introduction to Chapter 3

Chapter 3 focuses on the Priority Setting Partnership (PSP) study (Study 1) that was conducted to identify priorities for future research on reducing and stopping psychiatric medication. The James Lind Alliance (JLA) PSP methodology guided this process. This chapter provides a general overview of the PSP methodology and discusses the rationale for choosing this methodology. Patient and Public Involvement (PPI) is relevant to all areas of research, particularly mental health research (12). This chapter also presents an overview of PPI and outlines the link between PPI and the PSP methodology.

3.2 The PSP Methodology

The JLA guidance on PSPs helped to shape the research approach and development of the study protocol (190). The JLA is a non-profit initiative that was established in 2004 specifically to help achieve meaningful patient[1] involvement in research priority setting (15). The JLA has developed a structured process known as the PSP methodology for research teams to follow when developing future research priorities (191). The PSP methodology aims to identify and prioritise unanswered questions i.e., 'evidence uncertainties', in specific conditions or areas of healthcare through a combination of surveys and interactive workshops between people with lived experience, carers, and health care professionals. The PSP methodology adheres to a set of five underpinning principles: transparency of process, balanced inclusion of stakeholders' interests and perspectives, exclusion of non-clinician researchers for voting purposes, exclusion of

[1] The JLA use the term "patient"; however, this term was replaced with "people with lived experience" to remain consistent with other chapters in this PhD thesis.

those with significant competing interests such as pharmaceutical companies, and a maintained audit trail (192).

The PSP methodology comprises seven key steps, as illustrated in Figure 3.1, and outlined in greater detail in Sections 3.2.1 to 3.2.7 below. Briefly, the first steps involve establishing a Steering Group comprising key stakeholder representatives and identifying potential partners to assist with promoting the study. An anonymous survey is conducted to gather key stakeholders' uncertainties about the condition/topic of interest. Survey responses are summarised, reviewed, and checked against existing evidence. Unanswered questions are prioritised in a second anonymous survey. The most highly prioritised questions are discussed as part of the final prioritisation workshop involving the Steering Group and additional collaborators representing the key stakeholder groups, and the Top 10 priorities are agreed. The results of the study are then disseminated as part of a detailed dissemination plan. While the PSP methodology is a structured process, the JLA permits research teams to adapt the PSP methodology to suit the needs of the individual PSP study (193).

Figure 3.1: Overview of the Priority Setting Partnership (PSP) process

3.2.1 Step 1: Establishing the Steering Group

The first step involves establishing the Steering Group. The Steering Group has several roles which include overseeing and guiding the PSP study in accordance with the JLA guidance, agreeing the PSP's strategic orientation also known as the "scope" of the PSP, and promoting engagement from the key stakeholders in terms of the two surveys and the final prioritisation workshop (191).

3.2.1.1 Recruitment

The Steering Group comprises representatives from the key stakeholder groups. Key stakeholders typically include people with lived experience of the condition/topic, family members/friends/carers/supporters, and healthcare professionals. Members of charities or professional organisations relevant to the PSP study can also be recruited. There is no single approach for recruitment recommended in the JLA guidance. That said, recruitment typically involves identifying eligible individuals through individual and professional networks and other organisations with links to the condition/topic and inviting them to participate. Two documents are shared with all Steering Group members upon their recruitment: the Interests and Privacy Form and the Terms of Reference to capture any potential conflicts of interest and agree to the code of conduct.

3.2.1.2 Steering Group meetings

Regular Steering Group meetings are encouraged to maintain transparency and engagement throughout the PSP study. All meetings are chaired by an independent advisor appointed by the JLA. Additional roles of the JLA Advisor include ensuring that the JLA's five overarching principles are upheld and providing guidance throughout the PSP study. The purpose of the initial meetings is to discuss and agree on the scope of the PSP study. The scope is defined as the patient population of interest and the breadth of the topic and will ultimately determine which questions submitted in the Round 1 survey (Step 2) will be included in the final analysis (i.e., will be converted to a summary question and taken forward to later steps). The scope is agreed and finalised by the Steering Group prior to the dissemination of the Round 1 survey and subsequently helps to guide the focus of data analysis (Step 3) and Steering Group discussions.

3.2.1.3 Identifying and inviting potential partners

Potential partners affiliated with key stakeholder groups are identified and invited to support the PSP process. Partners are organisations or interest groups that represent members of the key stakeholder groups. Examples include charities, support groups, and professional organisations involved in the care of people with the health condition. The role of partners is to disseminate information about the study to their members and affiliates, including dissemination of the two surveys to potential respondents (191). An overview of all the stakeholders typically involved in a PSP study is illustrated in Figure 3.2.

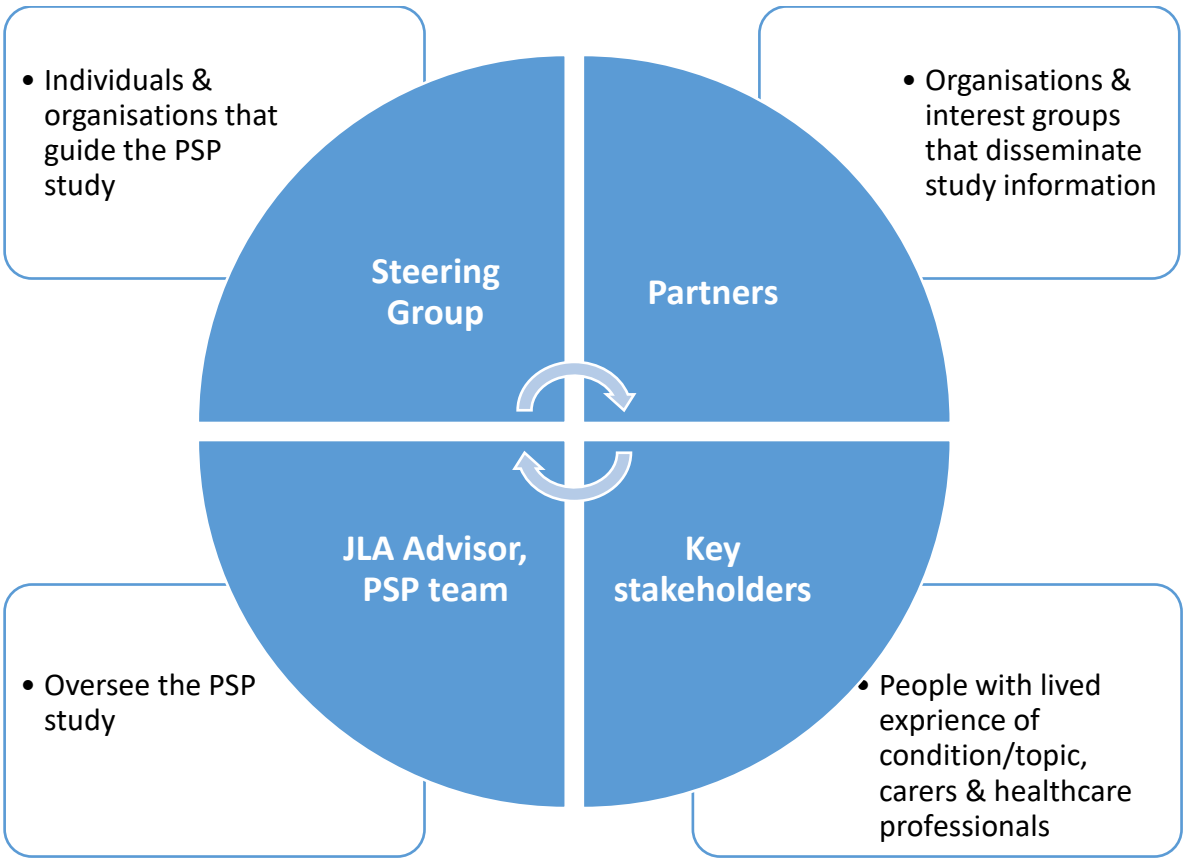

Figure 3.2: Overview of the stakeholders involved in the Priority Setting Partnership (PSP) study

3.2.2 Step 2: Gathering evidence uncertainties (Round 1 survey)

An anonymous survey is created and shared to gather uncertainties about the condition/topic of interest. The target population of survey respondents is diverse and mirrors the stakeholder groups represented by the Steering Group members. Despite previous claims that surveys only produce "*thin and perfunctory data*" when compared to qualitative interviews, Braun supports the use of surveys as a method to collect text based or qualitative data given their potential to harness rich and complex data (e.g., respondent's experiences and discourses) (194 p.642). Qualitative surveys consist of a series of open-ended questions that focus on a particular topic of interest. They are self-completed by respondents. Additional benefits offered by qualitative surveys include their ability to capture a diversity of perspectives, to give a voice to individuals who may be hesitant to share their perspectives at meetings, and to offer self-anonymity, which is especially useful for sensitive or polarised topics. They are also time efficient and cost effective (194, 195).

While the JLA permits the use of both online and paper-based surveys, as well as face-to-face consultations (i.e., interviews or discussion groups) for individuals who are not able to access or contribute electronically, online surveys are the most used method to gather evidence uncertainties. There are no guidelines to which all qualitative surveys must follow; however, the JLA encourages the inclusion of an open-ended question, or questions, which ask respondents to share their questions/uncertainties about the condition/topic of interest. The inclusion of demographic questions is also recommended to ascertain the diversity of respondents (e.g., stakeholder group, age, gender, and country of residence). Unlike a qualitative interview topic guide which may be adapted during each interview, surveys are more rigid by nature. Therefore, careful considerations are given to the wording of the questions and the survey length to minimise the potential for ambiguity, disengagement, and survey fatigue (194, 195).

There are no formal target sample sizes for a PSP survey. Surveys can remain open for weeks or months. The number of survey responses being returned by stakeholder groups is monitored on a weekly basis. If response rates for specific stakeholder groups are lower than others, efforts are made to target the promotion of the survey towards the under-represented groups. Surveys can be disseminated and promoted in various ways (e.g.,

newsletters, email networks and online message boards), however, a multi-strand approach is recommended (191).

3.2.3 Step 3: Summarising the responses gathered

The responses submitted to the Round 1 survey (Step 2) consist of uncertainties and questions about the condition/topic of interest. While there is no standardised approach to managing and processing survey responses, the JLA recommends a five-step approach. Firstly, all survey responses are downloaded and sorted. Questions classed as "out of scope" are excluded from this list and kept separately. Eligible survey submissions are categorised by grouping similar submissions together and combining duplicate submissions to reduce the volume of data. These submissions are refined and translated into summary questions which are taken forward to the evidence checking step (Step 4) and verified as uncertainties. To ensure that the raw survey data is being interpreted appropriately and that summary questions are clear, indicative, and addressable by research, the Steering Group agrees on the chosen approach and oversees of the whole data analysis process.

3.2.4 Step 4: Evidence checking

The purpose of this step is to check the new summary questions (Step 3) against the existing evidence to ascertain to what extent these questions have, or have not, been addressed by previous or ongoing research. The JLA recommend that relevant and reliable databases are searched for high quality evidence. This includes systematic reviews and evidence-based guidelines published within the last three years. A review is judged to be systematic when explicit methods were used to search, select, critically appraise, and synthesise individual studies. The JLA considers the following four sources to be reliable: The Cochrane Database of Systematic Reviews, National Institute for Health and Care Excellence (NICE) guidelines, Scottish Intercollegiate Guideline Network clinical guidelines

and the relevant Royal Colleges' guidance[2]. The Steering Group discusses and agrees on an appropriate strategy for checking all relevant evidence for the condition/topic of interest, i.e., the types and sources of evidence that will be searched. This strategy is documented in the Question Verification Form which is published on the JLA website for each specific PSP study.

Questions that are not adequately addressed by previous research are considered to be "verified uncertainties", which are then collated and recorded on a standard JLA template. The source of verification is cited for each uncertainty, e.g., the systematic review identified as being relevant. These uncertainties form the basis of the Round 2 survey (Step 5). Questions to which the answers have already been identified are not considered uncertainties. A record of the questions that have been addressed by previous research is also be kept and published to inform future awareness-raising exercises and education programmes.

3.2.5 Step 5: Interim prioritisation (Round 2 survey)

A second anonymous survey is conducted to identify which of the unanswered summary questions are considered most important by the same key stakeholder groups. Individuals can respond to the survey irrespective of whether they completed the previous survey. The questions are ranked based on the frequency with which they had been selected by each stakeholder group. Once the analysis is complete, the Steering Group review the findings and identify the most highly ranked questions across the three key stakeholder groups. The JLA recommends that up to 25-30 questions are taken forward to the final prioritisation workshop (Step 6).

[2] The Royal College of Psychiatrists guidance was searched. The JLA recommend that the Relevant Royal Colleges' guidance is checked.

3.2.6 Step 6: Final prioritisation workshop

The purpose of the final prioritisation workshop is to prioritise through consensus the most highly ranked questions from the Round 2 survey (Step 4). The JLA recommends a maximum of thirty workshop participants, comprised of Steering Group members and additional collaborators, all of whom represent one or more of the key stakeholder groups. Steering Group participation at this workshop offers several benefits; their oversight of the entire PSP study can lend credibility to the process, help to justify previous decisions, and clarify the questions that other participants may have. Observers and facilitators may also be present. Observers do not participate in any discussion; they simply observe the priority setting process. It can be advantageous for individuals from research or funding organisations who wish to gain an insight into the development of the research priorities to attend the workshop even though they do not participate directly in the decision-making process (191). Facilitators have a more active role, overseeing and moderating the small group and plenary sessions.

Bressen defines consensus *as "a cooperative process in which group members develop and agree to support a decision in the best interest of the whole"* (196). Given its collaborative nature, the consensus process has been shown to strengthen participation of members and produce higher quality decisions (197). Two commonly employed approaches to reaching consensus are the Delphi technique and the Nominal Group Technique (NGT). The Delphi technique typically involves a questionnaire which is completed over multiple rounds with feedback showing both individual respondents' responses and group level responses. The questionnaire typically takes place over the course of weeks, or months and is completed remotely (198). The Delphi technique lends itself well to the creation of guidelines (198, 199). Whereas the NGT involves direct interaction (face-to-face/online) which supports individual participants to share their views and perspectives by engaging in discussion. It typically involves small group and whole group "plenary" discussions during which participants complete several ranking exercises and reach a consensus. The NGT is a well-established and well-documented approach to decision making used by groups that want to make decisions quickly in a way that pays consideration to all participants' opinions (199). By preventing the domination of discussion by a single participant and encouraging the participation of less confident or

assertive members, this technique minimises the risk of creating a hierarchy amongst participants. The NGT is a highly adaptable and versatile method for identifying research priorities (200). The collaborative nature of this technique is consistent with the more modern, rights-based approach to mental health research, aligning with the principles of Public and Patient Involvement (PPI) and the JLA. More information on PPI is outlined in a subsequent section. For these reasons, the NGT is the JLA's recommended approach for determining the Top 10 priorities (191). As previously mentioned, the consensus process is typically moderated by a facilitator whose role is to support individual group members to share their views and perspectives whilst remaining neutral *"in word, deed, and appearance"* (196). Facilitators' approach is neutral and inclusive and has no influence over the outcomes of the discussions. JLA workshops are moderated by JLA facilitators and/or JLA-trained facilitators to ensure fairness, transparency, and accountability.

3.2.7 Step 7: Publish and promote the Top 10 research priorities

There is no universal formula that PSP studies can follow to guarantee a successful outcome. Previous PSP studies have taken various approaches to disseminate their findings (e.g., a launch event, using email lists of PSP survey participants, and giving public talks to key stakeholder groups) (201). A comprehensive dissemination plan is developed in consultation with the Steering Group to identify the target audiences and how best to reach them, and how the Steering Group and partners can engage with dissemination activities. Once the Top 10 priorities have been determined, the results are published on the JLA website and reported to various research funding and agenda setting organisations, as per the dissemination plan. A manuscript based on the PSP findings is submitted for publication in a peer reviewed open access journal, and a pre-print can be uploaded to an open access repository for immediate access.

3.3 Rationale for choosing the PSP methodology

The PSP methodology was chosen for several reasons. Firstly, it is a well-established methodology that is considered the "gold standard" for setting research priorities in terms of respecting all stakeholders involved in the process (202), positioned between the

priority setting and partnership frameworks (192). To date, over fifty PSP studies have been undertaken across a wide range of medical conditions worldwide (193).

Secondly, a hallmark of the PSP methodology is the representation of all key stakeholder groups throughout the priority setting process. Equitable involvement of the key stakeholders has been shown to facilitate the process of setting research priorities by developing a more holistic understanding of the 'unknown unknowns' and enables co-production (15). Co-produced research is research that has been produced by researchers and individuals with lived experience working together. Co-production has been widely advocated as a means of valuing and respecting knowledge from different sources and stakeholders, and thus promoting inclusive research practices and strengthening research impact (15). Co-produced research can improve the allocation of research funding and resources and improve the legitimacy and usefulness of research and achieve better health outcomes (8).

Finally, the PSP methodology is also in line with international best practice of PPI in research (15) which is described in more detail in the next section. The PSP methodology depends on the involvement of individuals with lived experience. Unlike previous studies which merely invite these individuals to the research table when the research agenda has already been set, this methodology allows them to have an active role in submitting and prioritising the research questions.

3.4 Public and Patient Involvement and the PSP

As outlined above, a core aspect of the PSP study is the equitable involvement of different stakeholders, including people with lived experience of the condition/topic of interest, or patients, which is often termed PPI. PPI is a form of collaborative research practice and refers to research that is done 'with' or 'by' people with lived experience or members of the public rather than 'to', 'about' or 'for' them (12). PPI adopts a rights-based perspective that recognises service users' rights to have an input in research that sees patients and members of the public as active partners in the design, delivery, and dissemination of research (12).

Staley et al. made three arguments to support PPI in research (201). Firstly, PPI aligns with the ethical principles of research that individuals affected by a condition, or medication, should have an input in research decisions that may affect them. Secondly, PPI improves the efficiency and value of research through the creation of more relevant and patient-centred research outputs which in turn improves population health and research allocation (203, 204). And finally, by supporting stakeholders to form alliances and address power imbalances, PPI improves accountability and transparency (205). However, incorporating PPI into the research process can also create challenges (13, 204). PPI can place additional strains on resources, time, and costs which may slow down the research process. By bringing together stakeholders with different backgrounds, and nationalities, PPI can create potential for conflict and miscommunication (13, 204). PPI has also been scrutinised for tokensim and exclusivity (12). When the level of PPI becomes variable after funding is secured, recruitment of people with lived experience or patients may become tokenistic, serving as a tick box exercise (206). Exclusivity involves narrow PPI selection processes which exclude those with the most to offer/gain from the decision-making, restricting the pool of ideas for improvement and limits the opportunity to break cycles of suboptimal care and services (12).

There are three levels of PPI in research (206): low, medium, and high. Low levels of PPI, also known as “consultation”, do not permit people with lived experience to partake in the active decision-making process. By regarding people with lived experience as active partners and forming equal partnerships between the stakeholder groups, the PSP methodology aligns with medium levels which are known as “partnerships”. To advance to the highest level of PPI is known as “shared leadership”, the process would have to give people with lived experience the dominant voice and allow them to manage and guide the research themselves.

Several attempts have been made to promote PPI in research. These include frameworks and supportive policy contexts (192, 206, 207). In the United Kingdom (UK), two frameworks were created; the “4Pi national involvement framework” developed by the National Involvement Partnership (206), and the National Institute of Health Research’s UK Standards for Public Involvement (208). The National Institute of Health Research is the British government's major funder of clinical, public health, social care, and

translational research. In Ireland, the Health Research Board (HRB) and Irish Research Council, two national research agencies, launched the joint call in 2017entitled “PPI Ignite” to support higher institutions to embed PPI in their organisational culture (209). Proof of PPI input also became a funding requirement for approval by most research funders, including the National Institute of Health Research and the HRB. As part of Trinity College Dublin’s (TCD) commitment to promote PPI across the university and involve people with lived experience, carers, and members of the public in health-related research, a PPI Ignite office was set up in TCD in 2017.

PPI takes on a particular significance in mental health as traditionally mental health research was solely conducted by the “experts”, as previously outlined in Chapter 2. This is regarded by many as a form of “epistemic injustice”, one in which individuals diagnosed with mental illness were discredited and refused the right to engage in knowledge production (8-10). More recently, there has been a paradigm shift in mental health research towards a more participatory model which integrates people with lived experience into the research process from an early stage (12, 13, 210). By placing an emphasis on collaborative research practice, PPI aligns with this more modern, collaborative model. PPI has been shown to offer additional benefits in mental health research (211). PPI is purported to reduce symptom severity, improve personal recovery, mental health literacy and provide a sense of empowerment for the individuals with lived experience. It has also been posited that PPI can improve recruitment, researchers’ knowledge, priorities, and lay communication skills which can serve to enhance team performance and create more useful research outcomes (206).

While PPI supports the active contribution of individuals with lived experience through discussion and involvement in decision making, the level of their involvement in research is variable (15). A survey commissioned by the International Alliance of Mental Health Research Funders found that most involvement of people with lived experience in health research has traditionally taken place at the level of feedback and information giving (i.e., “consultation” stages) (212). This aligned with other studies that explored people with lived experience perspectives and reported feelings of being marginalised in the research process (213). Consequently, people with lived experience of mental illness report difficulties in sharing their views and influencing the research agenda (214). These views

have been recognised, and additional efforts have been made to support service user involvement in mental health care planning. Examples include supportive policy contexts such as the UK mental health policy (213), and the guidance document jointly produced by the World Health Organization (WHO) and United Nations (14). Several frameworks have also been developed to promote and support PPI in research which include priority-setting frameworks (as per the JLA PSP methodology outlined above), power-focused frameworks (typically academically led and are interested in addressing power imbalances, values, and hidden motives), and study-focused frameworks (typically use a theory-based, more realist approach to explore link between context, mechanism and outcome) (192). The aim of priority-setting frameworks is to involve people with lived experience and members of the public in setting research priorities in a structured and transparent way.

3.5 Strengths & Limitations

Two major strengths of the JLA's PSP methodology are its rigorous framework and the assignment of a JLA Advisor to ensure adherence to the JLA's five core principles. The framework creates a transparent and reproducible methodology. The JLA Advisor oversees and guides the entire PSP study. By supporting the inclusion of the lived experience group throughout the entire process, the JLA methodology upholds the principles of PPI, aligning with the more modern rights-based, collaborative approach to mental health research. The credibility in the methodology and the potential impact of the Top 10 lists of priorities have been recognised by the National Institute of Health Research which has a rolling call for applications from researchers wanting to address priorities identified by JLA PSPs (191). In terms of limitations, the JLA PSP methodology has potential to create barriers to accessibility and representativeness. With respect to accessibility, for an individual to participate in the surveys, they must be able to receive, read, and comprehend written instructions and be capable of writing or typing their questions or uncertainties (15). Representativeness refers to the representation of all three key stakeholder groups in the responses. While equal representation is optimum, this is difficult to achieve. In an effort to improve representativeness, the JLA recommend

that survey responses are monitored on a weekly basis and efforts targeted to the underrepresented stakeholder groups are employed when necessary.

3.6 Summary

Chapter 3 provided a general overview of the Priority Setting Partnership (PSP) methodology which guided the PSP study (Study 1). The PSP methodology is a well-established methodology comprised of seven key steps used for setting research priorities. It was chosen as a method for Study 1 because it aligns the principles of PPI and the more collaborative approach to mental health research in terms of respecting all stakeholders involved in the process. The next chapter provides a more in-depth description on how the PSP methodology was operationalised to achieve the objectives in Study 1.

Chapter 4: Operationalising the methods for the Priority Setting Partnership Study

4.1 Introduction to Chapter 4

Chapter 4 focuses on a Priority Setting Partnership (PSP) study (Study 1) that was conducted to identify priorities for future research on reducing and stopping psychiatric medication. The James Lind Alliance (JLA) PSP methodology that was described in Chapter 3 guided this process. The chapter commences by outlining the aim and objectives of the study which is followed by an in-depth description of how the PSP methodology was operationalised. Any points of deviation from the JLA guidance are highlighted and justified. The chapter concludes with a discussion on ethical issues and rigor and how they applied to the PSP methodology.

4.2 Aims and Objectives

The aim of Study 1 was to determine the Top 10 priorities for future research on reducing and stopping psychiatric medication in collaboration with the three key stakeholder groups: people with lived experience of taking and/or stopping psychiatric medication, family members/friends/carers/supporters, and healthcare professionals. The term "priorities" encompasses all the unanswered research questions and uncertainties submitted to the Round 1 survey and prioritised in the Round 2 survey and final prioritisation workshop. The objectives were to:

- identify uncertainties and questions about reducing and stopping psychiatric medication that are most important to the three stakeholder groups.
- co-produce the Top 10 list of research priorities about reducing and stopping psychiatric medication by working collaboratively with the three stakeholder groups.
- publicise and share the Top 10 list of research priorities with research funders and researchers.

4.3 Methods for the PSP Study

Study 1 comprised seven key steps as outlined in Figure 4.1. The REporting guideline for PRIority SEtting of health research (REPRISE) was used to guide the reporting of this study (8) (see Appendix 4.1). Once the PSP study was approved by the JLA, a JLA Advisor (TAG) was appointed, and the PSP study formally commenced.

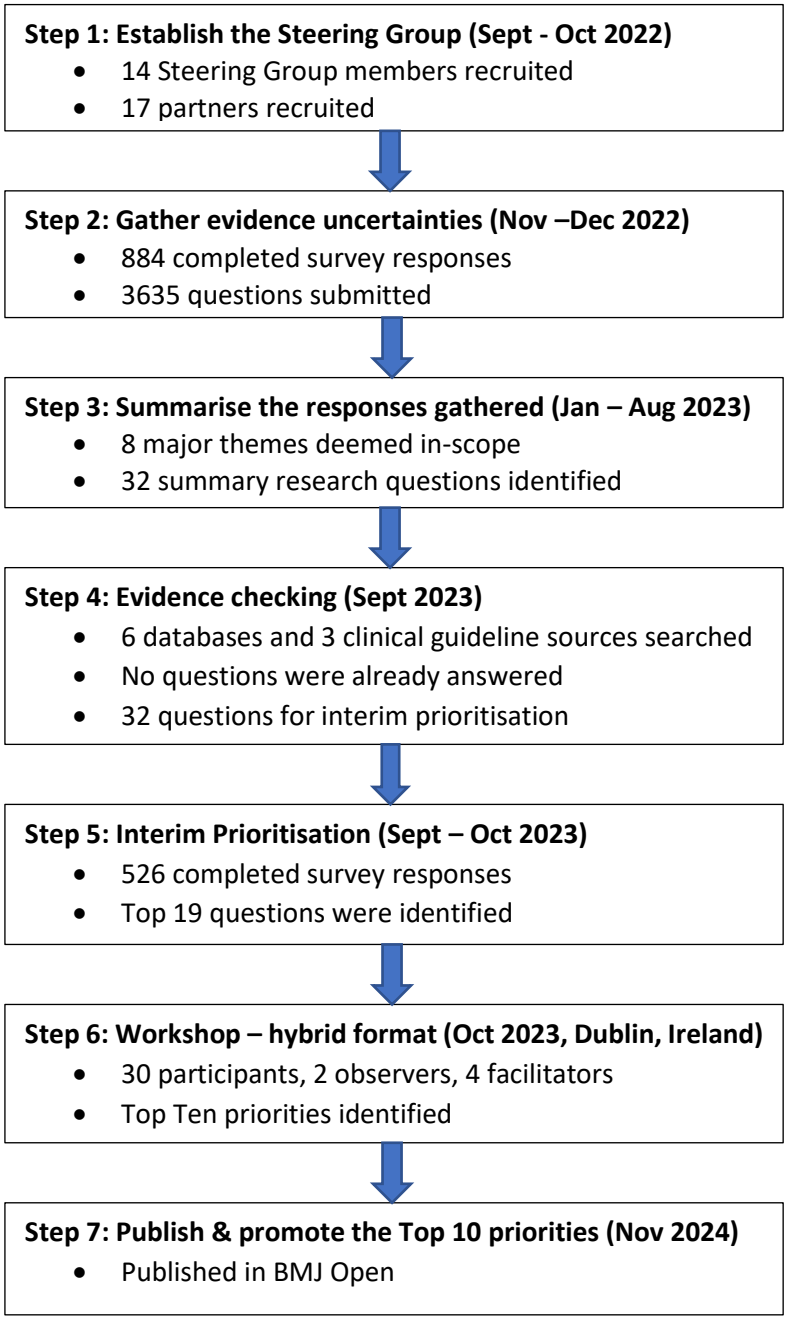

Figure 4.1: Overview of the James Lind Alliance Priority Setting Partnership (PSP) process

4.3.1 Step 1: Establishing the Steering Group

4.3.1.1 Recruitment of Steering Group members

Steering Group members were recruited through an iterative process. Individuals were identified through the researcher (MB) and supervisory team's (AH, CC) network of contacts, charities, and support groups representing the stakeholders involved in the Steering Group. These individuals received an email from the supervisory team to ascertain their interest in joining the Steering Group. Individuals were invited to attend a preliminary online meeting at which a more in-depth overview of the study aim, and methodology was provided. Individuals were asked to nominate other individuals who could make a meaningful contribution to the study. Prior to finalising the Steering Group membership, a gap analysis was undertaken to identify any groups or individuals that were not adequately represented. The gap analysis identified three groups who were under-represented: (1) People representing ethnic minorities, (2) People with lived experience of taking and/or stopping antipsychotics, and (3) People with lived experience of benefiting from psychiatric medication. Some progress was made with recruiting individuals representing the first two groups. However, efforts to recruit individuals with lived experience of benefiting from psychiatric medication were unsuccessful. This was noted as a limitation of the study. The Steering Group members' involvement in the recruitment process helped to ensure that the membership was not solely informed by the researcher and supervisory team. Due to resource constraints, there was no reimbursement for study participation. This was made clear to all participants during the recruitment process.

The final Steering Group comprised 14 members from four countries (Ireland, Sweden, United Kingdom, United States of America) representing the three stakeholder groups: people with lived experience of taking and/or stopping psychiatric medication (n=5, 36%) family members/carers/supporters (n=2, 14%) healthcare professionals (n=6, 43%), and other (n=1, 7%). The member marked as "other" was a representative of a national research funding body in Ireland. The rationale for their inclusion was to help raise awareness of the Top 10 priorities when guiding future research and informing policy. Several Steering Group members had dual roles (e.g., healthcare professional with lived

experience of psychiatric medication use/discontinuation). An overview of the Steering Group composition is presented in Table 4.1. By supporting the involvement of people with lived experience and regarding all members as equal experts, the establishment of the Steering Group embodied/upheld the principles of Patient and Public Involvement (PPI), outlined in Chapter 3, throughout the entire PSP process.

Table 4.1: Overview of the Steering Group composition

Steering Group members	n (%)
Gender	
Male	**5 (36%)**
Female	**9 (64%)**
Stakeholder group	
Person with lived experience	**5 (36%)**
Family member, friend, carer, supporter	**2 (14%)**
Healthcare professional	**6 (43%)**
Other	**1 (7%)**
Healthcare professional group	
General Practitioner/Primary care physician	**1 (17%)**
Nurse	**1 (17%)**
Pharmacist	**1 (17%)**
Psychiatrist	**3 (50%)**
Country of origin	
Ireland	**4 (29%)**
Sweden	**1 (7%)**
United Kingdom	**6 (43%)**
United States	**3 (21%)**

4.3.1.2 Steering Group meetings

Steering Group meetings were conducted online via Zoom. Meetings were scheduled at regular intervals between September 2022 and December 2023 to maintain transparency and promote engagement. The JLA Advisor chaired all Steering Group meetings. It was agreed at the outset that a minimum of three members each representing those with lived experience (i.e., people with lived experience of taking and/or stopping psychiatric

medication and family members/friends/carers/supporters) and those with clinical experience (i.e., healthcare professionals) would need to be present to have a quorum. A quorum represents the minimum number of members necessary to constitute the group at a meeting and make decisions related to the study. Prior to each meeting, a Doodle poll was shared to determine the date/time that suited most members. Meeting agendas and summary notes were shared with all members before and after each meeting by the researcher (MB), respectively. No meetings were cancelled because of the absence of a quorum. Decisions were made using group consensus, after everybody's viewpoint was heard. While there were differences of opinion expressed, arriving at a group consensus was not difficult.

4.3.1.3 Identifying and inviting potential partners

Potential partners affiliated with key stakeholder groups (described above) were identified through the supervisory teams' and Steering Group's network contacts. Potential partners were emailed a brief study overview by the supervisory team and invited to formally partner with the study. The final list of partners was composed of 17 national and international service user/carer organisations, charities, and professional bodies. Two examples of service user organisations successfully recruited were Mad in America and the International Institute for Psychiatric Drug Withdrawal which support individuals tapering psychiatric medication. The partners were listed on the study's website (www.tapersafer.org) with direct links to their individual websites. The names and mission statements of the partners are outlined in Table 4.2. No organisations affiliated with the pharmaceutical industry were included as partners. Previous studies have cautioned against the collaboration between pharmaceutical companies and patient organisations in light of the potential for ethical challenges. These challenges include negative influences on patient advocacy and creation of industry-driven inequalities across these organisations (215). This aligned with the JLA principle of transparency (191).

Table 4.2: Names and mission statements of the partner organisations

Name of organisation	Mission statement
Alliance for Benzodiazepine Best Practices	"To illustrate the problems associated with benzodiazepines, illuminate alternatives to their use, and provide tools for clinicians to assist benzodiazepine withdrawal syndrome sufferers."
Benzodiazepine Information Coalition	"To break the stigma and raise awareness around prescribed benzodiazepine injury, provide a voice to the patients who are suffering, and facilitate research and access to competent, evidence-based medical care for those impacted by benzodiazepine induced disability."
Benzodiazepine Action Work Group	"To increase benzodiazepine safety through education, patient support, and informed prescribing and deprescribing practices."
Council for Evidence-based Psychiatry	"To communicate evidence of the potentially harmful effects of psychiatric drugs to the people and institutions in the UK that can make a difference."
Data Based Medicine	"To raise the profile of this interlocked set of problems and the need for Data Based Medicine."
Easing Anxiety	"To manage anxiety and the complications of anxiety medication (benzodiazepines and Z-drugs)."
European Federation of Associations of Families of people with Mental Illness	"To represent all family members of persons affected by severe mental ill health at European level so that their rights and interests are recognised and protected."
GROW Mental Health Movement	"To create new hope, a sense of identity, meaning, and valued connection by empowering people to nurture their positive mental health and well-being, by supporting personal growth, and establishing a path to recovery through education, self-teaching, and peer support."
Health Research Board	"To support research that improves people's health, promotes evidence-informed care and creates solutions to societal challenges."
Inner Compass Initiative	"To help people make more informed choices about psychiatric diagnoses and drugs and build community with like-minded others thinking critically about today's mental health industry."

Table 4.2 [continued]: Names and mission statements of the partners

Name of organisation	Mission statement
International Institute for Psychiatric Drug Withdrawal	"To respond to a glaring need in mental health: to develop ways for helping people withdraw from psychiatric drugs."
Irish Association of Social Workers	"To advance the interests of our members, the profession and service users; working with our members and partner bodies for enhanced wellbeing, human rights, social justice, and equality for all."
Medicating Normal	"To present one very important and predominantly untold story so that as a society we can begin a meaningful, informed nationwide discussion about what it means to be fully human and mentally well."
MedShadow	"To empower individuals with the knowledge necessary to make informed decisions about their health, ensuring they are equipped to assess the risks, benefits, and alternatives of medicines."
Mental Health Reform	"To be the unifying voice that leads progressive and wide reform towards human rights-based mental health services and supports in Ireland."
Psychiatric Nurses Association	"To promote psychiatric-mental health nurses, improve mental health care for culturally diverse individuals, families, groups, and communities, and shape health policy for the delivery of mental health services."
Reconnexion	"To provide counselling and support for people dependent on benzodiazepines (tranquillisers and sleeping pills) and to raise awareness of the risk of dependency associated with long-term prescribing of these drugs."

4.3.1.4 Defining the scope

The purpose of the initial Steering Group meetings was to define the scope of the study (i.e., the population of interest and the breadth of the topic) (216). Initially, the scope was limited to three classes of psychiatric medication: antidepressants, antipsychotics, and benzodiazepine receptor agonists. The Steering Group noted that several classes of psychiatric medication are often used for multiple different conditions (including off-label use). To be inclusive, it was agreed that all classes of psychiatric medication should be considered within the scope of the study (i.e., antidepressants, antipsychotics, benzodiazepine receptor agonists, gabapentinoids, and stimulants). The point was also made that tapering is relevant to all individuals taking psychiatric medication regardless of the diagnosis or indication. There was consensus that the use of psychiatric medication for both physical and mental health problems should be considered within scope. The feasibility of making the surveys available in different languages was also discussed. Due to resource constraints, it was agreed that the PSP surveys would only be made available in the English language but would be shared internationally via the Steering Group's members' networks, partner organisations and on social media.

The initial study name was "PRiOrities for fuTure rEsearch on tapering psychotropiC medicaTion: The PROTECT study". To improve comprehension amongst target stakeholder groups, the Steering Group modified the study terminology from "tapering psychotropic medication" to "reducing and/or stopping psychiatric medication". The study name was updated to reflect this change; "Priorities for future research on reducing and stopping psychiatric medication: The PROTECT study". A dedicated study website (www.tapersafer.org) was also created to provide study-specific information and to host the two online surveys (Steps 2 and 5 below). The website also provided information on the PSP study's team and collaborators (see Figure 4.2). A study protocol focused on Study 1 was peer-reviewed and published on HRB Open Research (190), the JLA website, and the study's dedicated website.

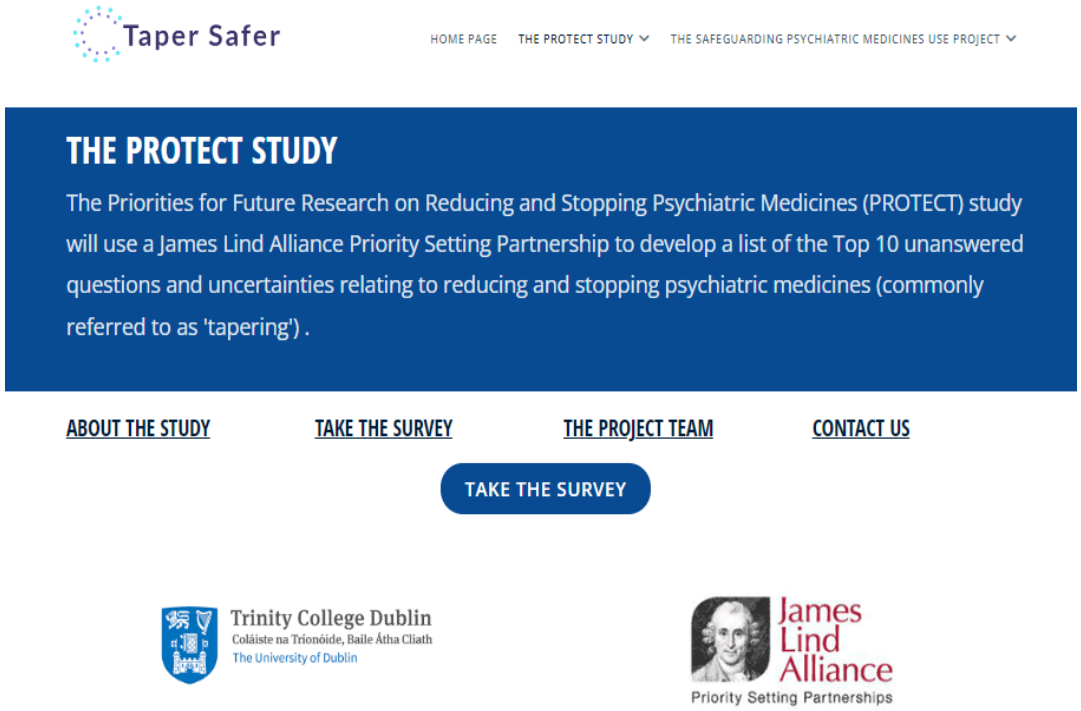

Figure 4.2: Screenshots of the study's website homepage (www.tapersafer.org)

Deviations from JLA guidance: The JLA recommend face-to-face Steering Group meetings. In this study, all Steering Group meetings were held virtually via Zoom to facilitate international representation. This decision was informed by a previous PSP study which used videoconferencing for all Steering Group meetings (193) and supported by the JLA Advisor.

4.3.2 Step 2: Gathering evidence uncertainties (Round 1 survey)

4.3.2.1 Development and piloting Round 1 survey

An anonymous online survey was used to capture research questions and uncertainties about reducing and stopping psychiatric medication from the three key stakeholder groups: people with lived experience of taking and/or stopping psychiatric medication, family members/friends/carers/supporters, and healthcare professionals. The survey design was informed by the JLA methodology. The survey was created in Qualtrics®, reviewed and piloted by the supervisory team and Steering Group for feedback purposes as recommended by previous literature (194). All Steering Group members were invited to pilot the Round 1 survey. Round 1 survey was piloted by 10 individuals representing the three stakeholder groups: people with lived experience of taking and/or stopping psychiatric medication (n=3, 30%), family members/friends/carers/supporters (n=2, 20%), healthcare professionals (n=5, 50%) (217). Compared to the final version of the survey, the pilot survey contained an additional feedback section which asked respondents to rate various aspects of the survey, e.g., the clarity of survey information and instructions on survey completion. Respondents were largely satisfied with the survey's format and the clarity of the questions. However, a number of modifications were made in light of the feedback received. Font sizes were increased throughout to improve readability, and text boxes were made to be expandable in the final version of the survey so that respondents could easily review their responses. A glossary of study-related terms was also created. This glossary defined the six classes of psychiatric medication considered within the scope and provided examples of each. The glossary was accessible on the study website, and a hyperlink to the glossary was inserted in the survey. Pilot responses were not included in the final analysis. The Steering Group also reviewed the Participant Information Leaflet (PIL) to ensure that it was accessible to all target respondents (see Appendix 4.2).

4.3.2.2 Survey design

The Round 1 survey comprised four sections; (1) Information about the survey; (2) Main survey question; (3) Demographic questions; (4) Additional comments/questions (see Appendix 4.3). Section 2 asked respondents to share their questions/uncertainties about reducing and stopping psychiatric medication as free-text responses with no word count limit. To be considered within the scope of the study, submitted questions had to relate to the decision-making process of reducing and/or stopping psychiatric medication, the methods used to reduce/stop psychiatric medication, the magnitude of dose reductions, and the withdrawal symptoms. Meanwhile, questions not related to the tapering of psychiatric medication (e.g., prescribing issues and mechanisms of action of psychiatric medication) were considered "out of scope" of the study. Section 3 asked respondents to provide some brief demographic information, e.g., age, gender, country of residence, and stakeholder group. Section 4 contained a free-text comments section where respondents had the option of adding any other comments about reducing and/or stopping psychiatric medication. Submissions to this section were analysed separately as detailed in Chapter 6.

4.3.2.3 Recruitment of survey respondents

The link to the online survey which was used in all recruitment activities directed individuals to the study website where they could also access the PIL (see Appendix 4.2). The survey was promoted using a multi-strand approach which included social media, newsletters, and emails. A dedicated Twitter account was set up (@TaperSafer). Snowball sampling was used to promote both surveys as it has been shown to be time-efficient, and effective at communicating with potentially vulnerable groups that are difficult to access (218). Steering Group members and partners were asked to complete the survey and share it with their networks to maximise the response rate.

The Round 1 survey was open for a total of eight weeks, from 4th November to 31st December 2022. There are no formal target sample sizes for PSP surveys (191). However, balanced representation of all stakeholder groups is desirable. Respondents' demographic profile was monitored on a weekly basis. After four weeks, it was noted that additional responses were needed from the healthcare professional group. Several

strategies were implemented to enhance engagement from this specific stakeholder groups. These included posting targeted tweets on Twitter, tagging relevant individuals and partner organisations, and an email from the supervisory team requesting assistance from specific organisations and groups in disseminating information about the study within their networks. Several organisations promoted the survey in through their newsletters and mailing lists which included the International Institute of Psychiatric Drug Withdrawal, the Irish Institute of Pharmacy, Mad in America, and the Black, African and Asian Therapy Network.

4.3.3 Step 3: Summarising the responses gathered

The process of identifying the Top 10 research priorities commenced with reviewing the Round 1 survey responses, removing out-of-scope and invalid responses (i.e., incomplete responses and responses not containing any question/uncertainty), and creating a list of unique, researchable questions.

4.3.3.1 Data analysis

In qualitative research, there is no one 'best' method of data analysis (219). Common approaches include thematic analysis, such as the Braun & Clarke method (219), content analysis (220), and constant comparative analysis (221). As the cornerstone of analysing text-based data is the coding process which involves applying tags/units of meaning to sections of the text, template analysis was the strategy of choice in this study (222). Template analysis is a technique for thematically organising and analysing qualitative data (222), used in research from a range of epistemological positions, including studies falling within the pragmatistic paradigm. King et al. defined template analysis as a method that *'balances a relatively high degree of structure in the process of analysing textual data with the flexibility to adapt it to the needs of a particular study'* (222 p.203). Within this approach, a list of codes or '*a priori* codes' forms the template used. Codes are descriptive labels attached to sections of text to index it as relating to a theme or issue (222). King identified three possible ways of developing the coding template: (i) identify codes based on a subset of the data; (ii) use codes based on a predefined framework; (iii) use a 'halfway approach', which using either of the previous two approaches (some initial codes) with an

openness to modification and the addition of codes as the analysis progresses (222). Within this study the third option was used, namely the combination of a deductive approach using '*a priori* codes', with an openness to new codes being added as and when they emerged from the data.

Data analysis involved three phases: (1) Data preparation; (2) Development of template for analysis; and (3) Application of template to analyse data, as outlined in Figure 4.3.

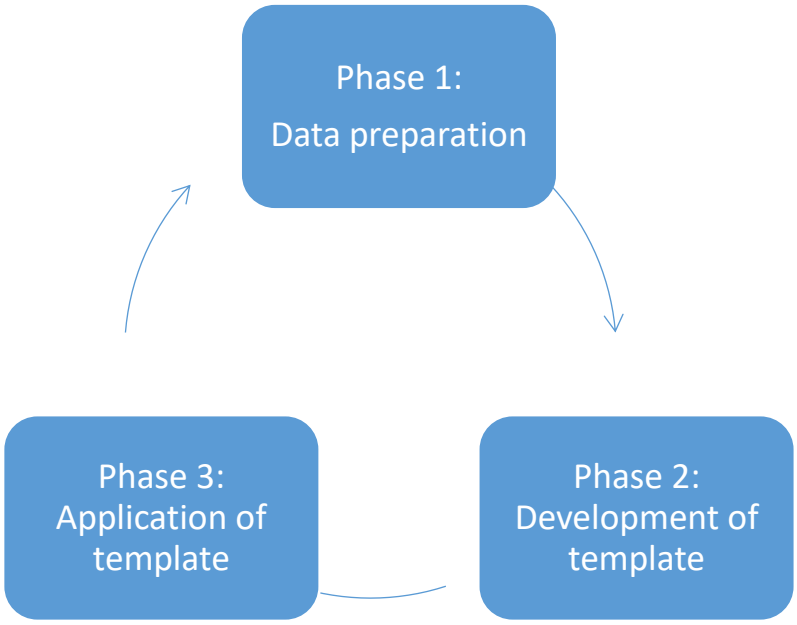

Figure 4.3: Phases 1-3 in the data analysis process

4.3.3.2 Data preparation

Survey responses were downloaded and exported into Microsoft Excel to facilitate the process of refining and collating uncertainties. Each respondent was assigned a unique response identifier/pseudonym [PSP001, PSP002, etc.] to maintain respondent anonymity.

4.3.3.3 Development of template

Central to this technique is the creation of a list of codes ('template') representing the themes identified in the data, organised in a hierarchical structure (222). Preliminary coding was undertaken on a subset of 50 responses by the researcher and the supervisory team to develop a provisional coding template. Once the lower-order codes were identified and defined, groups of similar codes were clustered and given a higher-order code title, feeding into the hierarchical structure. The higher-order codes represented major themes. The codes were defined in the coding template so that their meaning was explicit, and consistency of coding was improved (222). The provisional coding template was piloted on an additional subset of 200 responses by the researcher and reviewed by the supervisory team. Throughout the coding process, several modifications were made to the coding template. Template analysis is an iterative process that permits four types of modifications: (1) Insertion of codes, (2) Deletion of codes, (3) Change of scope, and (4) Change of higher-order classification.

4.3.3.4 Application of template

Once the final coding template was agreed, it was applied to the full dataset by the researcher (see Appendix 4.4). The Steering Group had oversight of the entire coding process and were sent samples of coded responses for review. This collaborative approach justified the inclusion of various codes, validated the coding process, and improved the credibility. Discussions were welcomed throughout the coding process given its highly subjective nature.

Most survey responses contained multiple questions/uncertainties and were not always written in the format of a research question. Once coding was complete, responses were split into individual questions/uncertainties and assigned a unique number [1.1, 1.2, 1.3, etc.] (223). Individual questions were grouped by high-order codes. In line with previous PSP studies/JLA guidance which employed three-level coding ranges, an additional level of lower-order codes was created to group the questions at a more granular level and facilitate data analysis (191).

The coded data were then converted into clear, indicative "summary" questions that were addressable by research using the PICO format (Patient or Population; Intervention;

Comparison or Control; Outcome) whilst retaining the sentiment of the original submission (224, 225). All questions underwent the same process of data analysis and coding regardless of the frequency at which they were asked (193) in line with JLA guidance (191). Submitted questions were reviewed for similarity, combined, and rephrased to create summary questions. Similar questions were merged to minimise duplication and reduce the volume of data. The summary questions underwent three rounds of review and refinement to improve clarity. In Round 1, the questions were discussed by the supervisory team. In Round 2, batches of summary questions grouped by major theme were shared with the Steering Group members and asked for any feedback/comments via email. Involvement in the review process was completely voluntary. Once all the feedback was collated, the questions were further refined. Changes to the questions included exclusion, merging and/or rewording of questions. In Round 3, a Steering Group meeting was held to discuss all question modifications and sign-off all questions for potential inclusion in the Round 2 survey (Step 5) once verified as true uncertainties in the evidence checking step (Step 4).

A similar approach was undertaken for the "out of scope" responses. General queries which were not directly related to research or answerable through research (e.g., queries about how to take legal action against a prescriber) were also coded as out-of-scope. A provisional coding template was developed based on preliminary coding, and then refined to create the final version. The responses were then coded, split, and grouped by major theme. A separate Microsoft Excel file was created for all responses considered "out of scope". These responses were excluded from the final analysis (i.e., not converted to summary question and checked against the evidence).

Responses submitted in the additional comments section were also screened for questions or uncertainties related to reducing/stopping psychiatric medication. These questions were included in the final analysis and moved to the Excel worksheet containing the list of in-scope questions. The remaining responses were revisited post completion of the PSP study as part of a separate qualitative analysis (Study 3) which is detailed in Chapter 6.

4.3.4 Step 4: Evidence checking

The purpose of this step was to verify that each summary question had not previously been answered. The search strategy consisted of two components: (1) A search of relevant electronic databases to identify empirical research, and (2) A search of organisational websites.

The first component included a search of six electronic databases: MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, Web of Science, and the Cochrane Database of Systematic Reviews (CDSR). A preliminary search of one electronic database (Web of Science) was undertaken with input from the research librarian (GS) with expertise in electronic database searching and systematic reviews to identify articles relevant to the review topic. The preliminary search enabled the identification of keywords and index terms from the titles and abstracts of relevant articles. Based on the above, a comprehensive search strategy was created in collaboration with the research librarian. The final search strategy contained three strands of search terms: (1) Medication-related terms; (2) Tapering-related terms; and (3) Study-related terms. A combination of Medical Subject Headings (MeSH) and free searching was utilised. The three strands were searched separately using "OR" in between terms, and then combined using "AND" in the final search. The search strategy was modified to each database accordingly. A time limit was applied to the database searches to restrict results to those published from 1st January 2019 onwards. The searches were also restricted to the English language and articles meeting inclusion criteria. Reference lists of articles meeting inclusion criteria were searched for additional material. The final search strategy was documented in the Question Verification Form and published on the JLA's website as per the JLA requirements (191). An example of the final search conducted on Web of Science is provided (see Appendix 4.5).

The second component comprised a search of the following three organisational websites for clinical guidelines: National Institute for Health and Care Excellence (NICE), Scottish Intercollegiate Guidelines Network, and the Royal College of Psychiatrists as per the JLA guidance (191). No keywords were used to search the guideline repositories. A time filter was applied to the NICE and SIGN websites to limit the search to guidelines published from

1st January 2019 onwards and all published guidelines were screened. It was not possible to apply this filter on the third repository.

4.3.4.1 Study selection

Once the two searches were complete, all identified articles were imported into Covidence (reference management software platform; https://www.covidence.org/), and Microsoft Excel respectively, and underwent deduplication. The two-step screening process was undertaken by the researcher and one member of the supervisory team (CC). All titles and abstracts were screened independently against the pre-specified inclusion criteria: systematic review or evidence-based guideline published within the last three years. When the article appeared to meet the inclusion criteria, or a decision could not be made based on the title and abstract alone, the full-text article was retrieved and screened independently. Any disagreements were resolved by consensus with the input of a third person, the other member of the supervisory team (AH).

4.3.4.2 Data extraction

The process of data extraction was undertaken by the researcher using the data extraction form which was designed by the supervisory team (see Appendix 4.6). The data extraction form was developed in Microsoft Excel, piloted on one article meeting inclusion criteria by the researcher, and reviewed by the supervisory team.

Data were extracted by the researcher relating to the main aim/purpose of the reference source, as well as key results and author conclusions. This information was used to determine whether any of the summary questions had already been answered. Within Microsoft Excel, a summary question was assigned to each row, and a class of psychiatric medication to each column. When a reference source answered the summary question for a class of medication, the key points were inserted into that class's column. Unless a reference source that addressed a summary question covered all classes of psychiatric medication, the question was considered only partially answered by existing evidence and retained as an existing uncertainty. Questions for which the answers were not known were collated and recorded on a standard JLA template. To maintain transparency within the PSP process, a summary of the evidence checking process findings linked to the list of

unanswered summary questions was shared with the Steering Group for review before inclusion in the Round 2 survey (Step 5). While reviewing the list of questions, Steering Group members were also asked to consider whether any of the questions had already been answered to strengthen the evidence checking step.

4.3.5 Step 5: Interim prioritisation (Round 2 survey)

A second anonymous online survey was conducted to determine which of the unanswered summary questions were considered most important by the key stakeholder groups: people with lived experience of taking and/or stopping psychiatric medication, family members, carers, or supporters, and healthcare professionals.

4.3.5.1 Development and piloting Round 2 survey

Similar to the Round 1 survey, the Round 2 survey was created in Qualtrics®, reviewed by the Steering Group and piloted by representatives from each of the three key stakeholder groups. Round 2 representatives included 10 individuals representing: people with lived experience of taking and/or stopping psychiatric medication (n=1 [10%]) family members/friends/carers/supporters (n=3, [30%]), healthcare professionals (n=2 [20%]), with the remainder unspecified (n=4, 40%). The pilot survey asked similar questions to the pilot of the Round 1 survey. Respondents were largely satisfied with the survey's format and the clarity of the questions. In light of the feedback received, the wording of the questions was refined to improve comprehension, and the order of the shortlisted questions was randomised for each new respondent to minimise the risk of bias due to survey fatigue and questions that appeared later in the survey not receiving the same level of attention as earlier questions. Information about the final prioritisation workshop (Step 6) and how respondents could express interest to participating in the workshop was added to the final page of the survey. Pilot responses were not included in the final analysis.

4.3.5.2 Survey design

Round 2 survey was very similar with that of the Round 1 survey, also containing the same four sections (see Appendix 4.7). The main component of the survey comprised two parts.

Part one asked respondents to review the full list of 32 summary questions and shortlist those that they felt were most important. Respondents could select any number of questions for shortlisting. The selected questions were taken forward to next screen. Part two asked respondents to review their shortlisted questions and select up to 10 questions from that list. Respondents were not asked to rank questions in order of importance.

4.3.5.3 Recruitment of survey respondents

The same processes for recruitment, monitoring engagement and obtaining consent were used as per Round 1 survey. To enhance inclusivity and reflect the perspectives of as many stakeholders as possible, individuals could respond to the survey irrespective of whether they had completed the previous Round 1 survey.

Round 2 survey was open for four weeks, from 14th September to 16th October 2023. After two weeks, it was noted that the healthcare professional group required specific targeting. The same strategies used to promote Round 1 survey (Step 2) were employed.

4.3.5.4 Data analysis of Round 2 survey

The survey responses were downloaded and exported into Microsoft Excel and analysed using descriptive summary statistics. Invalid responses (i.e., incomplete responses) were removed. The remaining responses were split into the three stakeholder groups: people with lived experience of taking and/or stopping psychiatric medication, family members, carers, or supporters, and healthcare professionals across three separate spreadsheets. For each stakeholder group, questions were ranked based on the frequency with which they had been selected. Once the analysis was complete, the Steering Group met to review the findings and the 19 most highly ranked questions across the three key stakeholder groups were taken forward to the final workshop (Step 6). No questions were merged/rephrased at this stage of the process.

4.3.6 Step 6: Final prioritisation workshop

A final prioritisation workshop was held in Trinity College Dublin (TCD), Ireland on 25th October 2023 to prioritise through consensus the most highly ranked questions about reducing and stopping psychiatric medication from the Round 2 survey. An adapted

Nominal Group Technique (NGT) was used to make decisions and ensure that all participants' opinions were considered. This one-day workshop was held as a hybrid event to enable participants to join remotely from any location and enhance international representation. The workshop was facilitated by a grant received from the Health Research Board (HRB) (grant number: CES2023-008), Ireland through its Conference and Event Sponsorship Scheme. The workshop provided a novel opportunity for discussion and collaboration between the three stakeholder groups which lend itself to new perspectives and new networks. All participants were seen as equal experts and research collaborators and given the same opportunity to participate in discussions and ranking exercises.

4.3.6.1 Recruitment of workshop participants

The JLA recommend a maximum sample size of 30 participants, with representation across each of the key stakeholder groups. The supervisory team targeted 35 participants anticipating some non-attendance. Firstly, the Round 2 survey respondents could express their interest in participating through a dedicated email address (tapersafer@tcd.ie) and meetings were arranged with prospective attendees to ensure that they understood what was involved. Secondly, all Steering Group members were invited to attend and asked to nominate other individuals within their networks who would make a useful contribution to the workshop. Steering Group members could choose to attend in either a participant or observer capacity. The response obtained exceeded expectations. Workshop participants were purposively selected to achieve a representation of stakeholder voices, genders, and nationalities. The latter was influenced by time zone constraints and resource limitations. Two observers were also present. One observer represented the HRB, an Irish research funding body, and the other was conducting a JLA PSP study on a different and unrelated topic.

The workshop was facilitated by two JLA Advisors and two JLA-trained facilitators who chaired the small group sessions. As previously mentioned in Chapter 3, a PPI Ignite office was set up in TCD as part of the university's commitment to promote PPI. A representative from that office assisted with the PSP study by acting as a facilitator in the final prioritisation workshop. Prior to the workshop, participants were provided with several

documents. These included the Interests & Needs form which asked participants to share biographical details, and consent to photographs and the publishing of the workshop results and the list of shortlisted questions to be discussed at the workshop (see Appendices 4.8 & 4.9). Participants were asked to select their top three and bottom three questions as part of their "pre-workshop homework". Other documents included the workshop guide and agenda to outline the workshop layout, and the list of workshop participants for transparency reasons.

Upon arrival, in-person participants were welcomed by the supervisory team. A sign-in sheet was used to log attendance, and participants were supplied with a name badge and printed versions of the pre-workshop documents to support discussion during the workshop. No professional titles or stakeholder group labels were included on name badges to reduce the possibility of participants making assumptions about any individual or group. It also allowed participants to control how they described and introduced themselves to the group. Concomitantly, the online participants were welcomed by the JLA Advisor as they logged into Zoom. Online participants were given a view of the plenary room and projected onto the main screen. The cameras and microphones were turned on to allow participants to communicate and create hybrid conversations.

The workshop involved three whole group "plenary" sessions and three small group sessions, as outlined in Sections 4.3.6.2 to 4.3.6.7 below, balanced according to participant background, stakeholder group and gender. The Steering Group members were evenly distributed amongst the small groups. During the small group sessions, participants completed three ranking exercises. All sessions were interspersed with refreshment breaks to minimise fatigue. Quiet spaces were also provided where participants could go at any time during the workshop if they needed time to themselves.

4.3.6.2 Plenary session 1

The workshop commenced with a plenary session during which the JLA Advisor provided the participants with a background to the general PSP process and an explanation on the aim of the workshop and the ways of working (see Figure 4.4). A brief overview of the study progress to date was provided by the supervisory team.

Figure 4.4: Plenary session 1; hybrid working group

4.3.6.3 Small group session 1

In the first and second small group sessions, participants were split into four groups, three in-person groups and one online group (see Figure 4.5). In the first session ("listening round") participants were asked to introduce themselves and share their top three and bottom three priorities. Similarities and differences between the individual rankings were documented by the facilitators, and participants were presented with different perspectives.

Figure 4.5: Small group session 1; hybrid working group

4.3.6.4 Small group session 2

During the second session, each group was tasked with ranking all 19 shortlisted questions in order of priority. Questions were assigned to gold, silver and bronze categories and then ordered within each category to assign a score to each question. Questions cards were used in the in-person groups, and visual aids on PowerPoint were used in hybrid and online working groups (see Figure 4.6). The scoring sheets were completed by the facilitators in real time during the session.

After this session, the facilitators and supervisory team met to share and collate data from the scoring sheets. The scores from the four small groups were collated by the JLA Advisor using Microsoft Excel. A combined rank was calculated by arithmetic averaging of the individual group rankings. These rankings were discussed amongst the facilitators and supervisory team, and anomalies were identified and noted for discussion at the Plenary session 2. For example, if a question received a high score by one group and low by another this was noted for discussion during the plenary session.

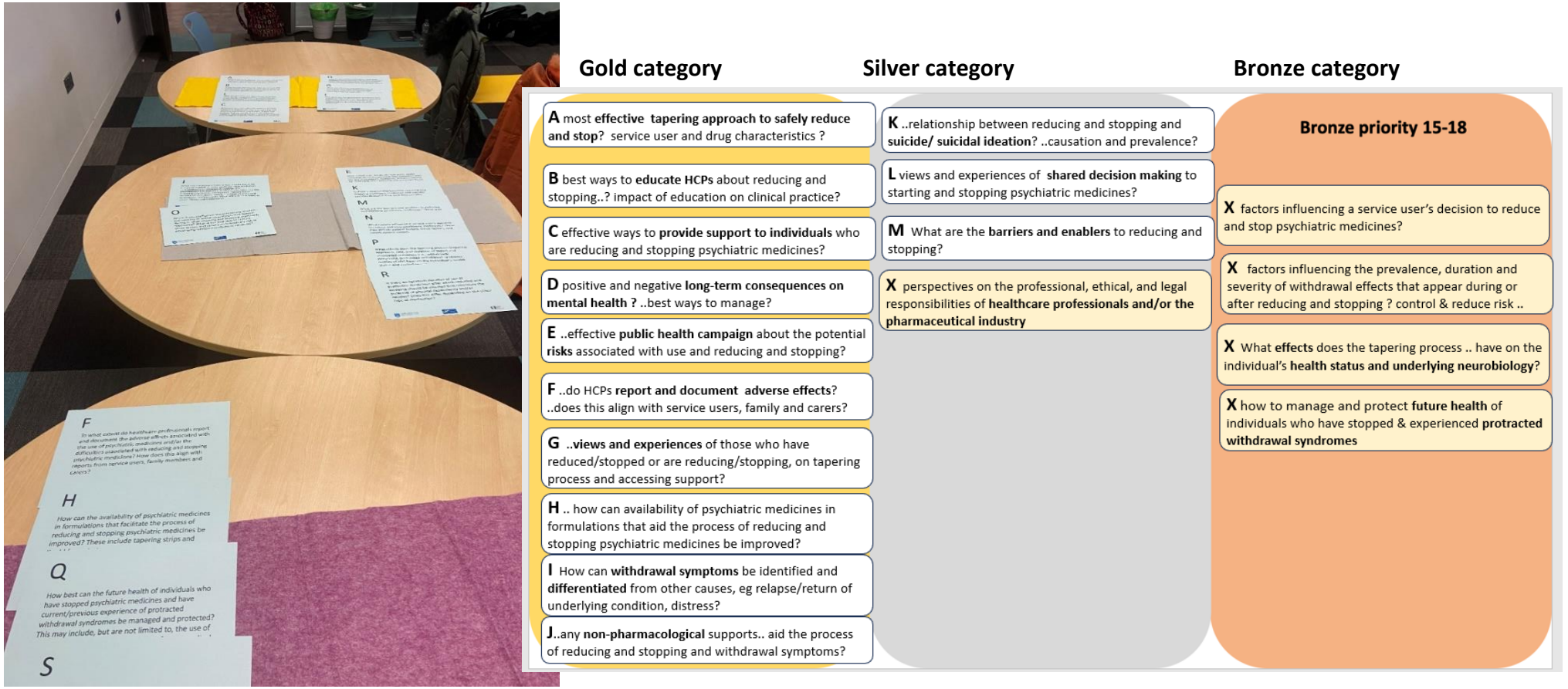

Figure 4.6: Small group session 2; the question cards and visual aids used to assist the ranking of questions in the in-person and hybrid groups

4.3.6.5 Plenary session 2

During the second plenary session, the combined priority order of the first round of ranking was shared with the entire group of participants and reviewed collectively (see Figure 4.7). Any consensus or difference in rankings was highlighted. There was a general sense of satisfaction amongst participants with the priority order of questions at this stage. Participants were actively engaged throughout the entire process. During this session, participants were encouraged to ask questions and share their views on the ranked order of the priorities.

Figure 4.7: Plenary group session 2; hybrid working group

4.3.6.6 Small group session 3

Participants were split into three groups, one in-person group and two hybrid groups. The groupings were revised to expose participants to different stakeholders and perspectives. During this session, each group started with the combined priority order from the earlier sessions and was given the opportunity to discuss and potentially revise the order as they wished. To facilitate discussion, the question cards were laid out in the combined priority order in hardcopy or digital form (see Figure 4.6). As the participants reviewed and revised the rankings, the question cards were moved around to reflect revisions. During this session, participants changed their mind several times based on the discussion. All participants were given equal opportunity to explain about why they chose an order. Participants were engaged in discussion as opposed to sitting quietly. Discussion and debate on priority rankings was encouraged. The rankings from each group were again collated by the JLA Advisor using Microsoft Excel.

4.3.6.7 Plenary session 3

The workshop concluded with a plenary discussion to review and reflect on the final Top 10 priorities. The combined priority order from the second round of ranking was presented and the Top 10 priorities were announced (see Figure 4.8). Participants were invited to share their reflections and comments on the workshop. The supervisory team shared the next steps for the study and the Top 10 priorities.

Figure 4.8: Whole group plenary session 3; hybrid working group

Deviations from JLA guidance: Traditionally, all JLA workshops have been held in-person. The workshop in this PSP study was held as a hybrid event to enable participants to join remotely from any location and enhance international representation. The hybrid working model is a relatively novel approach, only undertaken by a limited number of previous PSP studies (193). Traditionally, question cards and post-it notes are moved around on a table as part of the ranking exercises. In this JLA workshop, question cards were used in the in-person groups, in addition to real-time visual aids on PowerPoint which were used in hybrid and online working groups. Both the question cards and visual aids were controlled by the group facilitator. The use of visual aids gave all participants an equal view of the how the rankings were changing, supporting participants who were attending the workshop remotely to engage in discussion.

4.3.7 Step 7: Publish and promote the Top 10 research priorities

A comprehensive dissemination plan was developed in consultation with the Steering Group. This plan identified the study's target audiences and the dissemination activities that would help to reach them. The results of the study were published on the JLA website

and the study's dedicated website and shared with various research funding and agenda setting organisations. The final peer-reviewed study manuscript was published on the BMJ Open, an open access journal, in November 2024 (226). Additionally, the study methodology and findings were discussed as part of the European Society of Clinical Pharmacy conference in Krakow, Poland in October 2024 as part of a workshop and webinar. The sources of funding and any conflicts or competing interests were included in all study publications and presentations.

4.4 Ethics

The Oxford Dictionary defines ethics as *"moral principles, or a system of these"* (227) . Ethics is relevant to all areas of research (228-230). Upholding ethic principles is one of the key responsibilities of all researchers. To achieve consistency between research studies, and to protect welfare of participants, several ethical guidelines and standards have been developed. The first ethical guideline, the Nuremberg code was developed in 1947 and utilised as part of the Nuremberg trials involving the Nazis after the second World War. In 1978, the Belmont Report was published, followed by the Principles of Biomedical Ethics published by Beauchamps and Childress in 1979 (228, 229). In modern-day bioethics, the prevailing paradigm is the one put forward by Beauchamps and Childress which comprises four ethical principles: beneficence, nonmaleficence, autonomy, and justice (229). The first two principles, beneficence and nonmaleficence, date back to the time of Hippocrates*, "to help and do no harm"* (229 p.18). The second two, autonomy and justice, originated from Percival's book Medical Ethics which was written many years later (229). This PhD thesis was planned and conducted in accordance with the four ethical principles laid out in the Principles of Biomedical Ethics published by Beauchamps and Childress. High ethical standards were upheld throughout the entire PhD thesis.

4.4.1 Ethical approval

Ethical approval for the PSP study was obtained from the Faculty of Health Sciences Research Ethics Committee, Trinity College Dublin on 3rd August 2022 [Ref: 220509] (see Appendix 4.10).

4.4.2 Ethical principles

4.4.2.1 Beneficence and nonmaleficence

Beneficence is a foundational value in all healthcare ethics. It refers to researchers' obligation to act in the best interest of the participant, to benefit the participant and promote their wellbeing (229). Whereas nonmaleficence refers to researchers' obligation to assess the potential risks and impacts of participation to avoid causing harm or suffering to the participant (229). The potential risks should be weighed against the benefits of participation.

To uphold both principles, a model of collective support was in place. All individuals involved in the PSP study were informed of the risks and benefits of their participation. This included the survey respondents and workshop participants. The surveys (Steps 2 & 5) did not intend to address sensitive, embarrassing, or upsetting topics. However, there was potential for respondents to become upset when recounting their experience of taking and/or stopping psychiatric medication as it related to their mental health experience. The risk of this outcome occurring was outlined in the PIL (see Appendix 4.2). In the event of a respondent becoming distressed, they were advised to contact their healthcare provider, as it was an anonymous survey. Respondents also had the option of terminating the survey and withdrawing from the study at any point. If any substantive adverse events occurred, the supervisory team would have reported it to the Faculty Research Ethics Committee via ethicscommittee@tcd.ie. Similarly, participation in the final prioritisation workshop (Step 6) did not intend to provoke any difficult memories for the participants. In the event of a participant becoming distressed, they had the option or to leave the workshop at any point or stay, recognising that experiencing distress does not reduce an individuals' capacity to contribute. Both cohorts of individuals were regarded as study collaborators as opposed to participants. The model of collective support is further discussed in Chapter 9.

4.4.2.2 Autonomy

The philosophical underpinning of autonomy was first put forward by Immanuel Kant and James Stuart Mill who recognised that all individuals have intrinsic worth and should be

empowered to make rational decisions (229). Within autonomy lies informed consent and confidentiality. To obtain informed consent, there are several requirements that must be met: the participant must be competent to understand and decide, receive, and understand a full disclosure of the risks and benefits, give their explicit consent to participate in the research, free of coercion. On the other hand, to maintain confidentiality researchers must not disclose any information shared by the respondent or their identity without the respondent's permission. Both informed consent and confidentiality were evident throughout the entire study.

In this study, informed consent was particularly relevant to the stages of recruitment. Upon recruiting the Steering Group members (Step 1), all individuals were asked to complete the Interests and Privacy form prior to the first official Steering Group meeting as a form of ethical consent. With respect to the survey respondents, all individuals were provided with a PIL prior to completion of the surveys (Steps 2 & 5). The Round 1 and Round 2 surveys were also accompanied by a narrated video with additional information about the study and instructions on how to participate was also available on the study's website [https://youtu.be/a4t1O04ko2w; https://www.youtube.com/watch?v=tgONIyi9vVk] to overcome any readability issues, to improve equity of access, and to enhance informed consent. Before commencing either survey, all respondents were asked to self-declare their consent by confirming that they were ≥18 years old, represented one of the key stakeholder groups described above and agreed to complete the survey voluntarily. In the case where a respondent did not provide consent, they were brought to the end of the survey bypassing the survey questions. Respondents could opt-out of the survey at any point without needing to give a reason. To maintain confidentiality, all surveys, respondents were asked not to disclose any personal information that could identify themselves or other individuals. In addition, IP location tracking was disabled within Qualtrics® and each respondent was assigned a unique response identifier/pseudonym [PSP001, PSP002, etc.] before the survey data was analysed. The use of pseudonyms protected respondent's anonymity. While analysing the data, the researcher was careful not to include any data that might identify a person or service. The same principles were applicable to the final prioritisation workshop (Step 6). Upon recruiting the workshop participants, the Interests and Needs form was shared with

all individuals prior to the workshop to obtain their consent to participate and be photographed (see Appendix 4.8). Many conversations took place between the participants over the course of the workshop, including the official plenary and small group sessions, as well as during the refreshment breaks. The workshop was presented as a safe space, and participants were encouraged to actively engage in conversations with other participants. At the first plenary session, the JLA Advisor highlighted the importance of maintaining confidentiality and asked all participants not to disclose any topics that arose in any conversation.

Prior to listing any individual on any study-related document, publication or project website, all individuals were consulted. If the individual consented to being listed, they were asked how they wanted to be described so they could control the level of disclosure. This was particularly important for individuals from the lived experience group who may not wish to share their personal experience and may not have had an official title or affiliation. Written consent was obtained prior to any manuscript being submitted for publication. Similarly, the workshop participants were asked if and how they would like to be described on the list of participants that was shared with their fellow participants. As the study progressed, the model of consent evolved. Participation at any point of the study was entirely voluntary and free of coercion, relying on self-enrolment. This is an integral part of autonomy and voluntary participation.

4.4.2.3 Justice

Justice refers to the fair and equitable treatment of individuals. Social justice is of particular relevance to ethics in healthcare and health policy as it relies on the co-operation of individuals working together towards a common goal (229). In this study, all individuals were treated equally, regardless of which stakeholder group they represented. The presence of the JLA Advisor at all the Steering Group meetings enabled this. Upon the recruitment of the Steering Group members (Step 1) and workshop participants (Step 6), all individuals were asked to self-declare any conflicts of interest to comply with this ethical principle. The Interests and Privacy form shared with Steering Group members asked individuals to declare any competing interests that may influence their participation and how they would manage these interests where appropriate. These individuals were

also asked if they had strong opinions about the health topic/study area and to provide details of research interests. To maintain transparency, individuals were made aware that their responses would be circulated within the Steering Group. Similarly, the Interests and Needs form shared with workshop participants asked individuals to declare any competing interests (e.g., current research) that could be seen to influence their participation, and any strong opinions about the topic of the workshop.

4.5 Rigor and trustworthiness

Qualitative research design is more open to the researchers' interpretation of the data in comparison to quantitative research which follows a more structured, rigid design with all the methods prescribed. As a result, qualitative studies are considered more complex than quantitative studies. It is the shared responsibility of all researchers to ensure rigor in research. Rigor is defined as *"the quality or state of being very exact, careful, or with strict precision"* (231) or *"the quality or condition of being highly detailed, accurate, and thorough"* (232). The requirements of reliability, replication, and validity generally associated with demonstrating rigor in quantitative studies are less applicable to qualitative studies (233). A more appropriate criterion for evaluating qualitative studies, specifically the quality of the research design, is trustworthiness (233). Trustworthiness refers to "quality, authenticity, and truthfulness of findings of qualitative research. It relates to the degree of trust, or confidence, readers have in results" (233). To ensure trustworthiness, Guba and Lincoln proposed the research should satisfy four criteria (233): credibility, transferability, dependability and confirmability.

4.5.1 Credibility

Credibility ensures that the actual study outcomes match the study intentions, and that they are a true reflection of the participants' social reality (233). Several attempts were made to build credibility within the process. Both surveys were developed in collaboration with the Steering Group and piloted by representatives of the key stakeholder groups to assess clarity of the questions and improve accessibility. The high volume of responses submitted to both surveys captured the questions and uncertainties from hundreds of individuals. A coding template was developed as part of the coding process. The codes

were defined in this template so that their meaning was explicit, and consistency of coding was improved (222). The JLA Advisor and Steering Group had oversight of the entire coding and review process. This collaborative approach justified the inclusion of various codes and the retention of summary questions for the workshop, validating both processes. Upon performing the evidence check, assistance was sought from the research librarian to build a comprehensive search strategy. This collaboration served as quality and evidence checks and meant that the search strategy was not solely informed by the supervisory team. Upon reporting the study findings, quotes were used as exemplars.

4.5.2 Transferability

Transferability refers to the ability to transfer the findings to other contexts (234). Transferability is dependent on the level of description of the particular research context provided. This study demonstrated transferability through its study publications. All seven steps involved in the PSP methodology were described in detail in the published study protocol (190) and final study manuscript (226). While the study was conducted in line with the PSP methodology guidance, a number of minor modifications were made. All deviations from the JLA guidance were highlighted and justified. Information on all individuals involved in this study was also provided on study publications and study's dedicated website.

4.5.3 Dependability

Dependability ensures that the description of the research process is at a sufficient level to enable another researcher to repeat the same process. Dependability is typically characterised by having a clear audit trail (235). This study created a clear audit trail of all aspects of the process which aligned with the JLA principles. Upon recruiting the Steering Group members, partners and workshop participants, all individuals and organisations were listed in one Excel file. When contact was made, it was documented in this file together with the outcome. With respect to data analysis, another Excel file was used to outline the progression of the submitted questions and uncertainties to final summary questions. This file was available for any Steering Group member to view/discuss at any point throughout the study and was published on the JLA website for transparency when

the study was complete. Finally, the development of the coding template as part of the coding process reduced interpretative bias and improved coding consistency between the supervisory team. This coding template was included in the PhD thesis (see Appendix 4.4).

4.5.4 Confirmability

Confirmability aims to reduce the potential for bias by acknowledging researcher predispositions (235). Given the greater potential for subjectivity in qualitative research when compared to quantitative research, these studies are exposed to researcher bias insofar as that the reflection of the data is influenced by the thoughts and attitudes of the researchers. Four strategies were undertaken to build confirmability within the process. The first strategy was the involvement of multiple individuals in the coding and review processes. The second strategy relates to the Round 2 survey (Step 5) in which the order of the shortlisted questions was randomised for each new respondent to minimise the risk of bias due to survey fatigue and questions that appeared later in the survey not receiving the same level of attention as earlier questions. The third strategy was triangulation which refers to the use of a variety of data sources, methods, and/or researchers with the aim of overcoming intrinsic bias (234, 235). Triangulation was evident in the study through the integration of multiple sources of data (i.e., the three different stakeholder groups: people with lived experience of taking and/or stopping psychiatric medication, family members/friends/carers/supporters, and healthcare professionals). Triangulation made it possible to tease out the similarities and differences that existed between the stakeholder groups. The final strategy involved the assignment of an independent JLA Advisor for the entire PSP study who oversaw and guided the process, and the additional JLA Advisors during the final prioritisation workshop to facilitate the consensus making process.

4.6 Summary

Chapter 4 focused on how the PSP methodology was operationalised to achieve the aims of Study 1 (i.e., to identify the Top 10 priorities for future research on reducing and stopping psychiatric medication). Deviations to the PSP methodology such as hosting virtual Steering Group meetings and a hybrid final prioritisation were also highlighted, and

justified, as they may inform future research teams conducting PSP studies, particularly those relating to mental health research. The next chapter presents and discusses the outcomes of Study 1.

Chapter 5: Outcome of the Priority Setting Partnership Study

5.1 Introduction

Chapter 5 focuses on the outcomes of the Priority Setting Partnership (PSP) study (Study 1) that was conducted to identify priorities for future research on reducing and stopping psychiatric medication. The final peer-reviewed study manuscript was published on the BMJ Open in November 2024 (226). This chapter presents and discusses the main outcome of the PSP study which was the list of Top 10 research priorities on reducing and stopping psychiatric medication. This chapter also outlines the strengths and limitations of Study 1.

5.2 Results

As previously outlined in Chapter 4, the James Lind Alliance (JLA) PSP methodology guided Study 1. The PSP methodology involved seven key steps. Chapter 4 focused on the methodology of Study 1, whereas this chapter focused on the outcomes of Study 1. Given that the only results of Step 1 ("Establishing the Steering Group") related to the final composition of Steering Group and study partners, both of which were outlined in Chapter 4, this chapter commences with the results of Step 2 ("Gathering evidence uncertainties").

5.2.1 Step 2: Gathering evidence uncertainties (Round 1 survey)

5.2.1.1 Characteristics of Round 1 survey respondents

The survey was accessed by 1,743 individuals. After invalid responses were removed (n=859), there were 884 completed responses to the survey containing at least one question/uncertainty. All three stakeholder groups were represented in the responses: people with lived experience of taking and/or stopping psychiatric medication (n=609, 69%), family members/friends/carers/supporters (n=86, 10%), and healthcare professionals (n=186, 21%), Most respondents were female (n= 629, 71%) and were in the in the 55-64 years age band (n=236, 27%). Responses were submitted from 39 different countries. Most respondents resided in the United States (n=371, 42%), United Kingdom

(n=188, 21%) and Ireland (n=88, [10%]) with the remainder spread across Europe (n=118, [13%]), Canada (n=49, [6%]), Oceania (n=41, [5%]), Africa (n=5, [<1%]), Asia (n=15, [2%]), and Latin America (n=7, [<1%]). Full details of respondents' demographics are reported in Table 5.1.

Table 5.1: Breakdown of survey respondents in Round 1 survey

Survey respondents	**n (%)**
Total respondents	**884**
Gender	
Male	**232 (26%)**
Female	**629 (71%)**
Non-binary	**21 (2%)**
Did not specify	**2 (<1%)**
Stakeholder group	
Person with lived experience	**609 (69%)**
Family member, friend, carer, supporter	**86 (10%)**
Healthcare professional	**186 (21%)**
Other	**3 (<1%)**
Healthcare professional group	
General Practitioner/Primary care physician	**11 (6%)**
Nurse	**47 (25%)**
Pharmacist	**22 (12%)**
Psychiatrist	**64 (34%)**
Psychologist/Psychotherapist/Counsellor	**24 (13%)**
Social worker	**5 (3%)**
Specialist physician	**4 (2%)**
Occupational therapist	**0**
Other	**9 (5%)**
Age range (years)	
18-24	**22 (2%)**
25-34	**88 (10%)**
35-44	**164 (19%)**
45-54	**195 (22%)**
55-64	**236 (27%)**
65-74	**137 (15%)**
75-84	**39 (4%)**
>85	**2 (<1%)**

Table 5.1 (continued): Breakdown of survey respondents in Round 1 survey

Survey respondents	n (%)
Did not specify	**1 (<1%)**
Country of origin	
Africa	**5 (<1%)**
Asia	**15 (2%)**
Canada	**49 (6%)**
Europe	**118 (13%)**
Ireland	**88 (10%)**
Latin America	**7 (<1%)**
Oceania	**41 (5%)**
United States	**371 (42%)**
United Kingdom	**188 (21%)**
Did not specify	**2 (<1%)**

5.2.2 Step 3: Summarising the responses gathered

Round 1 survey respondents submitted 3635 individual questions/uncertainties. These were reviewed in consultation with the Steering Group and out-of-scope questions (n=1458) were removed, leaving 2177 questions, as outlined in Figure 5.1.

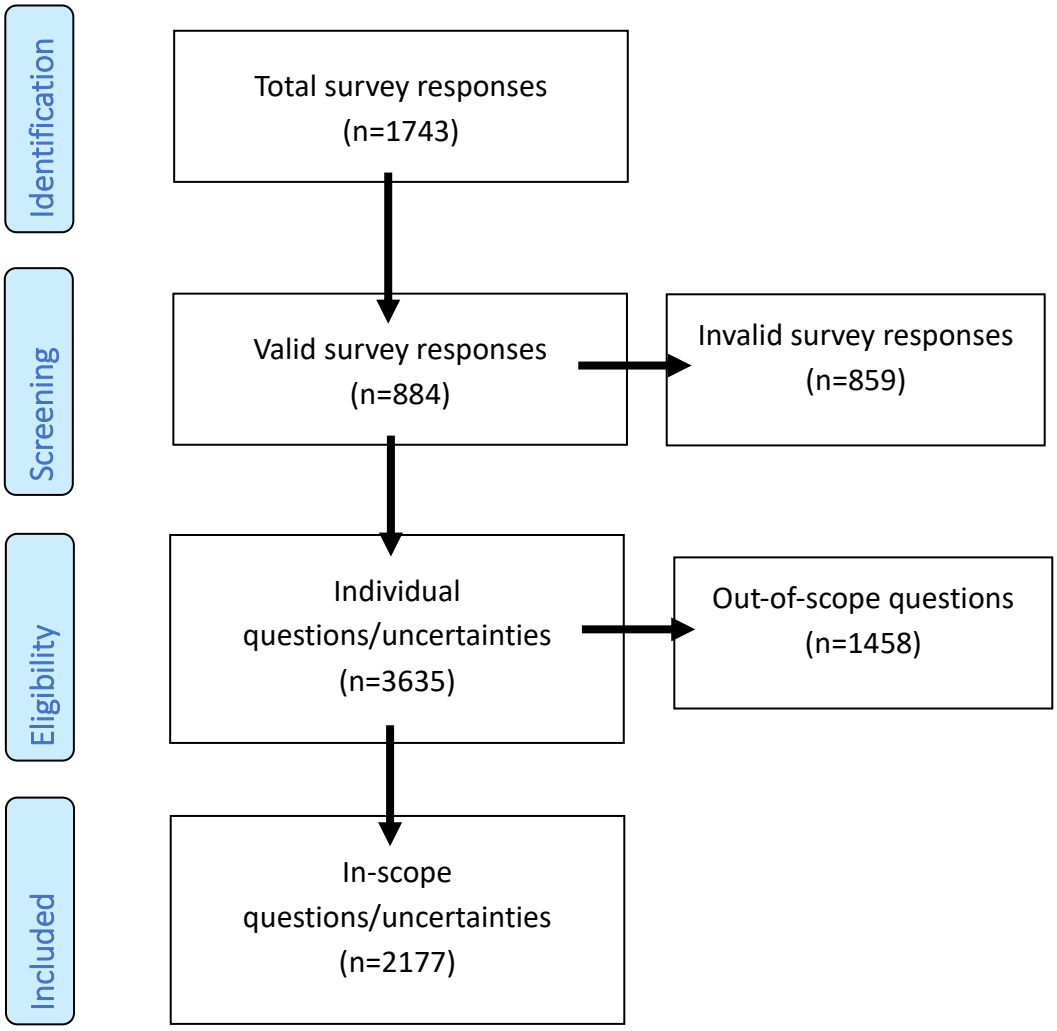

Figure 5.1: PRISMA flow diagram outlining the responses to the Round 1 survey

Using the process outlined in Chapter 3, the in-scope questions were then coded into the final coding template generating eight higher-order codes (i.e., major themes): (1) Tapering aids & supports; (2) Tapering process; (3) Post-taper; (4) Withdrawal symptoms & Adverse effects; (5) Accountability/Responsibility; (6) Acknowledgement/recognition of problems/issues; (7) Communication/decision making; (8) Healthcare professional knowledge/training. Examples of questions linked to each of these codes are outlined in Table 5.2.

Table 5.2: Round 1 survey response codes (higher & lower order codes) with linked examples

Higher-order code	Lower-order code	Examples of individual respondent submissions
1. Tapering aids & supports	**Pharmacological**	"What medications if any can help with symptoms due to discontinuation syndrome or even just side effects from coming off them?" [PSP1707, FFCS]
	Psychological/non-pharmacological/ social support	"Are there any foods or practical things I can do or take to help the experience not feel as difficult?" [PSP1316, PLE]
	Financial	"Can some of the money and resources that would have gone on the meds, and years of iatrogenic illness and being off work and social services etc be used to assist them while they are tapering off and to help them find new ways of coping?" [PSP0300, PLE]
	Education	"Where is there reliable information and support to safely withdraw from anti-depressants when a user has been taking them for 30+ years?" [PSP0460, PLE]
	Healthcare professional	"How can we as staff be supported to support the people with lived experience, we work with to be empowered to make choices about their meds when they are so often coerced and misinformed about the meds they are taking?" [PSP0531, HCP]
	Local/regional supports	"Why aren't there more places to go if you want to get off the medications?" [PSP0123, FFCS]

Table 5.2 (continued): Round 1 survey response codes (higher & lower order codes) with linked examples

Higher-order code	Lower-order code	Examples of individual respondent submissions
	Non-specific/ general support	"Why is there not more support for people wishing and those currently tapering off psych meds?" [PSP0423, PLE]
2. Tapering process	**Guidance/instructions**	"Why is the guideline for benzodiazepine taper for long-term patients not established?" [PSP0034, PLE]
	Practicalities	"How to safely taper from clonazepam without or having minimum withdrawal symptoms?" [PSP1300, PLE]
	Monitoring	"What are the most important things for people coming off anti-depressants to be vigilant for in terms of side effects or relapse?" [PSP1706, PLE]
	Experiences	"What are the opinions of patients who reduce/discontinue psychiatric medications of the effects on their wellbeing (quality of life) and recovery?" [PSP1531, HCP]
	Special populations	"What do women considering becoming pregnant and who take psychiatric medication need to be aware of in terms of coming off medication?" [PSP1706, PLE]

Table 5.2 (continued): Round 1 survey response codes (higher & lower order codes) with linked examples

Higher-order code	Lower-order code	Examples of individual respondent submissions
	Barriers/enablers	*"What are the barriers and facilitators to tapering or discontinuation of psychotropic medicine for people who have experienced an episode of severe illness such as psychosis/mania/depression in the context of bipolar disorder?"* [PSP1732, HCP]
	Restarting the medication	*"What are the criteria for knowing whether reinstating the drug is possible/wise if tapering/withdrawal proves too difficult? For example, is there an ideal time frame beyond which one cannot go back on and must complete the withdrawal?"* [PSP0339, FFCS]
	Underlying neurobiology	*"What is happening in the brain during withdrawal?"* [PSP0471, PLE]
3. Post-taper	**Positive outcomes**	*"Will my nervous system ever completely heal?"* [PSP0173, PLE]
	Negative outcomes	*"Can antidepressant withdrawal cause severe permanent irreversible damage?"* [PSP1482, PLE]
	Restarting the medication	*"Is reinstatement of benzodiazepines after a catastrophic unmanaged withdrawal an effective treatment strategy to stabilize the patient and if so at what dosage should a reinstatement level be set at to be effective?"* [PSP0443, FFCS]
	Underlying neurobiology	*"What was released in my brain when I stopped taking [nefazodone]?"* [PSP0073, PLE]

Table 5.2 (continued): Round 1 survey response codes (higher & lower order codes) with linked examples

Higher-order code	Lower-order code	Examples of individual respondent submissions
	Experiences	*"What to expect in the first year after stop taking antidepressant?"* [PSP0214, PLE]
4. Withdrawal symptoms & Adverse effects	**Risk of occurrence/ specific examples**	*"What is the risk of experiencing a psychotic episode when tapering or stopping antipsychotic (dopamine antagonist) drugs?"* [PSP0097, HCP]
	Underlying neurobiology	*"What causes side effects or withdrawal symptoms when medications are stopped?"* [PSP0087, HCP]
	Management & prevention	*"What is most helpful in easing the symptoms during the taper and in protracted withdrawal?"* [PSP0098, PLE]
	Identification	*"What symptoms might I experience which would indicate I was in withdrawal rather than relapse, and are prescribers aware of this?"* [PSP0276, PLE]
5. Accountability/ Responsibility	**Healthcare professional**	*"When will doctors take responsibility when prescribing and taking people off benzodiazepines?"* [PSP0064, PLE]
	Government	*"Why can't insurance pay for the right kind of medical and psychological support during tapering?"* [PSP0020, PLE]

Table 5.2 (continued): Round 1 survey response codes (higher & lower order codes) with linked examples

Higher-order code	Lower-order code	Examples of individual respondent submissions
	Pharmaceutical industry	*"How can we force drug companies to make tapering solutions or tapering strips readily available?"* [PSP0887, PLE]
	Information provision/informed consent	*"Why are doctors not required to inform patients of all side effects, dependency, withdrawal syndrome, etc.?"* [PSP1082, PLE]
	Compensation for the service user	*"Will there ever be any compensation for people who have suffered profoundly?"* [PSP0133, PLE]
6. Acknowledgement/ recognition of problems/ issues	**Healthcare professional**	*"Why is withdrawal syndrome not accepted by the majority of physicians?"* [PSP1082, PLE]
	Pharmaceutical industry	*"Why do the drugs companies ignore the needs of people who have severe reactions to their medications?"* [PSP1060, PLE]
	Wider context	*"How can we normalise tapering off given the negativity and ignorance the general population has about it?"* [PSP0300, PLE]
	Information provision/ informed consent	*"How can we get more people to be aware of the importance of gradual tapering, how do we get this information to be mainstream?"* [PSP1215, PLE]

Table 5.2 (continued): Round 1 survey response codes (higher & lower order codes) with linked examples

Higher-order code	Lower-order code	Examples of individual respondent submissions
	Evidence base	*"Why is there so little implementation research to support deprescribing in practice?"* [PSP1315, HCP]
7. Communication/ decision making	**Information provision/ informed consent**	*"What information should people who are taking medication be given in advance of starting so they are aware of what might be involved if/when they want to stop their medication?"* [PSP0377, FFCS]
	Treatment decisions	"What is the main rationale for the decision to reduce and stop taking a psychiatric drug?" [PSP0486, PLE]
	Recognition for the service user	*"What is the best way to get your psychiatrist to take you seriously?"* [PSP0398, PLE]
8. Healthcare professional knowledge/ training	**Education**	*"How can get the medical profession to more readily identify withdrawal and to differentiate this from "relapse"?"* [PSP0449, PLE]
	Knowledge	*"What percentage of GPs feel well informed about the taper process?"* [PSP0382, HCP]

Abbreviations: PLE (people with lived experience of taking and/or stopping psychiatric medication), FFCS (family members/friends/carers/supporters), and HCP (healthcare professionals).

Once coding was complete, the coded data were converted into researchable summary questions. Submitted questions were reviewed for similarity, combined, and rephrased to create summary questions. Initially, there were 105 summary questions. As outlined in Chapter 4, the process of reviewing and refining the summary questions involved three rounds. The number of summary questions that were identified after each round is outlined in Table 5.3. All changes made to the summary questions were documented and explained in one document (see Appendix 5.1). After the review process, 32 summary questions (see Appendix 5.2) were taken forward to the evidence checking step (Step 4).

Table 5.3: Overview of the process of reviewing and refining the summary questions following the Round 1 survey

Theme	Pre-review	Review 1	Review 2	Review 3
1. Tapering aids & supports	18	8	7	6
2. Tapering process	23	17	8	8
3. Post-taper	12	7	4	4
4. Withdrawal symptoms & adverse effects	11	9	7	5
5. Accountability	14	8	3	2
6. Acknowledgement of issues	17	4	3	3
7. Communication & Decision Making	7	6	3	3
8. Healthcare professional	3	1	1	1
Total number of questions	**105**	**60**	**36**	**32**

As outlined in Chapter 4, out-of-scope questions were not included in the final analysis. The out-of-scope questions fell under seven higher-order codes: (1) Adverse effects/Long-term effects of continued psychiatric medication use; (2) Efficacy of psychiatric medication; (3) Prescribing queries not directly related to tapering; (4) Alternative treatment options; (5) Mechanism of action of psychiatric medication; (6) Not specific/ unclear; (7) Causes/diagnosis of mental illness. Examples of out-of-scope questions linked to each of these codes are provided in Table 5.4.

Table 5.4: Round 1 survey out-of-scope response codes with linked examples

Code	Examples of individual respondent submissions
1. Adverse effects/ Long-term effects of continued psychiatric medication use	*"What exact damage does long term use of benzodiazepines cause to gaba receptors or other parts of nervous system?"* [PSP0022, FFCS]
2. Efficacy of psychiatric medication	*"What studies exist for prescribers, psychiatric doctors and the broader medical community concerning the long-term efficacy of psychiatric medications? As in, studies where subjects showed improvement after taking psychiatric medicines for longer than one year."* [PSP0157, PLE]
3. Prescribing queries not directly related to tapering	*"When will they stop so freely prescribing benzodiazepines?"* [PSP0064, PLE]
4. Alternative treatment options	*"If psychiatric medicine is completed stopped, what would be the "alternative " to these medications? Will there be evidenced based research to show replacement medicine, modalities or therapies that work on the same part of the brain that these medications targeted?"* [PSP0478, HCP]
5. Mechanism of action of psychiatric medication	*"I would like the scientific proof of how these psychiatric drugs work based on an epidemiological study and not just fake science."* [PSP0332, PLE]
6. Not specific/ unclear	*"How can we protect patients from dogmatic beliefs regarding discontinuing medication?"* [PSP0156, PLE]
7. Causes/diagnosis of mental illness	*"Are disorders such as depression and bipolar disorder really caused by a serotonin or other brain chemical imbalance, and how are psychiatric drugs researched when they are prescribed to treat such "chemical imbalances?"* [PSP0268, FFCS]

5.2.3 Step 4: Evidence checking

To determine if the summary questions had already been answered, a search of databases and guidelines was conducted in line with the study protocol and the JLA guidance, supported by the research librarian (GS). The results of the database and guideline searches are outlined in Figure 5.2. The database search yielded 5985 citations. After 1858 duplicates were removed, 4127 remaining underwent title and abstract screening of which 4040 were excluded as they did not meet inclusion criteria. The remaining 85 full-text articles were reviewed for eligibility. Forty-five peer-reviewed studies met inclusion criteria. The guideline searches yielded 177 citations. After one duplicate was removed, 176 remaining underwent title and abstract screening. 153 were excluded as they did not meet inclusion criteria. The remaining 23 full-text records were reviewed for eligibility. Thirteen guidelines met inclusion criteria. The main reasons for exclusion of records were: wrong study design, wrong intervention, conference abstract, and wrong outcomes.

The 32 summary questions from the previous step were checked against these 58 records (i.e., 45 peer reviewed studies and 13 guidelines). Unless the answer to the question covered all classes of psychiatric medication and all parts of the summary question, it was considered only partly answered by existing evidence. Partly answered questions indicated gaps in existing knowledge. Therefore, these questions were retained. A summary overview of peer-reviewed studies reviewed in relation to each question is included in Appendix 5.3. Following the evidence review, all 32 summary questions were considered as 'verified uncertainties' and were included the Round 2 survey (Step 5) for prioritisation.

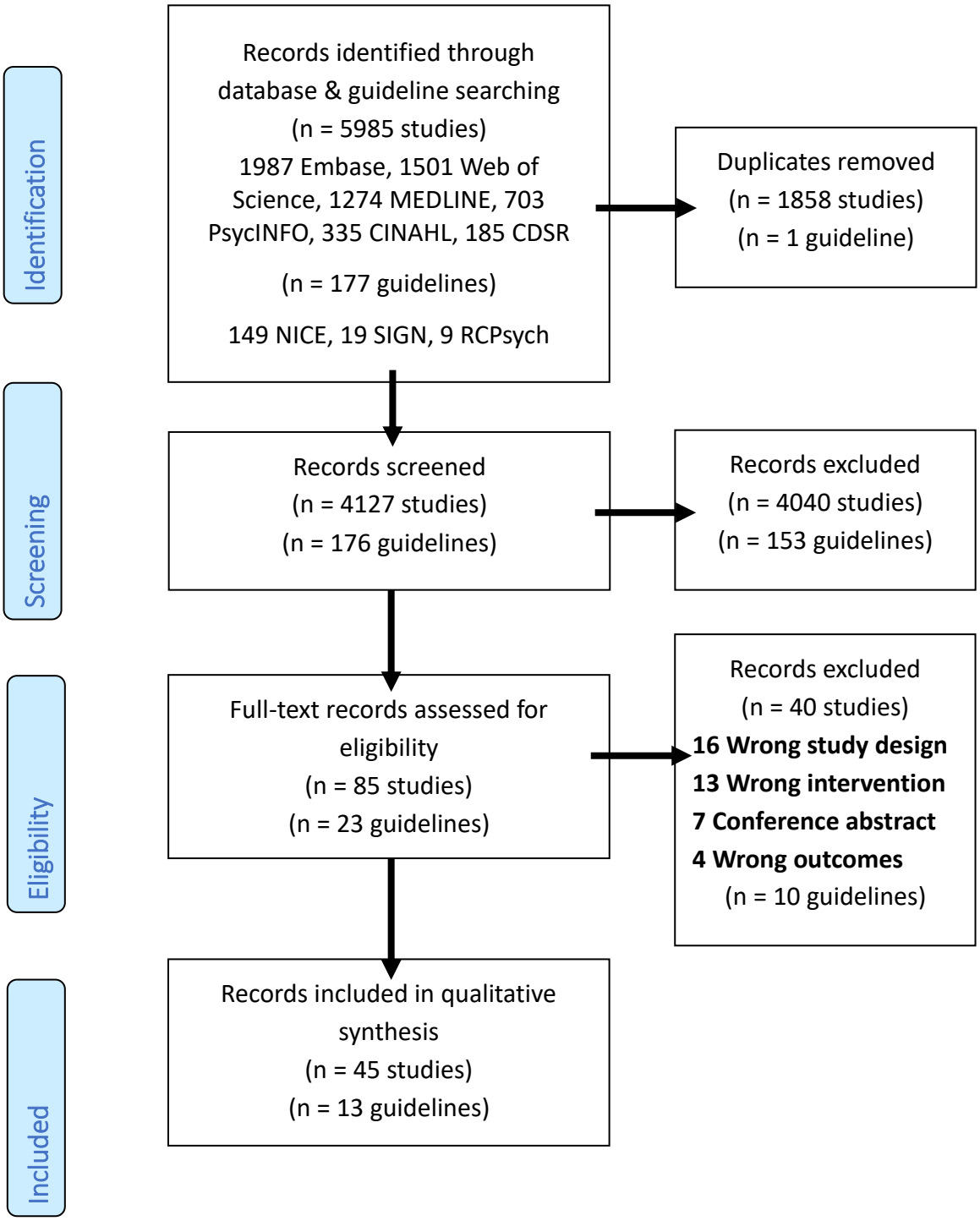

Figure 5.2: PRISMA flow diagram of the evidence checking step

5.2.4 Step 5: Interim prioritisation (Round 2 survey)

5.2.4.1 Characteristics of survey respondents in Round 2 survey

The Round 2 survey was accessed by a total of 993 individuals of which there were 526 completed responses (53%). The respondent profile was broadly similar to the Round 1 survey in terms of stakeholder group and geographic location. Most respondents were female (n=371, 71%) and were in the in the 55-64 years age band (n=129, 25%). Most respondents had lived experience of taking and/or stopping psychiatric medication (n=343, 65%), followed by healthcare professionals (n=151, 29%), and then family members/friends/carers/supporters (n=32, 6%). Responses were submitted from a total of 33 countries. Most responses were submitted by individuals in the United States (n=156, 30%); followed by the United Kingdom (n=147, 28%); and then Ireland (n=117, 22%). Full details of respondents' demographics are reported in Table 5.5.

Table 5.5: Breakdown of survey respondents in Round 1 & Round 2 surveys

Survey respondents	Round 1 survey	Round 2 survey
	n (%)	n (%)
Total respondents	**884**	**526**
Gender		
Male	**232 (26%)**	**143 (27%)**
Female	**629 (71%)**	**371 (71%)**
Non-binary	**21 (2%)**	**11 (2%)**
Did not specify	**2 (<1%)**	**1 (<1%)**
Stakeholder group		
Person with lived experience	**609 (69%)**	**343 (65%)**
Family member, friend, carer, supporter	**86 (10%)**	**32 (6%)**
Healthcare professional	**186 (21%)**	**151 (29%)**
Other	**3 (<1%)**	**0**
Healthcare professional group		
General Practitioner/Primary care physician	**11 (6%)**	**7 (5%)**
Nurse	**47 (25%)**	**66 (44%)**
Pharmacist	**22 (12%)**	**23 (15%)**
Psychiatrist	**64 (34%)**	**17 (11%)**

Table 5.5 (continued): Breakdown of survey respondents in Round 1 & Round 2 surveys

Survey respondents	Round 1 survey	Round 2 survey
Psychologist/Psychotherapist/Counsellor	**24 (13%)**	**17 (11%)**
Social worker	**5 (3%)**	**4 (3%)**
Specialist physician	**4 (2%)**	**1 (<1%)**
Occupational therapist	**0**	**7 (5%)**
Other	**9 (5%)**	**9 (6%)**
Age range (years)		
18-24	**22 (2%)**	**7 (1%)**
25-34	**88 (10%)**	**67 (13%)**
35-44	**164 (19%)**	**120 (23%)**
45-54	**195 (22%)**	**127 (24%)**
55-64	**236 (27%)**	**129 25%)**
65-74	**137 (15%)**	**62 (12%)**
75-84	**39 (4%)**	**14 (3%)**
>85	**2 (<1%)**	**0**
Did not specify	**1 (<1%)**	**0**
Country of origin		
Africa	**5 (<1%)**	**2 (<1%)**
Asia	**15 (2%)**	**9 (2%)**
Canada	**49 (6%)**	**35 (7%)**
Europe	**118 (13%)**	**44 (8%)**
Ireland	**88 (10%)**	**79 (15%)**
Latin America	**7 (<1%)**	**7 (1%)**
Oceania	**41 (5%)**	**36 (7%)**
United Kingdom	**188 (21%)**	**147 (28%)**
United States	**371 (42%)**	**156 (30%)**
Did not specify	**2 (<1%)**	**11 (2%)**

Finalisation of the questions for the final prioritisation workshop (Step 6)

As outlined in the previous chapter, a total of 32 summary questions (Q) were selected in consultation with the Steering Group for inclusion in the Round 2 survey. In the survey, respondents were asked to select the 10 questions that they felt were most important. Once the survey was closed, the questions were ranked based on the frequency with which they had been selected by each stakeholder group. The outcome of this ranking

process is outlined in Table 5.6. The Steering Group reviewed the survey results from the 526 respondents to decide on which questions would be taken forward to the final prioritisation workshop (Step 6), starting with the 13 most highly ranked questions (i.e., those that received the most votes in Round 2 survey) (Q9, Q32, Q3, Q16, Q28, Q23, Q4, Q25, Q2, Q26, Q6, Q22, Q7). It was agreed by the Steering Group that all 13 questions would be retained for the workshop except for Q4 ("*Are there any non-pharmacological supports that aid the process of reducing and stopping psychiatric medicines and reduce the withdrawal symptoms? If so, which are the best supports and who is best placed to deliver them? These may include, but are not limited to, family members, friends/peers, and healthcare professionals*.") which was considered too similar to Q3 *("What are the most effective ways to provide support to individuals who are reducing and stopping psychiatric medicines? These may include, but are not limited to, family/peer support, educational support, financial support, psychological support, and healthcare support.").* Both questions covered tapering supports, however Q3 was regarded as a wider research question compared to Q4. Q3 was the highest ranked question by two stakeholder groups: family/friends/carers/supporters, and the healthcare professional groups, and included examples which improved understanding for individuals whom English may not be their first language. The decision was made to retain Q3 and exclude Q4.

The next five most highly ranked questions were then discussed (Q19, Q14, Q18, Q24, Q31). Despite finding similarities between Q19 *("Which factors influence the prevalence, duration and severity of withdrawal effects that appear during or after reducing and stopping psychiatric medicines? What is the best way to control these factors and reduce an individual's risk of developing withdrawal effects or relapsing?"),* and Q9 *("What is the most effective way to safely reduce and stop psychiatric medicines in terms of tapering approach, rate of taper and duration of taper? What individual service user characteristics (e.g., age, gender, pregnancy, other medical conditions/diseases) and drug characteristics (e.g., medication type, duration of treatment, use of other medication) determine these?"),* they were regarded as two distinct questions and retained. Similarities were also found between Q14 and Q16, Q16 *("What are the positive and negative long-term consequences of reducing and stopping psychiatric medicines on an individual's physical and mental health status? For individuals who experience negative consequences, what*

are the best ways to manage these difficulties? Negative consequences may include withdrawal symptoms, relapse, and protracted withdrawal syndromes.") referred specifically to "long term" consequences while Q14 *("What effects does the tapering process (tapering approach, rate, and duration of taper) and associated outcomes (i.e., withdrawal symptoms, protracted withdrawal syndrome, quality of life) have on the individual's health status and underlying neurobiology?")* was less specific, covering short term/more acute consequences that may appear upon tapering. There was consensus to retain both questions. At this stage, 17 questions had been selected. The JLA methodology recommends that up to 25-30 questions are taken forward to the final workshop. As a result, the next two most highly ranked questions were discussed by the Steering Group members (Q15, Q12). Both questions were regarded as important questions that were not represented by the questions already selected retained. A total of 19 questions were taken forward to the final prioritisation workshop (Step 6).

Table 5.6: Ranked order (1-32) of summary questions from the Round 2 survey per stakeholder group

	Ranked order (1-32) according to stakeholder group		
Question	**People with lived experience**	**Family members/friends/ carers/supporters**	**Healthcare professionals**
1: Are pharmacological supports of any benefit to the process of reducing and stopping psychiatric medicines? These include medicines and supplements.	**26**	**12**	**25**
2: How can the availability of psychiatric medicines in formulations that facilitate the process of reducing and stopping psychiatric medicines be improved? These include tapering strips and liquid formulations.	**10**	**5**	**21**
3: What are the most effective ways to provide support to individuals who are reducing and stopping psychiatric medicines? These may include, but are not limited to, family/peer support, educational support, financial support, psychological support, and healthcare support.	**3**	**1**	**1**
4: Are there any non-pharmacological supports that aid the process of reducing and stopping psychiatric medicines and reduce the withdrawal symptoms? If so, which are the best supports and who is best placed to deliver them? These may include, but are not limited to, family members, friends/peers, and healthcare professionals.	**14**	**4**	**8**
5: Which educational interventions aimed at service users and healthcare professionals would improve outcomes for people reducing and stopping psychiatric medicines? How best can these interventions be delivered?	**23**	**9**	**9**

Table 5.6 (continued): Ranked order (1-32) of summary questions from the Round 2 survey per stakeholder group

	Ranked order (1-32) according to stakeholder group		
Question	**People with lived experience**	**Family members/friends/ carers/supporters**	**Healthcare professionals**
6: What are the views and experiences of individuals who have reduced/stopped psychiatric medicines or are currently reducing/stopping psychiatric medicines on the tapering process and accessing tapering support?	**9**	**7**	**4**
7: What are the barriers and enablers to reducing and stopping psychiatric medicines? These may include, but are not limited to, the service user, the healthcare professional, family, and society.	**25**	**10**	**6**
8: What is the quality of available guidelines/instructions on how to reduce and stop psychiatric medicines for service users and healthcare professionals? What is the best way to implement guidelines that are developed from high-quality evidence?	**16**	**9**	**10**
9: What is the most effective way to safely reduce and stop psychiatric medicines in terms of tapering approach, rate of taper and duration of taper? What individual service user characteristics (e.g., age, gender, pregnancy, other medical conditions/diseases) and drug characteristics (e.g., medication type, duration of treatment, use of other medication) determine these?	**1**	**3**	**5**
10: What is the most effective way for clinicians and/or service users to monitor the outcomes of reducing and stopping psychiatric medicines? How should the tapering process be adjusted if withdrawal symptoms arise?	**21**	**12**	**13**

Table 5.6 (continued): Ranked order (1-32) of summary questions from the Round 2 survey per stakeholder group

	Ranked order (1-32) according to stakeholder group		
Question	**People with lived experience**	**Family members/friends/ carers/supporters**	**Healthcare professionals**
11: Can existing psychiatric medicines be accurately altered or modified to achieve the doses required to taper? If so, what are the most effective ways to do so? These may include crushing, splitting and/or dissolving tablets.	**17**	**10**	**24**
12: Is there an optimum duration of use of psychiatric medicines after which reducing and stopping should be initiated that minimises the potential of physical dependency and/or relapse? Does this differ depending on the class/ type of medication?	**18**	**8**	**16**
13: Which factors influence the difficulty/ease of reducing and stopping psychiatric medicines? These may include, but are not limited to, service user factors, medication factors, and prescriber or health system factors.	**29**	**11**	**14**
14: What effects does the tapering process (tapering approach, rate, and duration of taper) and associated outcomes (i.e., withdrawal symptoms, protracted withdrawal syndrome, quality of life) have on the individual's health status and underlying neurobiology?	**11**	**7**	**21**
15: What is the rate/likelihood of recovery from withdrawal effects after reducing and stopping psychiatric medicines? Which factors influence/predict an individual's recovery outcomes?	**8**	**8**	**22**

Table 5.6 (continued): Ranked order (1-32) of summary questions from the Round 2 survey per stakeholder group

	Ranked order (1-32) according to stakeholder group		
Question	**People with lived experience**	**Family members/friends/ carers/supporters**	**Healthcare professionals**
16: What are the positive and negative long-term consequences of reducing and stopping psychiatric medicines on an individual's physical and mental health status? For individuals who experience negative consequences, what are the best ways to manage these difficulties? Negative consequences may include withdrawal symptoms, relapse, and protracted withdrawal syndromes.	**4**	**8**	**2**
17: How best can relapse (i.e., return of the underlying mental health issue) during/after reducing and stopping psychiatric medicines be explained in terms of causation, prevalence, and duration? Which factors impact an individual's risk of relapsing?	**30**	**10**	**18**
18: How best can the future health of individuals who have stopped psychiatric medicines and have current/previous experience of protracted withdrawal syndromes be managed and protected? This may include, but are not limited to, the use of similar drugs or class of drug during future medical encounters.	**20**	**7**	**23**
19: Which factors influence the prevalence, duration and severity of withdrawal effects that appear during or after reducing and stopping psychiatric medicines? What is the best way to control these factors and reduce an individual's risk of developing withdrawal effects or relapsing?	**7**	**10**	**20**

Table 5.6 (continued): Ranked order (1-32) of summary questions from the Round 2 survey per stakeholder group

	Ranked order (1-32) according to stakeholder group		
Question	**People with lived experience**	**Family members/friends/ carers/supporters**	**Healthcare professionals**
20: How best can the withdrawal effects that appear during or after reducing and stopping psychiatric medicines be explained in terms of type, causation, prevalence, severity, and duration?	**19**	**13**	**26**
21: What are the potential benefits and risks of reducing and stopping psychiatric medicines for the different stakeholders? These include service users, family members/carers and healthcare professionals.	**31**	**10**	**12**
22: Is there a relationship between reducing and stopping psychiatric medicines and suicide/ suicidal ideation? If so, how best can this relationship be explained in terms of causation and prevalence?	**15**	**6**	**16**
23: How best can the withdrawal symptoms that appear during or after reducing and stopping psychiatric medicines be identified and differentiated from other causes (e.g., relapse/return of underlying condition, distress)?	**12**	**3**	**17**
24: What are the perspectives of key stakeholders on the professional, ethical, and legal responsibilities of healthcare professionals and/or the pharmaceutical industry in relation to reducing and stopping psychiatric medicines? Stakeholders include service users, family members/carers and healthcare professionals. What are the best ways to enact these responsibilities?	**28**	**7**	**20**

Table 5.6 (continued): Ranked order (1-32) of summary questions from the Round 2 survey per stakeholder group

	Ranked order (1-32) according to stakeholder group		
Question	**People with lived experience**	**Family members/friends/ carers/supporters**	**Healthcare professionals**
25: What are the views and experiences of service users, family members/carers, and healthcare professionals around shared decision making in relation to starting and stopping psychiatric medicines? This includes informed consent. How can the process of implementing shared decision-making be improved when starting and stopping psychiatric medicines? What factors influence this process?	**22**	**4**	**4**
26: To what extent do healthcare professionals report and document the adverse effects associated with the use of psychiatric medicines and/or the difficulties associated with reducing and stopping psychiatric medicines? How does this align with reports from service users, family members and carers?	**6**	**5**	**11**
27: What are the views/attitudes held by healthcare professionals towards the withdrawal effects that appear during or after reducing and stopping psychiatric medicines? Which factors impact these attitudes?	**13**	**9**	**19**
28: What would make for an effective public health campaign about the potential risks associated with the use of psychiatric medicines, and the potential for challenges when reducing and stopping? These may include withdrawal symptoms and protracted withdrawal syndromes.	**5**	**4**	**15**

Table 5.6 (continued): Ranked order (1-32) of summary questions from the Round 2 survey per stakeholder group

	Ranked order (1-32) according to stakeholder group		
Question	**People with lived experience**	**Family members/friends/ carers/supporters**	**Healthcare professionals**
29: What is the best approach to discussing the potential risks associated with taking, reducing, and stopping psychiatric medicines? What are the barriers and enablers to implementing?	**27**	**9**	**12**
30: What is the best way for healthcare professionals to inform service users about the process of reducing and stopping psychiatric medicines, and the potential for associated challenges? What impact does this have on the service user's treatment decisions and outcomes?	**24**	**11**	**15**
31: What factors influence a service user's decision to reduce and stop psychiatric medicines? These may include patient factors, social factors, and health system factors.	**32**	**8**	**7**
32: What are the best ways to educate current and future healthcare professionals about reducing and stopping psychiatric medicines in terms of the tapering process, associated risks/difficulties, withdrawal symptoms, and supporting shared decision making? What is the impact of education on clinical practice?	**2**	**2**	**3**

5.2.5 Step 6: Final prioritisation workshop

Thirty individuals representing each of the three key stakeholder groups took part in the final prioritisation workshop: people with lived experience of taking and/or stopping psychiatric medication (n=9, 30%), family members/friends/carers/supporters (n=4, 13%), and healthcare professionals (n=17, 57%). Workshop participants represented seven countries, with majority from Ireland (n=20, 67%). An overview of workshop participant characteristics is presented in Table 5.7. Most participants attended in-person (n=21, 70%). Diversity between in-person and online participants was demonstrated by the mix of stakeholders and disciplines that participated both ways. The in-person cohort consisted of people with lived experience of taking and/or stopping psychiatric medication (n=4, 19%), family members/friends/carers/supporters (n=3, 14%), and healthcare professionals (n=14, 67%). In terms of online participants (n=9), people with lived experience of taking and/or stopping psychiatric medication (n=5, 56%), family members/carers/supporters (n=1, 11%), and healthcare professionals (n=3, 33%).

Table 5.7: Overview of workshop participants' characteristics

Total workshop participants	**N = 30**
Gender	
Male	**17 (57%)**
Female	**13 (43%)**
Stakeholder group	
Person with lived experience	**9 (30%)**
Family member, friend, carer, supporter	**4 (13%)**
Healthcare professional	**17 (57%)**
Healthcare professional group	
General Practitioner/Primary care physician	**5 (17%)**
Nurse	**5 (17%)**
Pharmacist	**3 (10%)**
Psychiatrist	**3 (10%)**
Psychologist	**1 (3%)**

Table 5.7 (continued): Overview of workshop participants' characteristics

Total workshop participants	**30**
Country of origin	
Belgium	**1 (3%)**
Canada	**1 (3%)**
Denmark	**1 (3%)**
Ireland	**20 (67%)**
Sweden	**1 (3%)**
United Kingdom	**5 (17%)**
United States	**1 (3%)**
Steering Group member	
Yes	**5 (17%)**
No	**25 (83%)**

As outlined in Chapter 4, the workshop was comprised of three whole group "plenary" sessions and three small group sessions, the latter of which involved question ranking. In small group session 1, participants shared their top three and bottom three questions. While no scores were used in this round, it guided the following session. In small group session 2, the 19 questions were ranked in order of priority (1-19). The ranked order of each small group was collated to find the combined ranked order which is outlined in Table 5.8.

Table 5.8: Ranked order (1-19) of summary questions after small group sessions 1 & 2

Ranked order (1-19) after small group sessions 1 & 2	Question
1	What is the most effective way to safely reduce and stop psychiatric medicines in terms of tapering approach, rate of taper and duration of taper? What individual service user characteristics (e.g., age, gender, pregnancy, other medical conditions/diseases) and drug characteristics (e.g., medication type, duration of treatment, use of other medication) determine these? [Originally Q9]
2	What are the most effective ways to provide support to individuals who are reducing and stopping psychiatric medicines? These may include, but are not limited to, family/peer support, educational support, financial support, psychological support, and healthcare support. [Originally Q3]
3	What are the best ways to educate current and future healthcare professionals about reducing and stopping psychiatric medicines in terms of the tapering process, associated risks/difficulties, withdrawal symptoms, and supporting shared decision making? What is the impact of education on clinical practice? [Originally Q32]
4	What are the views and experiences of individuals who have reduced/stopped psychiatric medicines or are currently reducing/stopping psychiatric medicines on the tapering process and accessing tapering support? [Originally Q6]
5	What are the views and experiences of service users, family members/carers, and healthcare professionals around shared decision making in relation to starting and stopping psychiatric medicines? This includes informed consent. How can the process of implementing shared decision-making be improved when starting and stopping psychiatric medicines? What factors influence this process? [Originally Q25]
6	What are the positive and negative long-term consequences of reducing and stopping psychiatric medicines on an individual's physical and mental health status? For individuals who experience negative consequences, what are the best ways to manage these difficulties? Negative consequences may include withdrawal symptoms, relapse, and protracted withdrawal syndromes. [Originally Q16]

Table 5.8 (continued): Ranked order (1-19) of summary questions after small group sessions 1 & 2

Ranked order (1-19) after small group sessions 1 & 2	Question
7	What are the perspectives of key stakeholders on the professional, ethical, and legal responsibilities of healthcare professionals and/or the pharmaceutical industry in relation to reducing and stopping psychiatric medicines? Stakeholders include service users, family members/carers and healthcare professionals. What are the best ways to enact these responsibilities? [Originally Q24]
8	How best can the withdrawal symptoms that appear during or after reducing and stopping psychiatric medicines be identified and differentiated from other causes (e.g., relapse/return of underlying condition, distress)? [Originally Q23]
9	Is there an optimum duration of use of psychiatric medicines after which reducing and stopping should be initiated that minimises the potential of physical dependency and/or relapse? Does this differ depending on the class/ type of medication? [Originally Q12]
10	What are the barriers and enablers to reducing and stopping psychiatric medicines? These may include, but are not limited to, the service user, the healthcare professional, family, and society. [Originally Q7]
11	Which factors influence the prevalence, duration and severity of withdrawal effects that appear during or after reducing and stopping psychiatric medicines? What is the best way to control these factors and reduce an individual's risk of developing withdrawal effects or relapsing? [Originally Q19]
12	What would make for an effective public health campaign about the potential risks associated with the use of psychiatric medicines, and the potential for challenges when reducing and stopping? These may include withdrawal symptoms and protracted withdrawal syndromes. [Originally Q28]

Table 5.8 (continued): Ranked order (1-19) of summary questions after small group sessions 1 & 2

Ranked order (1-19) after small group sessions 1 & 2	Question
13	What effects does the tapering process (tapering approach, rate, and duration of taper) and associated outcomes (i.e., withdrawal symptoms, protracted withdrawal syndrome, quality of life) have on the individual's health status and underlying neurobiology? [Originally Q14]
14	What is the rate/likelihood of recovery from withdrawal effects after reducing and stopping psychiatric medicines? Which factors influence/predict an individual's recovery outcomes? [Originally Q15]
15	How can the availability of psychiatric medicines in formulations that facilitate the process of reducing and stopping psychiatric medicines be improved? These include tapering strips and liquid formulations. [Originally Q2]
16	Is there a relationship between reducing and stopping psychiatric medicines and suicide/ suicidal ideation? If so, how best can this relationship be explained in terms of causation and prevalence? [Originally Q22]
17	What factors influence a service user's decision to reduce and stop psychiatric medicines? These may include patient factors, social factors, and health system factors. [Originally Q31]
18	To what extent do healthcare professionals report and document the adverse effects associated with the use of psychiatric medicines and/or the difficulties associated with reducing and stopping psychiatric medicines? How does this align with reports from service users, family members and carers? [Originally Q26]
19	How best can the future health of individuals who have stopped psychiatric medicines and have current/previous experience of protracted withdrawal syndromes be managed and protected? This may include, but are not limited to, the use of similar drugs or class of drug during future medical encounters. [Originally Q18]

In small group session 3, each group started with the combined priority order from the earlier sessions. Participants were given the opportunity to discuss and revise the order as they wished. Once all groups had finalised their rankings, these were again collated using Microsoft Excel to determine the final combined ranked order. The Top 10 priorities are outlined in Table 5.9. Priorities 11-19 are listed in Appendix 5.4.

The two highest ranked questions focused on the most effective ways of safely reducing/stopping psychiatric medication and providing support to individuals undergoing the discontinuation process. Another question asked about the best ways to educate healthcare professionals about reducing/stopping psychiatric medication. Other questions focused on understanding barriers and enablers to reducing/stopping psychiatric medication, and the views and experience of those who had reduced/stopped or were currently doing so. Questions also asked about the perspectives of key stakeholders on shared decision making, as well as the professional, ethical, and legal responsibilities of healthcare professionals and the pharmaceutical industry in relation to reducing/ stopping psychiatric medication. Other questions focused on the consequences (positive and negative) of reducing and stopping psychiatric medication on an individual's physical and mental health, as well as understanding the withdrawal symptoms.

Table 5.9: Top 10 priorities from the final prioritisation workshop

Top 10 priorities in ranked order (1-10)	Question
1	What is the most effective way to safely reduce and stop psychiatric medicines in terms of tapering approach, rate of taper and duration of taper? What individual service user characteristics (e.g., age, gender, pregnancy, other medical conditions/diseases) and drug characteristics (e.g., medication type, duration of treatment, use of other medication) determine these? [Originally Q9]
2	What are the most effective ways to provide support to individuals who are reducing and stopping psychiatric medicines? These may include, but are not limited to, family/peer support, educational support, financial support, psychological support, and healthcare support. [Originally Q3]
3	What are the best ways to educate current and future healthcare professionals about reducing and stopping psychiatric medicines in terms of the tapering process, associated risks/difficulties, withdrawal symptoms, and supporting shared decision making? What is the impact of education on clinical practice? [Originally Q32]
4	What are the views and experiences of individuals who have reduced/stopped psychiatric medicines or are currently reducing/stopping psychiatric medicines on the tapering process and accessing tapering support? [Originally Q6]
5	What are the views and experiences of service users, family members/carers, and healthcare professionals around shared decision making in relation to starting and stopping psychiatric medicines? This includes informed consent. How can the process of implementing shared decision-making be improved when starting and stopping psychiatric medicines? What factors influence this process? [Originally Q25]
6	What are the positive and negative long-term consequences of reducing and stopping psychiatric medicines on an individual's physical and mental health status? For individuals who experience negative consequences, what are the best ways to manage these difficulties? Negative consequences may include withdrawal symptoms, relapse, and protracted withdrawal syndromes. [Originally Q16]

Table 5.9: Top 10 priorities from the final prioritisation workshop (Step 6)

Top 10 priorities in ranked order (1-10)	Question
7	What are the perspectives of key stakeholders on the professional, ethical, and legal responsibilities of healthcare professionals and/or the pharmaceutical industry in relation to reducing and stopping psychiatric medicines? Stakeholders include service users, family members/carers and healthcare professionals. What are the best ways to enact these responsibilities? [Originally Q24]
8	Which factors influence the prevalence, duration and severity of withdrawal effects that appear during or after reducing and stopping psychiatric medicines? What is the best way to control these factors and reduce an individual's risk of developing withdrawal effects or relapsing? [Originally Q19]
9	How best can the withdrawal symptoms that appear during or after reducing and stopping psychiatric medicines be identified and differentiated from other causes (e.g., relapse/return of underlying condition, distress)? [Originally Q23]
10	What are the barriers and enablers to reducing and stopping psychiatric medicines? These may include, but are not limited to, the service user, the healthcare professional, family, and society. [Originally Q7]

5.3 Discussion

This aim of this study was to produce a Top 10 list of research priorities on reducing and stopping psychiatric medication through extensive engagement with key stakeholders representing people with lived experience of taking and/or stopping psychiatric medication, family members/friends/carers/supporters, and healthcare professionals. The list highlights important uncertainties and gaps in the existing evidence-base on this topic that need to be addressed by future research. As outlined in Chapter 2, traditionally mental health research was solely conducted by the "experts" i.e., the researchers and healthcare professionals. Individuals with lived experience of taking medication were discredited and refused the right to participate. This approach is now regarded as a form "epistemic injustice" (8-10). In line with the more rights-based and collaborative shift in mental health research, Patient and Public Involvement (PPI) has grown in popularity. PPI recognises the rights of individuals with lived experience to have an input in research and sees patients and members of the public as active partners in the design, delivery, and dissemination of research (12).

To the researcher's knowledge, this was the first James Lind Alliance (JLA) Priority Setting Partnership (PSP) study to focus on psychiatric medication. The process by which these priorities have been developed aligns with the principles of PPI and addresses an important deficit in current practices of stakeholder engagement as involvement of people with lived experience of mental health challenges in research is not widespread, particularly in the early stages of research priority and agenda setting (214). Consequently, people with lived experience of mental health challenges report difficulties in sharing their views and influencing the research agenda (214). A hallmark of the JLA approach is the representation of all stakeholder groups throughout the priority setting process. Equitable involvement of different stakeholders has been shown to facilitate the process of setting research priorities by developing a more holistic understanding of the 'unknown unknowns' (15).

The highest ranked question focused on the most effective ways of safely reducing/stopping psychiatric medication. This is a long-standing issue that has not been answered by previous research. To date, there is no standard approach on how best to

taper which has created many uncertainties regarding the tapering process (236). Studies have shown that the rate of taper is typically based on prescribers' clinical experience as opposed to high quality empirical evidence (7). Key organisations in the United Kingdom, such as the Royal College of Psychiatrists and the National Institute for Health and Care Excellence (NICE), recognise the importance of gradual dosage reduction at a rate that is tailored to the individual (170). There is a pressing need for further comprehensive research to establish an evidence base to support individuals looking to reduce and/or stop psychiatric medication (237).

Linked to this question about the most effective ways of safely reducing/stopping psychiatric medication, is the question about what the most effective ways are to support individuals undergoing the discontinuation process. The prioritisation of this question highlights a fundamental shift in the recognition of the potential challenges of discontinuing psychiatric medication and associated withdrawal symptoms, which were previously under acknowledged. For many years, guidelines described antidepressant withdrawal symptoms as mild and self-limiting, typically lasting only 1-2 weeks (175). Only in recent years have professional bodies and prescribing guidelines acknowledged that a proportion of individuals taking psychiatric medication, such as antidepressants, may experience significant withdrawal symptoms following discontinuation (170, 175). Although gradual dosage reduction is a core feature of many interventions, there is less robust evidence about additional measures such as psychological support (166, 167). In addition to this, the availability of dedicated withdrawal services is lacking (e.g., national helpline and specialist support services) (238). In the absence of empirical evidence, individuals are increasingly turning to online sources, such as discussion fora and peer support groups, for guidance and support while tapering psychiatric medication (153).

Another key question asked about the best ways to educate healthcare professionals about reducing and stopping psychiatric medication. Previous research has highlighted important perceived deficits in healthcare professionals' knowledge of psychiatric medicines and tapering approaches (239). This aligns with the views and reported experiences of people taking psychiatric medication (240). For example, a survey of members of an online discussion forum, who have stopped or tried to stop antidepressant use, found that 71% of respondents (n=906/1276) felt their doctors' advice regarding

stopping an antidepressant was unhelpful (241). Reasons included: their doctor recommended an abrupt taper and/or were unfamiliar with concept of withdrawal. Similar findings were reported by another survey involving antidepressant users in which 64% (n=205/319) of respondents reported receiving a lack of information about the potential for withdrawal symptoms from their doctor and 40% were advised to withdraw from their medication rapidly (242). Gaps in healthcare professionals' knowledge and training may create barriers to the safe discontinuation of psychiatric medication. According to this survey involving antidepressant users, the most frequently cited recommendation for future withdrawal services was to improve healthcare professional knowledge (242).

Other questions focused on the consequences of reducing and stopping psychiatric medication on an individual's physical and mental health, as well as understanding the withdrawal symptoms, and key stakeholders' perspectives on shared decision making. Various adverse effects are associated with the use and discontinuation of different psychiatric medications, about which individuals have reported not being informed before starting (243). According to the WHO, shared decision making, and informed consent are crucial to the provision of person-centred and recovery-oriented care (14). Service users have reported challenges in having their autonomy and choice respected and being involved in decisions around their medication (244). This does not align with a rights-based, recovery-oriented approach to mental healthcare that seeks to promotes open discussion about medication (14). Another related area of importance was the professional, ethical, and legal responsibilities of healthcare professionals and the pharmaceutical industry in relation to reducing and stopping psychiatric medication. This has not been examined by previous research.

Although the PSP study's key output was the Top 10 list of research priorities, it is important to note that several other shortlisted questions were discussed at length during the final prioritisation workshop. These questions may also provide a useful starting point for future research on reducing and stopping psychiatric medication. For example, the question about improving the availability of psychiatric medication in formulations and dosage ranges that facilitate the tapering process was deemed a key uncertainty among many survey respondents and workshop participants. There is currently a lack of evidence

informing clinicians or individuals as to what extent existing marketed formulations of psychiatric medication, which primarily consist of oral solid dosage forms (i.e., tablets, capsules, oral liquids/drops) can be further manipulated (e.g., split/crushed/diluted) to achieve smaller doses with due consideration to the physicochemical properties of individual medication and their formulations. Consequently, many individuals attempting dosage reduction use do-it-yourself methods that are shared online or through peer support forms that involve crushing tablets and making liquid preparations (99, 153). The accuracy, efficacy and safety of these approaches has not been evaluated. Tapering strips, consisting of psychiatric medication packaged into pouches of individual daily doses, have been developed in the Netherlands to enable gradual dosage reduction (189). However, tapering strips are not widely available or accessible on public health schemes. This is therefore an important area for future research, but ultimately, the stakeholder collaboration determined that other questions about the tapering process were of higher priority.

While the prioritisation of research uncertainties was the principle objective of the PSP study, it also sought to enhance and strengthen the manner in which research questions are identified. This was the first time that well-validated participatory methods involving all the key stakeholder groups have been used to identify research priorities for reducing and stopping psychiatric medication. The process by which these priorities have been developed addresses an important deficit in current practices of stakeholder engagement as involvement of people with lived experience of mental health challenges in research is not widespread, particularly in the early stages of research priority and agenda setting (214). In this sense, the PSP process aligns with more modern, rights-based approach to mental health research (16). The Top 10 research questions and uncertainties identified by this PSP study will help to guide future research and deliver responsive and strategic allocation of research resources, with a view to ultimately improving the future health and well-being of people who are taking psychiatric medication.

5.4 Strengths & limitations

While the strengths and limitations of the PSP methodology previously outlined in Chapter 3 are relevant to this study, there were additional strengths and limitations specific to this

study. Strengths included the robustness of the methodology and high level of engagement. The study followed the PSP methodology which has been used internationally in other healthcare domains and settings (201). It also followed the methods outlined in the published study protocol (190). Any points of deviation were highlighted and justified. The high level of engagement in this study was evident from the volume of responses to both surveys (Steps 2 & 5) and willingness to participate in the final prioritisation workshop (Step 6). Round 1 and Round 2 surveys were accessed by 1,743 individuals and 993 individuals respectively. In terms of the final prioritisation workshop, the positive response to the invitations to participate exceeded expectations. Purposeful sampling techniques were used to achieve a representation of different voices, genders, and nationalities.

The diversity of stakeholders involved at various points of the study was considered both a strength and limitation. On one hand, the research prioritisation process was strengthened by having Steering Group members, survey respondents, and workshop participants from the three key stakeholder groups, and of various ages, and ethnic groups. International collaboration was achieved at every step of the process. Collaboration is defined as *"the act of working with another person or group of people to create or produce something"* (245 p.1699). International collaboration has been shown to offer additional benefits such as ability to learn new methods and increase the visibility of the work (246). That said, the gap analysis conducted in Step 1 ("Establishing the Steering Group") identified two gaps in stakeholder representation in the Steering Group: individuals who had benefited from taking psychiatric medication and individuals from different ethnic groups, as well as global south countries. Efforts to fill these gaps were unsuccessful. As a result, it was not possible to capture the views and experiences regarding reducing and stopping amongst these nationalities and ethnic groups. There may be different research priorities in different countries with different health care systems. Indeed, different health care systems may impact on different priorities as perceived by both health care professionals and patients. Similar challenges to achieving equal representation were relevant to the recruitment of participants for the final prioritisation workshop (Step 6). With respect to the responses to both surveys (Steps 2 & 5), both were heavily dominated by the lived experience group despite efforts to target

the other two stakeholder groups (e.g., targeted Twitter posts and tagging relevant organisations). Survey responses were also dominated by the female gender.

Other limitations included accessibility and language restrictions, fixed survey questions, and the potential for lost information and bias. Although every effort was made to ensure that study information was accessible to a wide range of individuals (e.g., use of non-technical language and including examples) and both surveys were open to respondents from any country worldwide, they were only available in English and in digital format due to resource and time constraints. As a result, potential respondents who were not able to read English and did not have internet access may have been excluded.

With respect to the survey questions, one demographic question was included in both surveys which asked respondents to specify which stakeholder group best represented them. As previously mentioned, an individual may have represented multiple stakeholder groups. However, a focused set of questions was desirable in line with JLA guidance. For this reason, respondents were restricted to selecting one stakeholder group in both surveys. No question related to ethnic background was included. This decision was made in consultation with the Steering Group who agreed that the ethnicity of respondents would not contribute to directly to the prioritisation of uncertainties.

The final limitation acknowledges the potential for lost information and bias. Given that thousands of questions were submitted to the Round 1 survey (Step 2), it was not possible to retain every question. Specific questions on related themes were merged into broad questions that were reviewed and discussed with the Steering Group. Despite efforts to retain the sentiment of each question, there were challenges in reducing the uncertainties down, and a risk that information was lost in the process. In terms of bias, efforts were made to minimise the risk of bias throughout the study; questions were coded using a coding template that been developed in collaboration with the supervisory team, and the Steering Group, and the JLA Advisor had oversight over the entire coding process.

5.5 Summary

Chapter 5 focused the outcomes of the Priority Setting Partnership (PSP) study (Study 1). The major output of the PSP study was the Top 10 research priorities on reducing and

stopping psychiatric medication. The Top 10 research priorities produced in this study covered a range of questions and uncertainties relating to the tapering process and wider issues. Some questions had already been identified by previous research (e.g., optimal tapering methods and supports) while other questions were novel and had not yet been examined (e.g., the professional, ethical, and legal responsibilities of healthcare professionals and the pharmaceutical industry in relation to tapering psychiatric medication). It is intended that the study findings will help to guide future research in a way that is meaningful for all stakeholder groups, particularly those with lived experience. The next chapter focuses on Study 2 which involved analysing the free-text responses submitted to one of the surveys conducted as part of the PSP study to explore stakeholders' views and experiences of reducing and stopping psychiatric medication.

Chapter 6: Exploring stakeholders' views and experiences of reducing and stopping psychiatric medication use using a qualitative descriptive analysis

6.1 Introduction

Chapter 6 focuses on a qualitative descriptive analysis of free-text responses submitted to a survey to explore stakeholders' views and experiences of reducing and stopping psychiatric medication use (Study 2). The survey was conducted as part of the Priority Setting Partnership (PSP) study (Study 1). This chapter starts by outlining the study's aims and objectives followed by the study methods and findings. It then presents and discusses the study findings before concluding with a discussion on ethics and rigor.

6.2 Aim & objectives

The aim of this study was to explore stakeholders' views and experiences of reducing and stopping psychiatric medication use by analysing the responses submitted to Section 4 of the Round 1 survey conducted as part of Study 1. The objectives of this study were to:

- Describe stakeholders' views and experiences of reducing and stopping psychiatric medication use.
- Examine if similarities and differences in opinions exist between the three stakeholder groups around the use and discontinuation of psychiatric medication.

6.3 Methods

As outlined in Chapter 4, Study 1 was guided by the James Lind Alliance (JLA) PSP methodology which involved seven key steps. The aim of Study 1 was to identify the Top 10 priorities for future research on reducing and stopping psychiatric medication. Step 1 involved the establishment of an international Steering Group to guide and oversee the study. Step 2 involved the Round 1 survey which was an anonymous online survey conducted between 4th November and 31st December 2022, to gather key stakeholders'

uncertainties and questions about reducing and stopping psychiatric medication. The three key stakeholder groups comprised people with lived experience of taking and/or stopping psychiatric medication, family members/friends/carers/supporters, and healthcare professionals. Respondents had to represent one of these stakeholder groups to participate in the survey. The Round 1 survey contained four main sections. Section 4 contained a free-text comments section where respondents had the option of adding additional comments about reducing and/or stopping psychiatric medication if they so wished. This study analysed the responses to Section 4 of the survey.

6.3.1 Data analysis

Template analysis was the chosen methodology in this study. As discussed in Chapter 3, template analysis is a technique for thematically organising and analysing qualitative data (222).

6.3.1.1 Data preparation

All survey responses were downloaded from Qualtrics into a Microsoft Excel spreadsheet. The pseudonyms applied to the individual respondents [PSP001, PSP002, etc.] in Study 1 were also used in this study to protect the respondents' anonymity. The survey responses were then screened by the researcher (MB). Submissions to Section 4 responses were filtered and split according to the three stakeholder groups: people with lived experience of taking and/or stopping psychiatric medication, family members/friends/carers/supporters, and healthcare professionals. A separate Excel spreadsheet was created for each stakeholder group.

The supervisory team (AH, CC) met to define the scope of the analysis. In keeping with the aim of the study, comments relating to tapering psychiatric medication were considered within the scope (e.g., strategies used to reducing/stopping psychiatric medication and the challenges encountered upon doing so). If comments were not directly related to reducing/stopping psychiatric medication, they were considered "out-of-scope" (e.g., individual's views and experiences of taking psychiatric medication and reasons for starting medication). Comments that asked questions specific to the withdrawal process or questions about an individual's experience were categorised as "individual-level queries" and marked as out-of-scope, as these queries were already included in Study 1

and reflected in the summary questions. Out-of-scope responses were excluded from the final analysis. Some responses contained multiple comments. In this case, the responses were split into individual comments to facilitate the coding process.

6.3.1.2 Development of coding template

In line with the chosen methodology, the researcher, the supervisory team, and another researcher (a Year 4 MPharm student undertaking a four-month experiential learning placement in an academic setting) familiarised themselves with a sample of the free-text responses submitted by respondents from the lived experience group (n=50, 7%) by reading and re-reading them, noting their initial thoughts and any potential codes or patterns within the data. Given that most responses were submitted by the lived experience group, it was agreed with the supervisory team to commence the coding process with this stakeholder group. To enhance consistency in coding a brief definition or explanation was added to each preliminary code which formed the basis of the provisional coding template. This coding template was applied independently by the researcher, the other researcher, and the supervisory team to another subset of survey responses representing the lived experience group (n=50, 7%). Once complete, the researchers and the supervisory team met to discuss the provisional coding template and description of codes. At this stage, some lower-order codes were renamed to better reflect their content and similar codes were grouped together under a higher-order code, feeding into the hierarchical structure. The higher-order and lower-order codes represented the major themes and subthemes, respectively. This revised coding template was then piloted by the researcher on another subset of survey responses submitted by the same stakeholder group (n=30, 4%). The coded responses were reviewed by the supervisory team and minor modifications were made to the coding template before the final version was agreed (see Appendix 6.1).

6.3.1.3 Application of coding template

The final coding template was applied to the remaining responses submitted by respondents in the lived experience group. This was completed by the researcher and another researcher working independently. Once completed, all coded responses were compared by the two researchers. Disagreements were resolved through discussion with

the supervisory team. The same coding template and process was undertaken on the survey responses submitted by the other two stakeholder groups (i.e., supporters and healthcare professional groups).

Once all coding was complete, the survey responses were uploaded into NVivo to support data analysis and management. NVivo is a computer-assisted qualitative data analysis software which has proven useful when conducting qualitative research (247, 248). The application of electronic techniques to code data can help to enhance study rigor (249). “Nodes” were created on NVivo to match the codes in the coding template and applied to the relevant sections of data. Nodes represent codes, themes, or ideas about the data in a study (248). Once all the responses were inputted in NVivo, related sections of text were identified and grouped together, and exported back to Microsoft Word to enable the writeup of the study findings. While NVivo has been recommended for researchers working as part of team (248), the survey data was initially coded on Microsoft Excel because it was considered easier for the researcher and supervisory team to navigate in terms of familiarising themselves with the data, comparing codes, and resolving any coding disagreements.

6.4 Results

6.4.1 Characteristics of respondents who completed Section 4 in Round 1 survey

Of the 884 respondents who completed the Round 1 survey, 705 (80%) respondents had submitted additional comments in Section 4. Once out-of-scope responses (n=197) were excluded, 508 in-scope responses remained in the final analysis. The three stakeholder groups were represented in the in-scope responses: people with lived experience of taking and/or stopping psychiatric medication (n=389, 77%), healthcare professionals (n=66, 13%), and family members, friends, carers, or supporters (n=53, 10%). The breakdown of the stakeholder groups was broadly similar between the overall respondent group to the Round 1 survey and the subgroup that submitted additional comments in Section 4. Full details of respondents' demographics are reported in Table 6.1.

Table 6.1: Characteristics of Round 1 survey respondents and the subgroup of those respondents who submitted additional comments in Section 4

	Round 1 survey respondents	Round 1 survey respondents who submitted additional comments in Section 4	Round 1 survey respondents who submitted in-scope additional comments in Section 4
	n (%)	n (%)	n (%)
Total respondents	**884**	**705**	**508**
Gender			
Male	**232 (26%)**	**172 (25%)**	**106 (21%)**
Female	**629 (71%)**	**518 (73%)**	**393 (77%)**
Non-binary	**21 (2%)**	**10 (1%)**	**7 (1%)**
Did not specify	**2 (<1%)**	**5 (1%)**	**2 (<1%)**
Stakeholder group			
Person with lived experience	**609 (69%)**	**500 (69%)**	**389 (77%)**
Family member, friend, carer, supporter	**86 (10%)**	**80 (11%)**	**53 (10%)**
Healthcare professional	**186 (21%)**	**125 (18%)**	**66 (13%)**
Other	**3 (<1%)**	**0**	**0**
Age range, years			
18-24	**22 (2%)**	**14 (2%)**	**10 (2%)**
25-34	**88 (10%)**	**58 (8%)**	**40 (8%)**
35-44	**164 (19%)**	**122 (17%)**	**82 (16%)**
45-54	**195 (22%)**	**161 (23%)**	**115 (23%)**
55-64	**236 (27%)**	**197 (28%)**	**153 (30%)**
65-74	**137 (15%)**	**118 (17%)**	**83 (16%)**
75-84	**39 (4%)**	**32 (5%)**	**22 (4%)**
>85	**2 (<1%)**	**2 (<1%)**	**2 (<1%)**
Did not specify	**1 (<1%)**	**1 <1%)**	**1 (<1%)**
Country			
Africa	**15 (2%)**	**5 (<1%)**	**3 (<1%)**
Asia	**5 (<1%)**	**13 (2%)**	**4 (1%)**
Canada	**49 (6%)**	**44 (6%)**	**37 (7%)**
Europe	**118 (13%)**	**88 (13%)**	**55 (11%)**

Table 6.1 (continued): Characteristics of Round 1 survey respondents and the subgroup of those respondents who submitted additional comments in Section 4

	Round 1 survey respondents	Round 1 survey respondents who submitted additional comments in Section 4	Round 1 survey respondents who submitted in-scope additional comments in Section 4
Ireland	**88 (10%)**	**65 (9%)**	**34 (7%)**
Latin America	**7 (<1%)**	**5 (<1%)**	**5 (1%)**
Oceania	**41 (5%)**	**34 (5%)**	**28 (6%)**
United Kingdom	**188 (21%)**	**147 (21%)**	**105 (21%)**
United States	**371 (42%)**	**303 (43%)**	**236 (46%)**
Did not specify	**2 (<1%)**	**1 (<1%)**	**1 (<1%)**

6.4.2 Qualitative findings

Analysis of the in-scope responses (n=508) generated a coding template with eight main themes: (1) Perceived benefits/harms of taking psychiatric medication; (2) Decisions around reducing/stopping psychiatric medication; (3) Challenges to reducing/stopping psychiatric medication; (4) Strategies used by individuals to reduce/stop psychiatric medication; (5) Outcomes of reducing/stopping psychiatric medication; (6) Emotional context; (7) Areas for improvement; (8) Gratitude and appreciation. The main themes, subthemes, and examples of individual respondent submissions are outlined in Table 6.2.

Table 6.2: Overview of the in-scope themes & subthemes with examples from the dataset

Themes	Subthemes	Examples of individual respondent submissions
1: Perceived benefits/harms of taking psychiatric medication	**Benefits of taking psychiatric medication**	"*Lithium has literally been a lifesaver for me*." [PSP0539, PLE]
	Harms of taking psychiatric medication	*"They don't work, lives are put on-hold for years for withdrawal, and many are being left with life-altering harms."* [PSP0002, FFCS]
2: Decisions around reducing/stopping psychiatric medication	**Reasons for reducing/stopping psychiatric medication**	*"I took an SSRI for 6 months, became increasingly depressed and suicidal, then tapered off."* [PSP0071, PLE]
	Barriers to reducing/stopping psychiatric medication	*"I want to go off my meds but am afraid of the effects while doing it."* [PSP0971, PLE]
3: Challenges to reducing/stopping psychiatric medication	**Lack of support/recognition of withdrawal symptoms**	*"Doing it my own way since I have zero help from my current doctors who look at me like I have two heads when I talk about withdrawals."* [PSP0259, PLE]
	Lack of tapering supports & resources	*"The main problem for us has been finding a doctor who can support/advise about the whole process."* [PSP0429, FFCS]

Table 6.2 (continued): Overview of the in-scope themes, subthemes with examples from the dataset

Themes	Subthemes	Examples of individual respondent submissions
	Lack of autonomy	*"I have recently argued with him to allow me a much slower taper and that what he's doing could possibly kill me. He refuses to listen and thinks Dr Heather Ashton's manual is stupid."* [PSP1258, PLE]
	The tapering process & associated withdrawal symptoms	*"I have slowed down my reduction of psychotropic drugs but there remains substantial difficulty in doing this in practice."* [PSP0345, HCP]
4: Strategies used by individuals to reduce/stop psychiatric medication	**Abrupt discontinuation**	*"When I went for help, all he did was give me a prescription that brought me down to zero in a week. That was an unsafe taper, too fast."* [PSP1092, PLE]
	Tapering	*"I am still tapering diazepam using a liquid version. I'm taking 8 drops daily that equate to 0.4mg. I've tapered over 2 and 1/2 years from an initial amount of 80mg."* [PSP1424, PLE]

Table 6.2 (continued): Overview of the in-scope themes, subthemes with examples from the dataset

Themes	Subthemes	Examples of individual respondent submissions
	Pharmacological supports	*"I have finally been able to titer myself from all of the prescriptions that have been given to me over the years through the help of intravenous ketamine infusions."* [PSP1702, PLE]
	Non-pharmacological/psychological supports	*"Talk therapy with a trusted provider was the key to restoring his life."* [PSP0268, FFCS]
5: Outcomes of reducing/stopping psychiatric medication	**Positive outcomes of reducing/stopping psychiatric medication**	*"He says he has never felt suicidal again he since stopped the prescription drugs…. He is now 31, living independently, maintains a good job, and is enjoying life"* [PSP0268, FFCS]
	Negative outcomes of reducing/stopping psychiatric medication	*"I lost 2 years of work, was tempted to take my own life several times and am still not healed completely"* [PSP0853, PLE]
6: Emotional context	**Anger & frustration**	*"I am beyond frustrated with the lack of care and concern by medical field especially primary care physicians"* [PSP0273, FFCS]
	Loneliness & isolation	*"Reducing psych meds was a hell on earth and very lonely experience."* [PSP1333, PLE]
	Hopelessness & feeling trapped	*"I hate them and feel trapped to take them for the rest of my life."* [PSP0193, PLE]

Table 6.2 (continued): Overview of the in-scope themes, subthemes with examples from the dataset

Themes	Subthemes	Examples of individual respondent submissions
7: Areas for improvement	**Tapering resources**	*"I just need one for size guideline and have to go about tapering my patients safely from these neurotoxins. The information is everywhere but it's not in one precise place where I could call it "my go-to resource"."* [PSP1714, HCP]
	Regulatory oversight of the pharmaceutical industry	*"Explore if there are financial interests between pharmaceutical companies and practices who agree to "trial" drugs on their patients."* [PSP0908, FFCS]
	Healthcare professionals' accountability/responsibility	*"The problem with psychotropic drug withdrawal is enormous. It needs a multiprong approach, education: health care providers and students of these disciplines and to the public, legal: with prescribing restrictions for amount and duration."* [PSP0991, HCP]
	Healthcare professionals' education & training	*"Doctors should have a legal obligation to know about safe withdrawal and to provide that information to patients who would like to taper."* [PSP0320, PLE]
	Informed consent & public awareness	*"Please make society aware that is ok and natural to stop/end the psychiatric drugs and not take them permanently for every human being who had a hard time or reached another state of consciousness!"* [PSP0144, PLE]
8: Gratitude and appreciation	**No subthemes**	*"Thank you for the opportunity to speak."* [PSP1333, PLE]

Abbreviations: PLE (people with lived experience of taking and/or stopping psychiatric medication), FFCS (family members/friends/carers/supporters), and HCP (healthcare professionals).

6.4.2.1 Theme 1: Perceived benefits/harms of taking psychiatric medication

This theme focused on the positive and negative experiences of taking psychiatric medication. This theme was categorised into two subthemes: (1) Benefits of taking psychiatric medication; (2) Harms of taking psychiatric medication.

6.4.2.1.1 Benefits of taking psychiatric medication

Some respondents from the lived experience group reported benefiting from taking psychiatric medication. Perceived benefits included improved functionality and quality of life.

> *"Lithium has literally been a lifesaver for me."* [PSP0539, PLE]
>
> *"I am, a healthy, fit and socially active senior who is taking one medication that makes her life liveable."* [PSP0324, PLE]

The benefits of taking psychiatric medication were also identified by respondents from the healthcare professional group such as improved functionality and recovery.

> *"I think psychiatric medications are an important part of wellness and optimal functioning for anyone taking them"* [PSP0351, HCP]
>
> *"Many people manage to recover well with the assistance of psychiatric medication"* [PSP0538, HCP]

6.4.2.1.2 Harms of taking psychiatric medication

More respondents from the lived experience and supporters' groups reported being harmed from taking psychiatric medication compared to those who had benefited. Perceived harms included the medications' failure to manage their symptoms, and the potential to cause adverse effects. The language used by some respondents once again indicated the depth of their feeling, with words like '*poison'* and '*life altering harm'* being used. For some respondents, the harms caused by psychiatric medication were permanent.

> *"I think medications are poison and not conducive to healing whatsoever."* [PSP0299, PLE]
>
> *"Psych drugs caused me a permanent disability I'm yet to recover from"* [PSP0132, PLE]

> *"They don't work, lives are put on-hold for years for withdrawal, and many are being left with life-altering harms."* [PSP0002, FFCS]

While the perceived harms of taking psychiatric medication were not explicitly discussed by respondents from the healthcare professional group, some respondents questioned the efficacy of psychiatric medication, their potential overprescribing, and how they can negatively impact on individual's health and wellbeing.

> *"I think they are often over prescribed and often there is no improvement in quality of life, yet the medication is not stopped and then goes on to have detrimental effects."* [PSP0503, HCP]

> *"I think a lot of harm has been done by overprescribing."* [PSP1046, HCP]

> *"The incredible trouble we have caused them over the last few decades of massive prescribing"* [PSP1477, HCP]

> *"They are deeply damaging to some people's health and wellbeing."* [PSP1043, HCP]

One respondent from the healthcare professional group shared their reluctance to ever take psychiatric medication without providing additional elaboration, despite regularly prescribing them for service users.

> *"I have never been on psychotropic medication myself, and would highly resist taking it, although I prescribe it day in and day out for patients (who do have a much higher burden of mental illness than me)."* [PSP1623, HCP]

6.4.2.2 Theme 2: Decisions around reducing/stopping psychiatric medication

This theme focused on the decisions around reducing/stopping psychiatric medication. It was categorised into two subthemes: (1) Reasons for reducing/stopping psychiatric medication; (2) Barriers to reducing/stopping psychiatric medication. No responses submitted by the supporters' group were coded to this theme.

6.4.2.2.1 Reasons for reducing/stopping psychiatric medication

Adverse effects associated with the use of psychiatric medication was the main reason that respondents from the lived experience group reduced/stopped their psychiatric

medication. Adverse effects included headaches, nausea, weight changes, suicidal ideation and sexual dysfunction.

> *"I stopped them because I had so much nausea, my stomach is weaker than before."* [PSP0256, PLE]

"I took an SSRI for 6 months, became increasingly depressed and suicidal, then tapered off." [PSP0071, PLE]

In some cases, the individual felt that psychiatric medication was no longer needed or benefiting them.

> *"I began tapering soon after the symptoms started after discovering the issue was with the drug and not me."* [PSP0513, PLE]
>
> *"I myself alone made the decision to get off of them, and only when they were causing the very issues I was taking them for those many years ago."* [PSP0250, PLE]

Adverse effects associated with the use of psychiatric medication were also acknowledged by respondents from the healthcare professional group as a reason for reducing/stopping psychiatric medication.

> *"I think most people stop psychiatric medication because of side effects. They feel meds make them feel fuzzy, out of it, hungover. Increased appetite and weight gain is a massive worry and problem for people and many stop meds because of weight gain."* [PSP1157, HCP]

Respondents from the healthcare professional group did not share their reasons for recommending that individuals under their care consider reducing/stopping psychiatric medication.

6.4.2.2.2 Barriers to reducing/stopping psychiatric medication

Fear was a key barrier to reducing/stopping psychiatric medication for respondents from the lived experience group. This included fear of the tapering process, fear of developing withdrawal symptoms, and fear of relapsing.

> *"I'm scared to start tapering again."* [PSP1086, PLE]
>
> *"I want to go off my meds but am afraid of the effects while doing it."* [PSP0971, PLE]

"I was told categorically if stopped SSRIs earlier than 2 years post major depression would be at risk of relapse." [PSP0292, PLE]

Only one response from the healthcare professional group discussed barriers to reducing/stopping psychiatric medication. According to this respondent, getting the service user to consider reducing/stopping psychiatric medication was the biggest barrier due to the skewed/unbalanced information they had received regarding the safety and efficacy of psychiatric medication i.e., more emphasis placed on the benefits of medication than the limitations.

"The public has been given a consistent message that antidepressants are the most effective (and convenient) way to address feelings of low mood. It can be a great challenge to explain the limitations of medication treatment in helping the most prevalent forms of mood and anxiety difficulties to patients and families/supporters. I find that addressing this challenge is the major difficulty in weaning patients off medication (rather than the tapering process itself)." [PSP0367, HCP]

6.4.2.3 Theme 3: Challenges to reducing/stopping psychiatric medication

This theme focused on the challenges to reducing/stopping psychiatric medication. The challenges were grouped according to four subthemes: (1) Lack of support/recognition of withdrawal symptoms; (2) Lack of supports & tapering resources; (3) Lack of autonomy; (4) The tapering process & associated withdrawal symptoms.

6.4.2.3.1 Lack of support/recognition of withdrawal symptoms

Many respondents from the lived experience and supporters' groups were dissatisfied with the availability and accessibility of tapering supports, in particular professional support from healthcare professionals. Several respondents found it difficult to find a healthcare professional who would support them when reducing/stopping psychiatric medication.

"The main problem for us has been finding a doctor who can support/advise about the whole process." [PSP0429, FFCS]

"My doctor deserted me when I started tapering" [PSP0108, PLE]

"Difficult to find Doctors to assist, even if you live in a big city, have health insurance or willing to pay" [PSP0119, PLE]

> *"It's been impossible for me to stop having tried several times with minimal help from my doctor."* [PSP0460, PLE].

Some respondents from the lived experience and supporters' groups also experienced reluctance from healthcare professionals to reduce/stop psychiatric medication who believed that psychiatric medication should be continued long-term. In some cases, the prescriber suggested increasing the dose or switching to alternative medications instead of reducing/stopping the psychiatric medication.

> *"There is a general resistance from psychiatrists that makes the whole reduction process feel very risky - even when trying to do it very slowly and carefully."* [PSP0429, FFCS]

> *"My doctor gave me every excuse in the book why I shouldn't quit. Then sent the rest of my visit talking about raising my dose. At the end I imagined cartoon dollar signs in his eyes."* [PSP0141, PLE]

> *"Should be possible to find supportive psych health practitioners that will help with tapering - but all are brainwashed to believe mental health problems are biophysical and therefore meds are best to be on long term. Just keep switching meds rather than finding best health through physical and psychosocial health support."* [PSP0465, FFCS]

Respondents from the lived experience and supporters' groups also reported difficulties in discussing withdrawal symptoms with prescribers due to lack of recognition or awareness of withdrawal symptoms.

> *"Doing it my own way since I have zero help from my current doctors who look at me like I have two heads when I talk about withdrawals."* [PSP0259, PLE]

> *"If the providers don't know or don't believe in things like discontinuation syndrome then we're all just stuck in a vicious cycle."* [PSP1464, PLE]

> *"There's no help from doctors as they don't believe in withdrawal symptoms."* [PSP0091, FFCS]

One respondent from the lived experience group suggested that healthcare professionals disregard withdrawal symptoms as they see it as a challenge to their authority.

> *"Discussing withdrawal with medical professionals is exceptionally difficult as bringing data/info to bear for the case of withdrawal and how is often seen as a direct challenge of their authority (you practice that which you are told, and that*

which gives you learned informed authority over the patient/he, or she that does not know any better).” [PSP0880, PLE]

The reluctance amongst healthcare professionals to reduce/stop psychiatric medication was also discussed by some respondents from the healthcare professional group, several of whom included potential justifications for this behaviour in their responses. These included uncertainty/lack of knowledge about the tapering process and fear of criticism from other healthcare professionals.

“The myth that people relapse if they are not on medication still informs the practice of most psychiatrists in my experience and they still believe the chemical imbalance hypothesis.” [PSP0496, HCP]

“Fear of unfair criticism, ignorance of withdrawal and fear of admitting fault in assessing risks and benefits of meds are key to medical resistance to reducing and stopping meds.” [PSP0264, HCP]

Some respondents from the healthcare professional group also acknowledged the lack of recognition for, and underestimation of, withdrawal symptoms amongst their professional colleagues, particularly individuals in more senior roles.

“The withdrawal of effects of psychiatric medicine appears to me to be underestimated” [PSP0404, HCP]

“Sadly, many senior psychiatrists still dismiss and diminish this huge [tapering] issue.” [PSP1511, HCP]

6.4.2.3.2 Lack of tapering supports & resources

Tapering resources refers to evidence-based information, guidelines, and pharmaceutical formulations. In the absence of trustworthy information on reducing/stopping psychiatric medication, some respondents from the lived experience group sought information from alternative, non-evidence-based websites such as YouTube and other support sites.

“There is no science testing this, the drug companies make the pills tiny and incredibly hard to taper, and people are left to googling you tube videos and support sites for help.” [PSP0207, PLE]

The lack of tapering guidelines also created challenges for respondents from the healthcare professional group when making clinical decisions relating to the use and discontinuation of psychiatric medication e.g., determining the risk benefit ratio.

> *"The lack of clear guidelines makes it difficult to balance risk/benefit."* [PSP1293, HCP]

> *"Reduction and discontinuation of medications, particularly antipsychotics, is a feature of my practice, and in the absence of clear guidance, the process is largely determined by the service user."* [PSP1280, HCP]

Respondents from the lived experience and supporters' groups perceived the level of tapering knowledge amongst healthcare professionals as inadequate.

> *"My pharmacist has no clue. My primary care physician has no clue, and even my psychiatrist had no clue."* [PSP0325, PLE]

> *"The lack of knowledge by the medical profession on how to safely taper the drugs they prescribe is a worldwide scandal."* [PSP0257, PLE]

> *"Doctors are not trained on how to taper meds correctly. They reduce in large amounts too quickly and then recommend that the patient be put back on high dose because they can't function without it."* [PSP0537, FFCS]

The only response submitted by the healthcare professional group on the level of tapering knowledge amongst healthcare professionals shared the views held by respondents from the other two groups. In their response, the individual acknowledged the lack of tapering-related education they had received during their training as a pharmacist.

> *"Pharmacists were told nothing! All I knew about benzos from school was if you stop too fast you can have seizures."* [PSP0917, HCP]

The lack of taper-friendly formulations (i.e., liquids, low dose formulations, and tapering strips) created practical issues for respondents from the lived experience and supporters' groups in tapering the medication. These issues included difficulties with dose alterations and titrations to achieve desired medication doses.

> *"I was struggling to cut my own dose in water because I couldn't cut the pill any smaller."* [PSP0108, PLE]

> *"Tapering strips are not available for all psych meds and titration is not possible due to the composition of the tablet."* [PSP0880, PLE]

> *"Working out the measurements of how to taper is quite complicated."* [PSP0429, FFCS]

The lack of taper-friendly formulations also created practical challenges for respondents from the healthcare professional group in the form of placing additional burdens on their already busy workloads.

> *"We have no assess to tapering strips on National Health Service and I have no time to support liquid reductions in clinical practice."* [PSP0345, HCP]

6.4.2.3.3 Lack of autonomy

Several respondents from the lived experience group struggled to have an input in the decision-making process relating to reducing/stopping their use of psychiatric medication. In these cases, the prescriber was in full control of the tapering schedule.

> *"My doctor is also pressuring me to complete my taper on HIS terms and schedule. I am being forced into a rapid taper by him"* [PSP1618, PLE]

> *"I feel I've been pushed into this"* [PSP1258, PLE]

Some respondents who attempted to discuss tapering with their prescribers were dismissed and faced conflict. One respondent's prescriber dismissed the Ashton Manual which was developed by Dr Heather Ashton, a psychopharmacologist and physician, to guide the process of withdrawing benzodiazepines (85).

> *"I have recently argued with him to allow me a much slower taper and that what he's doing could possibly kill me. He refuses to listen and thinks Dr Heather Ashton's manual is stupid."* [PSP1258, PLE]

6.4.2.3.4 The tapering process & associated withdrawal symptoms

Many respondents from the lived experience and supporters' groups experienced a range of withdrawal symptoms that appeared after reducing/stopping psychiatric medication. Withdrawal symptoms included chronic pain, insomnia, nervous system dysfunction, suicidal ideation, and brain fog. For some respondents, the withdrawal symptoms were severe and persisted for prolonged periods after stopping psychiatric medication.

> *"Physically the itching, the sweating, the insomnia for months on end was so unbearable."* [PSP886, PLE]

> *"3 days later came the insomnia followed by flu-like symptoms. Then came the nausea and not being able to eat followed by uncontrollable anxiety and having to take beta blockers to slow down my heart rate. Lastly came the brain fog memory loss speech slurring and not being able to focus drive etc."* [PSP0281, PLE]

"I thought of suicide every day when in severe akathisia." [PSP1347, PLE]

"The high levels of psychiatric withdrawal symptoms were such a shocker to us; to me." [PSP1667, FFCS]

Withdrawal symptoms were only discussed by a handful of respondents from the healthcare professional group. These respondents acknowledged the potential severity of withdrawal symptoms and alluded to a general lack of understanding with respect to the underlying pathophysiology and management of withdrawal symptoms.

"I have known those who have found themselves physically unable to tolerate the withdrawal effects." [PSP0517, HCP]

"Benzodiazepines are the least understood – the paradoxical sensitivity, the more difficult withdrawals on each attempt, how to respond to people who experience this hypersensitivity to withdrawal." [PSP1528, HCP]

There was consensus across the three groups that the process of reducing/stopping psychiatric medication can be an extremely difficult experience. Although the comments lacked depth on why this might be the case, the language used gave an indication to the degree of difficulty encountered, with words like 'degrading' 'traumatic', 'horrific' being used.

"Getting off these drugs is a horrifying experience even for short term users, less than a month use. Unbelievable, traumatic experience." [PSP0369, PLE]

"The hell endured in protracted withdrawal is the stuff of demonic nightmares." [PSP1262, PLE]

"Our experience withdrawing from meds was/ is pretty horrific." [PSP0076, FFCS]

"I have slowed down my reduction of psychotropic drugs but there remains substantial difficulty in doing this in practice." [PSP0345, HCP]

6.4.2.4 Theme 4: Strategies used by individuals to reduce/stop psychiatric medication

This theme focused on the strategies used by individuals to support them to reduce/stop psychiatric medications. The strategies were grouped according to four subthemes: (1) Abrupt discontinuation; (2) Tapering; (3) Pharmacological supports; (4) Non-pharmacological/psychological supports.

6.4.2.4.1 Abrupt discontinuation

Several respondents from the lived experience and supporters' group had first or second-hand experience of stopping psychiatric medication abruptly over a short period (i.e., "cold turkey"). In most cases, it was reported as being prescriber-initiated, with some respondents commenting on how it felt 'unsafe'.

> *"When I went for help, all he did was give me a prescription that brought me down to zero in a week. That was an unsafe taper, too fast."* [PSP1092, PLE]

> *"I was on olanzapine for 3 years 2.5mg and went cold Turkey April 2018 under the false illusion that because 2.5mg is such a small dose that I'd be able to stop at any time."* [PSP281, PLE]

> *"The centre stopped him abruptly from all medications and did not give him phenobarbital as was indicated on his medical records."* [PSP0031, FFCS]

Abrupt discontinuation was only discussed by one respondent from the healthcare professional group. In this case, it appeared to be the only option given the lack of available pharmaceutical formulations.

> *"I have seen inpatients be abruptly stopped from psych meds when in ICU because there are no immediate release (crushable) forms available. Especially with duloxetine or other XR [extended release] meds. They just stop them! Maybe restart when they discharge."* [PSP0917, HCP]

6.4.2.4.2 Tapering

Most respondents from the lived experience and supporters' groups used or had experienced seeing a tapering strategy being used to reduce/stop psychiatric medication in the reported tapering strategies varied. Several respondents reduced the medication dose by fixed amounts every few weeks.

> *"Am 5 years into a fluoxetine taper at no more than 2-5% every 2-4+ weeks."* [PSP0700, PLE]

> *"He is reducing the medication by 10% each week."* [PSP0100, FFCS]

Some respondents reported cutting their tablets into smaller amounts to minimise withdrawal symptoms.

> *"Venlafaxine - took years to discontinue, fortunately managed in the end by cutting tablets into tiny portions and then increasing the length of time until the 'electric shocks' were unbearable and then taking another tiny portion."* [PSP0242, PLE]

Other respondents switched from solid to liquid formulations and reduced the medication dose by calculating the amount of medication per drop.

> *"I am still tapering diazepam using a liquid version. I'm taking 8 drops daily that equate to 0.4mg. I've tapered over 2 and 1/2 years from an initial amount of 80mg"* [PSP1424, PLE]

Many respondents reported that the tapering process took years to complete.

> *"I have been tapering medications for 3 years"* [PSP0136, PLE]
>
> *"I am at 6 mg of Duloxetine, down from 30. It has taken over 3 years."* [PSP0195, PLE}

No responses submitted by the healthcare professional group discussed tapering strategies.

6.4.2.4.3 Pharmacological supports

Several respondents from the lived experience and supporters' groups used or witnessed others using pharmacological supports when reducing/stopping psychiatric medication. Pharmacological supports refer to medication and supplements. Examples included ketamine, marijuana, benzodiazepines, and beta blockers. For some respondents, pharmacological supports facilitated the process of reducing/stopping psychiatric medication and minimised the withdrawal symptoms.

> *"I have finally been able to titre myself from all of the prescriptions that have been given to me over the years through the help of intravenous ketamine infusions."* [PSP1702, PLE]
>
> *"I use some limited [clonazepam] and [propranolol] just to get through events and responsibilities"* [PSP0098, PLE]
>
> *"Doing a Ketamine treatment on a monthly basis."* [PSP0100, FFCS]
>
> *"Only got through the horrific withdrawal with use of [legal] marijuana."* [PSP0268, FFCS]

Other respondents from the lived experience group switched to another psychiatric medication (i.e., "cross tapering") or another pharmaceutical formulation before starting to reduce. One respondent that switched from alprazolam to diazepam, the latter of which has a longer half-life, found that it minimised their withdrawal symptoms.

"I am now with a psychiatrist that has switched me to diazepam, which has helped with the inter-dose withdraw. After switching I no longer have the highs and lows that the [alprazolam] cause." [PSP0393, PLE]

"I have just swapped to a liquid form of a tricyclic medication before starting to reduce my meds." [PSP1240, PLE]

6.4.2.4.4 Non-pharmacological/psychological supports

A smaller number of respondents from the lived experience used non-pharmacological/psychological supports when reducing/stopping psychiatric medication. Non-pharmacological/psychological supports refer to those not containing any active pharmaceutical ingredients. Examples included diet and lifestyle changes, and cognitive behavioural therapy (CBT).

"I try to eat clean whole foods and very limited processed foods. I exercise every day - cycle, long walks, body pump, etc it really helps me." [PSP1206, PLE]

"Coping skills and self-care have helped me most... natural non-invasive things like good nutrition, good sleep hygiene, therapy twice a week, meditation, gentle exercise, getting outside for early morning sunlight in the eyes every single day just after sunrise, cold showers, positive self-talk out loud, humming, breathing exercises, etc. I'm so grateful to the online withdrawal community and everyone that is working to help others and prevent further harm." [PSP1259, PLE]

Psychological support in the form of online peer support forums was discussed by several respondents. For some respondents, online forums facilitated the process of reducing/stopping psychiatric medication by providing information, resources, and assistance.

"I'm so grateful to the online withdrawal community and everyone that is working to help others and prevent further harm." [PSP1259, PLE]

"I informed myself of the best way to do that by looking online and finding information on 'benzobuddies'." [PSP0419, PLE]

"I used resources at survivingantidepressants.org to help me taper and get through withdrawal symptoms." [PSP1222, PLE]

"I have relied exclusively on the internet for tapering benzodiazepines and citalopram. Information from The Ashton Manual, Surviving Antidepressants, Adele Framer, Mark Horowitz, David Taylor, and Christy Huff have provided the internet assistance which I have found useful." [PSP1249, PLE]

> *"The prescribed harm community and their online support groups seem to be the only source to receive accurate education on safely stopping psych drugs."* [PSP1459, PLE]

The importance of peer support in reframing their experience was highlighted by one respondent from the lived experience group.

> *"It's the main reason the support group "psychiatric sobriety" has been so helpful for me lately. It's important to get together with others who are struggling and try to reframe this experience as a way of "emerging" and healing, rather than being damaged/ broken."* [PSP0485, PLE]

Few responses submitted by the supporters' and healthcare professional groups discussed tapering supports when reducing/stopping psychiatric medication. However, among those that did, respondents also recognised the benefits of talking therapy and social supports in terms of facilitating the withdrawal process.

> *"Talk therapy with a trusted provider was the key to restoring his life."* [PSP0268, FFCS]

> *"My son was able to greatly reduce his medication and undergo withdraw in the safety of his parent's home with family support of his daily needs."* [PSP0370, FFCS]

> *"I have experienced clients finding talking therapy adequate to facilitate their stopping medication."* [PSP0517, HCP]

6.4.2.5 Theme 5: Outcomes of reducing/stopping psychiatric medication

This theme focused on the outcomes of reducing/stopping psychiatric medication. It was categorised into two subthemes: (1) Positive outcomes of reducing/stopping psychiatric medication; (2) Negative outcomes of reducing/stopping psychiatric medication.

6.4.2.5.1 Positive outcomes of reducing/stopping psychiatric medication

Many respondents from the lived experience and supporters' groups had experienced, or witnessed, positive outcomes after reducing/stopping psychiatric medication. These included a sense of freedom, the ability to feel emotion and purpose, and relief from the adverse effects and suicidal thoughts linked to medication use.

> *"Getting off the antipsychotic I was on has freed me from toxic psychiatry, brought more feeling, authentic emotion, more life, and more appreciation of life."* [PSP0428, PLE]

> *"I only began to truly recover when I chose to stop attending a psychiatrist and stop taking antipsychotics. I stopped experiencing symptoms almost immediately."* [PSP0770, PLE]

> *"Stopping the psych drugs is how to heal"* [PSP1383, PLE]

> *"He says he has never felt suicidal again he since stopped the prescription drugs…. He is now 31, living independently, maintains a good job, and is enjoying life"* [PSP0268, FFCS]

Several respondents from the healthcare professional group also reported witnessing the positive outcomes of reducing/stopping psychiatric medication. Similar to the other two groups, improved functionality was observed upon reducing psychiatric medication.

> *"MOST patients become more socially and occupationally functional AFTER I reduce their polypharmacy."* [PSP0857, HCP]

> *"When my clients have been ready to reduce, to date in my practice of 12 years, it has always been to their benefit."* [PSP0382, HCP]

6.4.2.5.2 Negative outcomes of reducing/stopping psychiatric medication

Negative outcomes of reducing/stopping psychiatric medication were more commonly reported by respondents from the lived experience and supporters' groups, compared to positive outcomes. Negative outcomes included debilitating withdrawal symptoms that lasted for pronged periods, and suicidal ideation.

> *"I lost 2 years of work, was tempted to take my own life several times and am still not healed completely"* [PSP0853, PLE]

> *"Stopping these medications (with the oversight of doctors) almost took my life. I had seizures and developed debilitating symptoms that lasted months and continue to afflict me today."* [PSP0275, PLE]

A number of respondents from the supporters' group wrote about how a person known to them died by suicide after stopping psychiatric medication due to unbearable withdrawal symptoms. For some respondents, the intensity of withdrawal symptoms was attributed to abrupt discontinuation of the psychiatric medication.

> *"My loved one took their life due to akathisia and other side effects from tapering too quickly off of a prescribed Benzodiazepine."* [PSP0328, FFCS]

> *"He subsequently suffered seizures, etc., developed severe PAWS [Post Acute Withdrawal Syndrome] and then killed himself 4 months later."* [PSP0031, FFCS]

In addition to suicidality, the above and other quotes highlighted other issues that appeared after reducing/stopping psychiatric medication such as seizures, relapses requiring higher doses of the medication and/or more medications, reduced functional capacity and negative impacts on personal and work life.

> *"I cannot sleep, eat, work, parent, think or live normally in any way."* [PSP1593, PLE]

> *"Cognitive damage and daily misery from withdrawal troughs are not worth it."* [PSP0021, FFCS]

One respondent from the healthcare professional group wrote about the multiple relapses they had witnessed in service users, using the word "catastrophic" to capture their severity, and the negative repercussions that followed.

> *"I have looked after numerous patients who have had catastrophic relapses after stopping their medication and it can be really difficult to get their symptoms back until control again, which often ends up with them being on more medication than they were before they stopped it."* [PSP1533, HCP]

6.4.2.6 Theme 6: Emotional context

Respondents from the lived experience and supporters' groups experienced a diverse range of emotions upon, or after, reducing/stopping psychiatric medication. The language used by respondents reflected the depth of emotion they experienced, which included feelings of anger, loneliness, hopeless and fear. This theme was categorised into three subthemes: (1) Anger & frustration; (2) Loneliness & isolation; (3) Hopelessness & feeling trapped.

6.4.2.6.1 Anger & frustration

Many respondents were angry about being put on psychiatric medication in the first place, and for not being fully informed of the potential risks prior to starting the medication. These respondents described taking psychiatric medication as one of the *'worst things'* that ever happened to them.

> *"I am angry that I have been put on this medication and not told what could happen to me."* [PSP0102, PLE]

> *"I am beyond frustrated with the lack of care and concern by medical field especially primary care physicians"* [PSP0273, FFCS]

"Being prescribed antidepressants was one of the worst things that has happened to me in my life" [PSP0197, PLE]

Some respondents were regretful about being put on psychiatric medication in the first place.

"For many many times I wished I could go back in time and never lay my hands on any of them." [PSP1279, PLE]

"If I had known withdrawal was a possibility, I never would have started taking the meds." [PSP0237, PLE]

"I wish I knew what hell these drugs were going to put me through I would've never ever taken even one." [PSP1591, PLE]

6.4.2.6.2 Loneliness & isolation

There was a sense of loneliness that arose for several respondents while undertaking the withdrawal process which was described as an '*isolating*' experience.

"Withdrawal is the worst, indescribable, socially isolating experience." [PSP1295, PLE]

"Reducing psych meds was a hell on earth and very lonely experience." [PSP1333, PLE]

"I had to do this all on my own, I lost everyone and everything important." [PSP0062, PLE]

6.4.2.6.3 Hopelessness & feeling trapped

Some respondents reported a sense of hopelessness about reducing and stopping psychiatric medication and feared that they had been permanently changed by taking psychiatric medication.

"I am devastated." [PSP1593, PLE]

"Hopeless." [PSP1092, PLE]

"The fear of never being able to come off and being normal again." [PSP1520, PLE]

Others felt trapped on psychiatric medication, fearing that they would be on them for life.

"I feel completely trapped on olanzapine." [PSP0173, PLE]

"I hate them and feel trapped to take them for the rest of my life." [PSP0193, PLE]

No responses submitted by the healthcare professional group discussed either the emotions they felt or reflected on the possible emotions that individuals from the other groups might have experienced.

6.4.2.7 Theme 7: Areas for improvement

This theme focused on potential areas that could be targeted to improve individuals' experiences of the withdrawal process. It was categorised into five subthemes: (1) Tapering resources; (2) Regulatory oversight of the pharmaceutical industry; (3) Healthcare professionals' accountability/responsibility; (4) Healthcare professionals' education & training; (5) Informed consent & public awareness.

6.4.2.7.1 Tapering resources

Respondents from the three groups suggested that evidence-based and accessible tapering guidelines should be developed to overcome the challenges previously discussed. Respondents believed that tapering guidelines have the potential to facilitate decision-making, to guide the tapering process, to minimise withdrawal symptoms, and inform individuals as to what they can expect during and after the withdrawal process.

> *"It would be great to have better, more up-to-date evidence-based guidelines to help clinicians like her make recommendations to patients like me."* [PSP1640, PLE]
>
> *"I would love it if a safe and comfortable way of tapering could be found and rolled out to the general public."* [PSP0499, PLE]
>
> *"Please develop easy to access guides for caregivers supporting their loved one through a safe taper and what to expect when their loved one is going through withdrawal?"* [PSP0321, FFCS]
>
> *"Need guidelines that will spare most from withdrawal affects that Read and coworkers have clearly elucidated."* [PSP1498, HCP]

One respondent from the healthcare professional group suggested that these guidelines should be easily accessible and centralised.

> *"I just need one for size guideline and have to go about tapering my patients safely from these neurotoxins. The information is everywhere but it's not in one precise place where I could call it" my go-to resource"."* [PSP1714, HCP]

Respondents from the three groups asked for more taper-friendly formulations, specifically lower dose formulations and tapering strips, to overcome the practical issues of manipulating solid dose formulations previously discussed in Section 6.4.2.3.2.

> *"It would be great if pharma companies held some accountability and supplied smaller mg capsules."* [PSP0134, PLE]
>
> *"There should be lower doses readily available without using expensive compounding pharmacies. The companies who make the drugs should also make lower doses to help people taper."* [PSP0302, PLE]
>
> *"Make pharmaceutical companies make many size dosing."* [PSP0163, FFCS]
>
> *"Can tapering packets/dossette boxes be made available?"* [PSP0531, HCP]

Respondents from the lived experience and supporters' groups also asked for improved tapering supports. A range of tapering supports were suggested in the responses including financial supports in the form of medical insurance/government assistance during and after the withdrawal process.

> *"More supports need to be mandated, so that mental health patients get the protections they need, when faced with difficult situations around medications, while being forced to work with flawed practitioners."* [PSP1578, PLE]
>
> *"We need to create a medical diagnosis or category called 'prescribed drug withdrawal syndrome' or similar, so we can access government support during and after withdrawal."* [PSP0418, PLE]

Other respondents from the lived experience and supporters' groups asked for more psychosocial supports in the form of online supports and residential care.

> *"Would be great to have online tapering psych health support available from anywhere in the world."* [PSP0465, FFCS]
>
> *"A few months residential care to admin temporary e.g., sleep aids etc. That would be a good help to monitor the process of withdrawal which can be dangerous"* [PSP0099, FFCS]

Some respondents from the healthcare professional group also asked for improved accessibility to trained healthcare professionals and the roll-out of tapering specific primary care interventions.

> *"Access to a clinic nurse or doctor after the tapering has started supports the patient with the process and also their family member/supporter."* [PSP0548, HCP]

"We need realistic care pathways/interventions that can be implemented in primary care so we can best support the large numbers of people who wish to reduce or stop psychotropic medicines. High-intensity interventions needing specialist staff will only ever be available to a small number of patients." [PSP1536, HCP]

6.4.2.7.2 Regulatory oversight of the pharmaceutical industry

Several respondents from the lived experience and supporters' groups queried the level of regulatory oversight of psychiatric medication and the pharmaceutical industry. Respondents asked for enhanced regulatory oversight of the prescribing of psychiatric medication (e.g., two-person prescribing), and the relationship between the pharmaceutical industry and prescribers.

"These should all be highly controlled drugs and require two doctor signatures of agreement that it is a correct option." [PSP0062, PLE]

"There also needs to be more regulation around the influence of the pharmaceutical industry on mental health practitioners." [PSP1578, PLE]

"Explore if there are financial interests between pharmaceutical companies and practices who agree to "trial" drugs on their patients." [PSP0908, FFCS]

Some respondents also queried the level of accountability and responsibility of the pharmaceutical industry for the harms caused by psychiatric medication.

"Why is big Pharm not responsible for destroying lives?" [PSP1113, PLE]

"Why are the pharmaceutical companies not accountable for the damage they have caused to so many." [PSP0471, PLE]

With respect to psychiatric medication, some respondents queried the low levels of information provided in Participant Information Leaflets (PILs) of psychiatric medication, particularly the potential for withdrawal symptoms.

"Why aren't withdrawal effects put into the drug information papers?" [PSP1089, PLE]

"Why pharmaceutical representant are not obliged to explain it, why it's not written in use notice etc problem is that big pharmaceutical says there is absolutely no withdrawal with their drug." [PSP0269, PLE]

6.4.2.7.3 Healthcare professionals' accountability/responsibility

Several respondents from the lived experience and supporters' groups queried the level of accountability and responsibility of healthcare professionals in areas relating to information provision, shared decision-making, prescribing and reducing/stopping psychiatric medication. Some respondents from the supporters' groups asked how prescribers could be held accountable for providing service users with all relevant information and obtain informed consent.

> *"How to MAKE prescribers warn patients about the addictive nature of these medications at the start of 'treatment'. And help patients understand what this will mean for their future."* [PSP0394, FFCS]

While respondents from the healthcare professional group raised similar questions, they appeared unclear as to what information they should be providing service users with upon initiating psychiatric medication.

> *"Should we be talking about patients about some of the issues re: stopping psychiatric medicines when we start them on then? So that they are fully informed."* [PSP1529, HCP]

Respondents from the three groups queried how prescribers could be held accountable for the harms caused by the medications they prescribed, malpractice and mistakes.

> *"Who truly holds the VA accountable for everyday medical malpractice and mistakes?"* [PSP0467, PLE]

> *"How could the doctors who prescribed the drugs now causing insufferable side effects and often even worse withdrawal effects be brought face to face with the suffering caused by their practice of medicine?"* [PSP0554, HCP]

> *"I believe medical professionals as a whole need to stop ignoring this and accept that it is a massive health problem"* [PSP1601, PLE]

Some respondents from the lived experience and supporters' groups queried the reluctance amongst healthcare professionals to reduce/stop psychiatric medication and how this could be overcome.

> *"Why is it not a priority for the prescribing psychiatrist to reduce medication and give proper and useful support to do so?"* [PSP0453, FFCS]

> *"Why are people not being proactively supported to withdraw from these medications, given their known and unknown harms, and is it simply because they are a profitable income stream for the manufacturers?"* [PSP0447, PLE]

Other respondents suggested that healthcare professionals be mandated to stop psychiatric medications when the risks outweigh the benefits.

> *"Doctors need to be mandated to discontinue medications that are causing uncomfortable side effects to the person taking the medications, not to others."* [PSP0078, FFCS]

6.4.2.7.4 Healthcare professionals' education & training

Many respondents from the lived experience and supporters' groups asked for enhanced training and accountability of healthcare professionals to address their perceived knowledge gaps surrounding psychiatric medication, specifically reducing/stopping psychiatric medication. Some suggested that this training be mandatory. It was postulated that enhanced education may overcome challenges relating to informed consent.

> *"Compulsory retraining of all prescribers of psychotropic medication, to include the most up-to-date evidence base of safe de-prescribing methods needs to happen as a matter of urgency to avoid large scale legal challenge from the public."* [PSP1448, PLE]

> *"Doctors should have a legal obligation to know about safe withdrawal and to provide that information to patients who would like to taper."* [PSP0320, PLE]

> *"Do everything to education doctors and hospice organizations to in turn thoroughly seriously warn their patients that you can be hooked in two weeks and take over a year to taper and you may not succeed."* [PSP0021, FFCS]

There was concordance with respondents from the healthcare professional group who also recognised the need for enhanced training of all healthcare professionals. Unlike the previous groups, none of these respondents suggested that training be compulsory. According to one respondent, legal changes were needed alongside education.

> *"The problem with psychotropic drug withdrawal is enormous. It needs a multiprong approach, education: health care providers and students of these disciplines and to the public, legal: with prescribing restrictions for amount and duration."* [PSP0991, HCP]

> *"We have to train professionals so that they can support people, especially doctors, even though we can all play a valuable part."* [PSP0526, HCP]

6.4.2.7.5 Informed consent & public awareness

Several respondents from the lived experience and supporters' groups asked for enhanced information provision at the individual service user level including a greater emphasis on the difficulties of reducing/stopping psychiatric medication. In their view, enhanced information provision may improve service users' decision-making capacity and their ability to give informed consent.

> *"I wish it were more often told to people BEFORE they are prescribed these medications how HARD it is to get off them."* [PSP0044, PLE]
>
> *"Difficulties with reducing and stopping must be part of informed consent before people start psychoactive medication."* [PSP0481, FFCS]
>
> *"Patients need information to support their decision making."* [PSP0548, HCP]

Respondents from the three groups also asked for enhanced information provision around the potential harms associated with the use and discontinuation of psychiatric medication at a wider, societal level to other groups, such as public and family members.

> *"Anything that can be done to better educate the public on withdrawals and the possible dangers of going on psych meds is so important."* [PSP0918, PLE]
>
> *"There needs to be more information available to these families that are effected."* [PSP0123, FFCS]
>
> *"I think the potential for iatrogenic harm should be highlighted far more than it is with a nuanced enough approach to ensure we don't throw the baby out with the bath water."* [PSP0552, HCP]

One respondent from the lived experience group perceived a need for a public conversation to remove the stigma around reducing/stopping psychiatric medication.

> *"Please make society aware that is ok and natural to stop/end the psychiatric drugs and not take them permanently for every human being who had a hard time or reached another state of consciousness!"* [PSP0144, PLE]

The previous view contrasted with views held by some respondents from the healthcare professional group. One respondent asked for a less polarised discourse around reducing/stopping psychiatric medication because in their view the current discussion was anti-medication. While another respondent asked for a more balanced approach when discussing psychiatric medication because in their opinion, psychiatric medication is a controversial issue, and it is easy to end up on one side.

"I would like to see less demonization of psychotropic medications in this discourse around reducing and stopping - most patients would benefit more from stopping tobacco, alcohol and other substances than from discontinuing psychotropics" [PSP0010, HCP]

"Being a member of an activist movement in mental health, I know that medication is the more controversial issue. There is no discussion without a reference to them. So, maybe we need a less polarized way of addressing this issue." [PSP0786, HCP]

6.4.2.8 Theme 8: Gratitude and appreciation

Respondents from across the three groups expressed their gratitude and appreciation to the research team and its collaborators for conducting research into this topic, and for the opportunity to participate, and speak, in said research. These responses demonstrated the importance and relevance of conducting research into this topic to each of the stakeholder groups.

"Thank you so much for your work on the behalf of people suffering from psychotropic drugs and their withdrawal." [PSP0555, PLE]

"Thank you for the opportunity to speak." [PSP1333, PLE]

"Grateful for your survey." [PSP1387, FFCS]

"Just give thanks to your efforts and remark the importance of this topic." [PSP0310, HCP]

6.5 Discussion

This study examined stakeholders' views and experiences of reducing or stopping psychiatric medication use by analysing the data from the free-text response collected in the Round 1 survey of PSP study (Study 1). For many respondents from the lived experience group who reduced and stopped psychiatric medication, the withdrawal process was a long and arduous journey. In their responses, respondents discussed their views and experiences of various parts of the withdrawal process. These included their reasons for reducing/stopping psychiatric medication, the challenges, and adverse effects they faced upon or after stopping the medication which for some, continued to persist for years after stopping the medication. While respondents from the supporter and healthcare professional groups offered different perspectives, there was a high level of concordance between the three stakeholder groups on many issues across all the major

themes. In addition to exploring the views and experiences of the withdrawal process, this study also highlighted stakeholders' suggestions on how the withdrawal process could potentially be improved.

Adverse effects associated with the use of psychiatric medication was the main reason that respondents from the lived experience group reduced/stopped their psychiatric medication. This aligns with a recent study involving 307 antidepressant users which found that 20% of users (n=61/307) stopped treatment because of adverse effects (27, 157). Fear was a key barrier that respondents reported to reducing/stopping psychiatric medication (i.e., fear of relapse, and withdrawal symptoms). In a study involving individuals taking antipsychotics, 70% (n=92/132) of those who did not want to discontinue antipsychotics cited fear of relapse as the reason (154). Few respondents from the healthcare professional group elaborated on reasons and barriers to reducing/stopping psychiatric medication in their responses, which made it difficult to compare the views of the stakeholder groups on this issue. That said, according to one respondent from the healthcare professional group, the biggest barrier was the service user themselves. Although previous research has identified resistance from service users towards stopping psychiatric medication, particularly benzodiazepines (250), the lack of comments by the healthcare professional group may suggest that respondents in the healthcare professional group may not see themselves as a potential barrier. This contradicts the responses submitted by respondents with lived experience which highlighted a lack of support from practitioners.

Most respondents from the lived experience group reported reducing/stopping their psychiatric medication by tapering the dose. Tapering involves gradually reducing the dose of a medication over a prolonged period (6, 99). To date, there is no standard approach on how best to taper (236). The study findings highlighted the lack of awareness among different stakeholders on how to reduce/stop psychiatric medication and the risks associated with abrupt discontinuation. Other respondents used various forms of non-pharmacological supports such as cognitive behavioural therapy (CBT), social support provided via online forums and support provided by healthcare professionals. There is a lack of evidence to support the use of non-pharmacological supports when reducing/stopping psychiatric medication particularly over extended follow-up periods

(166, 167). The potential for CBT in combination with tapering to reduce the risk of relapse has been recognised by the National Institute for Health and Care Excellence (NICE) guidelines published in 2022 which recommend that all individuals be provided with information on support groups, and those stopping benzodiazepines specifically be given the option of CBT (170). The reported scarcity of information and guidelines provided to healthcare professionals, and in turn, their patients, creates challenges with identifying and employing appropriate tapering methods. There is a pressing need for further comprehensive guidelines to support individuals looking to reduce and/or stop psychiatric medication (7).

Additional challenges to reducing/stopping psychiatric medication were noted. These included a lack of support and recognition by healthcare professionals, a lack of tapering resources, a lack of autonomy in relation to decision making, and withdrawal symptoms. Many respondents from the lived experience group reported difficulties in finding a supportive doctor who would guide the withdrawal process and recognise the adverse effects associated with the use and discontinuation of psychiatric medication. Studies involving people with lived experience have previously highlighted challenges around support from healthcare professionals (251). Previous research has also identified reluctance amongst clinicians to support individuals wishing to taper antipsychotics (252). Reluctance amongst healthcare professionals to reduce/stop psychiatric medication may have contributed to the lack of autonomy experienced by several respondents from the lived experience and supporter's groups in terms of having an input in the decision-making process. Potential justifications put forward by respondents from the healthcare professional group were fear of criticism by their colleagues, lack of high-quality evidence underpinning the process of withdrawal and the knowledge gaps that have been created as a result. Other respondents whose medication had been forcibly stopped by their prescriber regarded this as a threat to their autonomy. This challenge has been recognised by previous reports involving service users (244). The World Health Organization (WHO) promotes shared decision-making and informed consent as crucial components to the provision of person-centred and recovery-oriented care (14). Service users have previously reported challenges in having their autonomy and choice respected and being involved in decisions around their medication (244). This feeds back into traditional

paternalistic approach to mental healthcare, one in which the prescriber yields all the power. It does not align with the more modern, rights-based, recovery-oriented approach to mental healthcare that seeks to promotes open discussion about medication (14).

Many respondents from the lived experience group reported practical issues when following a tapering regimen which called for minor dose adjustments which they attributed to the lack of taper-friendly formulations (i.e., tapering strips and liquid formulations). These practical issues appeared to be more commonly experienced by respondents in the lived experience group compared to those in the healthcare professional group given the lack of related responses submitted by the latter group. These issues were reflected by responses submitted to a recent online survey involving individuals stopping antidepressants who discussed the difficulties in accessing suitable formulations to taper (189, 242). As outlined in Chapter 5, these issues also emerged as one of the priorities for future research in the Priority Setting Partnership (PSP) study (Study 1). The eleventh most highly ranked question focused on pharmaceutical formulations read as follows, *"How can the availability of psychiatric medicines in formulations that facilitate the process of reducing and stopping psychiatric medicines be improved? These include tapering strips and liquid formulations."* The Top 10 priorities (i.e., those ranked 1-10) were outlined in Table 5.9 in Chapter 5, and those ranked 11-19 were listed in Appendix 5.4.

It was not surprising that the use and discontinuation of psychiatric medication was an emotive topic for many respondents from the lived experience and supporters' groups, provoking a range of emotions which included anger, loneliness, and hopelessness. Previous studies involving individuals who had stopped psychiatric medication have also reported negative emotions regarding the use of psychiatric medication including a sense of regret over taking the medication in the first instance (180, 253, 254).

While some respondents reported positive outcomes after reducing/stopping psychiatric medication, such as functional and social improvements, several negative outcomes were reported by respondents including relapses and protracted withdrawal symptoms. Despite previous clinical guidelines which stated that withdrawal symptoms were unlikely to persist for longer than one to two weeks after stopping psychiatric medication (175), more recent evidence shows that withdrawal symptoms can persist for months or years

after reducing or stopping the medication (182). When this happens, acute withdrawal transitions into a protracted withdrawal syndrome (182).

Some respondents made suggestions on how the above challenges could be addressed with a view to improving the withdrawal process. The lack of robust evidence to inform guidance on tapering psychiatric medication has created many uncertainties about what constitutes the optimal tapering approach and which interventions best support individuals discontinuing psychiatric medication (7, 138). Respondents to the survey in Study 1 highlighted a lack of evidence-based guidelines to guide the withdrawal process and taper-friendly formulations to overcome this issue. Enhanced regulatory oversight of pharmaceutical industry was another area that was mentioned exclusively by respondents from the lived experience group. Specific examples included tighter controls of prescriptions for psychiatric medications, and enhanced oversight of the relationship between the pharmaceutical industry and prescribers. Similar issues were identified by a study involving individuals discontinuing from benzodiazepine receptor agonists (BZRAs) (251). Many respondents also called for better education and training of healthcare professionals, and increased accountability and responsibility for their actions. This recommendation was strengthened by respondents from the healthcare professional group who acknowledged the lack of education they had received and asked to be enrolled on tapering-related training programs. A previous study also identified important perceived deficits in healthcare professionals' knowledge of psychiatric medication and tapering approaches among individuals taking psychiatric medication (240). According to a survey involving individuals who had stopped antidepressants, the most frequently cited recommendation for future withdrawal services was to improve healthcare professional knowledge (242). However, little or no research exists that has evaluated educational programmes on reducing and stopping psychiatric medication for health professionals.

There was an immense sense of gratitude and appreciation expressed by respondents from the three stakeholder groups for the opportunity to contribute to this research and for being given the opportunity to have their voices heard. Traditionally, mental health research excluded individuals who had received a psychiatric diagnosis from participating in research (10). By regarding individuals from the three stakeholder groups as equal experts, this study gave all individuals the same opportunity to share their experiences of

taking and/or stopping psychiatric medication. This study aligned with the more modern, collaborative approach to mental health research (12).

Study 1 was undertaken to identify priorities for future research on reducing and stopping psychiatric medication. While the questions and uncertainties submitted to the Round 1 survey formed the basis of the Top 10 list of priorities as outlined in Chapter 5, the analysis of the additional commentary submitted to Section 4 was not included in the write-up of Study 1. The nature of the PSP methodology creates a risk that the depth of the information gathered might be lost upon summarising the survey responses gathered. This qualitative a descriptive analysis of free-text responses submitted as part of the PSP study was conducted as an important additional component to the standard PSP methodology to showcase the stakeholders' views and experiences that did not fit into the main survey question about priorities for future research on reducing/stopping psychiatric medication.

6.6 Ethics

6.6.1 Ethical approval

Ethical approval for the PSP study (Study 1) was obtained from the Faculty of Health Sciences Research Ethics Committee, Trinity College Dublin on 3rd August 2022 [Ref: 220509] (see Appendix 4.10). This study was conducted using the data collected by the Round 1 survey conducted as part of Study 1. The Round 1 survey was reviewed by the ethics committee as part of the approval process. All survey respondents consented to their information being used as part of Study 1. The free-text responses were analysed in the context of Study 1.

6.6.2 Ethical principles

The four ethical principles were defined and described in Chapter 4. Given that Study 1 and Study 2 both involved qualitative analysis of free-text response data to a survey, there was considerable overlap around how the ethical issues in both studies were addressed. Hence, this section will not repeat issues but highlight some extra precautions that were taken with the qualitative data. With respect to beneficence and nonmaleficence**,** the

Participant Information leaflet (PIL) (see Appendix 4.2) informed all survey respondents of the risks and benefits of their participation, including the potential to become upset when recounting their experience of taking or tapering psychiatric medication as it related to their mental health experience, and the actions to take in the event of them becoming distressed. With respect to informed consent, all respondents were provided with a written PIL (see Appendix 4.2) and a narrated video with instructions on how to participate and were asked to self-declare their consent prior to completion of the survey. Completion of Section 4 (additional comments) in the survey was optional. Given that respondents wrote about their views and experiences of reducing/stopping psychiatric medication as opposed to posing potential questions for research, the researcher was careful not to include any data that might identify a person or service to maintain respondent confidentiality. In terms of justice**,** upon analysing and coding the survey responses, the same coding template was applied to all survey responses regardless of their stakeholder group.

6.7 Rigor & trustworthiness

The definitions of rigor and trustworthiness were outlined in Chapter 4. Similar to the previous section on ethical issues, this section will not repeat the same examples of rigor and trustworthiness but highlight additional examples specific to this study. In terms of credibility, there was a good diversity of responses in terms of stakeholders and geographic locations submitted to Section 4 which captured the views and experiences of reducing/stopping psychiatric medication from hundreds of individuals. To obtain rigor, electronic techniques (i.e., NVivo) were used to code the data (249) and quotes were used as exemplars upon reporting the study findings. In terms of transferability, all the steps involved in conducting the study were described in detail in the PhD thesis, including any individual that was involved. In terms of dependability, a clear audit trial was creating using an Excel file which illustrated how the submissions in Section 4 of the survey were organised and coded. A coding template was also developed as part of the coding process to reduce interpretative bias and improve coding consistency between the researcher and the supervisory team. Finally, with respect to confirmability, the coding and review processes were overseen by the supervisory team, and the collection of data from the

three stakeholder groups facilitated triangulation. Triangulation made it possible to make comparisons between the three stakeholder groups and tease out the similarities and differences in opinions that existed between the stakeholder groups around the use and discontinuation of psychiatric medication.

6.8 Strengths & limitations

The strengths and limitations of Study 1 outlined in Chapter 5 (Section 5.4) are also relevant to this study. This section outlines additional examples of strengths and limitations that were specific to this study. The major strength of this study was the novelty of the approach. To my knowledge, this was the first PSP study to include an additional comments section within a PSP survey and to analyse the free-text responses submitted. By coding these comments, this study sought to analyse data that did not fit into the main survey question. The personal accounts submitted by the survey respondents provided important and novel insights into the human and emotional impact of taking and/or stopping psychiatric medication which may encourage healthcare professionals to rethink their current views about the role of these medications in treating mental illness, and when to start or stop treatment. The study illustrates the polarising voices and opinions that exist in mental health research around psychiatric medication use. In addition, this was the first study to explore this research topic involving an international cohort of respondents as opposed to previous studies which have typically involved cohorts of respondents from individual countries (158, 240).

The diversity of survey respondents was considered both a strength and limitation, as previously outlined in Chapter 5 (Section 5.4). A diverse sample of responses was obtained in terms of stakeholders and geographic location which allowed for a wide range of views and experiences to be captured. However, the free-text responses submitted to the additional section were heavily dominated by the lived experience group. As a result, it was not always possible to make comparisons with the supporter and healthcare professional groups.

There were two other study limitations. The survey relied on voluntary completion which created the potential for self-selection bias i.e. respondents may have had a negative experience of taking and/or stopping psychiatric medication which may have skewed the

study findings. Secondly, the survey content coded as part of this study consisted of free-text responses which meant that the researcher was fully reliant on written response data. It was not possible to clarify the responses due to the anonymous nature of the data collection methods. This created difficulty when the responses lacked depth and context or were unclear or ambiguous. Despite efforts to minimise interpretative bias while coding, such as double-blind coding, the subjective nature of coding qualitative data also created potential for bias.

6.9 Summary

Chapter 6 reported on the views and experiences of reducing/stopping psychiatric medication as reported by respondents in the free-text responses submitted to a survey conducted as part of the Priority Setting Partnership (PSP) study (Study 1). This study made comparisons between the views held by the three stakeholder groups, highlighting areas of concordance and dissonance. This study identified the numerous challenges faced by individuals upon withdrawing psychiatric medication, the uncertainty that prevails in terms of the best tapering strategy, and the emotional impact of taking and/or stopping psychiatric medication. It also outlined the importance of support during the withdrawal process, in particular psychosocial supports, and suggested potential areas that could be targeted to improve the withdrawal process. The next chapter reports on Study 3 which involved semi-structured interviews with stakeholders previously involved in Study 1 to explore their views on the PSP methodology as a priority setting exercise.

Chapter 7: A qualitative interview study of stakeholders' views on the Priority Setting Partnership methodology

7.1 Introduction to Chapter 7

Chapter 7 focuses on a qualitative interview study involving individuals who had participated in the Priority Setting Partnership (PSP) study (Study 1). Study 1 followed the PSP methodology to identify the Top 10 priorities for future research on reducing and stopping psychiatric medication. While the PSP methodology is well-established, few studies have sought to explore the views and experiences of those who have been involved in a PSP study. This study was conducted to explore stakeholders' views on the PSP methodology as a priority setting exercise (Study 3). This chapter starts by outlining the study's aim and methods. It then presents and discusses the study findings, before concluding with a discussion on ethics and rigor as they apply to this study.

7.2 Aim

The aim of this study was to explore stakeholders' views on the PSP methodology as a priority setting exercise by conducting semi-structured interviews with individuals who had participated in Study 1.

7.3 Rationale for choosing semi-structured interviews

Semi-structured interviews are a form of qualitative interviews which give researchers *"privileged access to people's basic experience of the lived world"* (255 p.3187). Qualitative interviews pose questions to create discussions with participants in their natural surroundings. Thus, they represent structured and purposeful conversations (255, 256). This interaction is a characteristic of qualitative inquiry. Semi-structured interviews represent a non-linear interview process in which participants can respond freely to each research question. The open-ended nature of semi-structured interviews facilitate the sharing of unanticipated ideas and experiences (255, 256).

7.4 Methods

As discussed in Chapter 4, Study 1 was guided by the James Lind Alliance (JLA) PSP methodology. The PSP methodology is a priority setting exercise that engages the key stakeholder groups in a structured way to enable the co-production of research priorities. The key stakeholder groups included people with lived experience of taking and/or stopping psychiatric medication, family members/friends/carers/supporters, and healthcare professionals. The aim of Study 1 was to identify the Top 10 priorities for future research on reducing and stopping psychiatric medication in collaboration with the three stakeholder groups. The study presented in this chapter involved semi-structured interviews with a subsample of the stakeholders who had participated in Study 1. All interviews were conducted by the researcher (MB). The researcher was a female, qualified pharmacist, undertaking a PhD who had no prior relationships with any of the stakeholders before working with them in Study 1. This was the researcher's first time conducting qualitative interviews. This study was reported in accordance with the Consolidated Criteria for Reporting Qualitative Studies (COREQ) guidelines (257) (see Appendix 7.1) .

7.4.1 Recruitment of participants

There were two criteria for an individual to be considered "eligible" to participate in this study; the individual was a member of the Steering Group and/or had participated in the final prioritisation workshop (Step 6) of Study 1. The target sample size was 12-15 participants. The approach to determining the sample size for this study was informed by Braun and Clarke who recommend providing a provisional, anticipated sample size range that is guided by researchers' previous experience and likely to generate adequately rich and complex data to address the research question (258). This approach was used instead of the more traditional concept of data saturation (i.e. point where no new themes/codes 'emerge' from the data) as the usefulness and appropriateness of data saturation for providing justification for sample sizes in qualitive studies is increasingly questioned as it is often used imprecisely and uncritically accepted as the gold standard quality marker (258).

All eligible individuals were invited to participate in anticipation of some refusals. There was a total of 37 eligible individuals comprising Steering Group members (n=12, 32%) and participants of the final prioritisation workshop (n=25, 68%). Five Steering Group members had participated in the final prioritisation workshop. These individuals were counted under the "Steering Group" cohort. A brief overview of the interview study was presented at the final prioritisation workshop on 25th October 2023 and the final Steering Group meeting on 5th December 2023. Official study invitation emails were sent to all eligible stakeholders on 15th January 2024. This email contained the Participant Information Leaflet (PIL) (see Appendix 7.2).

The response obtained exceeded expectations. As a result, the decision was made by the supervisory team (CC, AH) to include all willing Steering Group members and apply purposeful sampling techniques to the workshop participants to achieve a balanced representation of voices, genders, and nationalities. An equal number of Steering Group members and workshop participants was achieved. Selected participants received a follow-up email on 31st January 2024 from the researcher which contained the consent form (see Appendix 7.3) and a list of potential interview dates and times. Participants had the option of providing consent by returning the signed consent form or giving verbal consent on the day of the interview prior to its commencement. A week before the interviews were scheduled to take place, participants received a reminder email which contained the final ranked order of the questions from the final prioritisation workshop to facilitate discussion during the interview.

7.4.2 Data collection and analysis

The process of data collection and analysis involved four distinct phases; (1) Develop and pilot the interview topic guide; (2) Conduct semi-structured interviews; (3) Data preparation and transcription; (4) Data review and analysis.

7.4.2.1 Develop & pilot the interview topic guide

A provisional interview topic guide was developed by the researcher and supervisory team working in collaboration, informed by the study aims and the literature (259). Interview topic guides add structure to the interview process whilst retaining a degree of flexibility

to support the exploratory nature of the investigations. Interview topic guides are a requirement of several human subject's review committees (255). They typically contain the main interview questions and probing questions, also known as "prompts". The inclusion of probing questions has been shown to achieve greater discussion and collect the most salient ideas, to clarify previous statements, and to maintain consistency in the questioning technique across all interviews, which is important to enable subsequent data analysis (255).

Pilot study interviews were conducted internally by the researcher with both research supervisors. Pilot interviews provide an opportunity to evaluate the interview topic guide and refine the interview questions, to practice qualitative interviewing, to pre-empt areas that might cause deviation from the interview topic guide, and to refine the data collection methods (217). Minor modifications were made to the interview guide in light of the feedback received. Modifications included rephrasing questions, merging similar questions, and inserting additional follow-up questions to invite more in-depth discussion. The pilot interviews were not included in the final analysis.

The final interview topic guide comprised three sections: study information, the main interview questions, and reflection/review (see Appendix 7.4). The main interview questions covered four key areas: (1) The PSP process; (2) Motivations for involvement; (3) The PSP questions; (4) Collaboration between stakeholders. The interview questions were purposely written to invite in-depth discussion of the interview topic (255). The same interview topic guide was used for both cohorts i.e., the workshop participants and the Steering Group members.

7.4.2.2 Conduct semi-structured interviews

The final semi-structured interviews were conducted between 6th February and 7th March 2024 by the researcher virtually via Zoom. The participant could choose where the interview was held i.e., at home or workplace. Only the researcher and participant were present during the interviews. Interviews were not recorded on Zoom. Instead, all interviews were audio-recorded (using a Dictaphone). The audio-recording started after all the study information had been explained to the participant and before the main

interview questions were asked. The audio-recording continued until the interview was complete. The researcher made field notes during the interviews.

After the first four interviews were complete, both research supervisors members listened back to the audio and provided the researcher with their feedback and observations on their questioning technique and use of probing questions to achieve more in-depth answers. No changes were made to the interview guide.

7.4.2.3 Data preparation & transcription

After each interview was completed, the audio file was uploaded from the Dictaphone to the researcher's computer. Once all interviews were complete, the two cohorts of participants were split and coded accordingly. Participants were assigned a pseudonym to protect their identity. Steering Group members were coded as SG01, SG02, etc., and workshop participants were coded as WS01, WS02, etc. A code sheet was created which documented the link between participant identities and their coded transcripts.

Once the audio files had been renamed, they were uploaded onto SharePoint. Access was restricted to the supervisory team and the individual representing the external transcription company (AudioTrans) with which an institutional level service agreement exists. After the interviews were transcribed verbatim by the transcription company, an accuracy check was performed on all interview transcripts by the researcher. This involved listening to the audio recordings and comparing them to their corresponding interview transcript. Minor modifications were made to the transcripts e.g., correcting spelling mistakes. While completing the accuracy check, any potentially identifying data such as the participant's country of origin or place of work was assigned a code to protect participant's identity. A coding template was created to achieve consistency between interview transcripts.

All participants were given the option of reviewing their interview transcript prior to data analysis. Password-protected Word documents of individual interview transcripts were emailed to individual participants themselves if they wished to review their transcripts. Participants were asked to return any comments within seven days of receipt. No participants wished to review their transcript.

7.4.2.4 Data review & analysis

Data analysis involved searching for emerging themes, starting with one interview transcript, and then across all interview transcripts (256). Template analysis was the strategy of choice in this study (222). As previously discussed in Chapter 4, template analysis is a technique for thematically organising and analysing qualitative data (222) which involves the development and application of a coding template.

Prior to developing the coding template, the supervisory team defined the scope of the study in line with the study's aim and objectives. Commentary on issues not directly related to the study's aims and objectives were considered "out-of-scope" (e.g., the prescribing of psychiatric medication, mental health services, and psychiatric stigma). Out-of-scope commentary was not included in the final analysis.

7.4.3 Development of coding template

In line with the chosen methodology, the researcher and supervisory team engaged in a familiarisation process by reading and re-reading transcripts, noting their preliminary notes and any potential codes within the data. A subset of transcripts representing the workshop participant cohort were coded by the researcher and supervisory team working independently, constituting a mix of participants from the three stakeholder groups. These preliminary codes were compared and defined. Similar codes were grouped together under a higher order code, feeding into the hierarchical structure. The preliminary coding template was piloted on another subset of transcripts representing the Steering Group cohort by the researcher. Once complete, the coded responses were reviewed by the supervisory team, and disagreements were resolved through discussion. As new ideas emerged throughout the coding process, additional codes were added to the coding template. The coding process was a fully inductive and iterative process which permitted modifications to the coding template (256, 260).

7.4.4 Application of coding template

The final coding template was applied to the remaining transcripts by the researcher. In the case where two codes were relevant to the same section of text, both codes were applied. The supervisory team had oversight of the entire coding process to enhance study

rigor. A similar coding process was used for the transcripts representing the workshop participants and Steering Group members. Once coding was complete, the interview transcripts were uploaded into NVivo by the researcher to support the data analysis and management, as previously described in Chapter 6. “Nodes” (i.e., codes) were created on NVivo to match the codes in the coding template and applied to the relevant sections of data. Once all the interview transcripts were coded on NVivo, related sections of text were identified and exported back into Microsoft Word to enable the writeup of the study findings.

7.5 Results

7.5.1 Characteristics of interview participants

Thirty-seven individuals were invited to participate comprising Steering Group members (n=12, 32%) and participants of the final prioritisation workshop (n=25, 68%). Of those, 31 agreed to participate comprising Steering Group members (n=10, 32%) and participants of the final prioritisation workshop (n=21, 68%).

Twenty participants were interviewed comprising Steering Group members (n=10, 50%) and participants of the final prioritisation workshop (n=10, 50%). The three stakeholder groups were represented in the interviews: people with lived experience of taking and/or stopping psychiatric medication (n=7, 35%), family members/carers/supporters (n=2, 10%), and healthcare professionals (n=11, 55%). Full details of participants’ demographics are reported in Table 7.1. The average interview duration was 21.34 minutes (range 8.40 min to 45.30 min). No repeat interviews were required.

Table 7.1: Overview of interview participants' characteristics

Interview participants' characteristics	n (%)
Total number invited to participate	**37**
Workshop participants*	**25 (68%)**
Steering Group**	**12 (32%)**
Total number who agreed to participate	**31**
Workshop participants	**21 (68%)**
Steering Group	**10 (32%)**
Total number interviewed* **	**20**
Workshop participants	**10 (50%)**
Steering Group	**10 (50%)**
Gender	
Male	**8 (40%)**
Female	**12 (60%)**
Stakeholder group	
Person with lived experience	**7 (35%)**
Family member, friend, carer, supporter	**2 (10%)**
Healthcare professional (representing GPs, nurses, pharmacists, and psychiatrists)	**11 (55%)**
Country of origin	
Ireland	**8 (40%)**
United Kingdom	**6 (30%)**
United States	**3 (15%)**
Other	**3 (15%)**

* The workshop had 30 participants, 5 of whom were Steering Group members. These individuals were counted under the "Steering Group" cohort

** The Steering Group has 13 members however the one member representing the Health Research Board (HRB) was not invited to participate in this study

*** A more detailed breakdown of study participants' characteristics is not provided to protect their identity

7.5.2 Summary of interview participants

All participants from the lived experience and supporters' group had experience of reducing/stopping psychiatric medication and supporting the process, respectively. Some participants from the lived experience and supporters' group described the life changing impacts of taking psychiatric medication; *"I couldn't be the person I was before*". Others

described their experience of withdrawing from psychiatric medications using terms such as "*trainwreck*" and "*struggle*" and the various challenges they encountered upon doing so in terms of lack of guidance/support from their prescriber, and suitable pharmaceutical formations. Participants representing healthcare professionals also shared their concerns around the use of psychiatric medication; *"I have reservations about it, often very real concerns about when it's used, prescription patterns and so on and so forth".* These challenges reiterated those discussed in previous chapters (Chapters 5 & 6).

7.5.3 Themes generated from the interview data

The interview data generated four major themes: (1) Involvement in research; (2) Reflections on the PSP; (3) Reflections on the priorities; (4) Identifying & overcoming PSP challenges. The major themes and subthemes are outlined in Table 7.2.

Table 7.2: Overview of major themes and subthemes from the interview data

Themes	Subthemes
1: Involvement in research	I. Previous experience of involvement
	II. Motivations for involvement in the PSP study
2: Reflections on the PSP	I. PSP methodology
	II. Importance of multi-stakeholder involvement
	III. Achieving authentic collaboration
	IV. Impact of PSP involvement
3: Reflections on the priorities	I. Question terminology
	II. Final ranking of priorities
	III. Missing questions
4: Identifying & overcoming PSP challenges	I. Managing group dynamics
	II. Representation of stakeholder groups
	III. Suggestions for improvement

7.5.3.1 Theme 1: Involvement in research

The first theme focused on stakeholders' involvement in research. It was categorised into two subthemes: (1) Previous experience of involvement; (2) Motivations for involvement in the PSP Study.

7.5.3.1.1 Previous experience of involvement

Participants from the lived experience and healthcare professional groups had previous experience in research and shared their views on how the involvement of the lived experience group is typically managed in research. Based on their previous experience, participants from the lived experience group felt that their involvement in research was an afterthought, brought in at the end when all decisions had already been made. The terms *"lip service"* and *"box ticking"* were used to describe the level of lived experience involvement in other studies.

> *"It can be a bit of an afterthought as opposed to you know being there from the beginning and being part of the journey."* [WS03, PLE]

> *"I can think of three current examples right now where researchers are giving lip service to talking with people with lived experience. But they are not listening, they are basically blowing it off."* [WS05, PLE]

Whilst sharing their views on previous experiences of involvement in research, one participant from the lived experience group also noted how the PSP methodology was *"profoundly different"* in a positive way.

> *"When we engage in collaboration or even consultation or even an early stage of a project, a lot of times it's box ticking. So, you are asked very simply to green light a particular approach or to, to allow the organisation or the body that's trying to roll out this project to be able to communicate to the wider audience that they have consulted people with lived experience. The way in which you I suppose adopted your methodology and implemented it was profoundly different to that"* [WS06, PLE]

The challenges in recruiting individuals from the lived experience and supporters' groups were noted by one participant from the healthcare professional group. This participant believed that obtaining a diversity of perspectives is difficult. In their experience, recruiting individuals who share the same perspectives is more straightforward.

"…. when we select them [patients and carers], we look for controversy, we look for people who challenge but even, so it tends to be people who broadly agree with us who end up because people who really hate us don't want to come and work with us." [SG10, HCP]

7.5.3.1.2 Motivations for involvement in the PSP Study

Participants from the three stakeholder groups shared their reasons for getting involved in the PSP study. Most participants from the lived experience group were driven by their experiences of having mental illness or their negative experiences of taking and/or stopping psychiatric medication. Many of these participants reported suffering harm from taking these medications.

"I was harmed by psychiatric meds myself, so obviously I have a vested interest in seeing research done so that we can help people avoid you know disastrous outcomes like the one that I had." [SG07, PLE]

"...for me being involved in a research study that has to do with mental illness because of my own lived experience of mental illness that makes me like to be passionate in any studies when it comes to see how we can improve that, how we can make changes." [SG09, PLE]

A few participants from the healthcare professional group were also driven by the harms caused by psychiatric medication which affected individuals under their care.

"Well again I'm a psychiatrist, I'm a prescribing doctor and someone who has been I suppose aware like all psychiatrists of the downside of the medications that we prescribe. And the difficulties people have with side-effects and also with coming off these drugs when the side-effects are too much, you can't just make the decision to stop, there's a process." [SG04, HCP]

"I will talk to anybody and do anything to have more attention paid to the trouble that people have whether that's a research project, or a media interview because you know I think this is just an ongoing epidemic of harm and that's why I got involved in the PSP." [SG05, HCP]

Participants from the three groups shared the desire to shift the research agenda in a way that listens to the needs of people experiencing mental health problems and achieves multi-stakeholder involvement.

"Hoping that the PSP and your research will help engender a new era of research that pays more attention to the needs and priorities of the lived experience community." [WS05, PLE]

> *"I think the whole [PSP] proposal was a good one. That's why it attracted people who are really interested in making a change happen really."* [SG01, FFCS]

> *"It was of interest to me to participate to see how this process would work with professionals around the table, service users, different stakeholders being brought together."* [SG04, HCP]

One participant shared a different motivation for getting involved in the study. This participant's motivation stemmed from their desire to represent the perspectives of General Practitioners (GPs). According to this participant, given that most prescriptions for psychiatric medications are initiated in primary care, it was important that GPs were represented.

> *"I think the GP perspective is important because I know for anti-psychotics most prescriptions historically are initiated in secondary care. But for other psychiatric prescription and that includes anti-depressants and anti-anxiety medication they are nearly always initiated in primary care."* [SG06, HCP]

7.5.3.2 Theme 2: Reflections on the PSP

This theme focused on stakeholders' reflections on the PSP study. Stakeholders' reflections were categorised into four subthemes: (1) PSP methodology; (2) Importance of multi-stakeholder involvement; (3) Achieving authentic collaboration; (4) Impact of PSP involvement.

7.5.3.2.1 PSP methodology

Participants from the three stakeholder groups shared their perceptions of the PSP methodology using words such as "*amazing*" and "*structured*" to describe it.

> *"I think the whole process was really amazing. I was really impressed. I was impressed with it."* [SG01, FFCS]

> *"I thought the methodology was you know it was lovely and structured and it was something I could understand and be part of."* [SG03, HCP]

One participant from the healthcare professional group made several points to support the use of surveys as part of the PSP methodology e.g., surveys permit the respondent to complete the survey in their own time.

> *"I like surveys because then you can take your time and you can do them, you can take the surveys when you have time and you can also take, you can google and*

think about the questions, and you can go back. I like it. Before I would say just a couple of years ago, I hated surveys yeah, I did, but I think it's a good way to, and you don't stress people, and you open that link whenever you have time. And you set time for it, so I think it's a really good way to get people's both interest and participation." [SG02, HCP]

One participant from the lived experience group commented on how the PSP methodology supports multi-stakeholder involvement, particularly individuals from the lived experience group.

"You could really see the care that had gone into it and that lived experience was at the centre of not just the methodology but the reasons for why you did what you did…. I think if you try to apply other methodologies in that way you are not going televote the importance of the lived experiences in the same way. That's the gamechanger and it's important because without it society's perspective of mental illness and mental difficulties will never change." [WS06, PLE]

Several participants also commented on the success of the final prioritisation workshop. Participants were particularly impressed with the consensus making process and how it facilitated discussions around the questions.

"It was a really enriching experience and amazing way to really break down the questions and to discuss them and talk about them." [WS09, PLE]

"It felt quite magical in a way that suddenly it began to kind of take its own rhythm." [SG01, FFCS]

7.5.3.2.2 Importance of multi-stakeholder involvement

Participants from the three stakeholder groups stressed the importance of multi-stakeholder involvement in the PSP process. Participants from the lived experience group made the point that the voice of the lived experience group was silenced for many years and that involvement of this stakeholder group can help others to get a deeper insight into what is truly important to those who have lived experience of mental distress. In their view, it was essential that knowledge from lived experience was combined with practitioner knowledge.

"We have to have the person with lived experience at the table. Because it is bringing that other perspective and it's a perspective that was neglected for so many decades, centuries, in how we support people and how we view people with mental health. I think it's important because for years we did only have the mental health professionals and their opinions and so much went wrong with that. And so

many people were failed, we really shouldn't be doing anything without the people that understand and live with these challenges every day." [WS09, PLE]

"We are the ones who know what is and isn't going on and we are the ones who are suffering the harms. And again, it's the principle that actually came at least in this country out of the disability's movement. What is it…do nothing, nothing without us, nothing about us without us." [WS05, PLE]

"There is no reason for anybody to work in mental health unless you consider the views of people who actually use the service." [WS06, PLE]

These sentiments were also echoed within the healthcare professional group in that involvement of lived experience group was needed to shift the development of the research agenda from being led by healthcare professionals to a more democratic approach with input from all relevant stakeholders.

"For a long time *in mental health there has been a need for different kind of research agenda. One that would be genuinely more democratic in the sense of incorporating the views of service users more centrally."* [SG04, HCP]

Participants from the lived experience and healthcare professional groups were of the view that the involvement of the lived experience group can add legitimacy to both the process and outputs which may guide future research in a way that is meaningful for service users.

"When you introduce people and lived experience the way you did at the stage you did it means that we can actually shape the way in which the agenda is set. I think that's profoundly different, but it's different because then the research that is funded reflects our priorities because there's no point in funding research unless it supports people used services." [WS06, PLE]

"The whole issue of what is important to us, in terms of research is not necessarily what researchers are addressing. So, there's a gap there." [WS05, PLE]

"There are two things here one is giving legitimacy to the process because if it just comes from patients then you know psychiatrists and experts will say it doesn't take into account our views, this is you know this doesn't take into account informed views. And put it the other way round, just having professionals sitting around working on what they think is right means they miss what is important to people on the receiving end of these treatments." [SG05, HCP]

"The onus is on us now as professionals and researchers and you know to try our best to fill those gaps. And when they are highlighted in a process like this then

that's helpful you know in guiding how we contribute to the world and the better healthcare that we all want to see." [SG03, HCP]

Participants from the lived experience and healthcare professional groups also agreed that inclusion of different voices and perspectives challenged their ways of thinking in a positive way. Listening to different perspectives created potential for considering alternative viewpoints and perspectives, which in turn made them reconsider their own thinking and preferences on the ranked order of the research questions.

"… as conversations happened you could see where ah right, I'd move that [priority] to there, and move that to there and prioritise, because the in-person piece - it wasn't just, 'here's your statement and I think it should go here'. It was, 'here's the statement and here's the why, I think it has priority over something else'. So therefore, changing and shifting my own perspective because I was only coming from my own perspective of course I was. And seeing other people's experiences and obviously when it comes to medication the variation of medications and the effects of medications, that I wouldn't have been familiar with because that wouldn't have been my experience. So even getting that understanding in the room was really helpful." [WS03, PLE]

"I heard arguments for prioritising aspects of the territory if you like that I wouldn't have thought were immediately, I wouldn't have put them at the top but actually hearing people you know give their reasons for it, I was convinced and not convinced and I found myself changing my mind on what would be a priority and not. So, I was kind of surprised at myself in some ways, but it was an eye opener in terms of just how many questions can come up about you know a topic like this." [SG04, HCP].

One participant representing healthcare professionals was of the view that the lived experience group are not always listened to by their professional colleagues, stressing the importance of improving the dialogue between stakeholder groups.

"We are trying to enhance the dialogue between patient, family, and medics. It is really important. Because you have got to weigh up the risks and benefits of these things really carefully…. You want a balance. The groups moderate each other and learn to talk to each other. It's true to say that doctors and clinicians shall we say, to extend it in psychiatry especially to non-doctor clinicians who have very important roles in this, especially in psychiatry - often, think they are listening to patients, but they are not hearing everything, sometimes because the patients don't want to talk to them, or they might be embarrassed to or feel they might upset them or have angry feelings or all sorts of things, a whole range of feelings

that they don't want to share. So, it's important to have a neutral territory where they can share stuff." [SG06, HCP]

7.5.3.2.3 Achieving authentic collaboration

The PSP study employed several strategies to achieve authentic collaboration between the stakeholder groups. A number of participants from the healthcare professional group felt that the creation of the safe and welcoming space alongside the JLA moderation helped achieve authentic collaboration between the stakeholder groups during the Steering Group meetings.

> *"You felt very welcome, and if you got in a couple of minutes late and you were always you know everyone was welcomed and it felt like we knew each other even though we had never met. That is also very, you felt safe, safe when you got into these meetings. Which is extremely important I would say in this part…. you wouldn't share if you don't feel safe and if you don't feel you can trust the people in both, the steering group but also in the coordinators and you as researchers that was, but you really made us feel safe."* [SG02, HCP]

> *"I think it was very well moderated. Other people were fine, everyone was pretty nice. I mean you didn't have to agree with somebody to get on with them. You don't have to agree with everything."* [SG06, HCP]

The fact that the Steering Group members, particularly the academic members, remained engaged throughout the duration of the PSP study was regarded by one participant from the healthcare professional group as a success insofar as that they felt comfortable enough to remain and did not feel that their views were being submerged by the lived experience perspective.

> *"I know that some professors were there until the end, I think in that sense it was a success because they obviously didn't feel like they were being you know, they didn't feel like their views were being marginalised or trampled over."* [SG05, HCP]

Several participants from the healthcare professional group also found the sharing of documentation between Steering Group meetings useful in terms of allowing time for individual reflections and enabling members to submit feedback in various ways.

> *"It's been good you have been sending material to prepare, you have asked for questions, you have been sending surveys and thanks. So, it's been easy I would say."* [SG02, HCP]

"I did enjoy the piece where you sent out the, each sort of tranche of questions for us to reflect on and think about and get back to you. So, I guess different people can engage in group work in different ways and sometimes I might be someone who will think about it afterwards and go oh yeah, you know that's, that's really good or I never thought to say that. So, it was good to have the opportunity to comment or you know give that feedback in between the steering group meetings as well." [SG03, HCP]

With respect to the final prioritisation workshop, several participants from the lived experience and healthcare professional groups felt welcomed and respected. By introducing participants by their first names as opposed to their professional titles, participants felt that they were treated as equals, which in turn created a warm and inclusive workshop atmosphere.

"Quite often you go in and there's introductions and stuff like that. But none of that happened, which for me is always nicer, because you go round a room and it's who you, it depends how people started off. So, 'I'm such and such…' and people and institutions often follow with their title. So, then that immediately starts a process then of people feeling right I have to give my title now, and sometimes for people with lived experience then they feel a wee bit less than… so the balance in the room, the power shifts in the room…and divisions start. So just even how it was set up as sensitivities that it really was from the start it was a collective and everybody was equal. And then that lent to the process throughout the day." [WS03, PLE]

"Everybody came across primarily as a person, quite often when you go to events you will have a little huddle of psychiatrists in one place and all sticking together and then everybody else. I didn't find that in our group." [WS01, PLE]

"It was extremely affirming, it was welcoming, it allowed us to truly feel equal in the process, particularly in regard to being seen as being on I suppose having the same value and appearance as other psychiatrists and other experts and other people who work in this field." [WS06, PLE]

"Nobody came with a title, and I know when I've done PPI work before we actually all together we learnt something new together as the ice breaker. Because nobody knew about a particular topic, so we were all at the same level. So, when you are doing something new like a PSP everyone is on the same level, I don't know how it was going to go, or what's going to happen in it." [SG03, HCP]

Several participants from the lived experience and healthcare professional groups also discussed the workshop format. Participants from the lived experience group found the dynamic nature of the workshop was not only useful in terms of facilitating the ranking

process but was also helpful in maximising potential for social interaction. The dynamic nature of the workshop refers to the assignment of participants to small groups in the morning session and then re-shuffling the groups in the afternoon session. By breaking the divide between stakeholder groups, it helped the PSP study achieve authentic collaboration.

> *"I like how the groups split up and we in the second part had a wee different group, just to get the different perspectives. And how as a collective we did come to it, I don't think that there was really and truly much disagreement or shock or surprise because the process allowed for all them conversations to have, why something wasn't there, or you know it was teased out."* [WS03, PLE]

> *"I liked the way in which we moved between groups. I really liked that aspect of the methodology. Because like I mean engaging group think and especially if you have established relationships in the room, you taper your perspectives a certain way or it can be shaped in different ways. But by flipping it in that way it meant that every time a decision had to be made you had to make new arguments, or it forced you to think differently."* [WS06, PLE]

> *"It was great to see the range of voices that were included... there was a lot of space for discussion I thought was really useful. You know by the end of it I think the process had distilled down as much as could be gotten out of that group if you know what I mean. So, I don't think there was a lot left on the table in terms of people not having had the space to talk or share their views".* [WS02, HCP]

One participant from the healthcare professional group felt that the round table discussion format helped achieve authentic collaboration by giving all participants equal opportunity to share their opinions.

> *"The round table kind of format allowed lots of people an opportunity to share their point of view. Yeah, I think that was its strength, definitely, lots of voices included."* [WS02, HCP]

Strong facilitation at the workshop was also noted by several participants from the lived experience and healthcare professional groups. The presence of neutral facilitators guided the workshop discussions in a way that was fair and respected the views of all participants despite the added pressure of managing virtual participants. In the participants' view, the facilitators achieved a balance of professional and non-professional voices.

"I was quite amazed that it went as well as it did, particularly with the virtual participants. And again, I attribute a lot of that to [the JLA facilitator]. She did a good job, we had some people in our group that tended to want to dominate a little bit and stay focused on their particular hot button… I thought she did a pretty good job of making sure everybody was included and listened to and also moving us along." [WS05, PLE]

"I thought having the external James Lind Alliance facilitator was a good thing to have. You know it was helpful to have someone who wasn't maybe involved in the topic as such, or in the methodology there to drive it." [SG03, HCP]

"There was that group leader kind of thing, the facilitator at the table that made sure that everybody had their say. So, nobody was dominating, and nobody did, sometimes you also hide a little bit and there wasn't that chance of hiding for anybody really. I felt that was really nice". [WS08, HCP]

"… the collective wisdom comes across very strongly in the priority stetting partnerships. I think they do a very good job particularly of making sure that there are non-professional voices there and I think again it's important that those non-professional voices aren't given complete priority. Again, I was impressed on the day the way that the politics of that for want of a better phrase, is well managed. So, I do think that people are always treated with respect and feel that way." [WS07, HCP]

7.5.3.2.4 Impact of PSP involvement

Participants from the three stakeholder groups reported being positively impacted from their involvement in the PSP study. Some participants from the lived experience group left feeling inspired and hopeful for change in how mental health research is conducted.

"We felt inspired by it, motivated by it, it gives us a sense of hope particularly in an area that has for decades been the I suppose the epicentre of human rights violations." [WS06, PLE]

Another participant from the lived experience group left with newly formed friendships.

"He and I have become friends because of your workshop, so there's a benefit there." [WS05, PLE]

For several participants from the healthcare professional group, their involvement in the PSP study served as a learning experience in which they learned about themselves and the consensus making process.

"I have learnt a lot myself both from you guys but also from the other people in the steering group." [SG02, HCP]

"This was the first time I participated in this type of consensus development process, so it was really a good learning experience for me." [SG03, HCP]

No participants reported any negative impacts of their involvement in the PSP Study.

Participants from the three stakeholder groups expressed their gratitude for being invited to participate in the PSP study. These participants shared a sense of excitement for future research that could potentially address the questions identified.

"Thanks for doing the project and I'm excited for when it is out there for everybody to see and hopefully people will pick up on the research and do some of it." [SG07, PLE]

"I was very grateful to be given the opportunity to participate. I wish I would have been on the fun end where we got to shape the questions." [WS05, PLE]

"Thank you for the opportunity to be involved and looking forward to sticking the PSP results on the notice board here and saying come on guys give it a go." [SG03, HCP]

7.5.3.3 Theme 3: Reflections on the priorities

The third theme focused on stakeholders' reflections on the Top 10 list of priorities on reducing/stopping psychiatric medication. It was categorised into three subthemes: (1) Question terminology; (2) Final ranking of priorities; (3) Missing questions.

7.5.3.3.1 Question terminology

Participants from the lived experience group and healthcare professional groups found the question terminology and length of the questions challenging to work with at times. Some terms were perceived to cause ambiguity in understanding, e.g., "service user", "shared decision making", and "recovery". As a result, this created additional challenges upon completing the ranking exercises as part of the final prioritisation workshop.

"…this is where the differences across the different countries fore fronted, just terms, terminology like you folks use service user, I had no idea service user, we don't use that term here in this country. So, it took me a while to figure out oh they mean patients is what we would refer to them as our clients or something. Shared decision making, what is that exactly? Those kinds of issues." [WS05, PLE]

"…it was also not always so clear what, do I understand the same with the question as another participant that's the question also." [WS10, HCP]

"…sometimes I felt some of the discussions particularly maybe around the word 'recovery' or other words that were used that people had a different interpretation of what that might have meant for them. I was thinking maybe it wasn't actually what I had interpreted it as during the steering group process." [SG03, HCP]

7.5.3.3.2 Final ranking of priorities

Generally, participants from the three stakeholder groups were satisfied with the final ranked order of the research priorities. For several participants, the final ranked order was similar to the initial rankings that they had performed individually.

"It was the ones that I expected really to get pushed to the top especially because there were so many you know patient groups involved. I think what was frustrating or difficult is that we wanted, you know, I would have liked to see all of them, so it was hard they dropped below to not want that one as well you know. I want answers to all of them so it's just difficult to make sure that there were ten, but I'm not surprised at the ten that were chosen." [SG07, PLE]

"It was a really good solid list. I was very pleased with the outcome." [SG08, PLE]

"… all those nineteen questions were relevant. I checked out which ones I put down as my top ten and I think I actually had six or seven of mine already noted for the top ten." [SG01, FFCS]

"Nothing really surprises me. These are all the problems and ideas that I would have come up with as a priority and I think these are the main things that people discussed." [SG05, HCP]

However, not all participants from the healthcare professional group shared the same level of satisfaction with the final ranked order. According to one participant from the healthcare professional group, they would have ranked the questions differently had they been working alone.

"If I had to do it alone I would do it different." [WS10, HCP]

A similar view was held by another participant from the healthcare professional group who felt that ranked order was not a true reflection of reality and was ultimately dependant on the individuals involved in the ranking process.

"I don't think the order we have necessarily reflects reality, it reflects you know the fact that we had that group of people there on that day. If you did the whole thing

again maybe in a slightly different way we might come up with a different ordering." [WS04, HCP]

While some participants would have liked to modify the final ranking, the importance of including multiple perspectives in ranking the priorities was also recognised by others within the health care professional group.

"Looking at the questions that you have here there are clearly some questions that I would have moved around, but I think we all live in a democracy, and I think we've got to accept that we are you know, it's much stronger for having perceptions other than mine." [WS07, HCP]

7.5.3.3.3 Missing questions

Some participants from the lived experience and healthcare professional groups felt that some questions were missing from the final list of 19 questions. At this stage of the PSP process, it was not possible to edit the list of priorities. Questions perceived as missing related to policy and legislation, and underlying physiological changes that take place in the presence/absence of psychiatric medication.

"I would like to see included that wasn't included is in terms of where does this issue sit in the context of mental health policy explicitly and legislation? Because mental health professionals won't change their practice unless there's something with teeth I have found over time." [WS06, PLE]

"I guess I'd have liked the question - do you really know what's going on? And get a sense of how much people think yes, at this stage this is a problem, but we really understand it." [WS04, HCP]

"One question that wasn't in the top twenty I think I tried to shove it in at the end, but I didn't think of it because I wasn't clever enough. You know I think a central idea is that these drugs cause brain damage. The withdrawal either reveals that or is itself a sort of brain damage because you know if you have people that have for years shooting pains, muscle cramps, impaired memory, concentration, sleep, it has to represent some sort of damage to the organ, you know to the nervous system." [SG05, HCP]

7.5.3.4 Theme 4: Identifying & overcoming PSP challenges

The fourth theme focused on identifying challenges associated with the PSP study and how to overcome them by collecting stakeholders' suggestions for improvement. It was

categorised into three subthemes; (1) Managing group dynamics; (2) Representation of stakeholder groups; (3) Suggestions for improvement.

7.5.3.4.1 Managing group dynamics

One participant from the healthcare professional group identified group dynamics as a challenge during the Steering Group meetings. According to this participant, different perspectives, and levels of power held by individuals from different stakeholder groups can lead to a degree of politeness and ignoring of certain issues particularly by the individuals from the lived experience group to avoid conflict. This participant felt that these power dynamics were also present at the Steering Group meetings.

> *"There is a lot of cow towing to powerful people in these groups, to try and make them feel included which really involves patients who have been badly harmed by these drugs prescribed by such people. Then having to also exert efforts to be polite to people who have harmed them in order to have access to you know the corridors of power, research and priorities to get their harm addressed. As well as couching it in very polite terms, so one dynamic to this whole process was you know power dynamics, cow towing, dealing with people whose ignorance of their ignorance you know they are not aware of."* [SG05, HCP]

According to participants from the lived experience and healthcare professional groups, the group dynamics also created challenges when reaching consensus during the final prioritisation workshop. The involvement of multiple stakeholder groups lends to differences in opinions and perspectives.

> *"… there was a conversation in one of our rooms that somebody says, 'well that would happen anyway', and I said from a lived experience point of view but that doesn't you know, it's all likeminded people in a room you know, all working towards the same thing."* [WS03, PLE]

While overt conflict did not arise, one participant from the healthcare professional group felt that some healthcare professionals were not always truly listening to the participants representing the lived experience group.

> *"There wasn't anyone there who was obnoxious you know they were all genuine it felt. And you know they didn't argue too much with each other, they listened to some extent except that the doctors weren't completely listening, they weren't saying well we don't know what's going on so we really should be listening to patients closely. They were happy to have them there but the degree to which they*

were listening to the patient, I mean they were listening in the sense of thinking they were nice human beings but as I say not putting a huge amount of weight on their point of view." [WS04, HCP]

7.5.3.4.2 Representation of stakeholder groups

With respect to the Steering Group composition, a few participants from the healthcare professional group felt that individuals who had benefited from taking psychiatric medication were missing. These participants also recognised potential challenges to recruiting these individuals. For example, some individuals may have been discouraged by those already recruited because of differences of opinions or previous falling outs. The use and discontinuation of psychiatric medication is a contested space where individuals may have very polarising views.

"Did we have people who represented those who had a good experience of using medicines? And I think maybe sometimes that's hard to find, no matter what topic you are looking at. Because I guess if people have had a good experience they just want to get on with things and leave it all behind them then. And that perhaps you know that might have been you know, might have been good to have someone with maybe that perspective. However, I don't think it impacted on what the priorities were at the end." [SG03, HCP]

"If you were to do it again I think you'd really have to try and find people who are positive about medication, as well as people who are negative but the problem is I did ask one or two people but because of the names of the people on the group a lot of them you know they've all fallen out on Twitter, so you know patient advocates for medication were unwilling to, it would have been fine for them but they were unwilling to… You did the best you could, it was a really, a difficult topic and I think you did the best you could." [SG10, HCP]

Another potential barrier to recruitment put forward by a participant from the lived experience group was resource limitations; while travel and accommodation expenses were provided to those who attended the final prioritisation workshop in person, no participants were paid for their involvement in any aspect of the PSP study, which was seen as an issue for people with lived experience who may not be in full time employment or may not have an income.

"*… it's hard work you need money, but I know one thing that this research was they didn't have enough money as well. For instance, I wasn't paid anything for my*

contributions, I didn't mind because I was explaining you know you didn't have the funding there." [SG09, PLE]

In terms of stakeholder representation at the final prioritisation workshop, one participant from the lived experience group suggested that more individuals with lived experience should have been present, particularly older individuals, to achieve a wider range of ages.

> *"I wish there would have been more older people with lived experience."* [WS05, PLE]

7.5.3.4.3 Suggestions for improvement

Two suggestions were made by one participant from the healthcare professional group on how the Steering Group meetings could be improved. The first related to the times of the meetings. All meetings were held in the late afternoon or early evening time (GMT) to accommodate international members, particularly those in the United States. This participant suggested meetings be held earlier or later in the day.

> *"I think it would be better to do a different time point, usually the meetings were quite late. Or not late I wouldn't say but just because we have also different time zones and so it's hard. It's extremely hard…. to have a meeting past dinner time I think would be better or earlier during the day because it was usually in the late afternoons."* [SG02, HCP]

The participant also suggested that tools like Mentimeter (an online polling software) be used to facilitate group discussion and reduce the risk of some members dominating the discussion.

> *"Use tools like Mentimeter because … sometimes it might be easier to write, or to answer a question in mentee or any other tools."* [SG02, HCP]

In terms of the final prioritisation workshop, one participant from the healthcare professional group found the number of research questions difficult to manage when completing the ranking exercises.

> *"The amount of research questions was quite hard to handle in terms of the action of the outcome of trying to prioritise. It became a little bit futile because there was so many questions that were quite close to each other and it's very difficult to keep nineteen items in your mind when trying to think, which is most important".* [WS02, HCP]

Some suggestions were specific to the virtual workshop. For example, one participant recommended the inclusion *"virtual pastry breaks*" for online participants to provide more opportunities for them to interact with other participants. When the in-person are chatting over their refreshments, online participants should be encouraged to remain on the call and engage with other participants. Another suggestion by participants from the lived experience and healthcare professional groups was the creation of additional time to better equip participants for the ranking processes, and to allow for more discussion.

> *"More time just for free-flowing discussion among the virtual participants."* [WS05, PLE]
>
> *"It would have been good if we had been able to have an extra day maybe where either you know the early day, we could map out things we didn't know as opposed to trying to prioritise what we think we do know.*" [WS04, HCP]

7.6 Discussion

This study explored stakeholders' views and experiences of the PSP methodology as a priority setting exercise by analysing the data collected as part of semi-structured interviews with individuals who had been involved in the PSP study (Study 1). Study 1 followed the PSP methodology to identify the Top 10 priorities for future research on reducing and stopping psychiatric medication in collaboration with three stakeholder groups. Even though the PSP methodology is considered the "gold standard" in terms of priority setting exercises, the number of studies that have evaluated stakeholders' views of the PSP methodology is limited (261). This qualitative component of the PSP study was conducted as an important additional component to the standard PSP methodology to advance the evidence base and help to guide other researchers in undertaking PSP studies.

Negative experiences of taking and/or stopping psychiatric medication were a major motivation for participants from all stakeholder groups to get involved in the PSP study. Adverse effects associated with use of psychiatric medication have been previously identified by other studies exploring reasons for discontinuing medication (5). Other participants were driven by the desire to shift the research agenda in a way that aligns with the more modern, collaborative approach that achieves multi-stakeholder

involvement (210). Participants from the lived experience group emphasised the importance of representing other members from this stakeholder group.

Several participants from the lived experience group recalled their previous experiences of involvement in research in which they did not feel listened to or respected. Some of these participants felt that their involvement was more of a tick-box exercise. This is considered as tokenism and is one of the major criticisms of Patient and Public Involvement (PPI) (12). The concept of PPI was previously discussed in Chapter 3. Previous studies exploring service user perspectives on their involvement in the research process reported similar findings in terms of individuals feeling marginalised (213). By engaging people with lived experience of reducing/stopping psychiatric medication from the start and viewing all individuals as equal experts, the PSP methodology aligns with the ethical principles of research which favour the moral argument that individuals affected by a condition, or medication, should have an input in research decisions that may affect them, and facilitates the shift towards the more modern, rights-based approach to research (262). This was reflected by the strong sense of gratitude expressed by participants from the three stakeholder groups for being invited to participate in the PSP study.

Participants were largely satisfied with the PSP methodology through which the Top 10 priorities were co-produced. Co-produced research is research that has been produced by researchers and service users working together (13). According to a recent systematic review of PPI in health and social care research, the incorporation of real-world and lived experience perspective positively impacts the efficiency and value of research (204). This strengthens the argument for multi-stakeholder involvement in research and planning. Some participants experienced additional benefits to being involved in the PSP study such as newly formed friendships and learning experiences. PPI has been shown to not only be beneficial to the research itself, but also to those involved by improving researchers' knowledge and communication skills whilst empowering contributors and creating a sense of ownership (204).

Participants shared positive views on the study's ways of working, particularly the clear communication channels. Steering Group meetings were held on a regular basis throughout the study, and communications were also made via email, both of which align with previous recommendations on maximising PPI potential in research (12, 205). Strong

group facilitation was also identified as one of the key facilitators to achieving authentic collaboration. JLA facilitation was present at the Steering Group meetings and the final workshop to ensure fairness and transparency and support all individuals to share their views and perspectives (197, 263). Group facilitation not only aligns with the PSP methodology, but also aligns with the Nominal Group Technique (NGT) methodology (199).

Strong group facilitation was also perceived as useful in terms of managing group dynamics. Bringing together stakeholders with different personalities, backgrounds, nationalities can create potential for conflict and miscommunication, particularly in contested areas such as prescribing and discontinuation of psychiatric medication where polarising opinions are common. The extent of conflict is determined by the team dynamic (203, 204). Group facilitation helped to manage the group dynamics i.e., to prevent the loudest voices from dominating, to maintain the rules of conduct, and to resolve differences of opinion about the purpose and role of coproduction (209).

Although there was a general sense of satisfaction with the PSP methodology, some participants made suggestions on how it could be improved. The main suggestion related to improving stakeholder representation. Recruitment issues are a common challenge amongst studies involving PPI. Narrow PPI selection processes risk excluding those with the most to offer and gain from the decision-making which restricts the pool of ideas for improvement and limits the opportunity to break cycles of suboptimal care and services (12). Despite efforts to achieve equal representation of all stakeholder groups, individuals who had benefited from taking psychiatric medication were missing from the Steering Group and final workshop. That said, overall stakeholder representation in this study was considered a success. Other suggestions on improving the workshop were the allocation of additional time for more free-flowing discussion and “virtual pastry breaks” to support interaction between online participants. While the workshop structure closely followed the JLA guidance, it was held as a hybrid event (i.e., in-person and online participants) which deviated from the traditional in-person JLA workshops.

Several participants shared their views on the research priorities. A handful of participants felt that the question terminology led to differences in interpretation which ultimately created a level of ambiguity when completing the final ranking exercises. Others were

overwhelmed by the number of questions. All 19 summary questions discussed at the workshop were formatted in line with the PSP methodology (i.e., the PICO format), having been previously reviewed and discussed extensively by the Steering Group. In terms of the number of questions, 19 questions align with the JLA guidance which recommends that up to 25-30 questions are taken forward to the workshop. Despite their suggestions on improving the formatting of questions, most participants were satisfied with the final ranking of the priorities which built credibility in the methodology and strengthened the study outcome. There was a small number of participants from the healthcare professional group who also commented on the final ranked order, claiming that they would have ranked them differently had they worked alone. This feeds back into the paternalistic view of mental health that the people in power i.e., the researchers and healthcare professionals know best.

7.7 Ethics

7.7.1 Ethical approval

Ethical approval for this study was obtained from the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee, Trinity College Dublin on 9th January 2024 [Ref. 2023-06-01, REAMS-2613] (see Appendix 7.5).

7.7.2 Ethical principles

The four ethical principles were defined and described in Chapter 4. Given that Study 1 and Study 3 both involved qualitative analysis of information gathered from the same stakeholder groups, there was considerable overlap around how the ethical issues in both studies were addressed. Hence this section will not repeat issues but highlight some extra precautions that were taken with the qualitative data.

With respect to beneficence and nonmaleficence, the Participant Information Leaflet (PIL) informed all participants of the risks and benefits of their participation (see Appendix 7.2). In the event that a participant became distressed during the interview, the interview was paused, and the participant could choose whether to continue or stop the interview. As for informed consent, all participants received a consent form and were given time to

review the information prior to the interview (see Appendix 7.3). Participants could return the completed consent form or provide verbal consent on the day of the interview. All participants self-enrolled in the study, free of coercion. In terms of participant confidentiality, all participants were assigned a pseudonym to protect their identity. Steering Group members were coded as SG01, SG02, etc., and workshop participants were coded as WS01, WS02, etc. A code sheet was created which documented the link between participant identities and their coded transcripts. Given that some participants shared their personal experiences of reducing/stopping psychiatric medication, any potentially identifying data such as the participant's country of origin or place of work was also assigned a code to protect their identity. In terms of justice, the same interview topic guide was used in all interviews regardless of the participants' stakeholder group. Similarly, upon analysing and coding the survey responses, the same coding template was applied to all interview transcripts.

7.8 Rigor & trustworthiness

The definitions of rigor and trustworthiness were outlined in Chapter 4. This section will not repeat the same examples of rigor and trustworthiness but highlight additional examples specific to Study 3.

With respect to credibility, the interview topic guide was piloted with the supervisory team, and the supervisory team had oversight over the entire coding and review process. A 25% (n=5) sample of the interview transcripts was double coded by the researcher and supervisory team before applying the coding template to the remaining transcripts. This collaborative approach justified the final codes included in the coding template. Upon reporting the study findings, quotes were used as exemplars to strengthen the findings and provide the reader with a greater insight into the data collected. In terms of transferability, all the steps involved in conducting the study were described in detail in the PhD thesis. In terms of dependability, a clear audit trail was created to document all the steps involved in this study. An interview topic guide was developed to achieve consistency between the interviews and facilitate the process of analysing the interview data. A coding template was also developed to reduce interpretative bias and improve coding consistency between the researcher and the supervisory team. Finally,

confirmability was integrated into the study by collecting data from the three stakeholder groups which facilitated triangulation and allowed for comparisons between the groups. The similarities and differences in opinions that existed between the stakeholder groups around the PSP methodology were explored.

7.9 Strengths & Limitations

The study had several strengths and limitations. The first strength relates to the study's sample size. The means of determining adequate sample sizes in qualitative and quantitative studies differs. In qualitative studies, the concept of "saturation" has largely been replaced by that of "information power" (264). According to the latter, the amount of information held by the sample determines the number of participants needed i.e., the more information they have, the fewer participants needed (264). After reviewing and analysing the data, the researcher and supervisory team were confident that the sample of interviews gave a reasonably complete picture of stakeholders' views. The second strength relates to the robustness of the study methods. The study followed the methods laid out in the published study protocol and was reported in line with the COREQ guidelines (257).

In terms of study limitations, it was not possible to interview all willing individuals due to time and resource constraints. The supervisory team applied purposeful sampling techniques to achieve a balanced representation of the three stakeholder groups. However, this created potential for lost voices, perspectives, and valuable information about the PSP Study. Secondly, as the researcher who conducted the interviews and had had previous detailed engagements with all the participants in Study 1, this may have given rise to the potential for bias in terms of what they shared about the PSP study. On the other hand, because participants knew the researcher from previous interactions during the course of the PSP study, they may have felt more comfortable providing constructive feedback on the process and sharing their personal insights and experiences.

7.10 Summary

Chapter 7 reported on stakeholders' views and experiences of the PSP methodology as a priority setting exercise by analysing data collected from semi-structured interviews with

individuals who had been involved in the Priority Setting Partnership (PSP) study (Study 1). This study identified stakeholders' motivations for involvement, perceptions on multi-stakeholder involvement and how the PSP study achieved authentic collaboration between the stakeholder groups. This study also captured the perceived challenges to participating in a PSP study and stakeholders' suggestions for improvement. By identifying stakeholders' key learnings and practical insights on the PSP methodology, particularly the hybrid approach, which is a novel methodological approach, this study will help to guide and support future research teams conducting PSP studies and other collaborative research studies. The next chapter reports on Study 4 which involved a scoping review of mobile phone apps and app-based interventions that supported individuals tapering psychiatric medication.

Chapter 8: A scoping review of mobile phone applications & app-based interventions to support tapering of psychiatric medication

8.1 Introduction to Chapter 8

Chapter 8 presents a scoping review that explored mobile phone applications ("apps"), and app-based interventions that focused on supporting the tapering of psychiatric medication (Study 4). Tapering involves gradually reducing the dose of the psychiatric medication over a period of time (99). The importance of providing aids and supports for individuals tapering psychiatric medication is gaining increased recognition (265). As outlined in Chapter 5, this was demonstrated by the prioritisation of questions in the Priority Setting Partnership (PSP) study (Study 1) about reducing and stopping psychiatric medication. The second most highly ranked question of the Top 10 questions prioritised focused on tapering supports: *"What are the most effective ways to provide support to individuals who are reducing and stopping psychiatric medicines? These may include, but are not limited to, family/peer support, educational support, financial support, psychological support, and healthcare support".*

In the absence of dedicated withdrawal services and empirical evidence on the withdrawal process, individuals are increasingly turning to online sources, such as discussion fora and peer support groups, for guidance and support while tapering psychiatric medication (153, 266, 267). Given the use of these online platforms, apps are another resource that may have potential to provide support to individuals tapering psychiatric medication. Apps are defined as *"a computer program or piece of software designed for a particular purpose that you can download onto a mobile phone or other mobile device"* (268). The app stores offer a myriad of apps. In 2022, the Google Play Store (Android) was the largest the app store with 3.48 million apps available for download (269), followed by the Apple App Store (iOS) with roughly 2.22 million apps. Recently, there has been a proliferation of apps to support people with mental illness. As of 2020, there were more than 10,000 mental health and wellness related apps available for download, which equated to one third of the app

market (270). In relation to psychiatric medication specifically, some apps aid drug selection, while others promote and support medication adherence (271-273). The use and functioning of apps that aim to relieve depression symptoms (274) and promote adherence to psychiatric medication have been evaluated by several studies (275); however, the evidence base for apps and app-based interventions in supporting safe and effective discontinuation of psychiatric medication use has not been examined previously.

8.2 Aim and Objectives

The aim of this study was to examine the content, underpinning evidence base, and impact of mobile phone apps and app-based interventions that focused on supporting the tapering of psychiatric medication. The objectives were to:

- characterise the study populations included in evaluations of the apps.
- describe the identified apps in terms of functions, tapering recommendations, evidence base supporting recommendations, and any linked services or supports to promote recovery.
- characterise the identified apps' active components using the Behaviour Change Technique (BCT) taxonomy.
- examine the app development process (i.e., underpinning evidence and theory).
- identify the outcome measures that have been used to evaluate the apps and report the impact from both a qualitative and quantitative perspective.

8.3 Rationale for choosing the scoping review methodology

Given that the aim of this study was to provide a broad overview of the existing literature and commercially available apps, a scoping review was deemed the most suitable review methodology for this study by the researcher (276, 277). The first definition of a scoping review was put forward by May 2001 who suggested that scoping reviews *"aim to map rapidly the key concepts underpinning a research area and the main sources and types of evidence available and can be undertaken as stand-alone projects in their own right, especially where an area is complex or has not been reviewed comprehensively before"* (278). Scoping reviews provide a comprehensive overview of research previously

undertaken and reported in the literature to explore the depth of existing literature on a particular topic, identify knowledge gaps, and inform future research (279). On the other hand, systematic reviews follow a more structured and pre-defined process to identify evidence that is relevant to a particular question or set of questions i.e., determining feasibility or effectiveness of a particular intervention (276). Systematic reviews are typically used to inform practice and policy, and the development of clinical guidelines (276).

To achieve consistency and transparency in scoping review terminology and methods, several frameworks and reporting guidelines have been developed. The first framework was developed by Arksey and O'Malley in 2005 (278) which involved five stages; (1) Identify the research question; (2) Identify relevant studies; (3) Select studies for inclusion; (4) Chart the data; (5) Collate, summarise, and report the results. Methodological guidance on scoping reviews was published by the Joanna Briggs Institute (JBI) Scoping Review Methodology Group in 2014 and updated in 2020 (279). The updated guidance takes into account the development of the Preferred Reporting Items for Systematic Reviews extension for Scoping Reviews (PRISMA-ScR) reporting guideline (280) and provides further clarification when scoping reviews are appropriate and how to conduct a critical appraisal within a scoping review. The PRISMA-ScR was developed to be consistent with JBI's scoping review methodology and to provide reviewers with a reporting checklist for their reviews (280). As outlined below, the scoping review in this study was conducted in line with the JBI guidance.

8.4 Methods

This scoping review was conducted in line with the protocol which was developed in accordance with the JBI guidance (279, 281) and published as an open access peer-reviewed article on HRB Open Research (282). This review was reported in line with the PRISMA-ScR guidelines (280).

8.4.1 Inclusion and exclusion criteria

The Population-Intervention-Comparison-Outcome-Studies (PICOS) framework was used to guide study selection and to align the eligibility criteria with the aim of this scoping review (see Table 8.1).

Table 8.1: Overview of the inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Participants	Individuals who wanted to discontinue psychiatric medication (i.e., antidepressants, anxiolytics, hypnotics, mood stabilisers and antipsychotics).	Individuals who wanted to discontinue any other forms of medication (e.g. opioids) or psychoactive substances (e.g. cannabis).
Interventions	Apps that focused on supporting the tapering psychiatric medication.	Apps that focused on medication adherence or switching between psychiatric medication.
Comparison	Individuals receiving usual care or another intervention in controlled studies	None
Outcomes	Non-commercial apps: All outcomes for studies that met the inclusion criteria were included. Commercial apps: app ratings and comments.	None
Studies	Non-commercial apps: Quantitative, qualitative, and mixed methods evaluations. Commercial apps: Not applicable; apps did not have to have undergone empirical evaluation to be included.	Conference abstracts.

8.4.1.1 Types of participants

The review included studies of app-based interventions retrieved from searches of peer literature (i.e., "non-commercial" apps) and apps retrieved from searches of the commercial app stores (i.e., "commercial" apps) that targeted individuals who wanted to discontinue psychiatric medication use. The range of psychiatric medication of interest to this review consisted of antidepressants, anxiolytics, hypnotics, mood stabilisers and antipsychotics. Individuals were not limited by age or medical diagnosis.

8.4.1.2 Types of interventions

The review included apps that focused on supporting the tapering of psychiatric medication. Tapering-related guidance could come from any source. Apps did not have to

explicitly advise on how to taper to be included. Apps that focused on medication adherence were excluded, as were apps that focused on switching between psychiatric medication given that switching does not always equate to reducing or stopping medication.

8.4.1.3 Types of comparisons

The review included controlled studies in which individuals received usual care or another intervention.

8.4.1.4 Types of outcome measures

All outcomes for non-commercial and commercial apps that met the inclusion criteria were included. For the commercial apps, any feedback reported by service users and/or service providers on the app stores was reviewed (e.g., app ratings and comments).

8.4.1.5 Types of studies

Eligible studies included quantitative (e.g., randomised controlled trials, before and after studies) qualitative (e.g., descriptive, grounded theory), and mixed methods evaluations. The review included apps regardless of whether they had undergone any formal evaluation. Conference abstracts were excluded due to a lack of sufficient information. Studies and apps were not limited to the English language.

8.4.2 Search strategy

The search strategy consisted of two components: (1) a search of electronic databases to identify studies evaluation app-based interventions (i.e., non-commercial apps); and (2) a search of app stores to identify commercial apps. The first searches were conducted in January 2022, and updated searches were conducted in March 2024.

The first component included a search of the following seven electronic databases and digital libraries: MEDLINE, EMBASE, CINAHL, PsycINFO, Web of Science, ACM (a research database of literature and detailed bibliographic resources for computing professionals from a wide range of publishers) and IEEE Xplore (a research database with journal articles, and other related materials on computer science, electrical engineering and electronics, and allied fields). The electronic database searches consisted of three steps:

1. A preliminary search of one electronic database (Web of Science) was undertaken to identify articles relevant to the review topic. Initial key search terms included: “psychotropic”, “mobile applications”, “tapering” and “discontinuation”. The preliminary search enabled the identification of keywords and index terms from the titles and abstracts of relevant articles.
2. Based on the above, a comprehensive search strategy was designed and refined in collaboration with the research librarian (GS), who is an expert in database searching. The final search strategy consisted of four strands and employed Boolean operators as outlined in Table 8.2. Key terms relevant to the four strands were determined in consultation with the supervisory team (CC, AH) and the research librarian. A combination of Medical Subject Headings (MeSH) and free-text searching was used. The four strands were searched separately using “OR” in between terms, and then combined using “AND” in the final search.
3. A search of the seven databases listed above was conducted using all identified keywords and index terms. The search strategy for each database was unique. The final search strategy for one of the databases (Web of Science) is included as an Appendix (see Appendix 8.1).

Database searches were restricted to titles and abstracts published from January 2008 onwards. The year 2008 was specifically chosen as the start date as it was the year that the first app store was launched. Reference lists of identified studies were searched for other relevant studies. All searches were recorded to facilitate replication.

Table 8.2: Four key search strands of the database searches

Strand 1: Drugs	Strand 2: Apps	Strand 3: Phone	Strand 4: Tapering
Psychotropic	Application	Smartphone	Drug taper
Tranquiliser	App	Phone	Deprescribing
Tranquilizer	Apps	Apple	Withdraw
Hypnotic	User experience	iOS	Discontinuation
Sedative	UX	Android	Reduction
Sleeping tablet	Social media	Google Play Store	Quit
Cholinergic	mHealth	Windows store	Cease
Anticholinergic	Consumer facing		Cessation
Antimanic	intervention		Coming off
Anti manic	Mobile health		
Antidepressant	technology		
Antianxiety	Digital medication		
Antipsychotic			
Benzodiazepine			
BZD			
Zopiclone			
Zolpidem			
Zaleplon			
Eszopiclone			
Z-drug			
Anxiolytic			

The second component included a search of two app stores: Apple's App Store (iOS apps) and Google Play Store (Android apps), from their inception to align with the search of the electronic databases. The app store searches also consisted of three steps:

1. A preliminary search of the Apple App Store was conducted to identify relevant search terms. Initial key search terms included: “psychotropic”, “antidepressant”, “benzodiazepine” and “taper”. This initial search enabled the identification of the names and descriptions of relevant apps, including the use of relevant specific proprietary drug names, and guided subsequent searches.
2. Informed by these findings, a comprehensive search strategy was designed and refined in conjunction with the supervisory team and an academic collaborator with expertise in conducting reviews of apps (GD). The final search strategy

consisted of two strands as outlined in Table 8.3. The use of Boolean operators was not applicable to the app store searches.

3. A search of the two app stores was conducted using the same keywords. Separate searches for each keyword were conducted on each platform, across all app categories. An app store category presents a group of apps that have similar features, functionality, and themes (e.g., finance, health & fitness, and education).

Table 8.3: Two key search strands applied to the app store searches

Strand 1: Drugs	Strand 2: Tapering
Psychotropic Antidepressant Benzodiazepine Xanax	Taper Medication taper Drug taper

8.4.3 Study and app selection

All identified studies from the electronic databases searches were imported into Covidence (reference management software platform; https://www.covidence.org/) and underwent deduplication. A two-step screening process was undertaken by the researcher (MB) and one member of the supervisory team (CC) working independently:

1. All titles and abstracts were screened for inclusion based on the pre-specified criteria outlined above.
2. If a study appeared to meet inclusion criteria or a decision could not be made based on the title and abstract alone, the full-text article was retrieved. Any disagreements throughout the screening process were resolved by consensus with the other member of the supervisory team (AH).

All identified commercial apps retrieved from the app stores underwent a similar screening process. Details of the apps were entered into Microsoft Excel by the researcher. Details included: the app's name, brief description of its functions, the app store and app store category, the age rating (explained in Section 8.5 below), the author/app creator, and a link to access the app. Following deduplication, apps were screened for inclusion by the researcher and one member of the supervisory team (CC)

working independently. If an app appeared to meet the inclusion criteria or when a decision could not be made based on the app name and description alone, the app was downloaded directly onto an iPhone for iOS apps or onto a Mac computer using an emulator ("BlueStacks") for Android apps. Any disagreements were resolved by consensus with the other member of the supervisory team (AH).

In cases where apps were not publicly accessible, study authors and app developers were contacted to request access or provide additional information about the app content.

8.4.4 Data extraction

Data extraction ('data charting') was performed by the researcher and one member of the supervisory team (CC) using a data extraction form that was developed and piloted in Microsoft Excel. The form was developed in accordance with the relevant methodological guidance to record key information from each source (278). The same form was used to extract key information relating to the descriptive characteristics of evaluation studies of app-based interventions and commercial apps (see Appendix 8.2). Information included: country of origin, study design, aims and objectives, inclusion & exclusion criteria of participants, app functions and features, underpinning theory/evidence base and outcome measures. Information extracted from the commercially available apps and their linked websites included country of origin, source & cost, aims & description, functions and features, underpinning theory/evidence base and app reviews. The data extraction form was piloted on one non-commercial app and one commercial app that met inclusion criteria and refined accordingly. Once the final version was agreed, it was applied to the remaining apps and studies of app-based interventions by the researcher and one member of the supervisory team (CC) working independently. In addition to the data extraction forms, screenshots of the apps and any companion websites which were directly interlinked with the apps were taken and collated in Microsoft Word for each app to assist the coding of the app content in terms of functionalities and behaviour change techniques (BCTs) as described in Sections 8.4.6.1 & 8.4.6.2 below. Each screenshotted image of the app content was accompanied by a brief explanation. If an app was not available in English, all words in the screenshotted image were translated by the

researcher by copying and pasting the words into Google Translate. The translated text was inserted below the corresponding image.

8.4.5 Data analysis and synthesis

The JBI guidance recommends that the analysis of data be pre-specified within the study protocol to ensure transparency and justification (279). Given that the aim of this scoping review was to provide a broad overview of the existing literature and commercially available apps and not to pool outcome data, a narrative synthesis was conducted. A narrative synthesis is defined as *"an approach to the systematic review and synthesis of findings from multiple studies that relies primarily on the use of words and text to summarize and explain the findings"* (283 p.5). The narrative synthesis described the key findings and outlined how they related to the review's objectives. The approach to narrative synthesis was informed by the Synthesis Without Meta-analysis (SWiM) guidelines (284). Key study and app information was summarised and presented in tabular form, accompanied by a narrative summary which described how these results related to the review objectives and questions.

8.4.6 App coding

All identified non-commercial and commercial apps were coded in terms of their functionalities and components of the Behaviour Change Technique Taxonomy version 1 (BCTTv1). BCT coding is explained in Section 8.4.6.2 below. To facilitate the coding process and account for potential longitudinal features within the apps, a profile was created on the apps using a sample patient case (i.e., a patient tapering from 10 mg diazepam three times daily). This enabled the researcher to fully explore the apps' features and functionality, including any notifications and usage metrics over time.

8.4.6.1 Coding of app functionalities

The coding of app functionalities was guided by a previous study that evaluated apps for depression (271). This previous study identified three main types of app functionalities: screening, tracking, and provision of interventions. "Screening" included the monitoring symptoms, self-diagnosis of depression, and basis for personalised intervention. "Tracking" involved tracking of thought patterns, mood patterns, behaviour, and

symptoms. “Intervention” included thought diaries, psychoeducation, and mindfulness. These three functionalities informed the development of the provisional coding template for this scoping review which was then applied to one non-commercial app and two commercial apps by the researcher and one member of the supervisory team (CC) working independently. At this stage, additional functionalities (e.g. dose calculator and social support) were identified and added to the provisional coding template. This template was then applied to another commercial app by the researcher, refined, and finalised with the supervisory team (see Appendix 8.2). The final version of the coding template was applied to the remaining apps and studies of app-based interventions by the researcher and one member of the supervisory team (CC). Any coding disagreements were resolved through discussion with the other member of the supervisory team (AH).

8.4.6.2 BCT coding

All identified non-commercial and commercial apps were also coded using the BCTTv1 (285). A BCT is defined as *“observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour”.* A BCT is considered the active component of a behaviour change intervention (285). In other words, it is the observable and replicable component of an intervention which is responsible for changing behaviour (285). The BCTTv1 consists of 93 BCTs, grouped within 16 categories with detailed definitions of each BCT (285). The application of the BCT taxonomy in the scoping review enabled the identification and characterisation of the identified apps’ content using standardised terminology. This not only enhanced the robustness of the analysis but allowed for greater comparison of the components of the individual apps (286, 287). A previous study evaluating apps that focused on medication adherence also applied the BCT Taxonomy (273).

The BCT coding process consisted of three steps:

1. One non-commercial app and two commercial apps underwent preliminary coding by the researcher and one member of the supervisory team (CC) using the entire BCTTv1 taxonomy.

2. Based on the above, a coding template was developed. This template contained the definitions of the identified BCTs and examples of how they applied in the context of this study (see Appendix 8.2).
3. This coding template was applied to the remaining apps by the researcher and one member of the supervisory team (CC) working independently. Any coding disagreements were resolved through discussion with the other member of the supervisory team (AH).

8.4.7 Critical appraisal of quality

Given that scoping reviews aim to provide a comprehensive overview of research previously undertaken and not to critically appraise the identified studies, an assessment of methodological limitations or risk of bias of the evidence included is not typically performed (276). The critical appraisal process in this scoping review focused on the potential for bias and the extent to which it had been addressed by the included studies that evaluated app-based interventions. Critical appraisal of included studies was performed by the researcher and one member of the supervisory team (CC) working independently using the relevant JBI Critical Appraisal Checklist for different study types (see Appendix 8.3) (281, 288). The critical appraisal process was not used to exclude studies, but to help inform the synthesis and interpretation of the review findings. This checklist was designed to guide the critical appraisal of studies, not apps. As a result, it was not possible to apply the same method of critical appraisal to the commercial apps.

8.4.8 Refinements to the study protocol

8.4.8.1 Inclusion and exclusion criteria

Following the preliminary searches, the inclusion and exclusion criteria outlined in the study protocol (282) were further refined to make the search strategy more inclusive. In terms of population, the protocol included apps that targeted adults (≥18 years) who wanted to discontinue psychiatric medication use that were available in English. During the initial stages of conducting this review, two modifications to these criteria were made. Firstly, the age limit was removed because the app stores did not always differentiate based on ≥18 years in terms of target population. Secondly, the language restriction was

removed as the content of non-English language apps was readily translatable using the methods described in Section 8.4.4 above.

8.4.8.2 App coding

The study protocol only specified details of BCT coding (282). The final scoping review also included coding of app functionalities to enhance the overall description of the content of identified apps and facilitate a more in-depth comparison between the commercial apps and studies of app-based interventions.

8.5 Results

8.5.1 Search results

The results of the database and app store searches are outlined in Figure 8.1. The database searches yielded 1,092 citations. After 168 duplicates were removed, 924 remaining records underwent title and abstract screening. Eight hundred and eight three records were excluded as they did not meet inclusion criteria. The remaining 41 full-text articles were reviewed for eligibility. The main reasons for exclusion of studies were: the study did not focus on psychiatric medication ("wrong patient population") or the study did not focus on tapering psychiatric medication ("wrong intervention") (Figure 8.1). In total, three articles met inclusion criteria, two of which related to the same study: a study protocol (289) and post-trial evaluation report (290). As a result, only two unique studies evaluating app-based interventions (i.e., non-commercial apps) were identified (290, 291).

The app store searches yielded 181 apps. After 41 duplicates were removed, 137 apps underwent screening based on name and description. Of those, 23 apps were exclusive to the Apple Appstore, 110 apps were exclusive to the Google Play Store, and 4 apps were found on both app stores. 128 apps were excluded as they did not meet inclusion criteria. The remaining nine apps were downloaded and reviewed for eligibility. The same reasons for exclusion applied to the apps: the app did not focus on psychiatric medication ("wrong patient population"), or the app did not focus on tapering psychiatric medication ("wrong intervention").

In total, seven apps meeting inclusion criteria were identified comprising two non-commercial apps (i.e. retrieved from electronic database searches of the peer-reviewed literature), and five commercial apps (i.e. retrieved from searches of the app stores). Of the five commercial apps, four apps were no longer available on the app store following the updated search in March 2024.

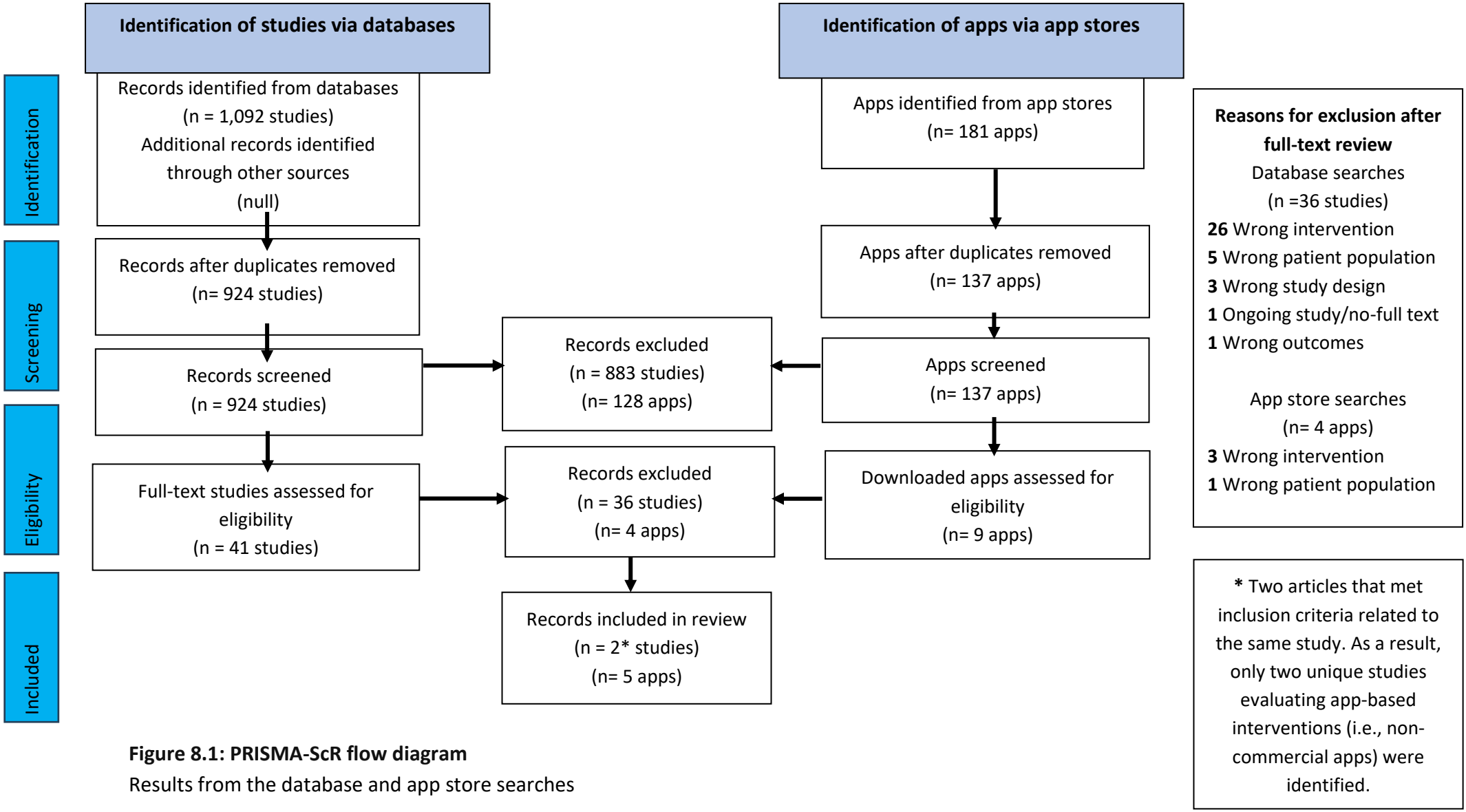

Figure 8.1: PRISMA-ScR flow diagram

Results from the database and app store searches

8.5.2 Overview of identified apps (Objectives 1-3)

An overview of the seven identified apps comprising two non-commercial apps and five commercial apps is presented in Table 8.4.

The study by Sturup et al. (2017) involved a randomised controlled trial that compared tapering of antipsychotic medication with antipsychotic maintenance treatment in individuals aged 18 years or older with newly diagnosed schizophrenia or persistent delusional disorder in terms of remission of psychotic symptoms (289). The target sample size was 250 participants. Participants in the intervention group and control group were in continuous contact with their outpatient psychiatric team ("OPUS") over the course of a year and received usual non-pharmacological treatment in their OPUS team. Participants in the intervention group gradually discontinued their antipsychotic medication by making monthly reductions of approximately 25% of the initial dose of medication, with at least five half-lives between each dose reduction over a minimum period of six months. These participants received access to a mobile phone application that allowed them to register their symptoms on a daily basis and this information was accessible to the OPUS team. The aim of the app was to discover early warning signs of relapse and thereby enhance service user safety. Meanwhile, participants in the control group received treatment as usual with the possibility to switch to another antipsychotic medication and change dose.

The study by Cucciare et al. (2022) also involved a randomised controlled trial which evaluated the effectiveness of an electronically delivered, direct-to-patient benzodiazepine cessation intervention, known as "EMPOWER-ED" (291). This study recruited individuals in primary care, specifically United States military veterans, taking benzodiazepines for at least three months and having access to a smartphone, tablet or desktop computer. There was no minimum age stated. The target sample size was 170 participants (85 intervention group, 85 control group). Participants in the intervention group received access to the intervention, the "EMPOWER-ED" protocol, on any digital device (e.g., smartphone, desktop, tablet) that they chose. If the participant decided to reduce or stop their benzodiazepines, EMPOWER-ED generated a taper schedule based on their information. The tapering schedule lasted up to 21 weeks with

each day's target pill consumption graphically displayed on a calendar. Meanwhile, participants in the control group followed their healthcare providers' recommendations regarding their benzodiazepine use.

The five commercial apps targeted either antidepressants ("BetterOff", "Cymbalta Withdrawal" and "TaperTracer") or benzodiazepines ("Quit Xanax Addiction") exclusively, with the exception of one app ("Prescriby") which targeted benzodiazepines and Z-drugs, as well as opioids. The minimum age to download the apps from the relevant app stores was 12 years (n=2 apps), 4 years (n=2 apps), or not stated (n=1 app), as outlined in Table 8.4. The apps supported individuals who were stopping psychiatric medication by providing a range of strategies which included the provision of tapering-related information, and access to a healthcare professional. The individual app functionalities are described in greater detail in Section 8.5.2.1.

In terms of accessibility and cost of the apps, neither of the non-commercial apps were commercially available on the app stores nor were any associated costs reported. With respect to the commercial apps, four apps were available to download from the app stores without any restrictions/limitations. One app ("Prescriby") required prior registration by the user's clinician on the app's companion website. Once registration was complete, the user could access the app with their phone number which served as an electronic ID. The user's clinician could create a tapering plan which they could either export as a PDF or save within the app. The user's clinician could also access the monitoring dashboard where they could monitor how the user was doing and get a list of all users that were considered high-risk of not adhering to the tapering plan.

While all apps were free to download and use, one app ("Quit Xanax Addiction") had a commercial element. This app offered in-app purchases and advertisements including "custom skins" i.e., visual features that changed the look of the app for €1.99 each. The user could pay to upgrade to the full version of the app which offered additional features (e.g., options to remove advertisements and to restrict app access to the user). One app's companion website ("Cymbalta Withdrawal") also had a commercial element in which the user could purchase two supplements, N-acetyl cysteine, and Black Seed Oil, which were promoted to help manage the withdrawal symptoms associated with tapering antidepressants. Three apps ("BetterOff", "Cymbalta Withdrawal" and "Prescriby") were

interlinked with a companion website. One app ("TaperTracer") contained a link to an external website that was not directly linked to the app. These websites were referred to as "app companion websites" and "app-linked websites", respectively.

With respect to tapering advice/recommendations, none of the commercial apps provided any explicit tapering advice directly. The "BetterOff" app recommended slow tapering with the support of a clinician. The app's companion website outlined six phases of tapering and had a link to a tapering chart which recommended dose reductions for thirteen antidepressants, ranging from 20 to 33% depending on the drug, to be completed every three weeks. At the time of study writeup, the link to the companion website was no longer active. The "Cymbalta Withdrawal" app's companion website recommended 10% monthly dose reductions based on the last dose. It also had a tapering handbook which provided additional tapering-related information. The "Prescriby" app's companion website provided the user's clinician with three tapering options (e.g., exponential, linear or logarithmic decay of dosages) when creating the tapering plan. Once the plan was created, it was exported to the user's app. The tapering plan showed the user the dose of medication that they should take each day, as well as the structure of the plan for the subsequent days and weeks. The "Taper Tracer" app allowed the user to plan the reduction frequency (monthly or fortnightly) and reduction amount as a percentage of their dose (max 10% reduction). The app's linked website (survivingantidepressants.org) recommended a 10% dose reduction every four weeks. The "Quit Xanax Addiction" app did not provide any tapering advice.

Table 8.4: Overview of the identified apps

Study/App ID	Country of origin	Source, cost & availability	App focus/summary	Tapering recommendations
Sturup et al. (2017)	Denmark	Published paper of a randomised controlled trial involving 29 participants (aged ≥18 years with newly diagnosed schizophrenia or persistent delusional disorder in remission of psychotic symptoms and who were taking antipsychotics) No cost reported Not commercially available on the app stores	Targeted medication(s): Antipsychotics The aim of this app was to discover early warning signs of relapse among patients in the intervention group who underwent tapering of their antipsychotic medication. Intervention group participants could make daily registrations which were accessible to the outpatient medical team.	Participants in the intervention group gradually discontinued their antipsychotic medication by making monthly reductions of approximately 25% of the initial dose of medication, with at least five half-lives between each dose reduction, over a minimum period of six months.

Table 8.4 (continued): Overview of the identified apps

Cucciare et al. (2022)	United States	Published protocol for a randomised controlled trial with a target sample size of 170 participants (US military veterans in primary care taking benzodiazepines for a minimum of three months. No minimum age was stated.). At the time of writeup (December 2024), the recruitment status on ClinicalTrials.gov was "Active, not recruiting". The estimated date of study completion was 30th September 2025. No cost reported Not commercially available on the app stores	Targeted medication(s): Benzodiazepines The intervention was an electronically delivered, direct-to-patient benzodiazepine cessation intervention known as "EMPOWER-ED". Participants in the intervention group could access the intervention on any platform (e.g., smartphone, desktop, tablet). The intervention consisted of a range of strategies which included a self-assessment of risks associated with long-term benzodiazepine use, information on the evidence for benzodiazepine-related harms, and recommendations for self-tapering.	The intervention provided participants with recommendations for self-tapering. No further detail on the types of recommendations was provided. Participants also had the option of generating a taper schedule which lasted up to 21 weeks.

Table 8.4 (continued): Overview of the identified apps

BetterOff	Denmark	Apple Appstore (iOS) Free to download No in app purchases or advertisements The age rating on the Apple Appstore was ≥4 years The app was only available in Danish	Targeted medication(s): Antidepressants The aim of this app was to support individuals who were stopping antidepressants by supplementing clinical advice received from the individuals' clinician or another healthcare professional.	**Within the app**: The app recommended slow tapering with continuous evaluation and support from the user's clinician. **App's companion website:** The website had a link to a tapering chart for 13 antidepressants. The chart recommended drug specific dosage reductions, ranging from 20 to 33% depending on the drug, to be completed every three weeks. The website also outlined the six phases of tapering: (1) Prepare your taper; (2) Start the taper; (3) Evaluate and adjust the process; (4) Continue the dose reduction; (5) Compete the taper; (6) Retention.

Table 8.4 (continued): Overview of the identified apps

Cymbalta Withdrawal - A Tapering Guide	Not reported	Google Play Store (Android) Free to download No in app purchases or advertisements. However, purchases could be made on the app's companion website. The age rating was not stated on the Google Play Store, but parental guidance was recommended.	Targeted medication(s): Antidepressant (duloxetine) The aim of this app was to support individuals who were tapering Cymbalta (duloxetine) by providing a number of strategies (e.g., education and dose calculator).	**Within the app**: The app did not provide any specific tapering advice **App's companion website**: One section of the website offered a handbook which provided information on different tapering approaches (e.g., gradual taper and micro-taper). The handbook promoted a slow taper involving 10% monthly dose reductions based on the previous dose. The website also provided information on supplements promoted as managing withdrawal symptoms (e.g., N-acetyl cysteine and black seed oil).

Table 8.4 (continued): Overview of the identified apps

Prescriby	Iceland	Apple Appstore (iOS) Google Play Store (Android) Free to download but required prior registration by user's clinician. No in-app purchases or advertisements The age rating on Apple Appstore was ≥4 years, and on the Google Play Store was PEGI 3 (suitable for all age groups)	Targeted medication(s): Benzodiazepines, z-drugs, and opioids The aim of this app was to help individuals stop benzodiazepines, Z-drugs, and/or opioids by creating an individualised tapering plan in collaboration with the user's clinician and enabling clinicians to monitor the users' tapering progress.	**Within the app**: The app displayed the tapering plan that was created by the user's clinician on the companion website. **App's companion website:** The website gave the user's clinician three options to choose from (i.e., exponential, linear or logarithmic decay of dosages) when creating the tapering plan. The option chosen informed the rate of tapering.

Table 8.4 (continued): Overview of the identified apps

Quit Xanax Addiction	Not reported	Apple Appstore (iOS) Google Play Store (Android) Free to download In-app purchases and option to upgrade to the full version The age rating on the Apple Appstore was ≥12 years, and on the Google Play Store was PEGI 3 (suitable for all age groups).	Targeted medication(s): Benzodiazepine (alprazolam) The aim of this app was to help individuals stop taking Xanax (alprazolam) by providing words of encouragement, and rewards in the form of virtual trophies to motivate users.	The app did not contain any specific recommendations on how to taper.

Table 8.4 (continued): Overview of the identified apps

TaperTracer	United Kingdom	Apple Appstore (iOS) Free to download No in app purchases or advertisements The age rating on the Apple Appstore was ≥12 years	Targeted medication(s): Antidepressants The aim of the app was to support individuals who are stopping antidepressants by allowing them to track their symptoms and medication doses and monitor their experience.	**Within the app**: The app did not provide any explicit tapering advice or guidance. However, it did allow the user to plan the dose reduction frequency (monthly or fortnightly) and reduction percentage (max 10%). **App-linked website:** The app had a link to a thread on an online peer support forum (survivingantidepressants.org). The thread recommended the 10% taper method (i.e., 10% reduction in dose every four weeks based on the last dose).

8.5.2.1 App functionalities (Objective 2)

Eight functionalities were identified across the seven included apps and app companion websites. The eight functionalities and examples of how they were operationalised are outlined in Table 8.5. The eight functionalities included; (1) Tracking symptoms (1 non-commercial app, 3 commercial apps); (2) Tracking medication use (1 non-commercial app, 4 commercial apps); (3) Dose calculator (1 non-commercial app, 2 commercial apps, 1 app companion website); (4) Education (1 non-commercial app, 4 commercial apps, 2 app companion websites,); (5) Goal setting (3 commercial apps); (6) Social support (2 non-commercial apps, 4 commercial apps, 2 app companion websites); (7) Rewards and incentives (1 commercial app); and (8) Notifications (2 commercial apps).

Table 8.5: Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

App ID	App functionalities	BCT codes	Specific examples
Sturup et al. (2017)	**Function 1:** Tracking symptoms	**BCT 2.4:** Self-monitoring of outcomes of the behaviour **BCT 12.5:** Adding objects to the environment	Participants received a user-developed mobile phone application to register their symptoms on the app each day to allow for detection of deterioration in symptoms/early warning signs of relapse.
	Function 3: Dose calculator	**BCT 8.7:** Graded tasks	The tapering schedule was tailored to the individual and involved: (1) approximately 25% monthly reductions of initial dose, (2) with at least five half-lives between each reduction, (3) over a minimum period of 6 months and (4) with regular assessments and evaluations.
	Function 5: Goal setting	**BCT 1.3:** Goal setting (outcome)	The intervention's app-based component aimed to achieve approximately 25% monthly reduction of initial dose.
	Function 6: Social support	**BCT 3.2:** Social support (practical)	Participant's clinician could access their symptom log to monitor for early warning signs of relapse and intervene when necessary. The participant's next of kin could add a daily note which will be visible to the patient.

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

Cucciare et al. (2022)	**Function 3:** Dose calculator	**BCT 1.4:** Action planning **BCT 8.7**: Graded tasks **BCT 12.5:** Adding objects to the environment	Participants could access the EMPOWER-ED protocol on any platform (e.g., smartphone, desktop, tablet) that they choose. EMPOWER-ED generated a personalised taper schedule based on the user's current daily medication dose, dose frequency, and desired date for starting the taper. The tapering schedule lasted up to 21 weeks with each day's target pill consumption graphically displayed on a calendar (e.g., full-pill, half-pill, quarter pill, or no pill for each time they take their medication).
	Function 4: Education	**BCT 4.1:** Instructions on how to perform the behaviour **BCT 5.1:** Information about health consequences	The user was provided with a self-assessment of risks associated with benzodiazepine use, information on the potential benzodiazepine-related harms, education about drug interactions, vignettes of peers who have successfully stopped using benzodiazepines and information about therapeutic alternatives.
	Function 5: Goal setting	**BCT 1.3:** Goal setting (outcome)	Participants could make a taper schedule if they decided that they wanted to reduce or discontinue their benzodiazepines.

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

	Function 6: Social support	**BCT 3.2**: Social support (practical)	The user had a note indicating their study involvement uploaded to their medical chart that was accessible by their clinician. The study team also provided the phone number to a study physician if the participants had questions about any concerning symptoms during their taper.
BetterOff app	**Function 1:** Tracking symptoms	**BCT 2.4**: Self-monitoring of outcomes of the behaviour	The user could log, rate and comment on the severity of withdrawal symptoms (physical and psychiatric symptoms). The user had the option of using pre-specified symptoms (i.e., anxiety, depresion, flu-like symptoms and headaches) or adding new symptoms. The user could rate their symptoms on a scale of 1-10. The user could also track the side effects of the medication.
	Function 2: Tracking medication use	**BCT 2.3**: Self-monitoring of the behaviour	The user could log their doses of medication.
	Function 4: Education	**BCT 4.1**: Instructions on how to perform the behaviour	The app did not provide any explicit tapering advice however it did recommend slow tapering with continuous evaluation and support from the user's clinician.

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

	Function 5: Goal setting	**BCT 1.3:** Goal setting (outcome)	The user could set a tapering goal by either choosing from one of the pre-loaded options (i.e., to be drug-free, to be on a lower dose, to have fewer side effects or to be able to feel their feelings) or they could write their own.
	Function 6: Social support	**BCT 3.1:** Social support (unreported)	The app had a link to an online user forum which offered peer support and professional support from "experts". **Note:** the user forum was still being developed/tested at the time of writeup.

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

BetterOff App's companion website	**Function 4:** Education	**BCT 4.1**: Instructions on how to perform the behaviour	The app's companion website had a "Knowledge" tab which provided information about the tapering process and tapering-related research articles. One section discussed the six phases of the tapering process: (1) "Prepare your taper", (2) "Start the taper" (3) "Evaluate and adjust the process"; (4) "Continue the dose reduction", (5) "Complete the taper"; (6) "Retention".
		BCT 8.7: Graded tasks	It had a link to a tapering chart which provided instructions for rate and frequency of dosage reductions.
		BCT 9.1: Credible source **BCT 10.4:** Social reward (includes positive reinforcement)	It had supportive quotes/testimonials about the BetterOff app and website as a tapering resource – including user cases in the "Inspiration" section. The website also listed media report with testimony from established clinicical academic who praises the app.
		BCT 12.5: Adding objects to the environment	It had newsletter which provided information and resources on tapering, and various other tapering resources.

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

	Function 6: Social support	**BCT 3.2**: Social support (practical)	The app's companion website had an online user forum and information about previous social events. It included details of walks/hikes led by pharmacists and mindfulness instructors where users could get additional information/advice/support regarding tapering.
Cymbalta Withdrawal - A Tapering Guide app	**Function 4:** Education	**BCT 11.1**: Pharmacological support	The app provided advice on managing withdrawal symptoms with two supplements, N-acetyl cysteine, and Black Seed Oil.

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

Cymbalta Withdrawal - A Tapering Guide app's companion website	**Function 4:** Education	**BCT 4.1:** Instructions on how to perform the behaviour	The app's companion website informed the user about the tapering process via an online handbook on five different tapering strategies (e.g., The Gradual Taper, Dividing Cymbalta into capsules, Tapering Generic Cymbalta, The Micro-Taper, and Switching/Bridging to Prozac). It provided advice on bead counting, micro-tapering switching to fluoxetine however it did not perform the dose calculations on behalf of the user.
		BCT 11.1: Pharmacological support	It provided advice (including recommended dosing schedule) on six different supplements to help with withdrawal symptoms: Black Seed Oil, Fish Oil, N-acetylcysteine, Ashwagandha, Melatonin and 5-HTP.
		BCT 9.1: Credible source	It included references to various PubMed articles to back up the information provided on the website.
	Function 6: Social support	**BCT 3.1:** Social support (unreported)	The app's companion website had a link to its Facebook page and Twitter account, and gave the user the option of contacting the app development team.

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

Prescriby	**Function 1:** Tracking symptoms	**BCT 2.4:** Self-monitoring of outcomes of the behaviour	The user could rate themselves on four symptoms: pain, anxiety, depression, and sleep deprivation, on a scale of 1-10. The app also had self-assessment questionnaires for anxiety and depression. The app recommended the user to complete the questionnaire was done every two weeks.
	Function 2: Tracking medication use	**BCT 2.3:** Self-monitoring of the behaviour **BCT 2.1**: Monitoring of behaviour by others without feedback	The user could log their doses and note whether the doses followed the tapering plan created by the app. The user could log whether they have taken their dose that day; including cases where they had taken an extra dose of the medication. The app calculated the user's adherence to the tapering plan.

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

	Function 3: Dose calculator	**BCT 1.4**: Action planning **BCT 4.1**: Instructions on how to perform the behaviour **BCT 8.7**: Graded tasks	The app displayed the tapering plan once it was created by the user's clinician on the app's companion website. The dose reductions were calculated based on the user's information (e.g., current medication dose and frequency) and tapering preference (e.g., exponential, linear or logarithmic decay of dosages). The app had an interactive calendar which displayed the dosage reductions at defined intervals until discontinuation was achieved. The user was asked to make specified dosage reductions to their medication at defined intervals until discontinuation was achieved.
	Function 4: Education	**BCT 4.1**: Instructions on how to perform the behaviour **BCT 12.4**: Distraction	The app provided the user with advice on navigating the tapering process. The app recommended distraction techniques (e.g. mindfulness, deep breathing).
	Function 5: Goal setting	**BCT 1.3**: Goal setting (outcome)	The app gave the user the option of setting a dosage reduction goal by reducing the dose by a certain percentage at defined intervals until discontinuation was achieved.

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

	Function 6: Social support	**BCT 3.2**: Social support (practical)	The app permitted the user's clinician to monitor their progress and intervene when necessary. The clinician could choose between four possible actions: (1) check the data; (2) contact the user; (3) book an appointment with the user; (4) write a note in their Electronic Health Record (EHR
	Function 8: Notifications	**BCT 7.1:** Prompts/cues	The app had electronic reminders in the form of pop-up notifications that reminded the user of when their next scheduled dosage reduction was and to record it.
Quit Xanax Addiction	**Function 2:** Tracking medication use	**BCT 2.3**: Self-monitoring of the behaviour	On the app's home screen, there was a graph which showed the user's progress (i.e., how long they had not taken alprazolam). If the user consumed alprazolam, they could reset the values.

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

	Function 4: Education	**BCT 5.1:** Information about health consequences	The app provided the user with reasons as to why they should stop the psychiatric medication (e.g., "change your life" and "regain your self-esteem"). The user could select one of the reasons provided or write their own. Additional information was provided on each of the reasons listed.
		BCT 12.4: Distraction	The app provided a set of images which could be used as an alternative focus for attention to avoid triggers for unwanted behaviour.
	Function 6: Social support	**BCT 3.3**: Social support (emotional)	The app had a "panic button" on the app's home screen. When pressed the user was taken out of the app and brought to the Messages app. A pre-loaded message would appear; "*I'm struggling with Xanax and need your help*." The user could choose whether to send the message to a pre-selected contact on their phone.

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

	Function 7: Rewards/ incentives	**BCT 10.4:** Social reward (includes positive reinforcement)	The app had trophies which were locked until the user's progress passes each "phase" (i.e., one week, two weeks, etc.). The user was awarded trophies to help them stay motivated and track their progress. The user's progress (i.e., how long they had not taken alprazolam)was displayed on the home screen, alongside the amount of money they had saved so far and the main reason they had decided to stop taking alpazolam. The app had several motivational quotes (e.g., "Every day brings new choices" – Martha Beck) and testimonials and have the use the option of sharing their story. The intention of these quotes was to act as positive reinforcement and keep the user on track.
	Function 8: Notifications	**BCT 7.1**: Prompts/Cues	The user could opt in to receive electronic reminders in the form of pop-up notifications. The notifications offered motivational quotes or words of encouragement.

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

TaperTracer app	**Function 1:** Tracking symptoms	**BCT 2.4:** Self-monitoring of outcomes of the behaviour	The user could log, rate and comment on the symptoms experienced during the tapering process. The user had the option of logging both pre-specified symptoms (e.g., anxiety, depression or fatigue) or adding new symptoms. The user could rate the severity of each symptom on a scale of 1-10 and make comments (e.g., "felt sad today"). The details of logged symptoms were stored and accessible under "Symptom History" tab.
	Function 2: Tracking medication use	**BCT 2.3:** Self-monitoring of the behaviour	The user could log whether they had taken their dose on any given day by clicking on the calendar icon in the "Taper" tab and selecting the specific day.
	Function 3: Dose calculator	**BCT 1.4:** Action planning **BCT 8.7**: Graded tasks	The app had a dosage reduction calculator that calculated the next dose reduction based on the user's current dose and in line with their tapering plan. The user could decide the magnitude (max 10%) and frequency (fornightly or monthly intervals) of dose reductions. The app had an interactive calendar which specified the drug and taper schedule and allowed the user to see what dose they are meant to be on any given day and when their reduction days are scheduled

Table 8.5 (continued): Overview of app functionalities and BCTs identified in the non-commercial apps, commercial apps, and app companion websites

	Function 4: Education	**BCT 9.1**: Credible source **BCT 4.1**: Instructions on how to perform the behaviour	The app directed users to survivingantidepressants.org website page which provides guidance on tapering with a specific focus on 10% reduction.
	Function 5: Goal setting	**BCT 1.3:** Goal setting (outcome)	The app gave the user the option of setting a dosage reduction goal by reducing the dose by a certain percentage (max of 10%) at defined intervals (i.e., monthly or fortnightly) until discontinuation was achieved.
	Function 6: Social support	**BCT 3.1:** Social support (unreported)	The app had a link to the survivingantidepressants.org website, an online community which provided peer support. In the "Contact" tab the user was asked if they wanted to send an email to the app developer. **Note:** at the time of writeup, clicking "Yes" did not result in any action.

8.5.2.1.1 Function 1: Tracking symptoms

One non-commercial app and three commercial apps allowed the user to log the type and severity of their withdrawal symptoms. This functionality was supported by a calendar feature in the apps. In Sturup et al. (2017)'s app the participant could register their symptoms each day by logging a daily score and adding additional free text. Participants could also add information about anxiety, stress, and contact with others. The aim of daily registrations was to allow for detection of deterioration in symptoms/early warning signs of relapse. According to the study author, the information recorded was informed by previous service users' experiences and interviews with clinicians about warnings signs of relapse and usability of the app. The "TaperTracer" app allowed the user to log, rate, and comment on their symptoms with the option of using both pre-specified symptoms (e.g., anxiety, depresion, flu-like symptoms and headaches) or adding new symptoms. The user could rate symptoms on a scale of 1-10 and add additional notes (e.g., felt sad today). The "BetterOff" app logged the user's withdrawal symptoms, and other information that they wanted to keep track of (e.g., side effects of the medication). The "Prescriby" app gave the user the option of logging four symptoms (e.g., pain, anxiety, depression, and sleep deprivation) on a scale of 1-10.

8.5.2.1.2 Function 2: Tracking medication use

One non-commercial app and four commercial apps allowed the user to log their medication use. Similar to above, this function was also supported by a calendar feature. In Sturup et al. (2017)'s app, the participant could log their medication doses. Three apps ("BetterOff", "TaperTracer", and "Prescriby") allowed the user to log whether they had taken their dose of medication that day. The "Prescriby" app also gave the user the option of noting whether the doses followed the tapering plan created by the app. The "Quit Xanax Addiction" app had a graph on the home screen which showed the user's progress in maintaining abstinence from the medication (i.e., how long they have been medication free). The user could reset the values to zero if they resumed consumption of the medication.

8.5.2.1.3 Function 3: Dose calculator

Two non-commercial apps and two commercial apps made dose calculations for the user. In Sturup et al. (2017)'s app, the tapering schedule was tailored to be approximately 25%

reductions of the initial dose at monthly intervals, with at least five half-lives between each reduction, over a minimum duration of six months. In Cucciare et al. (2022)'s app, the participant had the option of generating a personalised taper schedule based on their current daily medication dose, dose frequency, and desired date for starting the taper. The tapering schedule lasted up to 21 weeks with each day's target pill consumption graphically displayed on a calendar (e.g., full-pill, half-pill, quarter pill, or no pill for each time they take their medication). The "Prescriby" app imported a tapering plan based on the user's current medication and dose based on information that was uploaded by the user's clinician to the app's companion website. The user's clinician could select from three tapering approaches: exponential, linear, and logarithmic decay of dosages. Once created, the tapering plan was exported to the app and was fully accessible to the user. The plan displayed the recommended dose(s) of medication the user should take every day to achieve planned discontinuation. The "TaperTracer" app created a similar tapering plan based on the user's current medication dose, desired percentage dose reduction and frequency of reduction. The "TaperTracer" app did not permit dose reductions that exceeded 10% of the previous dose.

8.5.2.1.4 Function 4: Education

One non-commercial app and four commercial apps provided the user with tapering-related information or guidance. In Cucciare et al. (2022)'s app, the participant was provided with a self-assessment of risks associated with long-term benzodiazepine use, information on the evidence for benzodiazepine-related harms, knowledge statements designed to create ambivalence about the safety of benzodiazepines, education about drug interactions, vignettes of peers who have successfully stopped using benzodiazepines to support participants' self-efficacy to change, information about equally or more effective therapeutic alternatives for sleep difficulties and/or anxiety and recommendations for self-tapering. The "BetterOff" app's companion website contained a "Knowledge" tab which discussed the six phases of the tapering process: (1) "Prepare your taper", (2) "Start the taper" (3) "Evaluate and adjust the process"; (4) "Continue the dose reduction", (5) "Complete the taper"; (6) "Retention". The other two sections contained tapering-related research articles. The "Cymbalta Withdrawal" app provided advice on managing withdrawal symptoms with two supplements, N-acetyl cysteine, and

Black Seed Oil. Both supplements had their own page on the app's companion website comprising several hyperlinks that brought the user to published papers most of which were found on PubMed. Some articles were published papers of randomised controlled trials (292), others were systematic reviews (293). The app's companion website also informed the user about the tapering process via an online handbook. The handbook comprised five sections: (1) The gradual taper; (2) Dividing Cymbalta into capsules; (3) Tapering generic Cymbalta; (4) The micro-taper; and (5) Switching/Bridging to Prozac (fluoxetine). The "Prescriby" app provided the user with advice on navigating the tapering process (e.g., sticking to the tapering plan, getting enough sleep, and being active). The "TaperTracer" app took the user out of the app to an online peer support forum (survivingantidepressants.org) which provided guidance on tapering with a specific focus on reduction involves 10% of the dose. The "Quit Xanax Addiction" app provided the user with reasons as to why they should stop the psychiatric medication (e.g., stopping the pain, regaining self-esteem, and being the best version of oneself).

8.5.2.1.5 Function 5: Goal setting

Two non-commercial apps and three commercial apps allowed the user to set tapering goals. The intervention's app-based component in the study by Sturup et al. (2017) aimed to achieve approximately 25% monthly reductions of the initial dose. In Cucciare et al. (2022)'s study, participants could make a taper schedule if they decided that they wanted to reduce or discontinue their benzodiazepines. During the process of setting up their user profile, the "BetterOff" app gave the user the option of setting their goal from pre-loaded options (e.g., to be drug-free, to be on a lower dose, to have fewer side effects, or to be able to feel their feelings, or writing their own). The "Prescriby" and "TaperTracer" apps gave the user the option of setting a dosage reduction goal by reducing the dose by a certain percentage at defined intervals (monthly or fortnightly) until discontinuation was achieved.

8.5.2.1.6 Function 6: Social support

All identified non-commercial and commercial apps provided the user with social support. In Sturup et al. (2017)'s app the participant's clinician could access their symptom log to monitor for early warning signs of relapse and intervene when necessary. Participants could also grant access to the app to a relative or next of kin to add observations and

notes, which would be visible to both the participant and clinician. Participants in both intervention groups were in continuous contact with their psychiatric outpatient treatment team during the intervention year and received usual non-pharmacological treatment. In Cucciare et al. (2022)'s app, the participant had a note indicating their study involvement uploaded to their medical chart that was accessible to their clinician. The study team also provided the phone number to a study physician if the participants had questions about any concerning symptoms during their taper.

With respect to the commercial apps, social support was offered within the app themselves (n=2 apps), on the app's companion websites and/or an app-linked website (n=3 websites). Social support included peer forums and access to a healthcare professional. The "BetterOff" app's companion website had an online user forum and information about previous social events. The "Cymbalta Withdrawal" app's companion website contained links to its Facebook and Twitter accounts. The "Prescriby" app permitted the user's clinician to monitor their progress and intervene when necessary. The clinician could choose between four possible actions: (1) Check the data; (2) Contact the user; (3) Book an appointment with the user; (4) Write a note in their electronic health record. The "TaperTracer" app had a link to an online peer support forum (survivingantidepressants.org). The app had a companion website, Facebook page and Twitter account, however at the time of the study writeup, the website was not working and both social media sites were inactive. The "Quit Xanax Addiction" app had a "panic button" on the app's home screen. If pressed, the user was taken out of the app and brought to the Messages app. A pre-loaded message would appear; "*I'm struggling with Xanax and need your help*." The user could choose whether to send the message to a pre-selected contact on their phone. At the time of writeup/in December 2024, all app-linked social media forums and sites were inactive.

8.5.2.1.7 Function 7: Rewards & incentives

One commercial app rewarded the user for their achievements or progress made as they tapered their psychiatric medication. The "Quit Xanax Addiction" used virtual trophies to reward the user as they hit different time milestones (e.g., one week drug-free, two weeks drug-free, etc.) and to motivate them to continue and track their progress.

8.5.2.1.8 Function 8: Notifications

Two commercial apps provided optional pop-up notifications. The "Quit Xanax Addiction" app provided notifications that went off at a set time each day, as selected by the user. Notifications varied but typically included motivational quotes/words of encouragement (e.g., "Nothing will work unless you do", "You work hard for a reason", "Keep up the good work!"). The "Prescriby" app offered notifications to remind the user to record their medication use. There were two notifications options: each dose or last dose of the day. If the user turned on notifications for each dose, they received a notification 90 minutes after the scheduled time to remind them to take their dose or log it. The notification did not appear if the user had already logged their dose. For example, if the user scheduled one daily dose at 8:00 they received a notification at 9:30 (e.g., "Pill at 8:00 not registered").

8.5.2.2 BCT coding (Objective 3)

Seventeen BCTs were identified across the seven included apps and app companion websites all of which aligned with the various app functionalities (Table 8.5). Examples of how the BCTs were operationalised are outlined in Table 8.5. An overview of the presence and/or absence of the BCTs identified across the apps and app companion websites is outlined in Table 8.6. The number of BCTs identified per app and app-based intervention ranged from five to ten. The four most common BCT codes were: **1.3** 'Goal setting (outcome) [e.g., setting tapering/dose reduction goals and personal goals] (2 non-commercial apps, 3 commercial apps), **2.3** 'Self-monitoring of behaviour' [e.g., logging medication doses] (4 commercial apps), **4.1** 'Instructions on how to perform the behaviour' [e.g., calculating dose reductions and the provision of tapering guidance] (1 non-commercial app, 3 commercial apps, 2 app companion websites), and **8.7** 'Graded tasks' [e.g., specifying dosage reductions at defined intervals] (2 non-commercial apps, 2 commercial apps, 1 app companion website). The most commonly identified BCTs fell within four different BCTTV1: "Goals and planning", "Feedback and monitoring", "Shaping knowledge" and "Repetition and threats".

Table 8.6: Overview of BCTs identified in the non-commercial apps, commercial apps, and app companion websites

BCTs identified	Included non-commercial apps, commercial apps, and apps' companion websites						
	Sturup et al. (2017)	**Cucciare et al. (2022)**	**BetterOff**	**Cymbalta Withdrawal**	**Prescriby**	**Quit Xanax Addiction**	**TaperTracer**
1.3 Goal setting (outcome)	✓	✓	✓	×	✓	×	✓
1.4 Action planning	×	✓	×	×	✓	×	✓
2.1 Monitoring of behaviour by others without feedback	×	×	×	×	✓	×	×
2.3 Self-monitoring of the behaviour	×	×	✓	×	✓	✓	✓
2.4 Self-monitoring of outcomes of the behaviour	✓	×	✓	×	✓	×	✓
3.1 Social support (unreported)	×	×	✓	✓	×	×	✓

Table 8.6 (continued): Overview of BCTs identified in the non-commercial apps, commercial apps, and app companion websites

3.2 Social support (practical)	✓	✓	✓	×	✓	×	×
3.3 Social support (emotional)	×	×	×	×	×	✓	×
4.1 Instructions on how to perform the behaviour	×	✓	✓	✓	✓	×	✓
5.1 Instructions on health consequences	×	✓	×	×	×	✓	×
7.1 Prompts/Cues	×	×	×	×	✓	✓	×
8.7 Graded tasks	✓	✓	✓	×	✓	×	✓
9.1 Credible source	×	×	✓	✓	×	×	✓
10.4 Social reward (includes positive reinforcement)	×	×	✓	×	×	✓	×

Table 8.6 (continued): Overview of BCTs identified in the non-commercial apps, commercial apps, and app companion websites

11.1 Pharmacological support	×	×	×	✓	×	×	×
12.4 Distraction	×	×	×	×	✓	✓	×
12.5 Adding objects to the environment	✓	✓	✓	×	×	×	×
Number of identified BCTs	5	7	10	4	10	6	8

Table 8.6 key: (✓= BCT present, ×= BCT absent)

8.5.2.2 Additional app content (Objective 2)

In this review, additional app content referred to the provision of medical disclaimers (2 commercial apps) and safety support (1 non-commercial app, 2 commercial apps) as presented in Table 8.7. While the content varied between the apps, the medical disclaimers typically acknowledged the inability of the app to diagnose or cure any condition and recommended that the user seek advice from a healthcare professional. An app was considered as offering safety support when it provided a link between the user and a healthcare professional or another supporter. Finally, four commercial apps had privacy policies and stated the methods of data collection, storage and/or usage.

Table 8.7: Overview of additional app content

Study/App ID	Medical disclaimer	Safety/crisis support	Privacy policy
Sturup et al. (2017)	No	Within the app, it was possible to make an action plan, so that if the participant got worse they knew what to do, where to go, and who to call.	No
Cucciare et al. (2022)	No	None identified	No
BetterOff	**Within the app**: Yes **On the app store**: No **App's companion website:** No	**Within the app**: The user was encouraged to contact their clinician for support when tapering. **On the app store**: No **App's companion website:** Similar to the app, the website also encouraged the user to seek support from their clinican.	**Within the app**: Yes **On the app store**: No **App's companion website:** Yes
Cymbalta Withdrawal - A Tapering Guide	**Within the app**: No **On the app store**: No **App's companion website:** Yes	**Within the app**: No **On the app store**: No **App's companion website:** No. The website made it clear that app developers were not to be contacted in the event of an emergency.	**Within the app**: No **On the app store**: No **App's companion website:** Yes

Table 8.7 (continued): Overview of additional app content

Prescriby	**Within the app**: No **On the app store**: No **App's companion website:** No	**Within the app**: No **On the app store**: No **App's companion website:** The user's clinican could monitor their tapering progress via the app and intervene if necessary by taking one of four actions: (1) check the data; (2) contact the user; (3) book an appointment with the user; (4) write a note in their Electronic Health Record (EHR).	**Within the app**: No **On the app store:** Yes **App's companion website:** Yes
Quit Xanax Addiction	**Within the app**: No **On the app store**: No **App's companion website:** No	**Within the app**: The app had a panic button. When pressed, the user was taken out of the app to the Messages app with a pre-loaded message, "*I'm struggling with Xanax and need your help*." The user could decide whether to send the message to a pre-selected contact. **On the app store**: No **App's companion website:** No	**Within the app**: No **On the app store**: No **App's companion website:** Yes

Table 8.7 (continued): Overview of additional app content

TaperTracer	**Within the app**: No **On the app store**: No **App's companion website:** No	**Within the app**: No **On the app store**: No **App's companion website:** No	**Within the app**: No **On the app store**: No **App's linked website:** No

8.5.3 App development process (Objective 4)

The published study report by Sturup et al. (2017) did not provide any information on the development of the app-based component of the intervention. The study by Cucciare et al. (2022) reported that the app-based intervention was modelled on the Eliminating Medications Through Patient Ownership of End Results (EMPOWER) study conducted in Canada (294). The EMPOWER study demonstrated that older adults taking benzodiazepines long-term who were mailed a booklet of the EMPOWER materials, which provided information about the risks of long-term benzodiazepine use and suggested strategies for tapering down, were eight times more likely to discontinue benzodiazepines use compared to control group participants (294). To tailor the study materials to the target study population (i.e., veterans stopping benzodiazepines), the research team worked with veterans, prescribing providers, administrators. Software developers were then recruited to convert the intervention to a computer-delivered format called EMPOWER-ED (ED, Electronically Delivered) (291). No theory underpinning app development was reported for either of the two non-commercial apps which were evaluated as part of intervention studies.

Three commercial apps reported being developed in Denmark (n=1 app), Iceland (n=1 app), the United Kingdom (n=1 app). The apps were created by individuals with lived experience of reducing/stopping psychiatric medication (n=2 apps) or start-up companies (n=3 apps). The start-up companies did not specify if the individuals involved had lived experience of reducing/stopping psychiatric medication. The “BetterOff” app was developed by an individual with lived experience of antidepressant withdrawal with support of an app development team which included a psychologist, a psychiatrist, a PhD candidate, and a pharmacist. The “TaperTracer” app was also developed by an individual who had lived experience of antidepressant withdrawal. The “Cymbalta Withdrawal” app was developed by a start-up company, Z-Solutions, based in Germany. The “Prescriby” app was developed by Nordverse, a Nordic based health tech startup, in 2019 by two medical doctors and a PhD computer scientist. The “Quit Xanax Addiction” app was developed by a start-up company, AppDiggity. None of the identified commercial apps reported any theory underpinning app development. No app reported any affiliations with the pharmaceutical industry.

8.5.4 Overview of outcome measures & impact (Objective 5)

The two studies evaluating app-based interventions had different outcome measures. In the study by Sturup et al. (2017), the primary outcomes were remission of psychotic symptoms and discontinuation of antipsychotic medication use for at least three months at 1-year follow-up. The trial was ended prematurely, and no statistical analyses were conducted due to an insufficient number of recruited participants (295). As mentioned above, the target sample size was 250 participants, however only 29 participants (14 intervention, 15 control) were successfully recruited (295). In the study by Cucciare et al. (2022), the primary outcomes were cessation of benzodiazepines and dose reduction of benzodiazepines at six-month follow-up. Cessation was defined as the absence of a benzodiazepine prescription renewal in the three months prior to follow-up, and dose reduction was defined as a 25% or greater decrease in benzodiazepine use sustained for three months or more at follow-up. At the time of study writeup (December 2024) the recruitment status on clinicaltrials.gov was "Active, not recruiting". The estimated date of study completion was 30th September 2025 (296). No outcomes have been reported given that the trial is still ongoing (296).

Quantitative feedback was available for two commercial apps on the app stores. The "BetterOff" app was rated 2.3/5 based on one review. The rating was accompanied by qualitative feedback; while the user thought the idea was good, they found the app's interface difficult to use. The "TaperTracer" app was rated 5/5 based on two reviews. One of the reviewers also left a comment; while they were impressed with the app overall, they reported technical problems (i.e., difficulties entering text).

Given the lack of reported outcomes for the evaluation studies of app-based interventions and commercial apps it was not possible to report the impact from a qualitative and quantitative perspective.

8.6 Discussion

This scoping review identified a total of seven apps that focused on supporting the tapering of psychiatric medication. Two studies of app-based interventions (i.e., "non-commercial" apps) were identified from searches of peer literature, and five commercial apps were identified from searches of the app stores. These findings highlight a lack of

commercially available apps to support individuals who want to taper psychiatric medication, as well as a deficit of studies evaluating any such apps in the literature. Of the two intervention studies included in this review, the study that had concluded had to be stopped prematurely due to recruitment challenges (295). According to a recent systematic review of discontinued randomised control trials, recruitment challenges are common (297). Potential reasons include an overestimation of the prevalence of participants meeting inclusion criteria, concerns over the adverse effect profile, and lack of clinician engagement (295). This highlights a key challenge in addressing the core aim of this review in terms of examining the evidence base and impact of mobile phone apps and app-based interventions that focused on supporting the tapering of psychiatric medication.

All seven apps focused on supporting the tapering of psychiatric medication. The studies by Sturup et al. (2017) and Cucciare et al. (2022) targeted individuals taking antipsychotics and benzodiazepines, respectively. Whereas the five commercial apps targeted either antidepressants ("BetterOff", "Cymbalta Withdrawal" and "TaperTracer") or benzodiazepines ("Quit Xanax Addiction") exclusively, with the exception of one app ("Prescriby") which targeted benzodiazepines and Z-drugs. Two classes of psychiatric medication (i.e., mood stabilisers and gabapentinoids) were not targeted by any of the identified apps.

A range of functions were offered by the apps to support the withdrawal process, each of which aligned with different BCTs. These included education in the form of information about how to taper and potential risks of discontinuation, which aligned with BCT codes **4.1** 'Instructions on how to perform the behaviour' and **5.1** 'Information about health consequences.' Other functions included performing dose reduction calculations and tracking of withdrawal symptoms which aligned with BCT codes **1.4** Action planning' and **2.4 '**Self-monitoring of outcomes of the behaviour'. Very few of the apps provided explicit tapering advice/recommendations, and of those that did the information provided varied. Several apps recommended fixed dose reductions. For example, the "TaperTracer" app recommended fixed dose reductions at a maximum reduction percentage of 10% of the dose and cross-referred to a thread on the online peer support forum (survivingantidepressants.org) which recommended a 10% dose reduction every four

weeks. This 10% taper method was also recommended by the "Cymbalta Withdrawal" app's companion website. The study by Sturup et al. (2017) made monthly 25% reductions of the initial dose over a minimum period of six months, and the "BetterOff" app's website cross-referred to a tapering chart that recommended dose reductions ranging from 20-33% for individuals stopping antidepressants. This link to the website was no longer active at the time of study write-up. These tapering recommendations were not aligned with more recent recommendations in guidelines published by National Institute for Health and Care Excellence (NICE) in 2022 which advocate for *"a slow, stepwise rate of reduction proportionate to the existing dose, so that decrements become smaller as the dose is lowered"* (170 p.19). The NICE recommendations align with the hyperbolic tapering method which involves dose reductions in unequal steps in which the magnitude of dose reduction becomes smaller and smaller as the taper progresses (159). The dose is reduced exponentially under a constant rate based on the last current dose as opposed to the original dose. It has been suggested that hyperbolic tapering results in a linear reduction of receptor occupancy which has the potential to minimise withdrawal symptoms (162). None of the identified apps accounted for patient and drug-specific factors that may affect an individual's ability to taper (e.g., duration of use) (175).

In addition to tapering advice, the apps offered a range of social and pharmacological tapering supports which aligned with BCT codes **3.1 '**Social support (unreported)' and **3.2** 'Social support (practical)'. All apps provided some form of social support. Two apps ("TaperTracer" and "BetterOff") contained links to online peer support forums (e.g., survivingantidepressants.org). Many forums/groups have been developed to provide guidance and support to individuals who want to stop their psychiatric medication (99, 266). Other apps ("Prescriby" and the study by Sturup et al. (2017)) engaged with clinicians to monitor users' tapering progress and symptoms. In terms of pharmacological supports (i.e., adjunctive medications), one app ("Cymbalta Withdrawal") recommended two supplements (e.g. N-acetyl cysteine and black seed oil) to manage antidepressant withdrawal symptoms however there is a paucity of evidence to support their use (298). A previous Cochrane systematic review which assessed a number of medications including pregabalin and antidepressants on benzodiazepine discontinuation and withdrawal

symptoms was unable to draw any firm conclusions on the efficacy of pharmacological substitution for discontinuing long-term benzodiazepine use (169).

Most of the identified apps did not provide information about the app development process or specify any theoretical underpinning. This was in concordance with the findings of previous reviews which showed that most commercially available mental health apps were developed without expert input or academic training (299). The lack of available information on the app development process also made it difficult to understand the extent to which the apps had engaged target users (i.e. those with lived experience of taking/stopping psychiatric medication) and incorporated insights based on their lived experience. Two recent systematic reviews that evaluated commercial apps to treat anxiety and depression identified twenty apps that claimed to demonstrate significant efficacy. However, none of these apps were evaluated by independent research (274). Concerns have also been raised over the lack of certification and evaluation of apps which have resulted in a reliance on user ratings and reviews (271, 300). This makes the quality of mobile health literature highly variable (301), leaving vulnerable users at risk of receiving unsolicited and potentially inaccurate advice (302). O'Cathain et al. have developed an intervention development framework which considers intervention development to be a dynamic and iterative process that includes reviewing published research evidence and engaging key stakeholders (303). This framework has the potential to overcome these shortcomings in app development and evaluation.

Three of the identified commercial apps offered privacy features. In 2020, it was estimated that 70% of health apps did not provide a privacy policy (300). Personal data such as medical history and medication use is sensitive information and protected by General Data Protection Regulation (304). When no safeguards are in place to protect personal information, it puts the app in breach of General Data Protection Regulation indicating a lack of transparency and trust (305, 306). In 2023, the Medicines and Healthcare products Regulatory Agency and the NICE began a three-year project, working with international collaborators, to help drive consensus in digital mental health regulations globally (307).

Two of the identified commercial apps had safety support mechanisms in place. There is a paucity of research about safety supports and crisis language within apps (308). This has

raised concerns given that the users of these apps are tapering psychiatric medication and may experience challenges or crises relating to the taper or an underlying health condition (308). Mental health apps should include advice about suicidality, personal safety, and emergency contact information (300).

All identified commercial apps were rated as suitable for non-adult users (i.e., <18 years) within the app stores. There were no downloading restrictions for users below the minimum age rating. The same app design and functionalities were provided to all users of all ages. There was no customisation for users who were children, such as permitting the parent to monitor their child's use of the app. An app's age rating is typically determined by the extent of mature content, violence, offensive language, and sexual content within the app (309). Given the personal and sensitive nature of the content provided by healthcare apps, it has been proposed that such apps should have minimum age ratings (271). The age ratings for Android apps are provided by the app developer and are not verified by the app store. Whereas iOS apps are rated by the app store according to its own policies. Concerns have been raised amongst parents about the authenticity of maturity ratings (310). Unreliable content maturity ratings may result in appropriate risk exposure for children and adolescent users (309). In Ireland, the age of consent to medical treatment is 16 years (311). This is provided for under the Non-Fatal Offences Against the Person Act 1997 (311). This means that an individual 16 years or older can consent to medical treatment, however they cannot refuse medical treatment if they are less than 18 years old. Given that all identified apps in this study could be accessed by minors, there is cause for concern over that they could potentially use these apps to discontinue their psychiatric medication without oversight by parents, guardians, and/or clinicians.

The ability of apps to transfer information digitally and to improve access to mental health services makes them well-poised to overcome some of the challenges faced by individuals when tapering psychiatric medication, such as the lack of dedicated withdrawal services (242). However, the use of apps as stand-alone treatments for tapering psychiatric medication may appear premature as there is a paucity of evidence to demonstrate their safety or effectiveness. Additionally, there are several factors that will require consideration if apps are to be effectively implemented in real world settings such as the lack of regulation in terms of app development, evaluation, and access.

8.7 Strengths & limitations

The main strength of this scoping review was the robustness of the methods. The review followed the established methods as laid out in the published protocol (282) and any subsequent refinements to the methods were highlighted and justified. The electronic databases and app stores were systematically searched using a comprehensive search strategy developed in collaboration with a research librarian. Previous reviews have tended to focus on apps available on the Apple AppStore exclusively (273) whereas this review also searched the Google Play Store for relevant apps. The development and piloting of data extraction tools was conducted by the researcher and one member of the supervisory team (CC) working independently to improve transparency and validity within the data analysis process. Similarly, the coding template was developed by the researcher in collaboration with the supervisory team and was piloted on a subsample of the apps before the final version was agreed. The final strength relates to the use of an established taxonomy (BCTTv1) to systematically code the presence of BCTs in identified apps and studies of app-based interventions added rigor to the study. In terms of limitations, the lack of studies evaluating app-based interventions made it difficult to address the objective relating to the impact of the identified apps.

8.8 Summary

The scoping review findings presented in this chapter demonstrate a paucity of mobile phone apps and studies of app-based interventions that focused on supporting the tapering of psychiatric medication. By outlining the key functionalities offered by the identified apps and characterising them in terms of component BCTs, as well as raising awareness of the shortcomings of commercially available apps, the findings of this scoping review will help to guide future research on the development and evaluation of apps to support individuals who want to reduce or stop psychiatric medication use. The next chapter provides an overall discussion of the thesis.

Chapter 9: Final discussion, recommendations & reflection

9.1 Introduction to Chapter 9

Chapter 9 is the final chapter in this thesis. This chapter starts by discussing the thesis aims and objectives in relation to the literature on the use and discontinuation of psychiatric medication. It then expands on the strengths and limitations of the overall research presented in the thesis. The implications of the thesis findings are outlined, and their potential impact is discussed in terms of research, policy, and practice. The final parts of the chapter comprise my personal reflections on the research undertaken over the course of this PhD, and the dissemination plan for the thesis findings before reaching the final conclusion.

9.2 Summary of the Thesis Findings

The aim of this thesis was to develop a body of knowledge that would advance the evidence-base relating to the safe and appropriate tapering of psychiatric medication.

The thesis had four key objectives, each of which was addressed by an individual study:

- to determine the Top 10 priorities for future research on reducing and stopping psychiatric medication in collaboration with the three key stakeholder groups: people with lived experience of taking and/or stopping psychiatric medication, family members/friends/carers/supporters, and healthcare professionals.
- to explore stakeholders' views and experiences of reducing and stopping psychiatric medication use by analysing the responses submitted to Section 4 of the Round 1 survey conducted as part of Study 1.
- to explore stakeholder's views on the Priority Setting Partnership (PSP) methodology as a priority setting exercise by conducting semi-structured interviews with individuals who had participated in Study 1.
- to examine the content, underpinning evidence base, and impact of mobile phone apps and app-based interventions that focused on supporting the tapering of psychiatric medication.

The first objective was addressed by Study 1 which followed the James Lind Alliance (JLA) PSP methodology, as described in Chapter 4. The Top 10 priorities identified by this study cover a range of questions and uncertainties relating to the tapering process and wider issues around the discontinuation of psychiatric medication. Some questions had already been identified by previous research, such as the most effective ways of safely reducing/stopping psychiatric medication and providing support to individuals undergoing the withdrawal process. However, questions around the professional, ethical, and legal responsibilities of healthcare professionals and the pharmaceutical industry in relation to tapering psychiatric medication were novel to this study. While gaps in the evidence base around the discontinuation of psychiatric medication have long been recognised, the novel contribution of the PSP study was that it identified the uncertainties that were most important to key stakeholders and provided them with the opportunity to rank them in order of priority. It is intended that the study findings will help guide the responsive and strategic allocation of research resources to address these priorities. In doing so, the Top 10 priorities contribute to research prioritisation efforts which is an important means of minimising research waste and ensuring that research resources are targeted towards answering the most important questions (312). Thus, the study will guide future research in a way that is meaningful for all stakeholder groups, with a view to ultimately improving the future health and well-being of individuals who are taking or stopping psychiatric medication. The value of the PSP methodology as a means of identifying research priorities has been recognised by the UK's National Institute for Health and Care Research who have a rolling call to fund researchers wanting to address research priorities identified through official JLA PSP studies (191).

The second objective was addressed by Study 2 which involved analysing the free-text responses submitted to one of the surveys in the PSP study, as described in Chapter 6. In their narratives, respondents from the lived experience and supporters' groups shared the challenges they had faced during the withdrawal process which included lack of informed consent, lack of shared decision-making, and lack of support from their prescriber. Responses submitted by respondents from the healthcare professional group were also analysed. There was a high level of concordance between the three stakeholder groups on key issues and challenges across all the major themes. By sharing these

narratives and articulating the human and emotional impact of taking and stopping psychiatric medication, this study provided valuable insights into stakeholders' experience of discontinuing psychiatric medication in terms of people with lived experience, family members and carers, and healthcare professionals. The findings could encourage important reflections on current perspectives about the role of these medications in treating mental illness, and when to start or stop treatment in a way that respects individuals' rights to autonomy.

The third objective was addressed by Study 3 which involved analysing the data collected from interviews with individuals who had been involved in the PSP study, as described in Chapter 7. This study explored stakeholders' perspectives on the PSP methodology as a priority setting exercise in mental health research, capturing what they thought worked well in terms of achieving authentic collaboration between stakeholder groups, and what could be improved. This study is one of only ten PSP studies that have involved individuals with experience of mental illness and is one of the first PSP studies to evaluate stakeholders' experiences of involvement in research (261). By describing the steps involved in the PSP study and evaluating it in the form of interviews with the stakeholders, this thesis demonstrates how the PSP methodology can be used in mental health research to achieve authentic collaboration between the stakeholder groups.

The fourth objective was based on one of the priorities identified in Study 1 which focused on tapering supports. This objective was addressed by Study 4 which involved a scoping review of mobile phone applications that supported the tapering psychiatric medication, as described in Chapter 8. This review had two major findings; it revealed a lack of commercially available apps targeting individuals looking to taper psychiatric medication, as well as a deficit of studies evaluating any such apps in the literature. Given the ability of apps to transfer information digitally, they would appear well-poised to overcome some of the challenges faced by individuals when tapering psychiatric medication which are a recurring theme throughout this thesis. For example, apps have potential to help design taper schedules, provide information on how to practically achieve small enough doses and enable individuals and their clinicians to monitor progress with the taper over time.

9.3 Overall discussion

The results of each study have been discussed within the respective chapters preceding this final chapter. The discussion that follows positions the main study findings in relation to the existing evidence base and theory. While the Top 10 priorities are the major findings of this thesis, the additional findings from the other studies that are presented provide unique and added value to the overall thesis and the existing evidence base on reducing and stopping psychiatric medication. This thesis also contributes to research methodology, showcasing what can be achieved through multi-stakeholder involvement, particularly the involvement of those with lived experience. The three key contributions of this thesis are discussed below in terms of: (1) Shifting the discourse from adherence to rights-based narrative; (2) Addressing some of the epistemic injustice; (3) Contributing to the PSP methodology.

9.3.1 Shifting the discourse from adherence to rights-based narrative

Most studies involving individuals who have discontinued or want to discontinue psychiatric medication have been framed around a narrative of adherence (158, 313). The assumptions that underpin this narrative are that non-adherence is inherently negative and one of the key contributors to negative clinical outcomes including treatment failure and relapse (313). Along this line of thinking, when an individual discontinues psychiatric medication, they are thought to lack capacity, to have poor insight about their illness, and negative attitudes towards the medication (158, 313). As a result, the focus becomes how to improve adherence as opposed to how to support these individuals to make informed decisions about the use of their psychiatric medication, including safe and appropriate discontinuation (314).

In contrast, in this thesis service users' self-reported reasons for stopping their medication included concerns over side effects and the long-term effects of the medication which suggest that for some it is not about poor insight or lack of capacity. This narrative also emphasises the potential challenges associated with discontinuing psychiatric medication as opposed to the benefits, particularly the potential for relapse. Despite the growing body of evidence to suggest that the symptoms that appear after stopping the medication may be withdrawal symptoms as opposed to relapse, the narrative is framed in a way that

if individuals stop the medication, they will relapse which may ultimately deter them from discontinuing medication (313).

The World Health Organization (WHO) define medication non-adherence as, *"a case in which a person's behaviour in taking medication does not correspond with agreed recommendations from health personnel"* (313, 315). The evidence shows that non-adherence to treatment with psychiatric medications is high. With respect to antidepressants, non-adherence rates of 46% and 42% were reported by studies in five European countries (i.e., France, Germany, Italy, Spain, and the United Kingdom) and in the United States, respectively (316). It has been estimated that 50% of individuals with depression discontinue antidepressants within six months of initiation (316). In terms of antipsychotics, 30–40% of individuals are thought to become non-adherent within six months (317). Despite these suboptimal rates of adherence to psychiatric medication, issues of concern have been raised with the existing evidence on the efficacy of the medication.

Given the cohort of individuals wanting to discontinue psychiatric medication, there is a need to shift the discourse from one of adherence to more of a rights-based narrative where individuals have the choice and autonomy to make informed decisions regarding their medication (i.e., starting and stopping medication). This thesis supports this shift by respecting individuals' rights to make decisions about their health and wellbeing and demonstrating that an individuals' ability to contribute to research is not undermined by their experience of mental illness (318).

9.3.2 Addressing some of the epistemic injustice

As outlined in previous chapters, for decades individuals with a psychiatric diagnosis were seen as lacking capacity and excluded from the process of knowledge production. This approach is now regarded by many as a form of "epistemic injustice" (10). More recently, there has been a shift in mental health research towards a more participatory and collaborative model which gives greater primacy to the voice of lived experience at all stages of the research process (12, 13). Despite this shift, levels of lived experience involvement in mental health research remain low. This is also reflected by the limited number of PSP studies (i.e., ten studies) where individuals with experience of mental

illness have been asked to set the research agenda, which demonstrates a lack of lived experience involvement in setting an agenda for mental health research (319). The PSP study in this thesis invited individuals with experience of taking and/or stopping psychiatric medication to contribute to setting the research priorities, combining experiential knowledge with clinical knowledge to inform future research. In doing so, the PSP methodology aligns with the modern approach to mental health research, thereby helping to actively address epidemic injustice.

The PSP study in this thesis found several benefits to multi-stakeholder involvement. Bringing together individuals with different backgrounds and expertise provided a mean of sharing important insights into the topic from everyone involved. It created a space where individuals could share and listen to different perspectives, particularly the mix of real-world and clinical perspectives. It also demonstrated the value of co-production which informed the process of how the Top 10 priorities were agreed. The Top 10 priorities covered several different areas relating to tapering psychiatric medication, some of which may not have made the list had the lived experience group not been involved, particularly priorities focused on tapering supports.

However, the involvement of multiple stakeholder groups did not come without its challenges. The main challenge was achieving and maintaining balanced representation of stakeholder groups throughout the research process. For example, the responses to both surveys in the PSP study were dominated by the lived experience group despite the team's best efforts to boost engagement from the healthcare professional group through targeted social media posts and emailing relevant partner organisations. The involvement of the Steering Group in the decision-making process helped ensure that the final Top 10 priorities reflected what mattered most to the three stakeholder groups. Given that one of underlying goals for this thesis was to amplify the voice of individuals who are often silenced and excluded from research, the respondent and participant demographic profiles from the survey and the final prioritisation workshop, respectively, would suggest that the thesis was successful in meeting this aim. Issues around stakeholder engagement have been identified by previous studies, and recommendations have been made to overcome such issues (320). As outlined in Chapter 3, potential issues may include conflict and miscommunication between stakeholder groups, and tokenism in terms of

representation (12, 204). The benefits and challenges experienced by individuals involved in the PSP study were identified and discussed in Chapter 7 as part of a follow-up interview study.

9.3.3 Contribution to the PSP methodology

This thesis made four key contributions to the PSP methodology which may be used to inform future research teams conducting PSP studies. These included: (1) Ethical approval; (2) Managing stakeholders' identity; (3) Model of collective support; (4) Recruiting the lived experience group.

9.3.4.1 Ethical approval

Ethical approval was obtained for both the PSP study (Study 1) and the interview study (Study 3). The level of ethical approval required depends on the perceived level of risk to the participants associated with the study. There are three levels of ethical approval; Level 1 applies to studies that carry the lowest risk to participants, while Level 3 applies to studies that carry the highest risk to participants. The Trinity College Dublin (TCD) Research Ethics Committee considers several population subgroups as more "vulnerable" than others and has developed a policy to protect the welfare of these groups. According to this policy, the involvement of "vulnerable" groups supersedes Level 1 ethical approval, and requires Level 2 or 3 ethics approval, depending on the nature of the work (321). Given the involvement of "vulnerable" individuals (i.e., individuals with mental illness) in the PSP study, Level 2 ethical approval was required from the Faculty Research Ethics Committee. The association of vulnerability with individuals with mental illness feeds back into the previous section which discussed the paternalism that has dominated mental health research for many decades, dictating how this cohort of individuals are regarded by society.

9.3.4.2 Managing stakeholders' identity

As outlined above, the PSP study in this thesis involved three stakeholder groups. Efforts were made throughout the PSP study and its follow-up studies to protect the identity of all individuals involved regardless of their stakeholder group. With respect to individuals

representing the lived experience and supporters' groups, revealing their identities risks exposing their medical history or that of the person they are supporting, which may result in distress or harm. Whereas individuals from the healthcare professional group may not want to be publicly associated with any mental health related research studies which focuses on discontinuing psychiatric medication. While individuals may have been happy to reveal their identities within the confines of the Steering Group and/or the final prioritisation workshop, they may not want it to be made public as a co-author. To safeguard stakeholders' identity in this study, all Steering Group members were given the option of being listed on all study-related publications; no assumptions were made. If they agreed to be listed, they could choose how they wanted to be described so that they could control the level of disclosure.

The importance of safeguarding stakeholders' identity has not been addressed by previous PSP studies nor is it discussed by the JLA guidance. That said, it should be considered in any study involving external research collaborators, particularly when the study's topic of interest sits in a contested space where individuals tend to have polarising views and opinions and when exposing their identity has potential to cause distress or harm.

9.3.4.3 Model of collective support

The JLA recommend that a "support" person is specifically named and present at the final prioritisation workshop to offer additional support to workshop participants (191). While the PSP study in this thesis followed the JLA guidance in terms of informing workshop participants of potential risks and benefits of their participation, no specific person was named as the support person during the final prioritisation workshop. The naming and presence of a specific person who is constructed as the 'skilled expert' in emotional support feeds back into the paternalistic view that individuals with mental illness are "vulnerable" and require additional support. The assigning of someone as 'expert' in support also assumes that they or others in the final workshop do not have the expertise to provide peer support, which in turn contradicts the principles of partnership that the study sought to achieve. This is not to suggest that support was not considered important. In recognition of the capacity of each individual to offer support, in line with the

partnership model, and in an effort not to reproduce assumptions about an individuals' vulnerability based on being a member of a particular stakeholder group, a model of collective support was adopted. Hence at the beginning of the workshop the strengths of the participants in the room to support each other were explicitly acknowledged. In this way, support was a collective endeavour. This was also important as some individuals in attendance were members of peer support groups, and others had dual roles (e.g., healthcare professional with personal experience of taking/stopping psychiatric medication).

In terms of support, one other change was made. Participant information leaflets (PILs) typically state that if a participant becomes upset or distressed that they can pause the data collection process or withdraw from the study entirely. In this study we supported participants to make the decision as to whether they wanted to leave the workshop or stay, by saying that they could also stay within the room. In doing so, it recognised that while an individual may experience distress it does not reduce their capacity to contribute. The model of collective support offered within this PSP study is another way of enhancing a partnership approach and shifting away from the paternalism of naming a support person. This model of support should be considered by future research teams conducting mental health research which are coming from a partnership perspective.

9.3.4.4 Recruiting the lived experience group

All PSP studies involve a "patient" group; however, this study was one of only ten PSP studies that included individuals with experience of mental illness. Power imbalances between the researcher group and the "patient/public" group have been identified by previous research in which some researchers have adopted a top-down stance to decision making, restricting the input of the "patient" group (204). Recommendations to overcome these imbalances include researchers' acknowledgment of the potential value and contributions of the "patient/public" group to the research process and creating a code of conduct (322). These imbalances may affect an individual's ability or willingness to contribute to the research and feel comfortable sharing their perspectives across most PSP studies. Additional barriers may apply to studies that involve individuals with

experience of mental illness, which may stem from the traditional paternalism that surrounded these individuals in which they were seen as lacking capacity (322).

Cognisant of these potential barriers, the individuals recruited to the Steering Group were carefully identified. By recruiting individuals who had already found their voice in this space, it helped to offset the power issues that exist in mental health research. For example, partner organisations were consulted and asked to nominate individuals. While similar recommendations on identifying and selecting stakeholders have been made by previous studies such as recruiting individuals with "communication skills" and "previous stakeholder engagement" (323), using study partners to assist the recruitment process was not mentioned before. Another strategy to offset the power dynamics involved recruiting individuals who had dual roles, breaking the potential divide between stakeholder groups. Future research teams should consider using the strategies employed by this PSP study when establishing their Steering Group, particularly if recruiting individuals with mental illness.

9.4 Strengths and Limitations of the Thesis

Each of the preceding chapters outlined the strengths and limitations that were relevant to that specific study. This section, therefore, discusses the strengths and limitations of the overall research presented in this thesis.

In terms of strengths, this was the first study to involve an international group of key stakeholder representatives to co-produce a list of research questions on reducing and stopping psychiatric medication. Multi-stakeholder involvement strengthened the study findings by enabling the triangulation of the data from three stakeholder groups and providing new insights into the topic. The findings were actively discussed at Steering Group meetings and the final prioritisation workshop. This also built credibility within the thesis and increased the potential impact of the thesis findings on research, policy, and practice.

Secondly, this thesis went beyond the traditional PSP methodology by performing two additional linked studies. These studies involved a descriptive analysis of the free-text survey responses to capture individuals' experiences of reducing and stopping psychiatric medication (Study 2), and semi-structured interviews with the individuals who had been

involved in the PSP study to explore their views of the PSP methodology as a priority setting exercise (Study 3). While the major contribution of the thesis to the literature was the Top 10 list of research priorities on reducing and stopping psychiatric medication, completion of the follow-up studies allowed the thesis to contribute to the evidence base in a multitude of ways. It provided valuable insights into key stakeholders' experience of discontinuing psychiatric medication and involvement in research and revealed a lack of apps supporting individuals to taper psychiatric medication (Study 4).

This thesis also had some limitations. As previously outlined, the use and discontinuation of psychiatric medication lies in a contested space, which may raise some concerns that individuals only engaged with the research to promote their own personal agenda. While it was not possible to mitigate this risk entirely, efforts were made to control it. For example, all potential participants of the final prioritisation workshop were screened by me and my supervisory team by hosting short meetings via Zoom to assess their motivations for involvement and ability to contribute to the workshop in a meaningful way before they received the official invitation to participate. However, the same screening process was not applicable to the survey respondents. As a result, there is potential that the voice of people who had negative experiences of taking and/or stopping psychiatric medication and wanted to challenge the medical model as a way of thinking about mental distress were overrepresented.

The second limitation relates to the nature of a study that requires people to recall previous experiences. This study relied on individuals' memory to recount their experiences of taking and stopping psychiatric medication. Given that these experiences can be distressing as they are linked to their mental health experiences, this created potential for lost information or recall bias. Similar limitations apply to individuals representing the healthcare professional group in terms of relying on their memory.

The third limitation refers to the restrictions on participation. An individuals' ability to participate was dependant on them having internet access and relevant skills in the use of technology. While the final prioritisation workshop was held as a hybrid event, expressions of interest were made online, and all related documents were shared via email. As a result, some groups might have been missed such as individuals with poor digital literacy and those living in rural areas with poor internet access. Restricting

participation to individuals with internet access may have limited the generalisability of the findings of Studies 1-3.

The final limitation relates to the evidence base. While it has been shown that differences exist in terms of levels of treatment coverage (i.e., the number of people eligible to receive a treatment versus the number of people who actually receive treatment) and distribution of mental illness between high-income and lower- and middle-income countries, most of the evidence base around the use and discontinuation of psychiatric medication has been produced in the Western world (33, 41, 324). Given that this evidence base was used to inform this thesis, particularly Chapter 2, which set the thesis in context of the literature, it may limit the generalisability of the information provided.

9.5 Recommendations & implications for research, policy, and practice

This section outlines the implications of the thesis and its findings and discusses their potential impact under three themes, research, policy, and practice.

9.5.1 Research

The thesis findings have several potential impacts on research. The literature review in Chapter 2 showcases the gaps in the evidence base around the use and discontinuation of psychiatric medication, such as the uncertainty as to what constitutes the optimal tapering regimen. It also highlights some of the concerns that have been raised around clinical trials involving psychiatric medication in terms of trial duration and potential for bias (95, 325). Future research should address these gaps to strengthen the evidence base on psychiatric medication.

The Top 10 priorities identified by Study 1 comprise a co-produced list of questions on reducing and stopping psychiatric medication that reflects the unmet needs and priorities of key stakeholder groups. Future research teams should use this list of priorities when formulating their research questions. By doing so, they have potential to promote research that address uncertainties that exist among relevant stakeholders and generate findings that could ultimately help to improve the health and wellbeing of future individuals who are discontinuing psychiatric medication.

The narratives collected by the first survey in the PSP study and analysed as part of Study 2 captured individuals' first- and second-hand experiences of taking and stopping psychiatric medication. By demonstrating the similarities and differences between the stakeholder groups around the use and discontinuation of psychiatric medication, this study highlights the importance of representing all key stakeholder groups in future research studies so that the outputs of research represent the needs of all stakeholder groups and improves the relevance of research.

The views and experiences of individuals who had been involved in the PSP study on the PSP methodology captured in Study 3 should be used by future research teams who are conducting PSP studies, particularly in mental health research. By demonstrating the ability of the PSP methodology to achieve authentic collaboration between stakeholder groups, this study could help to inform future research teams in choosing to adopt the same methodology when the goal is to involve multiple stakeholder groups in research priority setting exercises.

Finally, Study 4 revealed the limited number of mobile phone apps and studies of app-based interventions that focused on supporting the tapering of psychiatric medication. By outlining the key functionalities offered by the identified apps and raising awareness of the shortcomings of existing apps, this study has the potential to guide the future development of apps to support individuals who are tapering their psychiatric medication use, and to overcome one of the major tapering challenges around the lack of tapering supports.

9.5.2 Policy

This section discusses the potential impact of the thesis on policy in the context of mental health. As outlined above, there is growing recognition to include individuals with experience of mental illness in setting the research agenda (41). Despite efforts to support this shift such as the creation of new and updated mental health policies, the evidence suggests low levels of lived experience involvement in mental health research (212).

As outlined in this thesis, the PSP methodology is well suited in mental health research as it recognises the value of co-production of research priorities and supports a collaborative working model between key stakeholder groups that is considered as authentic,

worthwhile and meaningful. It would also be applicable to other areas where epistemic injustice or power differentials are present. That said, the PSP study in this thesis is one of only ten PSP studies that have involved individuals with experience of mental illness. Mental health policies should be updated to include the PSP methodology as one of their recommended approaches to research priority setting. In Ireland, the Health Research Board (HRB) is developing a new mental health research policy which will address key areas in mental health such as promotion, prevention, early intervention (326). This policy will align with the "Sharing the Vision – a Mental Health Policy for Everyone 2020-2030" which was developed by the Health Service Executive to enhance provision of mental health services and supports (327). By inviting representatives of the HRB to attend the final prioritisation workshop in an observer capacity, the PSP study may support the inclusion of the PSP methodology as a recommended methodology in the new mental health research policy.

9.5.3 Practice

This section focuses on the education of healthcare professionals around the use and discontinuation of psychiatric medication which was a common theme throughout this thesis. This was the third most highly ranked priority in Study 1 (see Table 5.9) and re-emerged as an important issue in Studies 2 & 3. Individuals from the three stakeholder groups shared the view that healthcare professionals did not receive adequate training on psychiatric medication, particularly on discontinuing them. A previous study involving a sample of General Practitioners (GPs) found that GPs find it easier to start psychiatric medications as opposed to stopping them, particularly when they have been initiated by another clinician (328). Lack of education may contribute to prescribers' reluctance to stop psychiatric medication.

This thesis recommends the rethinking of the education of current and future healthcare professionals on the use and discontinuation of psychiatric medication in a way that integrates the voice of the lived experience group. The value of co-production is highlighted throughout the thesis. Therefore, it makes logical sense to involve the lived experience group in shaping the education of healthcare professionals (329). If successful, there is potential to overcome perceived gaps in healthcare professionals' knowledge and

improve clinical practice as well as the provision of support from prescribers which was another common theme in this thesis. Reframing healthcare professionals to extend the focus on psychiatric medication beyond their prescribing and use to their discontinuation supports the shift from the compliance narrative, as outlined above.

9.6 My personal reflections

As a pharmacist, my knowledge on psychiatric medication was largely shaped from the material I received throughout my undergraduate degree. After reviewing the literature, I learnt that evidence can be complex and contested, and that not everything that is published has been proven (e.g., the chemical imbalance theory). This PhD taught me how to adopt a critical thinking lens when reading the literature, and how to make the distinction between fact and theory. Despite my endeavours to enter this PhD from a neutral stance in relation to the prescribing and use of psychiatric medications, neutrality is a hard position to achieve on any issue. We are all influenced by our disciplinary background. Whilst being aware of the potential for my own personal biases and biases that exist in the literature, I have endeavoured to remain balanced and nuanced in my writing throughout this thesis.

Completing this PhD provided me with unique opportunities to engage with Patient and Public Involvement (PPI). One key moment for me was the final prioritisation workshop in the PSP study. While I had concerns over potential conflict between attendees and the healthcare professional group dominating the discussion, there was an immediate sense of mutual respect and feeling of empowerment. Despite differences in individuals' backgrounds and experiences, they shared the same desire for change. The workshop showed me how research has the power to bring people together and learn from one another.

This PhD also left me with an extensive skillset. I have learnt new skills such as how to critically read the literature, design a study and secure ethical approval, undertake qualitative data collection and analysis. I also improved other skills such as time management and project co-ordination skills from leading the PSP study. It also taught me how to work as part of a team and adapt to different roles. While the core team remained the same throughout the PhD, there were additional members at times such as

the fourth-year pharmacy student who assisted with coding in Study 2, the research librarian, and the Steering Group.

While this PhD has been one of the most difficult and rewarding tasks I have ever undertaken and I struggled at times to keep going, the willingness of other individuals to get involved and share their personal stories provided me with the reassurance that this PhD was adding something valuable and worthwhile to the evidence base, and that it could make a difference. This motivated me to see it to completion. Upon starting this PhD in September 2021, three years sounded so far away and now I am amazed at how quickly those years flew by. It was always my intention to become a community pharmacist. Now after completing this PhD, I do not know what my next chapter is, but I am excited to find out!

9.7 Dissemination Plan for the Thesis Findings

The main aim of thesis was to develop a body of knowledge that would advance the evidence-base relating to the safe and appropriate tapering of psychiatric medication. Given the nature of this work and its multi-stakeholder involvement, any previous and future study-related publications have been or will be made in open-access journals to ensure accessibility to all stakeholder groups. The list of publications and presentations to date is included in Chapter 1.

With respect to Study 1, a comprehensive dissemination plan was developed in consultation with the Steering Group which identified the study's target audiences and the dissemination activities that would help to reach them. There have been two publications from this study comprising a study protocol (190) and final study manuscript (226). The study findings were also published on the JLA website, the study's dedicated website (www.tapersafer.org) and Twitter account and shared with various research funding and agenda setting organisations. The PSP methodology was discussed as part of a webinar and as a workshop at the at the European Society of Clinical Pharmacy conference in Krakow, Poland in October 2024. I also gave an oral presentation based on the findings at the same pharmacy conference. Manuscripts are currently being drafted for the remaining studies. The protocol for Study 4 has already been published (282). I

intend to submit the final study manuscripts with the study findings for publication post completion of the PhD.

9.8 Final Conclusion of the Thesis

This thesis has developed a body of knowledge that could help to advance the evidence-base relating to the safe and appropriate tapering of psychiatric medication. This work is particularly important given that use of psychiatric medications is increasing, driven to a large extent by increases in the number of individuals taking the medications for extended periods. Despite the cohort of individuals looking to discontinue psychiatric medications, there is a paucity of high-quality evidence on the process of withdrawal. The combined findings of the four studies allowed this thesis to fulfil its aim and objectives. Each study contributed to the evidence base in different ways. By outlining the gaps in the evidence base around the use and discontinuation of psychiatric medication that are most important to key stakeholder groups, this thesis signposts the areas that need to be investigated and provides a solid foundation for future research. In addition, this thesis showcases the benefits of multistakeholder involvement in mental health research, and how the PSP methodology is a meaningful and worthwhile methodology in areas where epistemic injustice is present. In doing so, this thesis supports the shift in mental health research toward the more modern, collaborative, and rights-based model that challenges the traditional association of vulnerability with individuals with experience of mental illness.

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Appendices

Appendix 4.1: Completed Reporting guideline for priority setting of health research (REPRISE) Guideline

A Context and scope	Section within manuscript
1. Define geographical scope	Methods - Step 2: Gathering evidence uncertainties (Round 1 survey)
2. Define health area, field, focus	Methods - Step 1: Establishing the Steering Group
3. Define the intended beneficiaries	Methods - Step 1: Establishing the Steering Group; Methods - Step 2: Gathering evidence uncertainties (Round 1 survey)
4. Define the target audience of the priorities	Methods - Step 1: Establishing the Steering Group; Methods - Step 2: Gathering evidence uncertainties (Round 1 survey)
5. Identify the research area	Methods: Step 1: Establishing the Steering Group
6. Identify the type of research questions	Methods: Step 1: Establishing the Steering Group
7. Define the time frame	Methods: Step 1: Establishing the Steering Group - Step 6: Workshop (final prioritisation)
B Governance and team	**Section within manuscript**
8. Describe the selection and structure of the leadership and management team	Methods: Step 1: Establishing the Steering Group
9. Describe the characteristics of the team	Methods: Step 1: Establishing the Steering Group
10. Describe any training or experience relevant to conducting priority setting	N/A

C Framework for priority setting	Section within manuscript
11. State the framework used (if any)	Methods
D Stakeholders or participants	
12. Define the inclusion criteria for stakeholders involved in priority-setting	Methods: Step 2: Gathering evidence uncertainties (Round 1 survey); Step 5: Interim prioritisation (Round 2 survey); Step 6: Workshop (final prioritisation)
13. State the strategy or method for identifying and engaging stakeholders	Methods: Step 2: Gathering evidence uncertainties (Round 1 survey); Step 5: Interim prioritisation (Round 2 survey); Step 6: Workshop (final prioritisation)
14. Indicate the number of participants and/or organizations involved	Results: Step 2: Gathering evidence uncertainties (Round 1 survey); Step 5: Interim prioritisation (Round 2 survey); Step 6: Workshop (final prioritisation)
15. Describe the characteristics of stakeholders	Results: Step 2: Gathering evidence uncertainties (Round 1 survey); Step 5: Interim prioritisation (Round 2 survey); Step 6: Workshop (final prioritisation)
16. State if reimbursement for participation was provided	Methods: Step 1: Establishing the Steering Group; Step 6: Workshop (final prioritisation)
E Identification and collection of research priorities	**Section within manuscript**
17. Describe methods for collecting initial priorities	Methods: Step 2: Gathering evidence uncertainties (Round 1 survey)
18. Describe methods for collating and categorizing priorities	Methods: Step 3: Summarising the responses gathered
19. Describe methods and reasons for modifying (removing, adding, reframing) priorities	Methods: Step 3: Summarising the responses gathered

20. Describe methods for refining or translating priorities into research topics or questions	Methods: Step 3: Summarising the responses gathered
21. Describe methods for checking whether research questions or topics have been answered	Methods: Step 4: Evidence checking
22. Describe number of research questions or topics	Results: Step 3: Summarising the responses gathered.
F Prioritization of research topics/questions	**Section within manuscript**
23. Describe methods and criteria for prioritizing research topics or questions	Methods: Step 6: Workshop (final prioritisation)
24. State the method or threshold for excluding research topics/ questions	Methods: Step 6: Workshop (final prioritisation)
G Output	**Section within manuscript**
25. State the approach to formulating the research priorities	Results: Step 3: Summarising the responses gathered
26. Describe how the process of prioritization was evaluated Survey, workshop	Methods: Step 5: Interim prioritisation (Round 2 survey); Step 6: Workshop (final prioritisation)
27. Describe how priorities were fed back to stakeholders and/or to the public; and how feedback (if received) was addressed and integrated	Methods: Step 5: Interim prioritisation (Round 2 survey); Step 6: Workshop (final prioritisation)
28. Outline the strategy or action plans for implementing priorities	N/A
29. Describe plans, strategies, or suggestions to evaluate impact	N/A
J Funding and conflict of interest	**Section within manuscript**
30. State sources of funding	Funding
31. Declare any conflicts or competing interests	Competing interests

Appendix 4.2: Participant Information Leaflet for Round 1 survey

Name of Study: Psychotropic Tapering Priority Setting Partnership

Site	Trinity College Dublin
Principal Investigator(s) and Co-Investigator(s)	Miriam Boland, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin Dr Cathal Cadogan, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin Professor Agnes Higgins, School of Nursing and Midwifery, Trinity College Dublin

You are invited to take part in an anonymous online survey as part of a research study to determine the top unanswered research questions on the gradual reduction of dosage (also known as tapering) of psychotropic medication.

We think it is important that more research is done into the tapering process, and that future research focuses on the questions that are important to include individuals with lived experience of mental health problems and psychotropic tapering (Patient and carer representative/s) and clinicians.

We are therefore collecting questions that all these groups of people have about tapering psychotropic medication. We will use these to evaluate how people are tapering their psychotropic medication, identify what optimal tapering schedules entail and how best to support individuals throughout the tapering process. Gaining knowledge about your experience has the potential to help others withdraw their medication and reduce their symptoms.

We are looking for patient and public representatives, researchers, clinicians, and policy makers who are willing to share their views with us through an anonymous online survey.

This Participant Information Leaflet will explain the aim and purpose of this research, and what taking part will involve. Please take the time to read this information carefully and feel free to contact the research team if you have any questions. Contact details are included towards the end of this Participant Information Leaflet.

Part 1 – The Study

Do I have to take part?

If you decide to take part in the survey, you can exit the survey at any time before you submit your survey responses. Once you have submitted, we will not be able to link back to you as the survey is entirely anonymous.

How will the study be carried out?

Participation will involve taking part in an anonymous online survey about the tapering of psychotropic medication. We will provide you with an open-ended question about prescribed medicines, regimen details, etc.

We request that you tell us about a maximum of five questions you have about tapering, these questions do not have to be in any particular order of importance. You can write as much or as little as you like. All answers will be treated confidentially. To ensure anonymity, please do not disclose any personal information about yourself or any other individual.

Once we have collected enough answers to this survey, we will list all of the comments provided and then begin a process of putting them in order of priority for further research. The result will be a Top 10 list of priorities to guide future research into the tapering of psychotropic medication. These results will also be submitted to peer reviewed research journals for publication.

By taking part in this survey, you are agreeing to allow us to anonymously publish the research ideas that you help us to identify. It will not be possible to link you as an individual to any of the ideas generated.

Are there any benefits to taking part in this research?

By taking part in this research, it will assist us in identifying and agreeing the top 10 research questions relating to gradually reducing psychotropic medication.

This will allow future research to focus on the most important questions and thus help inform better health care decisions.

Are there any risks to me or others if I take part?

Even though we do not anticipate any risks to participants completing the survey, the survey does contain sensitive questions about your experiences of mental health. These questions have the potential to provoke difficult emotions and memories. If this is the

case, please contact a healthcare professional. You may stop your participation in this study at any time by exiting the survey before submission and your response will not be recorded.

Part 2 – Confidentiality

The survey responses in phase 1 are anonymous. Your identity will not be known to us for this part of the study.

We will delete all survey responses three years after the PhD has been completed. The PhD is currently being undertaken by the Principal Investigator, Miriam Boland, at Trinity College Dublin.

Access to the survey responses will be restricted to Principal Investigator and PSP Coordinators.

Part 3 – Costs, Funding and Approval

Has this study been approved by a research ethics committee?

Yes, this study has received approval from Faculty of Health Sciences Research Ethics Committee Trinity College Dublin on 3rd August 2022.

Reports on this project will be submitted to the Research Ethics Committee on an annual basis until the project is completed.

Who is organising and funding this study?

This study is being organised by Miriam Boland.

Is there any payment for taking part?

No, there is no payment for taking part in the research.

Part 4 – Further Information

Who should I contact for information?

If you have any concerns or questions, you can contact:

Principal Investigator: Miriam Boland, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin 2. Email: bolandm7@tcd.ie. Phone: +353-1-896-2809

Appendix 4.3: Final version of the Round 1 survey

Page 1: This page provides the respondent with information about the PROTECT study.

The PROTECT study

Priorities for future research on reducing and stopping psychiatric medicines

Have your say!

What questions would you like to see answered by research about reducing and stopping antidepressants, anti-anxiety medicines, sleeping tablets and other psychiatric medicines?

The PROTECT study team, in partnership with the James Lind Alliance, has set up this priority setting partnership to identify the Top 10 priorities for future research about reducing and stopping psychiatric medicines. Psychiatric medicines include antidepressants, anti-anxiety medicines, sleeping tablets, antipsychotics, mood stabilisers and stimulants. For a more detailed list of the types of medicines that we are referring to, please click on this link.

This is your chance to have your voice heard.

If the respondent clicks on the link in the last paragraph, they are re-directed to the glossary of terms in a new tab. Here they are presented with more detailed information on the various types of psychiatric medicines. Examples of each are also provided.

THE PROTECT STUDY

GLOSSARY

Antidepressants: These are medicines used to treat mental health conditions such as depression. They can also be used to treat physical health conditions such as pain.

Examples: escitalopram (Lexapro®), fluoxetine (Prozac®), sertraline (Lustral®/Zoloft®), paroxetine (Seroxat®/Paxil®)

Antipsychotics: These are medicines used to treat some types of mental health conditions, mainly schizophrenia and bipolar disorder. They are also sometimes used to treat anxiety and depression.

Examples: quetiapine (Seroquel®), olanzapine (Zyprexa®), aripiprazole (Abilify®), risperidone (Risperdal®)

Hypnotics and anxiolytics: These medicines include benzodiazepines ("Benzos") and Z-drugs and are often referred to as sleeping tablets or anti-anxiety. They are mainly used to treat insomnia (lack of adequate restful sleep) and anxiety.

Examples: diazepam (Valium®), alprazolam (Xanax®), chlordiazepoxide (Librium®), lorazepam (Ativan®), zolpidem (Stilnoct®/Ambien®) and zopiclone (Zimovane®)

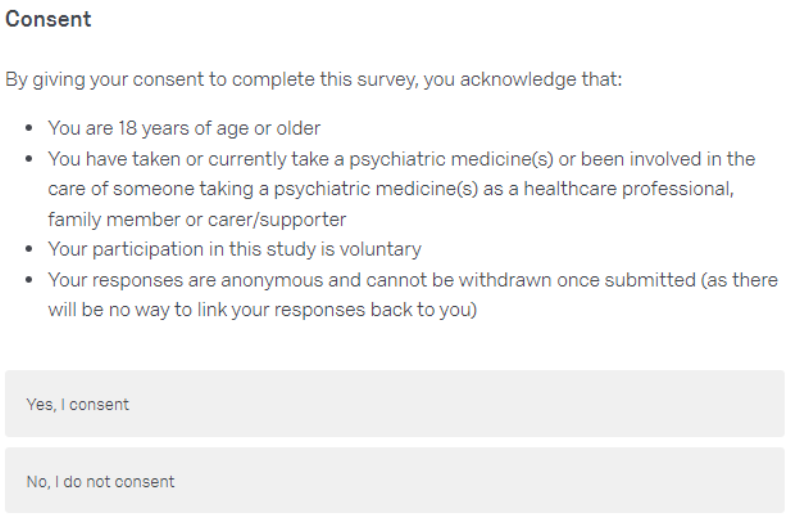
Stimulants: This group of are generally used to treat attention-deficit hyperactivity disorder (ADHD) and narcolepsy (uncontrollable episodes of deep sleep). In this study, stimulants does not include illicit substances such as cocaine.

Examples: atomoxetine (Strattera®), methylphenidate (Ritalin®/Concerta®)

Gabapentinoids: This term includes two drugs, gabapentin and pregabalin. These medicines are used for the management of neuropathic pain and epilepsy. Pregabalin is also used for generalised anxiety disorders.

Examples: gabapentin (Neurontin®), pregabalin (Lyrica®)

Page 2: This page asks the respondent to give their consent to participate. If the respondent selects "Yes, I consent" they are brought to the Page 3. If the respondent "No, I do not consent", they are brought to Page 8 which marks the end of the survey. The respondent is not able to access the survey questions. The respondent cannot proceed without answering this question ("forced response").



Consent

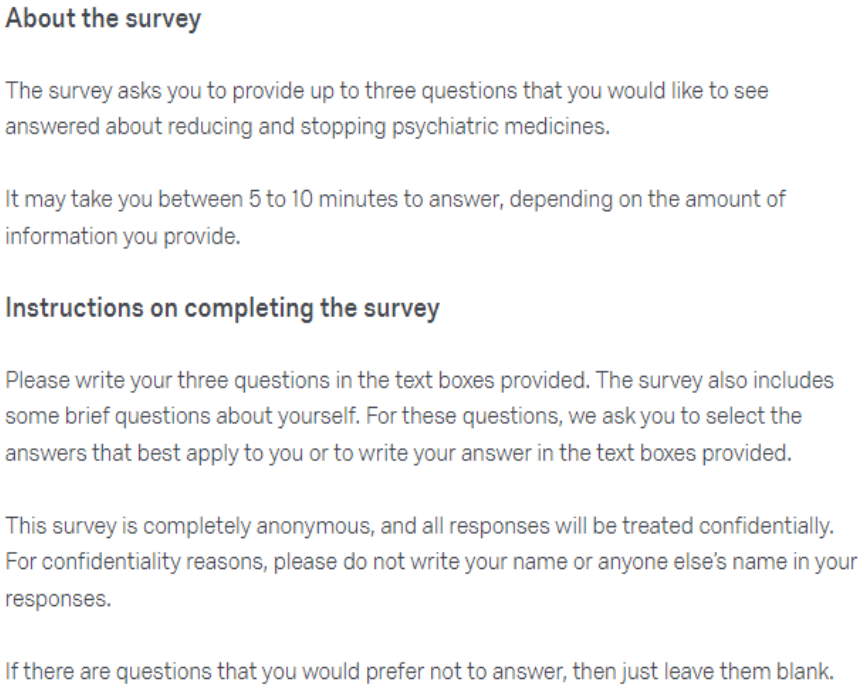
By giving your consent to complete this survey, you acknowledge that:

- You are 18 years of age or older
- You have taken or currently take a psychiatric medicine(s) or been involved in the care of someone taking a psychiatric medicine(s) as a healthcare professional, family member or carer/supporter
- Your participation in this study is voluntary
- Your responses are anonymous and cannot be withdrawn once submitted (as there will be no way to link your responses back to you)

Yes, I consent

No, I do not consent

Page 3: This page provides the respondent with further information about the survey and instructions on completion.



About the survey

The survey asks you to provide up to three questions that you would like to see answered about reducing and stopping psychiatric medicines.

It may take you between 5 to 10 minutes to answer, depending on the amount of information you provide.

Instructions on completing the survey

Please write your three questions in the text boxes provided. The survey also includes some brief questions about yourself. For these questions, we ask you to select the answers that best apply to you or to write your answer in the text boxes provided.

This survey is completely anonymous, and all responses will be treated confidentially. For confidentiality reasons, please do not write your name or anyone else's name in your responses.

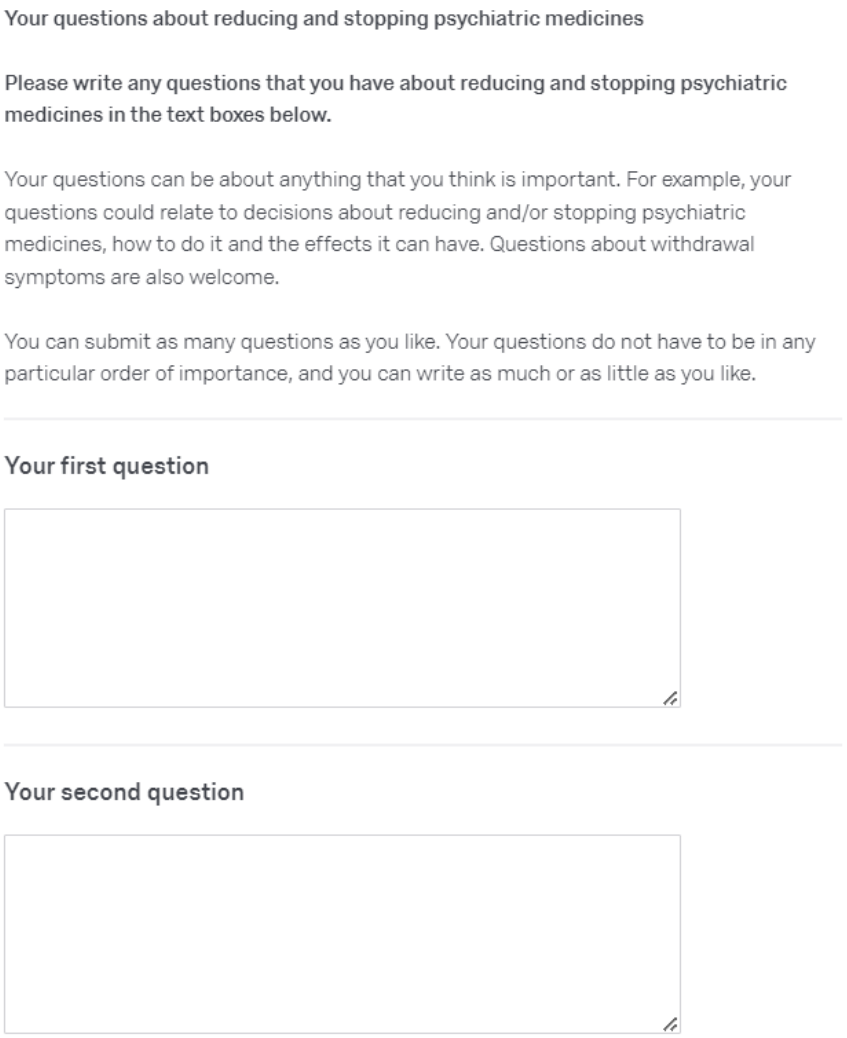
If there are questions that you would prefer not to answer, then just leave them blank.

Page 4: This page asks the respondent to specify which group best describes them. The respondent cannot proceed without answering this question ("forced response").

If the respondent selects "Healthcare professional", they are asked to specify which subgroup they belong to. The user cannot proceed without answering this question

("forced response").

Page 5: This page asks the respondent to submit their questions about reducing and stopping psychiatric medicines.



Your questions about reducing and stopping psychiatric medicines

Please write any questions that you have about reducing and stopping psychiatric medicines in the text boxes below.

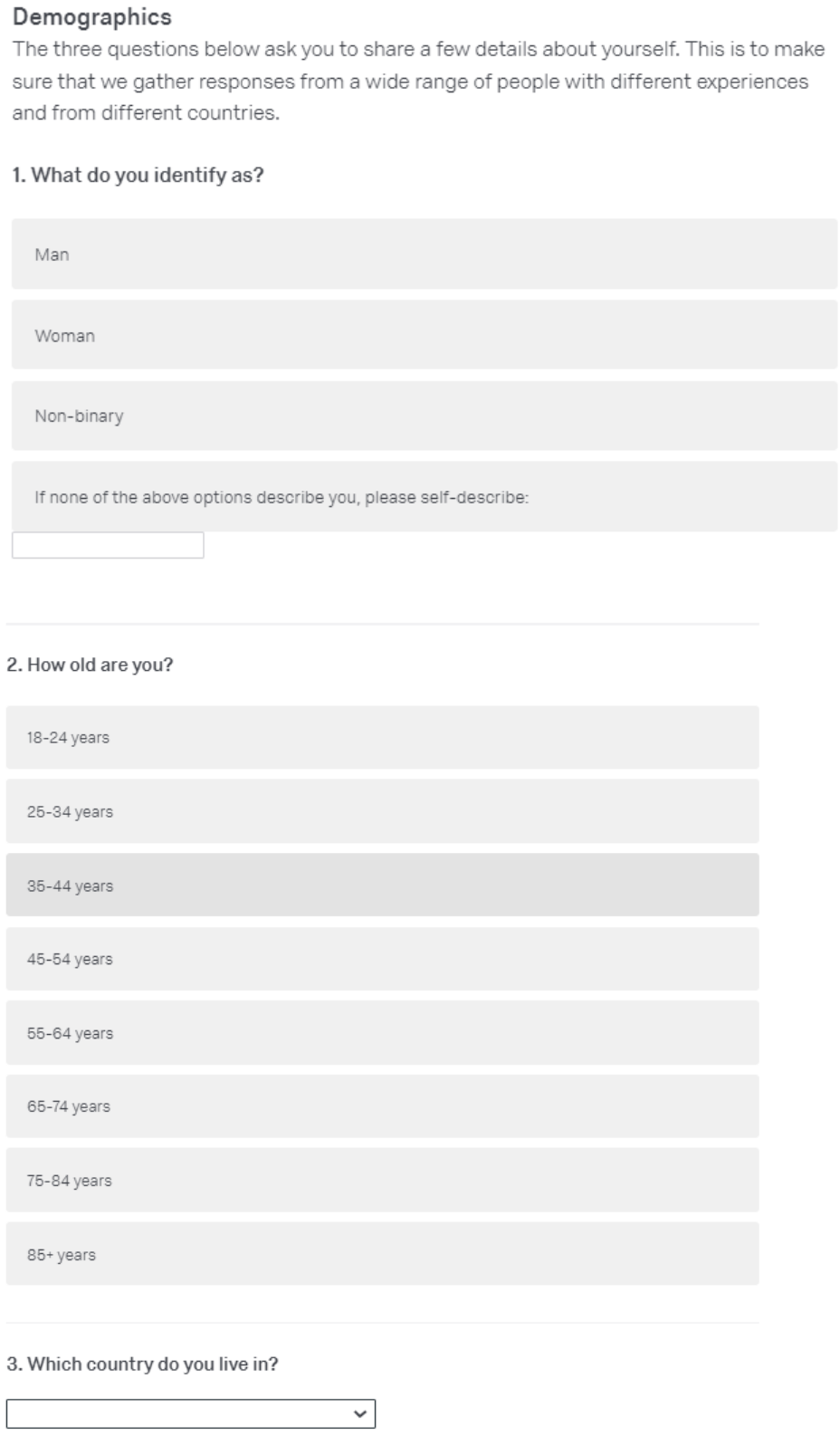
Your questions can be about anything that you think is important. For example, your questions could relate to decisions about reducing and/or stopping psychiatric medicines, how to do it and the effects it can have. Questions about withdrawal symptoms are also welcome.

You can submit as many questions as you like. Your questions do not have to be in any particular order of importance, and you can write as much or as little as you like.

Your first question

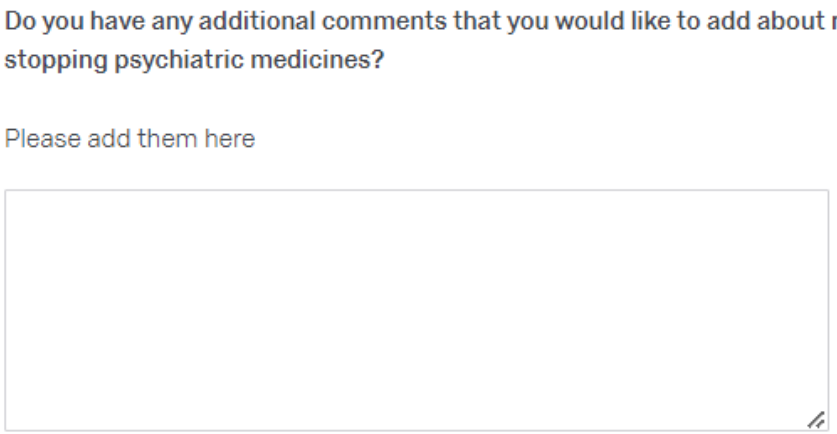
Your second question

Page 6: This page asks the respondent to provide demographic information: gender, age, and country of residence.

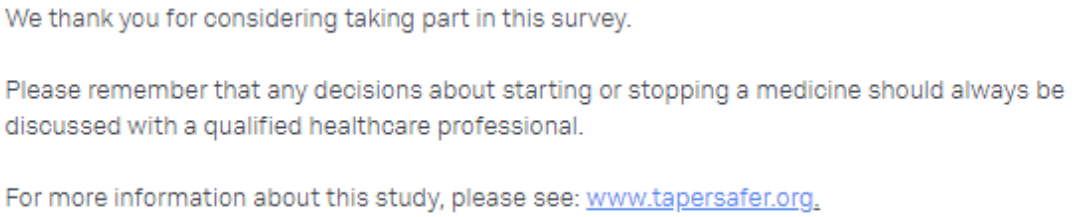


If the respondent does not answer the demographic questions, they are prompted to go back and answer them but if they do not wish to answer them, they can proceed to the end of the survey ("Prompted response").

Page 7: This page asks the respondent to submit any additional comments that they have about reducing and stopping psychiatric medicines.



Page 8: This is the last page of the survey. Respondents are directed to the study website for further information on the study.



Appendix 4.4: Final coding template for Round 1 survey responses (in scope)

Major theme	Explanation & subthemes
Theme 1: Tapering aids & supports	Covers questions related to everything that supports patients **during** and **after** the tapering process (including supports to prevent/minimise relapse and adverse effects/withdrawal symptoms)
	1. Pharmacological support
	2. Psychological support/non-pharmacological/social
	3. Financial support
	4. Educational support
	5. Healthcare professional
	6. Local/regional supports
	7. Non-specific/general support
Theme 2: Tapering process	Covers questions relating to the process of tapering (excluding withdrawal symptoms), such as:
	1. **Guidance/instructions**
	2. **Practicalities of the tapering process**
	3. **Monitoring**
	4. **Experiences**
	5. **Special populations**
	6. **Barriers/enablers**
	7. **Restarting psychiatric medicine(s)**
	8. **Underlying neurobiology/psychology**
Theme 3: Post-taper	Covers post-tapering related questions, such as:
	1. **Positive outcomes and experiences after tapering**
	2. **Negative outcomes and experiences after tapering**

	3. **Restarting psychiatric medicine(s) after tapering**
	4. Underlying neurobiology
	5. **Experiences**
Theme 4: Withdrawal symptoms & Adverse effects	Covers withdrawal symptom related questions (excluding tapering) that appear **during** the tapering process, such as:
	1. Risk of occurrence/ Specific examples
	2. Underlying mechanism/ neurobiology/psychology
	3. Management and prevention
	4. Identification
Theme 5: Accountability/ Responsibility	Covers questions related to the overall responsibility and duty of care of healthcare professionals and other organisations/professional bodies to service users, such as:
	1. **Healthcare professionals**
	2. **Government**
	3. **Pharmaceutical industry** - misleading claims, marketing strategies, making strips/lower dose formulations available.
	4. **Information provision/informed consent**
Theme 6: Acknowledgement/ recognition of problems/issues	Covers questions related to the acknowledgement/recognition of problems/issues with psychiatric medicines and the need for tapering, and lack of information provision, in terms of:
	1. Healthcare professionals
	2. Government
	3. Pharmaceutical industry
	4. Wider context
	5. Information provision/informed consent
Theme 7: Communication/ decision making	Covers questions relating to communication between service users and the multidisciplinary team (MDT)/decision making about stopping/starting psychiatric medicines, such as:
	1. Information/informed consent

	2. Treatment decisions
	3. Getting recognition for symptoms etc.
Theme 8: Healthcare professional knowledge/training	Covers questions relating to healthcare professional knowledge of the tapering process and the training strategies in place, such as:
	1. Education/training
	2. Knowledge

Appendix 4.5: Web of Science search strategy

("anti cholinergic*" OR "anti depress*" OR "anti psychotic*" OR "anti manic" OR anticholinergic* OR antidepress* OR antipsychotic* OR antimanic OR anxiolytic* OR benzodiazepine* OR eszopiclone OR gabapentin* OR hallucinogen* OR "mood stabiliser*" OR "mood stabilizer*" OR neuroleptic* OR pregabalin OR (psychiatric NEAR/2 (med* OR drug*)) OR psychotropic* OR "sleeping tablet*" OR tranquili* OR zaleplon OR zolpidem OR zopiclone OR "z drug*")

AND

(adheren* OR ceas* OR cessation OR "com* off" OR complian* OR deprescri* OR discontinu* OR nonadheren* OR noncomplian* OR quit* OR reduc* OR stop* OR taper* OR wean* OR withdraw*)

AND

(((evidence OR gap) NEAR/2 map*) OR EGM OR "meta analy*" OR metaanaly* OR "research synthes*" OR ((systematic OR rapid OR realist OR impact) NEAR/2 (review* OR assessment* OR stud*)))

Appendix 4.6: Data extraction form for Round 1 survey responses

PSP Question Number	Summary Question	Source of evidence	Overview	Individual drug class*	Non-class specific	Key author recommendations	Was the question answered by the evidence search? Yes/No/Partly	Explanation/ Justification	Include/exclude question in Round 2 survey?
1.1, etc.									

*Each class of psychiatric medication (e.g., antidepressants, antipsychotics, etc.) was allocated an individual column.

Appendix 4.7: Final version of the Round 2 survey

Page 1: This page provides the respondent with information about the PROTECT study.

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

James Lind Alliance
Priority Setting Partnerships

The PROTECT study: Round 2 survey

Priorities for future research on reducing and stopping psychiatric medicines

Have your say!

What are the most important questions about reducing and stopping antidepressants, anti-anxiety medicines, sleeping tablets and other psychiatric medicines?

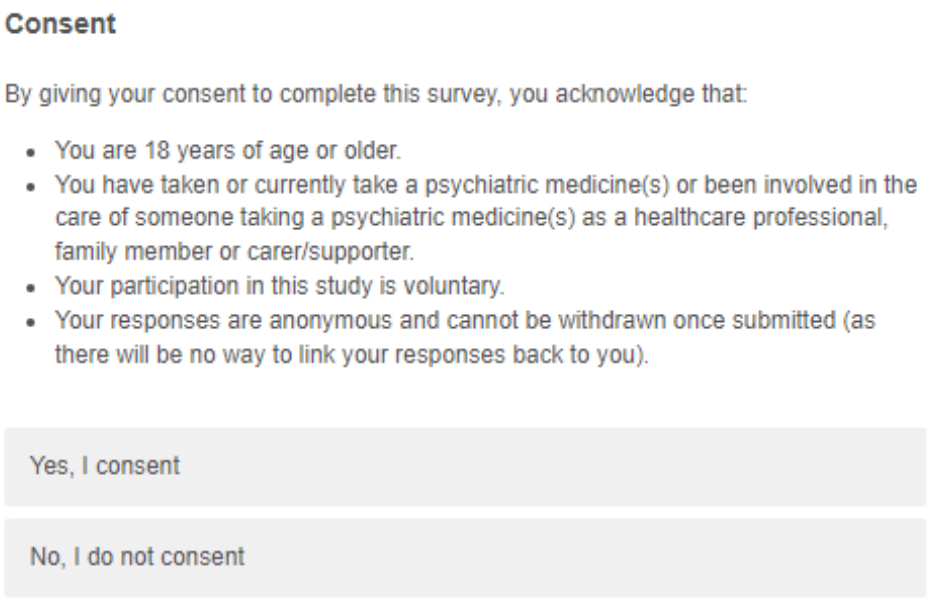
The PROTECT study team, in partnership with the James Lind Alliance, has set up this priority setting partnership to identify the Top 10 priorities for future research about reducing and stopping psychiatric medicines. Psychiatric medicines include antidepressants, anti-anxiety medicines, sleeping tablets, antipsychotics, mood stabilisers and stimulants. For a more detailed list of the types of medicines that we are referring to, please click on this link. This study could help to change the research agenda which will allow future research to focus on the most important questions.

In the Round 1 survey, we collected questions and uncertainties that people have about reducing and stopping psychiatric medicines. These people included individuals with lived experience of taking and/or stopping psychiatric medicines, family members, carers/supporters, and healthcare professionals. Then, through a process of analysis and consultation with the project's Steering Group we have come up with 32 potential research questions.

Now as part of the **Round 2 survey**, you are invited to select up to 10 questions that you think are the most important for future research.

This is your chance to have your say about the future research agenda.

Page 2: This page asks the respondent to give their consent to participate. If the respondent selects "Yes, I consent" they are brought to the Page 3. If the respondent selects "No, I do not consent", they are brought to Page 8 which marks the end of the survey. The respondent is not able to access the survey questions. The respondent must answer this question to proceed ("forced response").



Consent

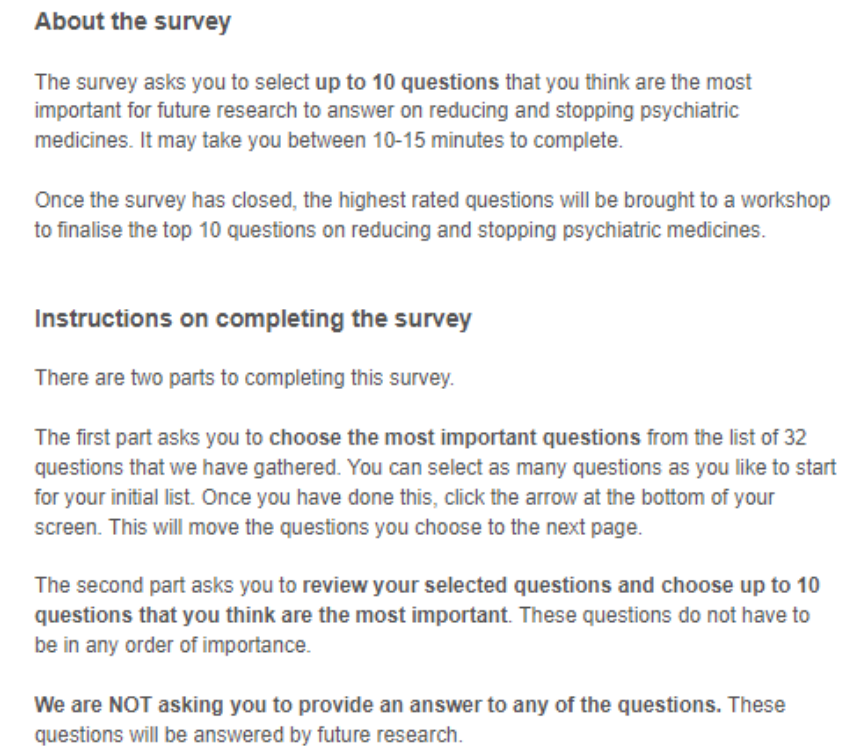
By giving your consent to complete this survey, you acknowledge that:

- You are 18 years of age or older.
- You have taken or currently take a psychiatric medicine(s) or been involved in the care of someone taking a psychiatric medicine(s) as a healthcare professional, family member or carer/supporter.
- Your participation in this study is voluntary.
- Your responses are anonymous and cannot be withdrawn once submitted (as there will be no way to link your responses back to you).

Yes, I consent

No, I do not consent

Page 3: This page provides the respondent with further information about the survey and instructions on completion.



About the survey

The survey asks you to select **up to 10 questions** that you think are the most important for future research to answer on reducing and stopping psychiatric medicines. It may take you between 10-15 minutes to complete.

Once the survey has closed, the highest rated questions will be brought to a workshop to finalise the top 10 questions on reducing and stopping psychiatric medicines.

Instructions on completing the survey

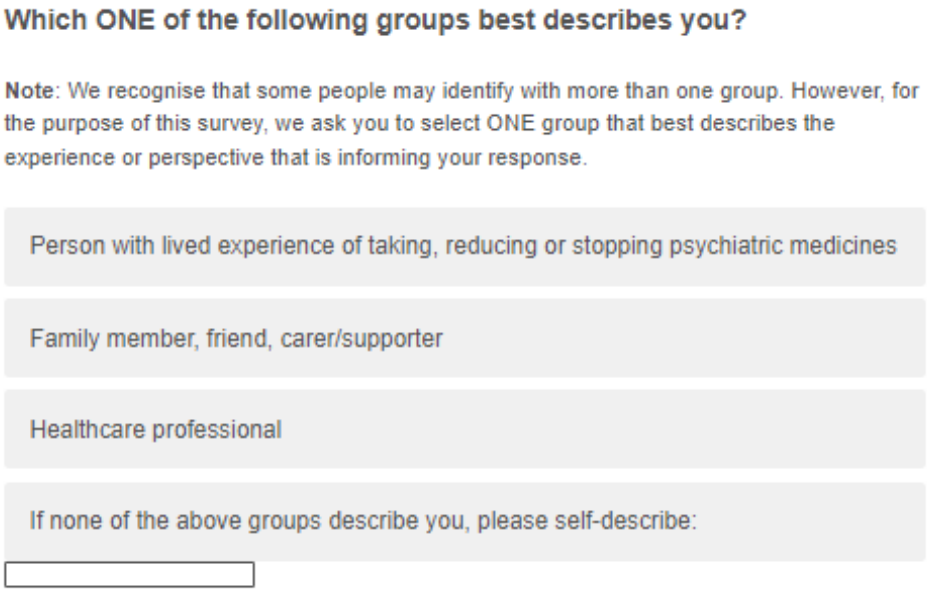
There are two parts to completing this survey.

The first part asks you to **choose the most important questions** from the list of 32 questions that we have gathered. You can select as many questions as you like to start for your initial list. Once you have done this, click the arrow at the bottom of your screen. This will move the questions you choose to the next page.

The second part asks you to **review your selected questions and choose up to 10 questions that you think are the most important**. These questions do not have to be in any order of importance.

We are NOT asking you to provide an answer to any of the questions. These questions will be answered by future research.

Page 4: This page asks the respondent to specify which group best describes them. The user cannot proceed without answering this question (“forced response”).



Page 5: Part 1 asks the respondent to select the most important questions about reducing and stopping psychiatric medicines.

Part 1: Select the most important questions about reducing and stopping psychiatric medicines

Below is the list of questions from the Round 1 survey about reducing and stopping psychiatric medicines. You can select as many questions as you like to start.

Once you have selected your most important questions and clicked the arrow at the bottom of the screen, you will then be asked to review those questions and choose up to 10 questions that you think are the most important.

What are the barriers and enablers to reducing and stopping psychiatric medicines? These may include, but are not limited to, the service user, the healthcare professional, family, and society.

What would make for an effective public health campaign about the potential risks associated with the use of psychiatric medicines, and the potential for challenges when reducing and stopping? These may include withdrawal symptoms and protracted withdrawal syndromes.

What are the views and experiences of service users, family members/carers, and healthcare professionals around shared decision making in relation to starting and stopping psychiatric medicines? This includes informed consent. How can the process of implementing shared decision-making be improved when starting and stopping psychiatric medicines? What factors influence this process?

Is there a relationship between reducing and stopping psychiatric medicines and suicide/ suicidal ideation? If so, how best can this relationship be explained in terms of causation and prevalence?

What are the most effective ways to provide support to individuals who are reducing and stopping psychiatric medicines? These may include, but are not limited to, family/peer support, educational support, financial support, psychological support, and healthcare support.

What are the views and experiences of individuals who have reduced/stopped psychiatric medicines or are currently reducing/stopping psychiatric medicines on the tapering process and accessing tapering support?

Page 6: Part 2 asks the respondent to choose the Top 10 questions from their pre-selected list of questions. The respondents can move forwards and backwards between Part 1 and Part 2.

Part 2: Choose your Top 10 questions about reducing and stopping psychiatric medicines

Please select **up to 10 questions** you think are the most important. If you want to change the questions you have selected, you can return to the previous page by clicking the backwards arrow.

What are the barriers and enablers to reducing and stopping psychiatric medicines? These may include, but are not limited to, the service user, the healthcare professional, family, and society.

What would make for an effective public health campaign about the potential risks associated with the use of psychiatric medicines, and the potential for challenges when reducing and stopping? These may include withdrawal symptoms and protracted withdrawal syndromes.

What are the views and experiences of service users, family members/carers, and healthcare professionals around shared decision making in relation to starting and stopping psychiatric medicines? This includes informed consent. How can the process of implementing shared decision-making be improved when starting and stopping psychiatric medicines? What factors influence this process?

Is there a relationship between reducing and stopping psychiatric medicines and suicide/ suicidal ideation? If so, how best can this relationship be explained in terms of causation and prevalence?

What are the most effective ways to provide support to individuals who are reducing and stopping psychiatric medicines? These may include, but are not limited to, family/peer support, educational support, financial support, psychological support, and healthcare support.

Page 7: This page asks the respondent to provide demographic information: gender, age, and country of residence.

Demographics

The three questions below ask you to share a few details about yourself. This is to make sure that we gather responses from a wide range of people with different experiences and from different countries.

1. What do you identify as?

- Man
- Woman
- Non-binary
- If none of the above options describe you, please self-describe:

2. How old are you?

- 18-24 years
- 25-34 years
- 35-44 years
- 45-54 years
- 55-64 years
- 65-74 years
- 75-84 years
- 85+ years

3. Which country do you live in?

Page 8: This is the last page of the survey. Respondents are invited to express interest in participating in the final prioritisation workshop by emailing the research team. Respondents are directed to the study website for further information on the study.

Thank you for taking part in this survey.

Please remember that any decisions about starting or stopping a medicine should always be discussed with a qualified healthcare professional.

Next stage

The final stage of the study is a one-day hybrid workshop (online and in-person) that will bring together people with lived experience of taking/stopping psychiatric medicines, family members, friends, carers/supporters, and healthcare professionals to discuss the findings to date and agree on the final Top 10 research questions that will guide future research on reducing/stopping psychiatric medicines.

The workshop will be held on **Wednesday 25th October 2023** in **Trinity College Dublin, Ireland**. The event will likely run from approximately 10am to 4pm BST with breaks.

If you are interested in being involved in this workshop, please email the team at tapersafer@tcd.ie with a few details about yourself including what you would bring to the workshop discussions. We also ask that you specify which stakeholder group you represent (person with lived experience, family member/friend/carer, or healthcare professional) and which country you live in.

Please note that spaces are limited and we may not be able to include all those who express interest in the workshop. However, all study findings will be made publicly available.

For more information about this study, please see: www.tapersafer.org.

Appendix 4.8: Interests and Needs form for workshop participants

The PROTECT Priority Setting Partnership (PSP) Final Consensus Workshop

Declaration of Interests, Statement of Needs and Short Biography

All participants are asked to complete this short form and return the form to bolandm7@tcd.ie by 6th October 2023.

The James Lind Alliance (JLA) will be facilitating the workshop, which will be held in line with the JLA principles of transparency and inclusiveness.

This form helps us to support your full participation in the event and encourages you to consider how you can support the JLA principles. The form asks about the following:

Any needs or wishes for your full participation.

Confirmation of shared goals and values.

Transparency about your interests in the topic.

About you

What is your full name? Please also include any preferred name or pseudonym or pronouns you would prefer to use in the workshop.

Name: Preferred name for workshop, if different: Preferred pronoun:

Please tell us about any special dietary requirements. (e.g., gluten free, vegetarian)

Please tell us about any other needs, for example: access, hearing loops, extra breaks.

A shared vision for the priority setting process

An important JLA principle is to work with people with lived experience, carers and health and care professionals, as equal partners in the process of setting shared priorities for research. Do you agree to participate in support of this principle?

Yes / No (Please delete as appropriate)

If 'no', how do you see yourself working with the PSP?

Transparency

Do you have any competing interests (e.g., current research) that could be seen to influence your participation and which you feel we should be aware of?

Yes / No (Please delete as appropriate)

If 'yes', please describe how you will manage this.

Have, or do, you publicly declare any strong opinions about the topic of the workshop?

Yes /No (Please delete as appropriate)

If 'yes', please explain.

Please provide a short biography (up to 100 words) describing your interest in/experience in this area. We would like to share all participant biographies, so please only include information you are happy to share with others at the workshop.

We will be taking photographs at the workshop as a record of the day. Do you agree to your photograph being taken at the workshop and the photos being used in print and online publications by the PSP, and by the James Lind Alliance, for the purposes of publicising this research priorities project? If you do not wish your photo to be taken and used, we will make sure we exclude you from any photos on the day.

Yes / No (Please delete as appropriate)

We will be publishing the results of this workshop. It will not be possible to identify any individuals from any information that will be published. Are you happy for us to publish the information collected at this workshop?

Yes / No (Please delete as appropriate)

Publication guidelines permitting, would you like to be included as a named member of the project in any future reports or publications that arise from this workshop?

Yes / No (Please delete as appropriate)

If 'yes', what name do you wish us to use?

Please return your completed form by 6th October by email to **bolandm7@tcd.ie**

Privacy Notice

The information you provide on this form will be used by the PROTECT PSP to ensure that on the day of the workshop, we provide for your requirements, ensure you understand the need for shared goals and values of the day and identify any potential competing interests.

The information you provide will be used by the PSP for the purposes of managing the workshop. Your preferred name and the biography will be shared with everyone attending the workshop. We will not share any of this information with other organisations or individuals without your further written consent.

We will hold the personal data you provided us with until three years after completion of the PhD. We do not use profiling or automated decision-making processes.

If you have any queries, please contact the PROTECT PSP Lead, via email at bolandm7@tcd.ie

Appendix 4.9: List of shortlisted questions shared with workshop participants

The PROTECT Priority Setting Workshop 25th October 2023

Pre-workshop homework: your ranking of the questions

This is a list of 19 questions for future research on reducing/stopping psychiatric medicines. They have come from a survey we carried out with people with lived experience of taking and/or stopping psychiatric medicines, family members, carers, and supporters, and healthcare professionals. The questions have been checked against current evidence to make sure they have not already been fully answered by research.

Please spend some time before the workshop reading this list of questions. We would like you to rank them from 1– 19, 1 being the most important in your opinion and 19 being the least important for research to answer.

If you find it too difficult to rank all the questions, please choose the 3 questions that are the most important to you, and 3 questions that are the least important to you. Please do still read all the questions as we will be discussing them together at the workshop.

Make a note of any comments in the right-hand column. **Please have this with you when you join the workshop**. You are not asked to send it in. Everyone will share and discuss their choices in small groups in the workshop.

Ref	Question	Your rank	Notes
A	What is the most effective way to safely reduce and stop psychiatric medicines in terms of tapering approach, rate of taper and duration of taper? What individual service user characteristics (e.g., age, gender, pregnancy, other medical conditions/diseases) and drug		

	characteristics (e.g., medication type, duration of treatment, use of other medication) determine these?		
B	What are the best ways to educate current and future healthcare professionals about reducing and stopping psychiatric medicines in terms of the tapering process, associated risks/difficulties, withdrawal symptoms, and supporting shared decision making? What is the impact of education on clinical practice?		
C	What are the most effective ways to provide support to individuals who are reducing and stopping psychiatric medicines? These may include, but are not limited to, family/peer support, educational support, financial support, psychological support, and healthcare support.		
D	What are the positive and negative long-term consequences of reducing and stopping psychiatric medicines on an individual's physical and mental health status? For individuals who experience negative consequences, what are the best ways to manage these difficulties? Negative consequences may include withdrawal symptoms, relapse, and protracted withdrawal syndromes.		
E	What would make for an effective public health campaign about the potential risks associated with the use of psychiatric medicines, and the potential for challenges when reducing and stopping? These may include withdrawal symptoms and protracted withdrawal syndromes.		
F	To what extent do healthcare professionals report and document the adverse effects associated with the use of psychiatric medicines and/or the difficulties associated with reducing and stopping psychiatric medicines? How does this align with reports from service users, family members and carers?		

G	What are the views and experiences of individuals who have reduced/stopped psychiatric medicines or are currently reducing/stopping psychiatric medicines on the tapering process and accessing tapering support?		
H	How can the availability of psychiatric medicines in formulations that facilitate the process of reducing and stopping psychiatric medicines be improved? These include tapering strips and liquid formulations.		
I	How best can the withdrawal symptoms that appear during or after reducing and stopping psychiatric medicines be identified and differentiated from other causes (e.g., relapse/return of underlying condition, distress)?		
J	What are the perspectives of key stakeholders on the professional, ethical, and legal responsibilities of healthcare professionals and/or the pharmaceutical industry in relation to reducing and stopping psychiatric medicines? Stakeholders include service users, family members/carers and healthcare professionals. What are the best ways to enact these responsibilities?		
K	Is there a relationship between reducing and stopping psychiatric medicines and suicide/ suicidal ideation? If so, how best can this relationship be explained in terms of causation and prevalence?		
L	What are the views and experiences of service users, family members/carers, and healthcare professionals around shared decision making in relation to starting and stopping psychiatric medicines? This includes informed consent. How can the process of implementing shared decision-making be improved when starting and stopping psychiatric medicines? What factors influence this process?		
M	What are the barriers and enablers to reducing and stopping psychiatric medicines? These may include, but are not limited to, the service user, the healthcare professional, family, and society.		

N	What factors influence a service user's decision to reduce and stop psychiatric medicines? These may include patient factors, social factors, and health system factors.		
O	Which factors influence the prevalence, duration and severity of withdrawal effects that appear during or after reducing and stopping psychiatric medicines? What is the best way to control these factors and reduce an individual's risk of developing withdrawal effects or relapsing?		
P	What effects does the tapering process (tapering approach, rate, and duration of taper) and associated outcomes (i.e., withdrawal symptoms, protracted withdrawal syndrome, quality of life) have on the individual's health status and underlying neurobiology?		
Q	How best can the future health of individuals who have stopped psychiatric medicines and have current/previous experience of protracted withdrawal syndromes be managed and protected? This may include, but are not limited to, the use of similar drugs or class of drug during future medical encounters		
R	Is there an optimum duration of use of psychiatric medicines after which reducing and stopping should be initiated that minimises the potential of physical dependency and/or relapse? Does this differ depending on the class/ type of medication?		
S	What is the rate/likelihood of recovery from withdrawal effects after reducing and stopping psychiatric medicines? Which factors influence/predict an individual's recovery outcomes?		

Appendix 4.10: Letter of ethical approval for the PSP study

Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Ms. Miriam Boland
The School of Pharmacy & Pharmaceutical Sciences,
Panoz Institute,
Trinity College Dublin, The University of Dublin
Dublin 2, Ireland
D02PN40

3rd August 2022

Ref: 220509
Title of Study: Psychotropic tapering: Identifying key uncertainties using a James Lind Alliance (JLA) Priority Setting Partnership (PSP)

Dear Miriam,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in August 2022. 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,

Jacintha O'Sullivan

Prof. Jacintha O'Sullivan
Chairperson
Faculty Research Ethics Committee

Dámh na nEolaíochtaí Sláinte
Foirgneamh na Ceimice,
Coláiste na Tríonóide,
Ollscoil Átha Cliath,
Baile Átha Cliath 2, Éire.

Faculty of Health Sciences
Chemistry Building,
Trinity College Dublin,
The University of Dublin,
Dublin 2, Ireland.

www.healthsciences.tcd.ie

Appendix 5.1: An overview of the changes made to the summary questions

Original question (Circulated to the Steering Group for review)	**Collated feedback from Steering Group (SG) members** (To maintain anonymity, no members are named, instead their stakeholder group may be indicated)	**Was the question retained, refined, or excluded?**
Theme 1: Tapering aids & supports		
1.1 Are pharmacological supports (e.g., medicines, supplements) of any benefit to the tapering process?	SG recommended relocation of the word "supplements" to Q1.4 to avoid confusion.	Updated question: Are pharmacological supports of any benefit to the process of reducing and stopping psychiatric medicines? These include medicines and supplements. [Final question number: 1]
1.2 What are the barriers and enablers to creating psychiatric medicines in taper-friendly formulations (e.g., tapering strips, liquid formulations) that are readily accessible?	Queries were raised as to whether this was unanswered/ an actual research question in light of recognised issues around general availability and reimbursement. The decision was made to retain the question following rephrasing.	Updated question: How can the availability of psychiatric medicines in formulations that facilitate the process of reducing and stopping psychiatric medicines be improved? These include tapering strips and liquid formulations. [Final question number: 2]
1.3 What are the barriers/enablers of providing tapering support (e.g., psychosocial interventions, information/education) to individuals who are tapering psychiatric medicines?	This question was seen as very similar to Q1.2. It was reworded to make it more distinct.	Updated question: What are the most effective ways to provide support to individuals who are reducing and stopping psychiatric medicines? These may include, but are not limited to, family/peer support,

		educational support, financial support, psychological support, and healthcare support. [Final question number: 3]
1.4 What services are currently available that provide support to individuals who are tapering and/or are experiencing withdrawal symptoms (e.g., specialist services, psychiatric services)? How can the availability/accessibility of such services be improved?	Queries were raised as to whether this was an actual research question or a general enquiry. The examples in the brackets were removed to avoid leading.	Merged with Q1.3.
1.5 What are the barriers and enablers to developing services that provide support to individuals who are tapering psychiatric medicines (e.g., specialist services, psychiatric services)?	This question was found to be very similar to Q1.4	Merged with Q1.3
1.6 Are there any non-pharmacological supports (e.g., psychosocial interventions such as group therapy, counselling and peer support, lifestyle approaches, nutritional changes) that aid the tapering process and lessen the withdrawal symptoms. If so, which are the best and who is best placed to deliver (e.g., family members, friends, carers, healthcare professionals, etc.)?	This was regarded as an important question because it shifted the focus to alternative supports outside the psychiatry/medical model systems.	Updated question: Are there any non-pharmacological supports that aid the process of reducing and stopping psychiatric medicines and reduce the withdrawal symptoms? If so, which are the best supports and who is best placed to deliver them? These may include, but are not limited to, family members, friends/peers, and healthcare professionals. [Final question number: 4]

1.7 What is the best format (e.g., online, print, in-person event) to provide education/information (e.g., tapering guidance and processes, tapering supports, tapering outcomes) to healthcare professionals and individuals on tapering psychiatric medicines?	SG liked that this question was targeted at healthcare professionals and service users. Suggestions were made to revise the language and clearly define the outcomes.	Updated question: Which educational interventions aimed at service users and healthcare professionals would improve outcomes for people reducing and stopping psychiatric medicines? How best can these interventions be delivered? [Final question number: 5]
1.8 What are the views and experiences of individuals who have tapered/are tapering psychiatric medicines on accessing tapering support?	SG liked this question and were in favour of retaining it.	Updated question: What are the views and experiences of individuals who have reduced/stopped psychiatric medicines or are currently reducing/stopping psychiatric medicines on the tapering process and accessing tapering support? [Final question number: 6]
Theme 2: Tapering process		
2.1 What are the barriers and enablers to tapering psychiatric medicines (e.g., service user, healthcare professional, family, societal)?	Suggestions were made to remove examples as the inclusion of such may risk forgetting other examples and may lead the respondents.	Updated question: What are the barriers and enablers to reducing and stopping psychiatric medicines? These may include, but are not limited to, the service user, the healthcare professional, family, and society. [Final question number: 7]
2.2 What guidelines/instructions on how to taper psychiatric medicines (e.g., Ashton Manual, NICE guidelines) are currently available for service users and healthcare professionals? What are the	The term “barriers and enablers” was removed as it is covered by Q2.1 Several members made the point that despite the availability of several guidelines,	Updated question: What is the quality of available guidelines/instructions on how to reduce and stop psychiatric medicines for service users and healthcare professionals? What is the best way to implement

barriers and enablers to the development and implementation of guidelines?	the quality of these guidelines is debatable. This point was incorporated into the revised question.	guidelines that are developed from high-quality evidence? [Final question number: 8]
2.3 What is the optimum approach to tapering psychiatric medicines in terms of taper rate and duration?	There was consensus to merge questions asking how to taper the individual classes of psychiatric medicines into one overarching question (Q2.3 to Q2.9). The question was reframed to focus on three major concepts (1) rate of taper; (2) pattern of taper; and (3) characteristics that determine these.	Updated question: What is the most effective way to safely reduce and stop psychiatric medicines in terms of tapering approach, rate of taper and duration of taper? What individual service user characteristics (e.g., age, gender, pregnancy, other medical conditions/diseases) and drug characteristics (e.g., medication type, duration of treatment, use of other medication) determine these? [Final question number: 9]
2.4 What is the optimum approach to tapering **antidepressants** in terms of taper rate and duration?	See comment above	Merged with Q2.3
2.5 What is the optimum approach to tapering **antipsychotics** in terms of taper rate and duration?	See comment above	Merged with Q2.3
2.6 What is the optimum approach to tapering **benzodiazepines receptor agonists** in terms of taper rate and duration?	See comment above	Merged with Q2.3

2.7 What is the optimum approach to tapering **gabapentinoids** in terms of taper rate and duration?	See comment above	Merged with Q2.3
2.8 What is the optimum approach to tapering **mood stabilisers** in terms of taper rate and duration?	See comment above	Merged with Q2.3
2.9 Is there an optimum tapering approach for individuals from specific population subgroups (e.g., psychiatric polypharmacy, previously relapsed or are at high risk of relapsing, extremes of age, pregnancy, acute psychosis, perimenopause)?	See comment above	Merged with Q2.3
2.10 How should an individual's response be monitored when tapering psychiatric medicines (e.g., symptoms, blood tests)?	SG had mixed opinions on inclusion/exclusion of this question. Final decision was to retain this question.	Updated question: What is the most effective way for clinicians and/or service users to monitor the outcomes of reducing and stopping psychiatric medicines? How should the tapering process be adjusted if withdrawal symptoms arise? [Final question number: 10]
2.11 What is the best way to determine if a psychiatric medicine should be restarted during an unsuccessful/ difficult taper?	The use of the word "unsuccessful" was discouraged as it implies failure. This question was regarded as vague and was merged with a previous question.	Merged with Q2.10
2.12 What is the optimum approach to cross-tapering (i.e., stopping one	Cross-tapering involves switching of medicines as opposed to	Merged with Q2.3

psychiatric medicine and replacing it with another) psychiatric medicines in terms of taper rate and duration?	reducing/stopping. This question was not deemed in scope.	
2.13 What is the optimum approach for making dose alterations when tapering psychiatric medicines (e.g., crushing/splitting/dissolving tablets)?	SG regarded this as an important question.	Updated question: Can existing psychiatric medicines be accurately altered or modified to achieve the doses required to taper? If so, what are the most effective ways to do so? These may include crushing, splitting and/or dissolving tablets. [Final question number: 11]
2.14 Is there an optimum timepoint to start tapering psychiatric medicines?	The word "timepoint" created confusion. Members suggested "duration of use" in its place. Concerns were raised with this question as the optimum duration will vary depending on the different medicines. A sub question was added to address these concerns.	Updated question: Is there an optimum duration of use of psychiatric medicines after which reducing and stopping should be initiated that minimises the potential of physical dependency and/or relapse? Does this differ depending on the class/ type of medication? [Final question number: 12]
2.15 Which factors, if any, influence the success/failure of tapering psychiatric medicines (e.g., service user factors, medication factors)?	SG suggested that the rewording of this question; "success/failure" was replaced with "difficulty/ease".	Updated question: Which factors influence the difficulty/ease of reducing and stopping psychiatric medicines? These may include, but are not limited to, service user factors, medication factors, and prescriber or health system factors. [Final question number: 13]
2.16 What are the views and experiences of individuals who have tapered/are	SG regarded this as an important question, worthy of inclusion.	Merged with Q1.8

tapering psychiatric medicines on the tapering process?		
2.17 What impacts, if any, does tapering psychiatric medicines have on the individual's health (e.g., physical, and mental health) and underlying neurobiology (e.g., nervous system)?	The examples were deemed unnecessary by the SG. The impact of tapering is not specific, i.e., is the question referring to the effect of the withdrawal process from the drug or the effect of being off the drug? The question was amended appropriately.	Updated question: What effects does the tapering process (tapering approach, rate, and duration of taper) and associated outcomes (i.e., withdrawal symptoms, protracted withdrawal syndrome, quality of life) have on the individual's health status and underlying neurobiology? [Final question number: 14]
Theme 3: Post-taper		
3.1 What is the best way to determine the likeliness of recovery after reducing/stopping psychiatric medicines? Which factors influence an individual's chance of recovering?	SG raised the query as to whether a definition of recovery should be included in the question or whether there was a better term that has fewer possible interpretations. Suggestions included "healing", "return to normal function", and "recovery from withdrawal effects". The question was updated accordingly.	Updated question: What is the rate/likelihood of recovery from withdrawal effects after reducing and stopping psychiatric medicines? Which factors influence/predict an individual's recovery outcomes? [Final question number: 15]
3.2 What are the positive and negative long term-consequences of reducing/stopping psychiatric medicines on an individual's physical and mental health status?	SG regarded this as an important question. Lots of research conducted on short-term consequences of tapering, e.g., relapse. Few studies have looked at the long-term consequences.	Updated question: What are the positive and negative long-term consequences of reducing and stopping psychiatric medicines on an individual's physical and mental health status? For individuals who experience negative consequences, what are the best ways to manage these difficulties? Negative

		consequences may include withdrawal symptoms, relapse, and protracted withdrawal syndromes. [Final question number: 16]
3.3 What are the most effective ways to manage the negative outcomes that appear during/after reducing/stopping psychiatric medicines (e.g., withdrawal symptoms, relapse)?	The previous wording may imply that negative outcomes are inevitable upon tapering. The wording was revised and merged with a previous question.	Merged with 3.2
3.4 How best can rebound psychosis that appears after tapering psychiatric medicines be explained in terms of causation and duration?	This question was regarded as too specific. Given that it is one of the negative outcomes that can appear upon tapering, it was merged with a previous question.	Merged with 3.2
3.5 What is the best way to determine if a psychiatric medicine should be restarted after completing a taper? Is there an optimum way to restart a psychiatric medicine? What impacts, if any, does restarting a psychiatric medicine have (i.e., on the individual and the effectiveness of the medicine)?	This question did not ask a question about tapering. It was merged with a previous question.	Merged with Q3.2
3.6 How best can relapse (i.e., return of the underlying mental health issue) during/after reducing and stopping psychiatric medicines be explained in	SG regarded this as an important question. While studies have been conducted on relapse, few have looked at the factors impacting relapse.	No changes [Final question number: 17]

terms of causation, prevalence, and duration? Which factors impact an individual's risk of relapsing?		
3.7 How best can future surgical procedures be managed in individuals who have previously stopped benzodiazepines?	While the SG thought this was an interesting question, concerns were raised that it was too specific. The question was amended appropriately.	Updated question: How best can the future health of individuals who have stopped psychiatric medicines and have current/previous experience of protracted withdrawal syndromes be managed and protected? This may include, but are not limited to, the use of similar drugs or class of drug during future medical encounters. [Final question number: 18]
Theme 4: Withdrawal symptoms & adverse effects		
4.1 Which factors influence the prevalence, duration and severity of withdrawal symptoms and adverse effects during/after reducing/stopping psychiatric medicines (e.g., service user factors, medication factors)?	SG made suggestions to replace the terms "withdrawal symptoms and adverse effects" with "withdrawal effects" to avoid confusion.	Updated question: Which factors influence the prevalence, duration and severity of withdrawal effects that appear during or after reducing and stopping psychiatric medicines? What is the best way to control these factors and reduce an individual's risk of developing withdrawal effects or relapsing? [Final question number: 19]
4.2 Are there any ways to reduce an individual's risk of developing withdrawal symptoms or relapsing upon	This question was seen as a sub question of Q4.1 so they were merged.	Merged with Q4.1

tapering psychiatric medicines? If so, what are they?		
4.3 How best can the withdrawal symptoms and adverse effects that appear during/after reducing/stopping psychiatric medicines be explained in terms of type, causation, prevalence, severity, and duration?	Queries were raised as to whether this question was referring to general withdrawal effects or specifically protracted withdrawal. The question was reworded as per Q4.1. Protracted withdrawal falls under "withdrawal effects".	Updated question: How best can the withdrawal effects that appear during or after reducing and stopping psychiatric medicines be explained in terms of type, causation, prevalence, severity, and duration? [Final question number: 20]
4.4 What are the potential benefits and dangers to reducing/stopping psychiatric medicines?	SG suggested to replace the word "dangers" with "risks".	Updated question: What are the potential benefits and risks of reducing and stopping psychiatric medicines for the different stakeholders? These include service users, family members/carers and healthcare professionals. [Final question number: 21]
4.5 Is there a relationship between reducing and stopping psychiatric medicines and suicide/ suicidal ideation? If so, how best can this relationship be explained in terms of causation and prevalence?	SG queried as to whether this question had already been covered by Q4.3. However, it was important to evaluate how common suicidal ideation and complete suicide is in withdrawal. The decision was made to retain this question.	No changes [Final question number: 22]
4.6 Does something equivalent to BIND occur during/after tapering all psychiatric medicines?	SG queried whether BIND (Benzodiazepine-Induced Neurological Dysfunction) was in scope. BIND is more to do with the effects of the drugs as opposed to tapering. There was consensus to exclude this question.	Exclude

4.7 What impacts do the withdrawal symptoms that appear during/after tapering psychiatric medicines have on an individual's health (e.g., physical, mental) and underlying neurobiology (e.g., nervous system)?	Given the overlap with Q2.17, these questions were merged.	Merged with Q2.17
4.8 What are the most effective ways to manage withdrawal symptoms that appear during/after reducing/stopping psychiatric medicines (e.g., medicines, coping tools/strategies)?	Suggestions were made to merge this question with Q3.3 given the overlap between the two questions.	Merged with Q3.3
4.9 How best can the withdrawal symptoms that appear during/after tapering psychiatric medicines be identified and differentiated from other causes (e.g., relapse, distress)?	SG regarded this as an important question.	Updated question: How best can the withdrawal symptoms that appear during or after reducing and stopping psychiatric medicines be identified and differentiated from other causes (e.g., relapse/return of underlying condition, distress)? [Final question number: 23]
Theme 5: Accountability		
5.1 What are the legal, ethical, and professional responsibilities of **healthcare professionals** in relation to reducing/stopping psychiatric medicines? What are the best ways to enact these responsibilities?	Queries were raised as to whether this was a research question or a legal query.	Updated question: What are the perspectives of key stakeholders on the professional, ethical and legal responsibilities of **healthcare professionals and/or the pharmaceutical industry** in relation to reducing and stopping psychiatric medicines? Stakeholders

		include service users, family members/carers and healthcare professionals. What are the best ways to enact these responsibilities? [Final question number: 24]
5.2 What are the legal and ethical responsibilities of the **pharmaceutical industry** in relation to reducing/stopping psychiatric medicines? What are the best ways to enact these responsibilities?	Queries were raised as to whether this was a research question or a legal query. Suggestion was made to merge Q5.2 with Q5.1 and create one broader question.	Merged with Q5.1
5.3 How can the process of service users providing informed consent relating to starting/stopping psychiatric medicines be improved?	Informed consent was regarded by some members as signing document for legal reason. Suggestions were made to reframe this question as shared decision making which is an ongoing process. This was incorporated into the updated question.	Updated question: What are the views and experiences of service users, family members/carers, and healthcare professionals around shared decision making in relation to starting and stopping psychiatric medicines? This includes informed consent. How can the process of implementing shared decision-making be improved when starting and stopping psychiatric medicines? What factors influence this process? [Final question number: 25]
5.4 How best can service users who have been harmed by psychiatric medicines be compensated?	Queries were raised as to whether this was a research question or a general enquiry/legal query.	Exclude

5.5 What are the best ways for an individual to take legal action against prescribers who have caused harm by prescribing or discontinuing psychiatric medicines?	Queries were raised as to whether Q's 5.5 to 5.8 were research questions and in scope. These questions are asking about the legal ramifications of prescribing/stopping as opposed to tapering itself.	Exclude
5.6 What are the barriers to taking legal action against the prescribers of psychiatric medicines?	See comments above	Exclude
5.7 What are the best ways to take legal action against the pharmaceutical companies for the damage done to patients as a result of taking and/ or stopping psychiatric medicines?	See comments above	Exclude
5.8 How best can healthcare professionals be prepared for and navigate any legal action taken against them in relation to psychiatric medicines?	See comments above	Exclude
Theme 6: Acknowledgement/recognition of issues		
6.1 Why do many service users report that healthcare professionals under-recognise/do not acknowledge the adverse effects associated with the use of psychiatric medicines and/or the	SG raised concerns over the wording. Some members felt that was assumptive. Suggestions were made to merge with Q6.2 or reframe the question to look at why	Updated question: To what extent do healthcare professionals report and document the adverse effects associated with the use of psychiatric medicines and/or the difficulties associated with

difficulties associated with reducing/stopping psychiatric medicines? How can this be improved?	healthcare professionals are not more focused on adverse effects.	reducing and stopping psychiatric medicines? How does this align with reports from service users, family members and carers? [Final question number: 26]
6.2 What are the views/attitudes held by healthcare professionals towards reducing/stopping psychiatric medicines? Which factors impact these attitudes?	SG suggested that withdrawal effects be specified within the question.	Updated question: What are the views/attitudes held by healthcare professionals towards the withdrawal effects that appear during or after reducing and stopping psychiatric medicines? Which factors impact these attitudes? [Final question number: 27]
6.3 What are the best ways to raise public awareness and promote open discussion of the challenges (e.g., withdrawal symptoms) associated with reducing/stopping psychiatric medicines?	One query was raised as to whether this was a research question. Suggestions were made to reframe the question as to what would make for an effective public health campaign.	Updated question: What would make for an effective public health campaign about the potential risks associated with the use of psychiatric medicines, and the potential for challenges when reducing and stopping? These may include withdrawal symptoms and protracted withdrawal syndromes. [Final question number: 28]
6.4 What is the best way to obtain informed consent from the service user prior to initiating psychiatric medicines? What are the barriers and enablers to obtaining informed consent?	Suggestions were made to include shared decision making in the question.	Merged with Q5.3
Theme 7: Communication & decision making		

7.1 What are the views and experiences of individuals who have tapered/are currently tapering on discussing psychiatric medicines with healthcare professionals and engaging in shared decision making?	Several of the questions in Theme 7 were found to be very similar. Suggestions were made to merge multiple questions into one overarching question.	Merged with Q5.3
7.2 What is the optimum approach to informing service users about the potential risks associated with the use and discontinuation of psychiatric medicines to allow them to make informed decisions? What are the barriers and enablers to implementing?	SG suggested that this question was reworded, replacing the word "optimum" with "best".	Updated question: What is the best approach to discussing the potential risks associated with taking, reducing, and stopping psychiatric medicines? What are the barriers and enablers to implementing? [Final question number: 29]
7.3 What is the best way to initiate a conversation about reducing/stopping psychiatric medicines between an individual and a healthcare professional?	SG regarded this as an important question.	Updated question: What is the best way for healthcare professionals to inform service users about the process of reducing and stopping psychiatric medicines, and the potential for associated challenges? What impact does this have on the service user's treatment decisions and outcomes? [Final question number: 30]
7.4 What are the impacts of informing service users about the difficulties of tapering at the point of prescribing on	SG identified overlap with this question and a previous question. The decision was made to merge questions.	Merged with Q7.3

their treatment decisions and outcomes?		
7.5 What is the best way to identify the optimal time to start tapering psychiatric medicines be identified?	SG identified overlap with this question and a previous question. The decision was made to merge questions.	Merged with Q2.14
7.6 What factors influence a service user's decision to stop/reduce their psychiatric medicines?	SG suggested that the types of factors at play be specified in the question. The question was amended appropriately.	Updated question: What factors influence a service user's decision to reduce and stop psychiatric medicines? These may include patient factors, social factors, and health system factors. [Final question number: 31]
Theme 8: Healthcare professional knowledge & education		
8.1 What are the best ways to educate healthcare professionals (student and qualified) about reducing/stopping psychiatric medicines (e.g., the tapering process, associated risks/difficulties, withdrawal symptoms, shared decision making)? What are the barriers and enablers to educating healthcare professionals?	Despite overlap in this question with questions in other themes, SG felt that the question was worthy of inclusion. The decision was made to retain the question.	Updated question: What are the best ways to educate current and future healthcare professionals about reducing and stopping psychiatric medicines in terms of the tapering process, associated risks/difficulties, withdrawal symptoms, and supporting shared decision making? What is the impact of education on clinical practice? [Final question number: 32]

Appendix 5.2: The 32 summary questions taken forward to the evidence checking step

Final Q number in survey	Final question
Theme 1	
Q1	Are pharmacological supports of any benefit to the process of reducing and stopping psychiatric medicines? These include medicines and supplements.
Q2	How can the availability of psychiatric medicines in formulations that facilitate the process of reducing and stopping psychiatric medicines be improved? These include tapering strips and liquid formulations.
Q3	What are the most effective ways to provide support to individuals who are reducing and stopping psychiatric medicines? These may include, but are not limited to, family/peer support, educational support, financial support, psychological support, and healthcare support.
Q4	Are there any non-pharmacological supports that aid the process of reducing and stopping psychiatric medicines and reduce the withdrawal symptoms? If so, which are the best supports and who is best placed to deliver them? These may include, but are not limited to, family members, friends/peers, and healthcare professionals.
Q5	Which educational interventions aimed at service users and healthcare professionals would improve outcomes for people reducing and stopping psychiatric medicines? How best can these interventions be delivered?
Q6	What are the views and experiences of individuals who have reduced/stopped psychiatric medicines or are currently reducing/stopping psychiatric medicines on the tapering process and accessing tapering support?
Theme 2	
Q7	What are the barriers and enablers to reducing and stopping psychiatric medicines? These may include, but are not limited to, the service user, the healthcare professional, family, and society.
Q8	What is the quality of available guidelines/instructions on how to reduce and stop psychiatric medicines for service users and healthcare

	professionals? What is the best way to implement guidelines that are developed from high-quality evidence?
Q9	What is the most effective way to safely reduce and stop psychiatric medicines in terms of tapering approach, rate of taper and duration of taper? What individual service user characteristics (e.g., age, gender, pregnancy, other medical conditions/diseases) and drug characteristics (e.g., medication type, duration of treatment, use of other medication) determine these?
Q10	What is the most effective way for clinicians and/or service users to monitor the outcomes of reducing and stopping psychiatric medicines? How should the tapering process be adjusted if withdrawal symptoms arise?
Q11	Can existing psychiatric medicines be accurately altered or modified to achieve the doses required to taper? If so, what are the most effective ways to do so? These may include crushing, splitting and/or dissolving tablets.
Q12	Is there an optimum duration of use of psychiatric medicines after which reducing and stopping should be initiated that minimises the potential of physical dependency and/or relapse? Does this differ depending on the class/ type of medication?
Q13	Which factors influence the difficulty/ease of reducing and stopping psychiatric medicines? These may include, but are not limited to, service user factors, medication factors, and prescriber or health system factors.
Q14	What effects does the tapering process (tapering approach, rate, and duration of taper) and associated outcomes (i.e., withdrawal symptoms, protracted withdrawal syndrome, quality of life) have on the individual's health status and underlying neurobiology?
Theme 3	
Q15	What is the rate/likelihood of recovery from withdrawal effects after reducing and stopping psychiatric medicines? Which factors influence/predict an individual's recovery outcomes?
Q16	What are the positive and negative long-term consequences of reducing and stopping psychiatric medicines on an individual's physical and mental health status? For individuals who experience negative consequences, what are the best ways to manage these difficulties? Negative

	consequences may include withdrawal symptoms, relapse, and protracted withdrawal syndromes.
Q17	How best can relapse (i.e., return of the underlying mental health issue) during/after reducing and stopping psychiatric medicines be explained in terms of causation, prevalence, and duration? Which factors impact an individual's risk of relapsing?
Q18	How best can the future health of individuals who have stopped psychiatric medicines and have current/previous experience of protracted withdrawal syndromes be managed and protected? This may include, but are not limited to, the use of similar drugs or class of drug during future medical encounters
Theme 4	
Q19	Which factors influence the prevalence, duration and severity of withdrawal effects that appear during or after reducing and stopping psychiatric medicines? What is the best way to control these factors and reduce an individual's risk of developing withdrawal effects or relapsing?
Q20	How best can the withdrawal effects that appear during or after reducing and stopping psychiatric medicines be explained in terms of type, causation, prevalence, severity, and duration?
Q21	What are the potential benefits and risks of reducing and stopping psychiatric medicines for the different stakeholders? These include service users, family members/carers and healthcare professionals.
Q22	Is there a relationship between reducing and stopping psychiatric medicines and suicide/ suicidal ideation? If so, how best can this relationship be explained in terms of causation and prevalence?
Q23	How best can the withdrawal symptoms that appear during or after reducing and stopping psychiatric medicines be identified and differentiated from other causes (e.g., relapse/return of underlying condition, distress)?
Theme 5	
Q24	What are the perspectives of key stakeholders on the professional, ethical, and legal responsibilities of healthcare professionals and/or the pharmaceutical industry in relation to reducing and stopping psychiatric medicines? Stakeholders include service users, family members/carers and healthcare professionals. What are the best ways to enact these responsibilities?

Q25	What are the views and experiences of service users, family members/carers, and healthcare professionals around shared decision making in relation to starting and stopping psychiatric medicines? This includes informed consent. How can the process of implementing shared decision-making be improved when starting and stopping psychiatric medicines? What factors influence this process?
Theme 6	
Q26	To what extent do healthcare professionals report and document the adverse effects associated with the use of psychiatric medicines and/or the difficulties associated with reducing and stopping psychiatric medicines? How does this align with reports from service users, family members and carers?
Q27	What are the views/attitudes held by healthcare professionals towards the withdrawal effects that appear during or after reducing and stopping psychiatric medicines? Which factors impact these attitudes?
Q28	What would make for an effective public health campaign about the potential risks associated with the use of psychiatric medicines, and the potential for challenges when reducing and stopping? These may include withdrawal symptoms and protracted withdrawal syndromes.
Theme 7	
Q29	What is the best approach to discussing the potential risks associated with taking, reducing, and stopping psychiatric medicines? What are the barriers and enablers to implementing?
Q30	What is the best way for healthcare professionals to inform service users about the process of reducing and stopping psychiatric medicines, and the potential for associated challenges? What impact does this have on the service user's treatment decisions and outcomes?
Q31	What factors influence a service user's decision to reduce and stop psychiatric medicines? These may include patient factors, social factors, and health system factors.
Theme 8	
Q32	What are the best ways to educate current and future healthcare professionals about reducing and stopping psychiatric medicines in terms of the tapering process, associated risks/difficulties, withdrawal symptoms, and supporting shared decision making? What is the impact of education on clinical practice?

Appendix 5.3: An overview of the reference lists of peer-reviewed studies reviewed as part of the evidence checking step

Summary Question	**Source of evidence** (Author & year, level of evidence, title, DOI)	**Key author conclusions**	**Was the question answered?**	**Was the question answered by the evidence search?** **Explanation**
Are pharmacological supports of any benefit to the process of reducing and stopping psychiatric medicines? These include medicines and supplements. [Final question number: 1]	**Morera-Fumero 2020;** Systematic review Melatonin and melatonin agonists as treatments for benzodiazepines and hypnotics withdrawal in patients with primary insomnia. A systematic review https://doi.org/10.1016/j.drugalcdep.2020.107994	The review points to the utility of using MLT for the treatment of withdrawal of BZD and/or HYP drugs in patients with primary insomnia.	Partly	The use of pharmacological supports in the process of reducing and stopping psychiatric medicines has only been assessed for a limited number of drug classes and often only in a limited number of studies.
	Artukoglu 2020; Systematic Review Pharmacologic Treatment of Tardive Dyskinesia: A Meta-Analysis and Systematic Review DOI: 10.4088/JCP.19r12798	Data suggests that VMAT2 inhibitors, vitamin E, vitamin B_6, and amantadine may be effective for the treatment of TD. Evidence of publication bias and a significant negative association of dose and duration of treatment with measured efficacy suggest that the benefits of vitamin E in TD may be overstated.		
	Palagini 2021; Systematic review International Expert Opinions and	The administration of prolonged release melatonin at 2–10 mg, 1–2 h before bedtime, might be used in the		

	Recommendations on the Use of Melatonin in the Treatment of Insomnia and Circadian Sleep Disturbances in Adult Neuropsychiatric Disorders DOI: 10.3389/fpsyt.2021.688890	treatment of insomnia symptoms or comorbid insomnia in mood disorders, schizophrenia, in adults with autism spectrum disorders, neurocognitive disorders and during sedative-hypnotics discontinuation.		
	Williams 2022; Systematic Review and meta-analysis Pharmacological treatment for methamphetamine withdrawal: A systematic review and meta-analysis of randomised controlled trials DOI: 10.1111/dar.13511	No medication displayed convincing results for the treatment of methamphetamine withdrawal, however, there is insufficient evidence to conclusively rule out any medication trialled to date due to poor quality evidence.		
	Siefried 2020; Systematic review Pharmacological Treatment of Methamphetamine/ Amphetamine Dependence: A Systematic Review https://doi.org/10.1007/s40263-020-00711-x	No pharmacotherapy yielded convincing results for the treatment of AMPH/MA dependence; mostly studies were underpowered and had low treatment completion rates.		
How can the availability of psychiatric medicines in formulations that facilitate the process of reducing and stopping psychiatric			No	This question has not been addressed by any existing literature.

medicines be improved? These include tapering strips and liquid formulations. [Final question number: 2]	[redacted]			
What are the most effective ways to provide support to individuals who are reducing and stopping psychiatric medicines? These may include, but are not limited to, family/peer support, educational support, financial support, psychological support, and healthcare support. [Final question number: 3]			No	This question has not been addressed by any existing literature.
Are there any non-pharmacological supports that aid the process of reducing and stopping psychiatric medicines	**Dou 2019**; Systematic review Interventions to improve benzodiazepine tapering success in the elderly: a systematic review	Patient education is a successful, time- and cost-effective intervention that can significantly help with benzodiazepine discontinuation success. CBT may also be an effective approach.	Partly	Only a limited number of non-pharmacological supports have been assessed for use in the process of

and reduce the withdrawal symptoms? If so, which are the best supports and who is best placed to deliver them? These may include, but are not limited to, family members, friends/peers, and healthcare professionals. [Final question number: 4]	https://doi.org/10.1080/13607863.2017.1423030			reducing and stopping psychiatric medicines and reduce the withdrawal symptoms, all focused on BZRAs and often only in a limited number of studies.
	Lynch 2020; Systematic review and meta-analysis Brief interventions targeting long-term benzodiazepine and Z-drug use in primary care: a systematic review and meta-analysis DOI:10.1111/add.14981	Brief interventions delivered in primary care are more effective than usual care in reducing and discontinuing long-term benzodiazepine/ Z-drug use.		
	Takaseu 2019; Systematic review and meta-analysis Psychosocial intervention for discontinuing benzodiazepine hypnotics in patients with chronic insomnia: A systematic review and meta-analysis https://doi.org/10.1016/j.smrv.2019.101214	The results indicate the significant effects of CBT-I in discontinuing BZD hypnotics as well as improving insomnia severity over a short-term period.		
	Soni 2021; Systematic review and meta-analysis Feasibility and effectiveness of deprescribing benzodiazepines and Z-drugs: systematic review and meta-analysis DOI: 10.1111/add.15997	It may be feasible to deprescribe benzodiazepines depending on the process and support mechanisms employed.		
	Takeshima 2021; Systematic review and meta-analysis	CBT may be effective for discontinuing BZD anxiolytics, both in the short term		

	Does cognitive behavioral therapy for anxiety disorders assist the discontinuation of benzodiazepines among patients with anxiety disorders? A systematic review and meta-analysis http://onlinelibrary.wiley.com/doi/10.1111/pcn.13195/full	and in the long term after the allocation.		
Which educational interventions aimed at service users and healthcare professionals would improve outcomes for people reducing and stopping psychiatric medicines? How best can these interventions be delivered? [Final question number: 5]	[redacted]		No	This question has not been addressed by any existing literature.
What are the views and experiences of individuals who have reduced/stopped psychiatric medicines or are currently reducing/stopping	**Crowe 2022**; Meta-synthesis Experience of antidepressant use and discontinuation: A qualitative synthesis of the evidence DOI: 10.1111/jpm.12850	Those with lived experience of depression need to be actively involved in decision-making about their treatment and provided with alternatives to the biochemical deficit model, and if they choose to take	Partly	The views and experiences of individuals who have reduced/stopped psychiatric medicines or are currently

psychiatric medicines on the tapering process and accessing tapering support? [Final question number: 6]		antidepressants, they need to be made aware of their limitations.		reducing/stopping psychiatric medicines have only been explored for a limited number of classes of psychiatric medication.
	Keogh 2021; Systematic review Mental health service users experiences of medication discontinuation: a systematic review of qualitative studies https://doi.org/10.1080/09638237.2021.1922644	Service providers need to be aware that for some service user's psychotropic medication is not deemed a suitable treatment approach. Those who wish to discontinue medication need to be supported in the context of positive, therapeutic risk where their mental and physical health can be monitored, and the likelihood of success increased.		
What are the barriers and enablers to reducing and stopping psychiatric medicines? These may include, but are not limited to, the service user, the healthcare professional, family, and society. [Final question number: 7]	**Evrard 2022;** Systematic review Barriers and enablers for deprescribing benzodiazepine receptor agonists in older adults: a systematic review of qualitative and quantitative studies using the theoretical domains framework https://doi.org/10.1186/s13012-022-01206-7	The relevant TDF domains identified can now be linked to behavioural change techniques to help in the design of future strategies and health policies.	Partly	The barriers and enablers to reducing and stopping psychiatric medicines have only been looked at for a limited number of classes of psychiatric medicines.
	Bednarcyzk 2022; Systematic review Stakeholders' views on the use of psychotropic medication in older people: a systematic review https://doi.org/10.1093/ageing/afac060	Psychotropic medicine use in older adults remains a complex issue, which needs to be addressed on a broad level. Attitudes of older people and healthcare professionals encourage long-term use. Meanwhile, various internal and external factors act as		

		barriers to the use of non-drug alternatives in this population.		
	Maund 2018; Systematic review Barriers and facilitators to discontinuing antidepressant use: A systematic review and thematic synthesis https://doi.org/10.1016/j.jad.2018.10.107	Barriers and facilitators to discontinuing antidepressant use are numerous and complex, and likely to require detailed conversations between patients and their general practitioners (GPs). These conversations are more likely to happen if GPs raise the issue of discontinuation.		
	Moth 2021; Systematic review What Makes Deprescription of Psychotropic Drugs in Nursing Home Residents with Dementia so Challenging? A Qualitative Systematic Review of Barriers and Facilitators https://doi.org/10.1007/s40266-021-00875-1	Deprescribing psychotropic drugs used for behavioural and psychological symptoms of dementia in nursing home residents is challenging. Resources need to be in place for deprescribing, as well as there being a focus on the positive patient-related outcomes of doing so. Managerial support, staff routines, and interprofessional collaboration are some factors facilitating the process, in addition to there being routines and systematic procedures in place allowing for operationality and a common understanding.		
	Rasmussen 2021; Systematic review The Barriers and Facilitators of Different Stakeholders When Deprescribing	This review indicated that the deprescribing process is influenced by the attitudes		

	Benzodiazepine Receptor Agonists in Older Patients—A Systematic Review https://doi.org/10.3390/metabo11040254	of different stakeholders i.e., patients, physicians, nurses, and caregivers.		
	Ribeiro 2021; Systematic review Benzodiazepine deprescription strategies in chronic users: a systematic review DOI: 10.1093/fampra/cmab017	Although the comparison of different strategies was impaired by the high risk of bias in some studies, patient education focused interventions presented good results.		
What is the quality of available guidelines/instructions on how to reduce and stop psychiatric medicines for service users and healthcare professionals? What is the best way to implement guidelines that are developed from high-quality evidence? [Final question number: 8]	**Sorensen 2022;** Systematic Review Description of antidepressant withdrawal symptoms in clinical practice guidelines on depression: A systematic review https://doi.org/10.1016/j.jad.2022.08.011	Clinical practice guidelines provide scarce and inadequate information on antidepressant withdrawal symptoms and limited guidance for distinguishing withdrawal symptoms from symptoms of relapse.	No	The only systematic review comprised two linked publication focused on antidepressants. There was limited information within the guidelines on how to reduce and stop psychiatric medicines and manage withdrawal symptoms, and the overall quality of available guidelines was low
	Sorensen 2022; Systematic review Clinical practice guideline recommendations on tapering and discontinuing antidepressants for depression: a systematic review DOI: 10.1177/20451253211067656	Current major clinical practice guidelines provide little support for clinicians wishing to help patients discontinue or taper antidepressants in terms of mitigating and managing withdrawal symptoms. Patients who have deteriorated upon following current guidance on tapering and discontinuing antidepressants thus cannot be concluded to have experienced a relapse. Better guidance requires better randomised		

		trials investigating interventions for discontinuing or tapering antidepressants		
What is the most effective way to safely reduce and stop psychiatric medicines in terms of tapering approach, rate of taper and duration of taper? What individual service user characteristics (e.g., age, gender, pregnancy, other medical conditions/diseases) and drug characteristics (e.g., medication type, duration of treatment, use of other medication) determine these? [Final question number: 9]	**Maund 2019**; Systematic review Managing Antidepressant Discontinuation: A Systematic Review https://doi.org/10.1370/afm.2336	Cognitive behavioural therapy or mindfulness-based cognitive therapy can help patients discontinue antidepressants without increasing the risk of relapse/recurrence but are resource intensive.	Partly	The most effective way to safely reduce and stop psychiatric medicines has only been assessed for a limited number of drug classes (antidepressant and antipsychotics). Reviews to date have either focused on different approaches or drawn different conclusions
	Tani 2020; Systematic review and meta-analysis Factors associated with successful antipsychotic dose reduction in schizophrenia: a systematic review of prospective clinical trials and meta-analysis of randomized controlled trials https://doi.org/10.1038/s41386-019-0573-7	When reducing antipsychotic doses, clinicians should consider the long-term risk of relapse in younger patients with a relatively short illness duration and keep the final doses higher than CPZE 200 mg/day.		
	Takeuchi 2020; Meta-analysis Immediate versus wait-and-gradual discontinuation in antipsychotic switching: A meta-analysis https://doi.org/10.1177/026988112092	Findings suggested that wait-and-gradual antipsychotic discontinuation may be preferable when a more cautious antipsychotic switch is needed.		
	Van Leeuwen 2021; Cochrane review Approaches for discontinuation versus continuation of long-term antidepressant use for depressive and anxiety disorders in adults	The review cannot make any firm conclusions about effects and safety of the approaches studied to date. The true effects and safety are likely to be substantially different from the data presented due to assessment of		

	DOI: 10.1002/14651858.CD013495.pub2.	relapse of depression that is confounded by withdrawal symptoms. All other outcomes are confounded with withdrawal symptoms. Most tapering regimens were limited to four weeks or less. In the studies with rapid tapering schemes the risk of withdrawal symptoms may be similar to studies using abrupt discontinuation which may influence the effectiveness of the interventions. Nearly all data come from people with recurrent depression.		
What is the most effective way for clinicians and/or service users to monitor the outcomes of reducing and stopping psychiatric medicines? How should the tapering process be adjusted if withdrawal symptoms arise? [Final question number: 10]	[redacted]		No	This question has not been addressed by any existing literature.
Can existing psychiatric medicines be accurately altered	**Saran 2022;** Systematic review Concerns regarding tablet splitting: a systematic	With the exception of sustained-release tablets, which should not be split, and excepting those older	Partly	This review did not focus specifically on psychiatric

or modified to achieve the doses required to taper? If so, what are the most effective ways to do so? These may include crushing, splitting and/or dissolving tablets. [Final question number: 11]	review DOI: 10.3399/BJGPO.2022.0001	people who may struggle to split tablets based on physical limitations, there is little evidence to support tablet-splitting concerns.		medicines. No reference was made to crushing and dissolving tablets. The studies involving the splitting of tablets only looked at halving tablets. Tablets were not split any further.
Is there an optimum duration of use of psychiatric medicines after which reducing and stopping should be initiated that minimises the potential of physical dependency and/or relapse? Does this differ depending on the class/ type of medication? [Final question number: 12]	**Arikan 2023**; Systematic review and meta-analysis When to stop medication in unipolar depression: A systematic review and a meta-analysis of randomized controlled trials https://doi.org/10.1016/j.jad.2023.01.024	The results may indicate that long term use of antidepressants may not be justified, and this strategy may expose the patients to more adverse effects.	No	The optimum duration of use of psychiatric medicines after which reducing and stopping should be initiated that minimises the potential of physical dependency and/or relapse was only assessed for one drug class and no definitive answer was obtained.
	Kato 2020; Systematic review and meta-analysis Effects of Discontinuation of Drugs Used for Augmentation Therapy on Treatment Outcomes in Depression: A Systematic Review and Meta-analysis https://doi.org/10.1055/a-1330-8587	No firm conclusions could be drawn in light of the small number of studies included. Currently available evidence suggests that add-on drugs, other than esketamine, used for augmentation therapy for depression may be discontinued. This may not be the case for patients who are maintained with augmentation therapy after remission.		
Which factors influence the			No	This question has not been addressed

difficulty/ease of reducing and stopping psychiatric medicines? These may include, but are not limited to, service user factors, medication factors, and prescriber or health system factors. [Final question number: 13]	[redacted]		by any existing literature.
What effects does the tapering process (tapering approach, rate, and duration of taper) and associated outcomes (i.e., withdrawal symptoms, protracted withdrawal syndrome, quality of life) have on the individual's health status and underlying neurobiology? [Final question number: 14]		No	This question has not been addressed by any existing literature.
What is the rate/likelihood of recovery from withdrawal effects		No	This question has not been addressed by any existing literature.

after reducing and stopping psychiatric medicines? Which factors influence/predict an individual's recovery outcomes? [Final question number: 15]	[redacted]			
What are the positive and negative long-term consequences of reducing and stopping psychiatric medicines on an individual's physical and mental health status? For individuals who experience negative consequences, what are the best ways to manage these difficulties? Negative consequences may include withdrawal symptoms, relapse, and protracted withdrawal syndromes.	**Brandt 2022**; Meta-analysis Adverse events after antipsychotic discontinuation: an individual participant data meta-analysis DOI: 10.1016/S2215-0366(22)00014-1	We detected moderate evidence of emerging somatic adverse events after discontinuation of first-generation and second-generation antipsychotics, particularly after discontinuation of longer durations of treatment. Tapered discontinuation can mitigate the risk of emerging somatic adverse events after antipsychotic discontinuation. These findings have implications for the safety of treatment discontinuation and could be used for tailored treatment planning.	Partly	The positive and negative long-term consequences of reducing and stopping psychiatric medicines on an individual's physical and mental health status have only been looked at for one drug classes. A number of the reviews highlighted a limited body of existing evidence and low-quality evidence. There was a lack of information as to how best to manage the negative consequences.
	Ostuzzi 2022; Systematic review and meta-analysis Continuing, reducing, switching, or stopping antipsychotics in individuals with schizophrenia-spectrum disorders who are clinically stable: a systematic review and network meta-analysis	The review found that continuing antipsychotic treatment at standard doses or switching to a different antipsychotic are similarly effective treatment strategies, whereas reducing antipsychotic doses below standard doses is associated with		

[Final question number: 16]	DOI: 10.1016/S2215-0366(22)00158-4	higher risk of relapse than the other two maintenance treatment strategies and should therefore be limited to selected cases.		
	Miura 2022; Systematic review Clinical Outcomes after Clozapine Discontinuation in Patients with Schizophrenia: A Systematic Review DOI: 10.1055/a-1811-7318	Clinical outcomes generally worsen after clozapine discontinuation. Clozapine rechallenge and olanzapine may be considered following clozapine discontinuation. The outcomes after clozapine discontinuation in clozapine non-responders remain inconclusive.		
	Bighelli 2022; Cochrane review Antipsychotic polypharmacy reduction versus polypharmacy continuation for people with schizophrenia DOI: 10.1002/14651858.CD014383.pub2.	This review summarises the latest evidence on polypharmacy continuation compared with polypharmacy reduction. Our results show that polypharmacy continuation might be associated with a lower number of participants leaving the study early, especially due to inefficacy. However, the evidence is of low and very low certainty and the data analyses based on few study only, so that it is not possible to draw strong conclusions based on the results of the present review.		
	Essaldi 2019; Cochrane review Haloperidol discontinuation for people with schizophrenia	This review provides limited evidence derived from small, short-term studies. The longest study was for one year, making it difficult to generalise		

	DOI: 10.1002/14651858.CD011408.pub2	the results to a life-long disorder. Very low-quality evidence shows that discontinuation of haloperidol is associated with an increased risk of relapse and a reduction in the risk of 'global state improvement'. However, participant satisfaction with haloperidol treatment was not different from participant satisfaction with haloperidol discontinuation as measured by leaving the studies early. Due to the very low quality of these results, firm conclusions cannot be made. In addition, the available studies did not report usable data regarding the adverse effects of haloperidol treatment		
How best can relapse (i.e., return of the underlying mental health issue) during/after reducing and stopping psychiatric medicines be explained in terms of causation, prevalence, and duration? Which factors impact an	**Bayrampour 2020**; Systematic Review and Meta-Analysis The Risk of Relapse of Depression During Pregnancy After Discontinuation of Antidepressants: A Systematic Review and Meta-Analysis DOI: 10.4088/JCP.19r13134	Women with severe or recurrent depression should be informed about the increased risk of relapse following antidepressant discontinuation, and those who discontinue antidepressants should be monitored for relapse.	Partly	Relapse during/after reducing and stopping psychiatric medicines has only been investigated for a limited number of drug classes and in some cases only involving a limited number of studies
	Bogers 2021; Systematic review and meta-analysis	In patients with chronic schizophrenia discontinuing, and to a lesser extent DR till end-dose<5mgHE, patients who		

individual's risk of relapsing? [Final question number: 17]	Risk factors for psychotic relapse in chronic schizophrenia after dose-reduction or discontinuation of antipsychotics. A systematic review and meta-analysis DOI: https://doi.org/10.1192/j.eurpsy.2021.1426	reduce doses abrupt, inpatients, and patients with a short duration of illness carry highest relapse risk. Most relapses occur during the first half year after DR		
	Bogers 2023; Meta-analysis Risk Factors for Psychotic Relapse After Dose Reduction or Discontinuation of Antipsychotics in Patients With Chronic Schizophrenia. A Meta-Analysis of Randomized Controlled Trials DOI: 10.1093/schbul/sbac138	Clinicians should take several risk factors for psychotic relapse into account when considering dose reduction in patients with chronic schizophrenia. Studies of a relatively fast reduction in antipsychotic dose support a minimum dose of 3-5 mg HE. However, if the dose is tapered more gradually, relapses related to medication withdrawal might be avoided, possibly enabling lower-end doses to be achieved.		
	Breedvelt; Meta-analysis Continuation of Antidepressants vs Sequential Psychological Interventions to Prevent Relapse in Depression. An Individual Participant Data Meta-analysis DOI:10.1001/jamapsychiatry.2021.0823	The findings of this individual participant data meta-analysis suggest that regardless of the clinical factors included in these studies, the sequential delivery of a psychological intervention during and/or after tapering may be an effective relapse prevention strategy instead of long-term use of antidepressants.		
	Kishi 2019; Meta-analysis	Maintaining antipsychotic treatment prevented relapse for up to 24 months		

	Effect of discontinuation v. maintenance of antipsychotic medication on relapse rates in patients with remitted/ stable first-episode psychosis: a meta-analysis DOI: 10.1017/S0033291718001393	in FEP patients. Discontinuation of antipsychotics for ⩾2 months significantly increased the risk of relapse. However, 45.7% of patients who discontinued antipsychotics for 12 months (39.4% after 18-24 months) did not experience a relapse.		
	Kishi 2021; Systematic review and meta-analysis Recurrence rates in stable bipolar disorder patients after drug discontinuation v. drug maintenance: a systematic review and meta-analysis DOI: 10.1017/S0033291720003505	Maintaining drug treatment during clinically stable BD prevented recurrence for up to 24 months. Discontinuation of medications for ⩾1 month significantly increased recurrence risk. However, 47.3% of patients who discontinued drugs for 6 months did not experience recurrence.		
	Fournier 2022; Meta-analysis Initial Severity and Depressive Relapse in Cognitive Behavioral Therapy and Antidepressant Medications: An Individual Patient Data Meta-analysis https://doi.org/10.1007/s10608-021-10281-x	Regardless of a patient's baseline symptom severity, CBT and ADM-c both prevent depressive relapse substantially better than medication discontinuation. Given the shorter duration of treatment and equivalent longer-term outcomes, treatment with CBT might be considered a first choice for adults with depression.		
How best can the future health of individuals who have stopped psychiatric medicines and have			No	This question has not been addressed by any existing literature.

current/previous experience of protracted withdrawal syndromes be managed and protected? This may include, but are not limited to, the use of similar drugs or class of drug during future medical encounters. [Final question number: 18]	[redacted]			
Which factors influence the prevalence, duration and severity of withdrawal effects that appear during or after reducing and stopping psychiatric medicines? What is the best way to control these factors and reduce an individual's risk of developing withdrawal effects or relapsing? [Final question number: 19]	**Brandt 2020**; Systematic Review and Meta-Analysis Antipsychotic Withdrawal Symptoms: A Systematic Review and Meta-Analysis DOI: 10.3389/fpsyt.2020.569912	Withdrawal symptoms appear to occur frequently after abrupt discontinuation of an oral antipsychotic. The lack of randomized controlled trials with low risk of bias on antipsychotic withdrawal symptoms highlights the need for further research	Partly	The factors that influence the prevalence, duration and severity of withdrawal effects that appear during or after reducing and stopping psychiatric medicines have only been investigated for a limited number of drug classes and often involving only a limited number of studies
	Takeuchi 2023; Pooled analysis Does short-term antipsychotic discontinuation of up to 3 weeks worsen symptoms in acute schizophrenia? A pooled analysis of placebo washout data http://onlinelibrary.wiley.com/doi/10.1111/pcn.13534/full	Symptoms may not worsen to a clinically meaningful degree after short-term discontinuation of non-clozapine antipsychotics up to 3 weeks in patients with acute exacerbation of schizophrenia, suggesting that antipsychotic efficacy persists at least several days after discontinuation. This finding		

		supports once-daily dosing regimen of antipsychotics and abrupt antipsychotic discontinuation when switching to another antipsychotic		
How best can the withdrawal effects that appear during or after reducing and stopping psychiatric medicines be explained in terms of type, causation, prevalence, severity, and duration? [Final question number: 20]	**Davies 2019**; Systematic review A systematic review into the incidence, severity and duration of antidepressant withdrawal effects: Are guidelines evidence-based? https://doi.org/10.1016/j.addbeh.2018.08.027	We recommend that U.K. and U.S.A. guidelines on antidepressant withdrawal be urgently updated as they are clearly at variance with the evidence on the incidence, severity, and duration of antidepressant withdrawal, and are probably leading to the widespread misdiagnosing of withdrawal, the consequent lengthening of antidepressant use, much unnecessary antidepressant prescribing and higher rates of antidepressant prescriptions overall. We also recommend that prescribers fully inform patients about the possibility of withdrawal effects.	Partly	the withdrawal effects that appear during or after reducing and stopping psychiatric medicines have only been investigated for a limited number of drug classes and often involving only a limited number of studies
	Monahan 2020; Systematic review Quetiapine withdrawal: A systematic review https://doi.org/10.1177/0004867420965693	Discontinuation symptoms are an uncommon side effect of quetiapine cessation, which may have clinical implications. Clinicians should be alert to the possibility of quetiapine withdrawal in individuals who present with somatic symptoms or choreiform movements.		

	Yee 2023; Systematic Review Non-Psychosis Symptoms of Clozapine Withdrawal: a Systematic Review https://doi.org/10.12809/eaap2261	Non-psychosis symptoms following clozapine withdrawal have important clinical implications. Clinicians should be aware of the possible presentations of symptoms to ensure early recognition and management.		
What are the potential benefits and risks of reducing and stopping psychiatric medicines for the different stakeholders? These include service users, family members/carers and healthcare professionals. [Final question number: 21]	[redacted]		No	This question has not been addressed by any existing literature.
Is there a relationship between reducing and stopping psychiatric medicines and suicide/ suicidal ideation? If so, how best can this relationship be explained in terms of causation and prevalence?			No	This question has not been addressed by any existing literature.

[Final question number: 22]	[redacted]			
How best can the withdrawal symptoms that appear during or after reducing and stopping psychiatric medicines be identified and differentiated from other causes (e.g., relapse/return of underlying condition, distress)? [Final question number: 23]	**Cohen 2019**; Systematic Review Discontinuing Psychotropic Drugs from Participants in Randomized Controlled Trials: A Systematic Review DOI: 10.1159/000496733	RCTs use drug discontinuation to study several key issues in psychopharmacology but infrequently justify how they implement it or acknowledge that possible withdrawal symptoms may threaten internal validity.	No	It remains unclear as to how best to identify and differentiate withdrawal symptoms from other causes.
What are the perspectives of key stakeholders on the professional, ethical and legal responsibilities of **healthcare professionals and/or the pharmaceutical industry** in relation to reducing and stopping psychiatric medicines? Stakeholders include service users, family	[redacted]		No	This question has not been addressed by any existing literature.

members/carers and healthcare professionals. What are the best ways to enact these responsibilities? [Final question number: 24]	[redacted]		[redacted]	
What are the views and experiences of service users, family members/carers, and healthcare professionals around shared decision making in relation to starting and stopping psychiatric medicines? This includes informed consent. How can the process of implementing shared decision-making be improved when starting and stopping psychiatric medicines? What factors influence this process? [Final question number: 25]	**Chmielowska 2023**; Umbrella review Trends, challenges, and priorities for shared decision making in mental health: The first umbrella review DOI: 10.1177/00207640221140291	The current landscape of SDM in mental health is overwhelmingly disconnected from the needs and experiences of potential end-users, clients, clinicians, and family members. Most SDM interventions and tools were adapted from physical health and are mainly geared to psychopharmacological decision-making. The SDM in Mental Health Framework (SDM-MH), developed here, expands the scope of decisions to non-psychopharmacological discussions, diversifies the pool of SDM participants and settings, and offers potential primary target outcomes of SDM in mental health to reduce heterogeneity across studies	Partly	The views and experiences of all stakeholders involved in the process of starting and stopping psychiatric medicines have not been comprehensively investigated, nor were the factors that influence the SDM process.

To what extent do healthcare professionals report and document the adverse effects associated with the use of psychiatric medicines and/or the difficulties associated with reducing and stopping psychiatric medicines? How does this align with reports from service users, family members and carers? [Final question number: 26]	[redacted]	No	This question has not been addressed by any existing literature.
What are the views/attitudes held by healthcare professionals towards the withdrawal effects that appear during or after reducing and stopping psychiatric medicines? Which factors impact these attitudes?		No	This question has not been addressed by any existing literature.

[Final question number: 27]	[redacted]		
What would make for an effective public health campaign about the potential risks associated with the use of psychiatric medicines, and the potential for challenges when reducing and stopping? These may include withdrawal symptoms and protracted withdrawal syndromes. [Final question number: 28]		No	This question has not been addressed by any existing literature.
What is the best approach to discussing the potential risks associated with taking, reducing, and stopping psychiatric medicines? What are the barriers and enablers to implementing?		No	This question has not been addressed by any existing literature.

[Final question number: 29]	[redacted]		
What is the best way for healthcare professionals to inform service users about the process of reducing and stopping psychiatric medicines, and the potential for associated challenges? What impact does this have on the service user's treatment decisions and outcomes? [Final question number: 30]		No	This question has not been addressed by any existing literature.
What factors influence a service user's decision to reduce and stop psychiatric medicines? These may include patient factors, social factors, and health system factors. [Final question number: 31]		No	This question has not been addressed by any existing literature.

What are the best ways to educate current and future healthcare professionals about reducing and stopping psychiatric medicines in terms of the tapering process, associated risks/difficulties, withdrawal symptoms, and supporting shared decision making? What is the impact of education on clinical practice? [Final question number: 32]	[redacted]	No	This question has not been addressed by any existing literature.

Appendix 5.4: The final priorities ranked 11-19

Final ranking	Question
11	How can the availability of psychiatric medicines in formulations that facilitate the process of reducing and stopping psychiatric medicines be improved? These include tapering strips and liquid formulations.
12	Is there an optimum duration of use of psychiatric medicines after which reducing and stopping should be initiated that minimises the potential of physical dependency and/or relapse? Does this differ depending on the class/ type of medication?
13	What would make for an effective public health campaign about the potential risks associated with the use of psychiatric medicines, and the potential for challenges when reducing and stopping? These may include withdrawal symptoms and protracted withdrawal syndromes.
14	What effects does the tapering process (tapering approach, rate, and duration of taper) and associated outcomes (i.e., withdrawal symptoms, protracted withdrawal syndrome, quality of life) have on the individual's health status and underlying neurobiology?
15	Is there a relationship between reducing and stopping psychiatric medicines and suicide/ suicidal ideation? If so, how best can this relationship be explained in terms of causation and prevalence?
16	What is the rate/likelihood of recovery from withdrawal effects after reducing and stopping psychiatric medicines? Which factors influence/predict an individual's recovery outcomes?
17	What factors influence a service user's decision to reduce and stop psychiatric medicines? These may include patient factors, social factors, and health system factors.
18	To what extent do healthcare professionals report and document the adverse effects associated with the use of psychiatric medicines and/or the difficulties associated with reducing and stopping psychiatric medicines? How does this align with reports from service users, family members and carers?
19	How best can the future health of individuals who have stopped psychiatric medicines and have current/previous experience of protracted withdrawal syndromes be managed and protected? This may include, but are not limited to, the use of similar drugs or class of drug during future medical encounters

Appendix 6.1: Final coding template for in-scope responses

Themes	Subthemes
1: Perceived benefits/harms of taking psychiatric medication	Benefits of taking psychiatric medication
	Harms of taking psychiatric medication

2: Decisions around reducing/ stopping psychiatric medication	Reasons for reducing/stopping psychiatric medication
	Barriers to reducing/stopping psychiatric medication
3: Challenges to reducing/stopping psychiatric medication	Lack of recognition of withdrawal symptoms
	Lack of tapering supports & resources
	Lack of autonomy
	The tapering process & associated withdrawal symptoms
4: Strategies used by individuals to reduce/stop psychiatric medication	Abrupt discontinuation
	Tapering
	Pharmacological supports
	Non-pharmacological/psychological supports
5: Outcomes of reducing/stopping psychiatric medication	Positive outcomes of reducing/stopping psychiatric medication
	Negative outcomes of reducing/stopping psychiatric medication
6: Emotional context	Anger & frustration
	Loneliness & isolation
	Hopelessness & feeling trapped
7: Areas for improvement	Tapering resources
	Regulatory oversight of the pharmaceutical industry
	Healthcare professionals' accountability/responsibility
	Healthcare professionals' education & training
	Informed consent & public awareness
8: Gratitude and appreciation	No subthemes

Appendix 7.1: Completed Consolidated criteria for reporting qualitative research (COREQ) Guidelines

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	194
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	194
Occupation	3	What was their occupation at the time of the study?	194
Gender	4	Was the researcher male or female?	194
Experience and training	5	What experience or training did the researcher have?	194
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	194
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	194
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	194
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	197
Participant selection			

Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	194
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	195
Sample size	12	How many participants were in the study?	199
Non-participation	13	How many people refused to participate or dropped out? Reasons?	199
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	196
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	196
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	199
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	195,196
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	199
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	196
Field notes	20	Were field notes made during and/or after the inter view or focus group?	196
Duration	21	What was the duration of the inter views or focus group?	199
Data saturation	22	Was data saturation discussed?	194
Transcripts returned	23	Were transcripts returned to participants for comment and/or correction?	197
Domain 3: Analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	198
Description of the coding	25	Did authors provide a description of the coding tree?	198

tree			
Derivation of themes	26	Were themes identified in advance or derived from the data?	198
Software	27	What software, if applicable, was used to manage the data?	198
Participant checking	28	Did participants provide feedback on the findings?	197
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	202-217
Data and findings consistent	30	Was there consistency between the data presented and the findings?	202-217
Clarity of major themes	31	Were major themes clearly presented in the findings?	201
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	202-217

Appendix 7.2: Participant Information Leaflet for the interview study

Name of Study: A qualitative exploration of key stakeholder's views and experiences of a Priority Setting Partnership process

Site	Trinity College Dublin
Principal Investigator(s) and Co-Investigator(s) (insert names, titles and contact details)	Miriam Boland, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin (phD candidate) Dr Cathal Cadogan, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin (supervisor) Professor Agnes Higgins, School of Nursing and Midwifery, Trinity College Dublin (supervisor)
Study Organiser/ Sponsor (if applicable)	N/A
Data Controllers	Trinity College Dublin
Data Protection Officer	Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2

You are receiving this invite as you are either a Steering Group member and/or attendee at the final prioritisation workshop, on the PROTECT Study. The PROTECT Study is a Priority Setting Partnership (PSP) that is being conducted in line with the James Lind Alliance (JLA) recommendations. The PROTECT Study aims to determine the Top 10 unanswered questions and uncertainties about reducing and stopping psychiatric medicines. The purpose of this follow-up study is to explore the views and experiences of the people involved with the PROTECT Study on the PSP process.

We are looking for willing Steering Group members and/or attendees at the final prioritisation workshop to share their views through an online interview.

This Participant Information Leaflet will explain the aim and purpose of this study, and what taking part will involve. Please take the time to read this information carefully and feel free to contact the research team if you have any questions. Contact details are included towards the end of this Participant Information Leaflet.

Part 1 – The Study

Why is this study being done?

The purpose of this study is to explore the views and experiences of people (Steering Group members and attendees at the final prioritisation workshop) involved with the PROTECT Study on the PSP process. This study is in part fulfilment for the award of PhD to Miriam Boland.

Why have I been invited to take part?

You have been invited to take part in this study because of your participation in the PROTECT Study, as a Steering Group member and/or attendee at the final prioritisation workshop. We are asking participants to share their views and experiences on the PSP process.

Do I have to take part? Can I withdraw?

It is your decision whether you choose to take part in this study but feel free to contact the researcher (Miriam Boland) if you have any questions. If you decide to take part in the study, you can withdraw from the study at any time. You are not required to give a reason for your withdrawal.

What happens if I change my mind?

Participation in this study is entirely **voluntary**. If you change your mind, all you need to do is contact the researcher (Miriam Boland) and tell her. You will not be required to give a reason for your withdrawal and the information that you have provided will then be removed from the study. However, if you decide to withdraw from the study post analysis and publication, it will not be possible to remove the information that you have provided.

How will the study be carried out?

The study will consist of a short, online interview. The information collected during these interviews will be analysed, and the results will be written up as part of my PhD and published in a medical journal.

What will happen to me if I decide to take part?

Participation will involve taking part in a short, online interview with one member of the research team. The interview will be conducted virtually via the Zoom platform. The interview will take approximately 30-40 minutes.

During the interview, you will be asked a series of questions. Three examples of the types of questions that will be asked are listed below:

1. What were your motivations for being involved?
2. What are your thoughts/reflections on the PSP process?
3. What do you see the key value of the PSP in terms of future research on tapering psychiatric medicines?

The interview will be audio recorded. You will have the opportunity, should you wish, to review and edit the transcript of this recording. Any comments on the transcript must be returned within seven days.

What will happen to the information collected?

All information collected as part of the study will be securely stored on the Principal Investigator's computer. Access will be restricted to the research team.

This information will be deleted three years after the PhD has been completed. The PhD is currently being undertaken by the Principal Investigator (Miriam Boland) at Trinity College Dublin.

Are there any benefits to taking part in this research?

If you choose to take part in this study, you will be providing valuable information on the PSP process, which can guide future research practices.

Are there any risks to me or others if I take part?

There are no apparent risks if you take part in the study. However, the questions asked as part of the interview have the potential to provoke difficult emotions and memories. You can terminate the interview at any time, without the need to provide a reason and you will be withdrawn from the study.

Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?

The results of this study will be published on the project's website, www.tapersafer.org, and reported in medical journals. No information which reveals your identity will be disclosed.

Part 2 – Data Protection

1. **What information about me (personal data) will be used as part of this study?**

We will need your name and email addresses to contact you and conduct the interview.

Any audio recordings and information shared in the interview will be masked so you will not be identifiable from the transcript.

2. Who will access and use my personal data as part of this study?

Access to personal data will be restricted to Principal Investigator (Miriam Boland) and members of the research team (Cathal Cadogan, Agnes Higgins).

3. How will the information be kept secure?

All information will be securely stored by the Principal Investigator using Microsoft systems and SharePoint. The link between you and the information will be deleted three years after the PhD has been completed.

4. What is the lawful basis to use my personal data?

We will only use your personal data for this research project. This is in line with Article 6,1, e and 9, 2 J of the GDPR.

5. What are my rights in relation to my personal data?

You are entitled to request:

- *access to and receive a copy of your personal data*
- *restrict or object to us continuing to use your personal data*
- *have inaccurate personal data corrected or deleted*
- *request deletion of your personal data*

By law you can exercise the above rights in relation to your contact details. You can exercise these rights by contacting Miriam Boland, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin 2. Email: bolandm7@tcd.ie. Phone: +353-1-896-2809 or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

Part 3 – Costs, Funding and Approval

Has this study been approved by a research ethics committee?

Yes, this study has received approval from the School of Pharmacy & Pharmaceutical Sciences Research Ethics Committee, Trinity College Dublin on 9th January 2024.
Reports on this project will be submitted to the Research Ethics Committee on an annual basis until the project is completed.

Who is organising and funding this study? Will the results be used for commercial purposes?

This study is being organised by Miriam Boland as part of her PhD which is supported by the 1252 Scholarship from Trinity College Dublin.

Is there any payment for taking part? Will it cost me anything if I agree to take part?

No, there is no payment for taking part in the research. You will not incur any financial cost if you take part in the research.

Part 4 – Further Information

Who should I contact for information or complaints?

If you have any concerns or questions, you can contact:

Principal Investigator: Miriam Boland, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin 2. Email: bolandm7@tcd.ie. Phone: +353-1-896-2809

Appendix 7.3: Consent form for the interview

STUDY NAME: A qualitative exploration of key stakeholder's views and experiences of a Priority Setting Partnership process

Centre ID: School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin

Consent Form

There are two sections in this form. Section 1 has a statement and asks you to indicate if you understand. **Please ask <u>any</u> questions you may have when reading each of the statements.** **Please <u>select yes or no in Section 2</u> if you agree/disagree with the statement. Please feel free to ask questions if there is something you do not understand.** **The end of this form is for the researchers to complete.** **Thank you for participating.**	
Section 1 - General	**Select Yes or No**
I confirm I have read and understood the **Information Leaflet** for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	***Y or N***
I understand that this study **is entirely voluntary, and I can stop taking part in this study without giving a reason,** but I must do so before the interview has stopped/data is analysed.	***Y or N***
I understand that I **will not be paid for taking part in this study**.	***Y or N***
Section 2 - Consent	**Select Yes or No**
I agree to take part in this research study having been fully informed of the risks, benefits which are set out in full in the information leaflet which I have been provided with.	***Y or N***
I agree to being contacted by researchers by email as part of this research study.	***Y or N***
I agree to the use of personal data for this project (participant names and email addresses, de-identified interview transcripts, audio recordings, consent forms, and the code sheet linking pseudonyms to participant identities). I understand that I will not be identifiable in the report.	***Y or N***

Participant Name (Block Capitals):

Participant Signature:

Date:

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.
I have given a copy of the information leaflet and consent form to the participant with contacts of the study team.

Researcher name:

Title and qualifications:

Signature:

Date:

Appendix 7.4: Interview topic guide

Start of interview

Section 1: Study information

Hello! Thank you for making the time to talk to me today. This is one of a number of interviews that I am conducting as part of a follow-up study to the PROTECT study. The aim of the interview is to explore your views and experiences of a Priority Setting Partnership (PSP) process as a [workshop attendee and/or Steering Group member]. There are no right or wrong answers; we are trying to understand what worked and what didn't work, so please answer frankly. I won't take any offence. Feel free to ask me any questions throughout. Before we get started, just to mention…

- The interview will be **audio-recorded.**
- No video imagery will be recorded.
- All the data collected will be **anonymised,**
- You can choose to stop the interview at any point, and your information will be deleted.

Do you have any questions before we get started? If it is okay with you, we will start the interview and the audio recording.

Switch on Dictaphone/recording device

Section 2: Main interview questions

Question 1. What are your thoughts on the PSP process as a way of identifying priorities relating to coming off/tapering psychiatric medicines?

Follow-up questions:

- Why do you think having the three groups around the table is important?
- Do you have any thoughts on the workshop specifically?
- I am interested in hearing your experiences, did it differ from your expectations?
- What do you think worked well?
- Were there any benefits to getting involved?
- Is there anything that could have been done better or that you would do differently?

- Did you experience any challenges to being involved?

Question 2. What were your motivations for getting involved in this PSP?

Alternative phrasing:

What were your reasons for getting involved in this PSP? / What did you hope to get out of the PSP? / What did you hope the PSP would achieve?

Follow-up questions:

What do you see as the major issues related to tapering at the minute?

***Question 3. Did any of the questions in the final Top 10 list surprise you*… in terms of what was included and excluded?**

Follow-up questions:

- If so, why?
- Were there any questions that did not make the Top 10 list that you would have liked to have seen included?
- What questions did you not expect to be included/to be discussed as part of the workshop?

Question 4. Do you think your views were heard throughout the PSP process (and at the workshop)?

Follow-up questions:

If not,

- How do you think this could be improved in future projects and PSPs?

If yes,

- What was it about the space/process that enabled that?
- When you say your voice was heard and you were comfortable, what was it about the process that helped that?
- Was there anything that hindered you sharing/expressing your view?
- What made the process inclusive? What helped?

Section 3: Review and reflect

That brings us to the end of the interview. Is there anything else you would like to add? Do you have any additional comments relating to anything we have discussed that you would like to make?

Once all the interviews have taken place, the interviews will be transcribed. You will have the option to review your transcript, but you under no obligation to do so. Have a think about it, and if you decide that you would like to review your transcript, please let me know by the end of the week by email, then I will know to send it. If I don't hear from you, I will assume that you do not wish to review the transcripts.

Thank you again for speaking with me today.

End of interview

Appendix 7.5: Ethical approval letter for the interview study

Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Assoc. Prof. Cathal Cadogan,
School of Pharmacy and Pharmaceutical Sciences,
Trinity College Dublin,
Dublin 2.

Ref. 2023-06-01, REAMS-2613

09 January 2024

Dear Cathal,

Re: A qualitative exploration of key stakeholders' views and experiences of a Priority Setting Partnership process

I am pleased to inform you that the above project now has approval from the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee. Please note that a number of the revisions sought arose from review by the DPO (Research). Your response to these has been found acceptable for the purpose of REC approval. However, if any additional issues arise from further consideration by the DPO, the updated documentation should be provided to the REC.

You are reminded that any significant deviation from the research description in the application requires approval from the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee before implementation.

Please also note the reporting requirements outlined on the Committee's website (http://pharmacy.tcd.ie/research/SoPPS_REC.php), in particular the need for:

- An immediate report in writing (by email to pharmacy.ethics@tcd.ie) of any serious or unexpected adverse events on participants, or unforeseen events that might affect the benefits/risks ratio as outlined in the application.
- Annual reports (report form on the Committee's website).
- An end of project report (report form on the Committee's website).

Please quote the reference number 2023-06-01/REAMS-2613 in any further correspondence.

We wish you success with your research.

Yours sincerely,

_____

Sheila Ryder,
Chairperson,
School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee.

Sheila Ryder
Chairperson
Research Ethics Committee
School of Pharmacy and Pharmaceutical Sciences

Panoz Building, East End 4/5,
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Tel. +353 1 896 2786
E-mail pharmacy.ethics@tcd.ie
http://pharmacy.tcd.ie/research/SoPPS_REC.php

Síle Ní Mharcaigh
Cathaoirleach
Coiste um Eitic Thaighde
Scoil na Cógaisíochta agus na nEolaíochtaí Cogaisíochta

Foirgneamh Panoz, An Taobh Thoir 4/5,
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Teil. +353 1 896 2786
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http://pharmacy.tcd.ie/research/SoPPS_REC.php

Appendix 8.1: Final search strategy for Web of Science

Strand 1: Drugs

psychotropic* OR tranquilis* OR tranquiliz* OR hypnotic* OR sedati* OR "sleeping tablet*" OR "cholinergic" OR anticholinergic* OR "antimanic" OR "anti manic" OR antidepress* OR "anti depress*" OR antianxiety OR "anti anxiety" OR antipsycho* OR "anti psycho*" OR benzodiazepine* OR BZD OR zopiclone OR zolpidem OR zaleplon OR eszopiclone OR "z drug*" OR anxiolytic*

Strand 2: Apps

application* OR app OR apps OR "user experience" OR "UX" OR "social media" OR mHealth OR "consumer facing intervention*" OR "mobile health technolog*" OR "digital medication"

Strand 3: Phone

smartphone* OR phone* OR Apple OR "iOS" OR Android OR "Google Play Store" OR "Windows store"

Strand 4: Coming off

"drug taper*" OR "deprescri*" OR withdraw* OR discontinu* OR reduc* OR quit* OR ceas* OR cessation OR "com* off"

Appendix 8.2: Final data extraction form and coding template for BCT and app function coding

Study/App ID	
Study/App reference details (Title; journal citation/app platform)	
Reference type	☐ Study of an app-based intervention (use Part A of data extraction form) ☐ Standalone app from a commercial app store (use Part B of data extraction form)
Study/App eligibility	

Study/App Characteristics	Eligibility criteria	Eligibility criteria met? Yes	No	Unclear	
Types of participants	Studies of app-based interventions and apps that targeted individuals who wanted to discontinue psychiatric medication use. Psychiatric medication included antidepressants, anxiolytics, hypnotics, mood stabilisers and antipsychotics. Individuals were not limited by age or medical diagnosis.	☐	☐	☐	
Types of intervention	Apps had to focus on tapering psychiatric medication. Tapering-related guidance could come from any source. Apps that focused on medication adherence and/or switching between psychiatric medication were excluded.	☐	☐	☐	
Types of studies/apps	Eligible studies included quantitative (e.g., randomised controlled trials, before and after studies) qualitative (e.g., descriptive, grounded theory), and mixed methods evaluations. The	☐	☐	☐	

	review included apps regardless of whether they had undergone any formal evaluation. Conference abstracts were excluded due to a lack of sufficient information. Studies and apps were not limited to the English language.		
Types of outcome measures	All outcomes for non-commercial and commercial apps that met the inclusion criteria were included. For the commercial apps, any feedback reported by service users and/or service providers on the app stores was reviewed (e.g., app ratings and comments).	☐ ☐ ☐	
INCLUDE ☐		EXCLUDE ☐	
Reason for exclusion			
Notes:			

Part A: App-based interventions studies	
Study details (for app-based interventions studies)	
Source origin/country of origin	
Study dates	
Study aims/objectives	
Study design	
Study outcome measures	

Study outcome measurement tools	
Study setting + number of study sites	
Population (for app-based interventions studies)	
Inclusion/exclusion criteria	
Sample size	
Sample size calculation performed?	
Age	
Gender	
Type(s) of mental health challenges	
Other medical conditions	
Type(s) of psychiatric medication taken	
Duration of psychiatric medication use	
Number of medicines per patient	
Intervention details (for app-based interventions studies)	

Intervention description (including any non-app components)		
• Timing *(e.g. frequency, duration of each episode)*		
• Intervention recipients		
• Intervention deliverer(s) *(e.g. no., profession, training etc.)*		
• Delivery *(e.g. mechanism, medium, intensity, fidelity)*		
• Intervention duration		
• Co-intervention(s)		
• Intervention costs/ resource requirements		
Control group/comparator		
App description		
App functions (for app-based interventions studies)		
Type of functionalities	**Functionality description**	**Extracted data**
Function 1: Tracking symptoms	The app allowed the user to track their withdrawal symptoms and the severity of symptoms.	
Function 2: Tracking doses	The app allowed the user to track their medication doses and/or displays the doses in a calendar.	

Function 3: Dose calculator	The app provided the user with guidance on how to calculate the dose reductions such as the amounts and frequency.	
Function 4: Education	The app provided educational content (e.g., information about the tapering process, withdrawal symptoms, and psychiatric medications).	
Function 5: Goal setting	The app supported the users to set tapering goals.	
Function 6: Social support	The app offered social support (e.g., access to an online peer support forum and involvement with healthcare professional).	
Function 7: Reward/incentive	The app rewarded the user for their participation and/or tapering progress.	
Function 8: Notifications	The app offered pop-up notifications to remind the user to log their medication use and/or to motivate the user.	
App features (for app-based interventions studies)		
Tapering guidance /approach/ advice		
Underlying information sources		
Notifications *(e.g. push notifications)*		
Medical disclaimer		
Safety/crisis support		
Privacy policy		
Grouping (by category) and BCTs	**BCT name and description**	**Extracted data**
1. Goals and planning	***1.3*** *Goal setting (outcome)*	

	The user could set tapering/dose reduction goals (e.g., to be drug-free, to be on a lower dose, or to have fewer side effects) or other goals.	
	1.4 *Action planning* The app created a tapering plan that the user could follow.	
2. Feedback and monitoring	***2.1*** *Monitoring of behaviour by others without feedback* The app calculated the user's adherence to the tapering plan.	
	2.3 *Self-monitoring of the behaviour* The user could log their doses of medication.	
	2.4 Self-monitoring of outcomes of the behaviour The user could log, rate and/or comment on the severity of their withdrawal symptoms.	
3. Social support	***3.1*** *Social support (unreported)* The app had a link to an online user forum or alternative site.	
	3.2 *Social support (practical)* The app provided the user with access to support from healthcare professionals.	
	3.3 *Social support (emotional)* The app connected the user with their friends/family who could provide emotional support.	
4. Shaping knowledge	***4.1*** *Instructions on how to perform the behaviour* The app provided the user with tapering-related information (e.g., how to taper the medication and how to perform dose reduction calculations).	
5. Natural consequences	***5.1*** *Information about health consequences* The app provided the user with written or verbal information on the health consequences of discontinuing psychiatric medication use e.g. withdrawal symptoms.	

7. Associations	***7.1*** *Prompts/Cues* The user received electronic reminders in the form of pop-up notifications to remind them to log their medication use.	
8. Repetition and substitution	***8.7*** *Graded tasks* The app had a tapering chart/plan which specified the dosage reductions at defined intervals.	
9. Comparison of outcomes	***9.1*** *Credible source* The app included references to back up the information provided.	
10. Rewards and threats	***10.4*** *Social reward (includes positive reinforcement)* The app rewarded the user for their tapering progress.	
11. Regulation	***11.1*** *Pharmacological support* The app provided advice on supplements/medications to assist the tapering process.	
12. Antecedents	***12.4*** *Distraction* The app recommended distraction techniques (e.g. mindfulness, deep breathing).	
	12.5 *Adding objects to the environment* The app offered additional tapering resources (e.g., newsletter) to facilitate the user's tapering process.	
Outcome measures used to evaluate the intervention (for app-based interventions studies)		
Reported outcomes		
Outcome 1		
Outcome 1: Assessment time points		
Outcome 1: Results		

Outcome 2	
Outcome 2: Assessment time points	
Outcome 2: Results	
Outcome 3	
Outcome 3: Assessment time points	
Outcome 3: Results	
Notes	
Additional comments/ notes/observervations (by person performing data extraction)	
Part B: Stanadlone apps	
Details for standalone apps	
Source origin/country of origin	
Year of creation	
App source (AppStore, Google Play Store)	
App category	
App costs *(e.g. download cost, in app purchases, advertisements)*	

App description		
App aims/objectives		
Target population (for standalone apps)		
Age		
Gender		
Type(s) of mental health challenges		
Type(s) of psychiatric medications taken		
App functions (for standalone apps)		
Functionality type	**Functionality description**	**Extracted data**
As above (Part A)	As above (Part A)	Give example
App features (for standalone apps)		
Tapering guidance /approach/ advice		
Underlying information sources		
Notifications *(e.g. push notifications)*		
Medical disclaimer		
Safety/crisis support		
Privacy policy		

App reviews		
Grouping (by category) and BCTs	**BCT name and description**	**Extracted data**
As above (Part A)	As above (Part A)	
App development details (for standalone apps)		
Details of any underpinning evidence/theory base for the app		
App developer		
Notes		
Additional comments/notes/observervations (by person performing data extraction)		

Appendix 8.3: Completed Joanna Briggs Institute (JBI) Critical Appraisal Checklist for study by Sturup et al. (2017)

JBI Critical Appraisal Checklist for systematic reviews and research syntheses

Reviewer: MB_____Date: 14.10.24_____

Author: Sturup_____Year: 2017_____ Record Number: N/A____

	Yes	No	Unclear	Not applicable
1. Is the review question clearly and explicitly stated?	X	☐	☐	☐
2. Were the inclusion criteria appropriate for the review question?	X	☐	☐	☐
3. Was the search strategy appropriate?	X	☐	☐	☐
4. Were the sources and resources used to search for studies adequate?	X	☐	☐	☐
5. Were the criteria for appraising studies appropriate?	X	☐	☐	☐
6. Was critical appraisal conducted by two or more reviewers independently?	X	☐	☐	☐
7. Were there methods to minimize errors in data extraction?	X	☐	☐	☐
8. Were the methods used to combine studies appropriate?	☐	☐	☐	X
9. Was the likelihood of publication bias assessed?	☐	X	☐	☐
10. Were recommendations for policy and/or practice supported by the reported data?	☐	☐	☐	X
11. Were the specific directives for new research appropriate?	☐	☐	☐	X

Overall appraisal: Include X Exclude ☐ Seek further info ☐