Allan, Stephanie (2023) *A mixed-methods process evaluation of Early signs Monitoring to Prevent relapse in psychosis and prOmote Well-being, Engagement, and Recovery (EMPOWER) – a blended digital intervention for relapse prevention in schizophrenia tested with a feasibility cluster randomised controlled trial in Scotland and Australia.* PhD thesis.

http://theses.gla.ac.uk/83714/

A mixed-methods process evaluation of Early signs Monitoring to Prevent relapse in psychosis and prOmote Well-being, Engagement, and Recovery (EMPOWER) – a blended digital intervention for relapse prevention in schizophrenia tested with a feasibility cluster randomised controlled trial in Scotland and Australia

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MA

Submitted in fulfilment of the requirements for the degree of Doctor of Philosophy

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December 2022

1.1 Abstract

Introduction: schizophrenia is described as a severe mental illness affecting individuals, their families, and society. Many people with schizophrenia across the world do not have access to evidence-based care. User-led digital interventions that deliver treatment to patients in the community may help upscale provision. However, this will only happen if the interventions are implemented, and digital interventions frequently face implementation barriers. Standard clinical trials do not always generate evidence which can help answer questions related to implementation which means additional studies are required. EMPOWER was a user-led relapse prevention mobile app trialled in a feasibility cluster randomised control trial both the UK and Australia. This provided an opportunity to conduct implementation research using process evaluations. Researchers conducting process evaluations are encouraged to engage in cumulative science and build upon previous work conducted in interventions underpinned by similar intervention theory.

Methods: Seven studies were conducted. Following two introductory chapters, a systematic review (Chapter 3) summarised what user-led interventions exist and what intervention theory underpinned them. None were like EMPOWER which justified developing a novel process evaluation framework (Chapter 6) underpinned by the qualitative work from Chapters 4 and 5. Chapter 6 revealed key uncertainties such as the recruitment process which resulted in the ethnography conducted for Chapter 7, understanding end user experiences which resulted in the qualitative interviews in Chapter 8, and a need to more fully understand the underlying intervention theory using temporal methods which resulted in the multilevel vector autoregression of ecological momentary assessment data in Chapter 9.

Results: Chapter 3 suggested user-led interventions target a variety of problems faced by people with schizophrenia, but the field is young and there is high risk of bias. Additionally, there is low adherence and high dropout suggesting a key need to understand implementation. Chapters 4 and 5 analysed data from focus groups to understand how early warning signs of relapse are managed in clinical care and implementation expectations and the data were used to develop the novel process evaluation framework in Chapter 6. The findings from Chapter 7 suggest trial recruitment process was complex and the patient participants who took part are likely to be a highly selective sample. Two overarching themes were constructed in Chapter 8 that were relevant for understanding end-user experiences within the EMPOWER trial: Affordances and Change Processes. Affordances described the processes underpinning how and why participants interacted with or avoided the various components of the intervention. Affordances spanned all EMPOWER components, including self-monitoring, peer support workers, clinical triaging, self-management messages and diary function. The affordances were Access to Social Connection, Access to Digital, Access to Mental Health Support, the Ability to Gauge Mental Health and Access to Mental Health Information. The affordances framework helped explain the multitude of engagement trajectories observed within the main EMPOWER trial. Chapter 9 found that experiencing fear of relapse predicted next day experiences of depression and anxiety which supports the assumptions of the underlying intervention theory. However, observed effect sizes were very small.

Discussion: The findings present a holistic process evaluation of EMPOWER. Across all studies, implementation issues were found to be complex. Conducting qualitative research was essential for developing theory to explain and understand the implementation processes within the EMPOWER trial and highlights the value of conducting implementation research in parallel with RCTs. A revised logic model was created and is presented in Chapter 10 which can be used to evaluate a future full-scale trial.

1.2 Table of Contents

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1.6 Acknowledgement

"It takes a village to finish a thesis". Many times during this PhD journey I have looked to others for guidance and I wanted to take some time to thank them.

First and foremost, thank you to every participant who took part. Research could not exist without you, and I am privileged that you gave me your valuable time.

Next, I am especially grateful to my esteemed supervisors Professors Andrew Gumley and Hamish Mcleod for their endless well of wisdom, encouragement, and patience.

Every single co-author. The EMPOWER team in Glasgow and Melbourne. The “PRG” past and present: Suzy Syrett, Louise Beattie, Charlie Heriot-Maitland, Andrea Clark, Leonie Richardson, Bridey Rudd, Claire Matrunola, Kathryn O’Hare, Nikos Xanidis, Moya Clancy, Simon Bradstreet, and the RAPID team. My wonderful fellow PhD student cohort - Drs Nicola McGuire and Warut Aunjitsakul. This has been a real “team science” PhD.

Simon Stuart, Heather Roberts, Maddie, Michelle Jamieson, Vik Nair, Charlie McKenzie-Nash, Karina Braekkan - researching, and publishing work about people’s experiences of the benefits system has taught me so much about being a researcher.

Nev Jones, Rai Waddingham, Jen Kilyon, Veenu Gupta, Suzy Clarke, Akiko Hart, DrEM_79, Rachel Rowan, Jay Watts, Sophie Allan.

The “Hillhead Street” psychologists who have inspired me: Rebecca Lai, Jude Stevenson, Giada Miolucci, Hollie Sneddon, Naomi Clark, Anna Henschel, Emily Nordman, Lisa DeBruine and Niamh Stack.

Stella Chan and the rest at Project Soothe. The AVATAR2 Team who are many.

The Niners: Sophie, MJ, Debz, Fiona, Zibby, Ari.

Jamie, Victoria, Ciaran, Astrid, Claire, Gillian, Coleen, Cat, Adam, Liz, Amreet, Lisa-Marie, Lynsey, Xan, Veronica, Jenna (for the mind maps), Aliénor (for suggesting the dictation function) Rosa, and Lisa.

For my family, my mum, Aunt Ruth, Aunt Janice, Aunt Margaret, Alex, Gran and Olivia. Rhys and Carrie. Sandy, who has supported and encouraged me and inspires

me with their commitment to try and make the world a wee bit of a better place. And who encouraged me to move to embrace Zotero.

This research was funded by The Cremore Research Fund.

1.7 Author's Declaration

I declare that I am the sole author of this thesis, except where the assistance of others has been acknowledged. The work in this thesis has not been submitted in any form for another degree or professional qualification.

Stephanie Allan

December 2022

1.8 Abbreviations

Abbreviations have been kept to a minimum in this thesis and where they are used, they are referred to in each specific chapter.

1.9 Publications Arising from this Thesis that are Reproduced Entirely in the Respective Chapters

Allan, S., Bradstreet, S., McLeod, H., Farhall, J., Lambrou, M., Gleeson, J., ... & EMPOWER Group. (2019). Developing a hypothetical implementation framework of expectations for monitoring early signs of psychosis relapse using a mobile app:

qualitative study. *Journal of medical Internet research*, 21(10), e14366 (Chapter 4)

Allan, S., Bradstreet, S., McLeod, H. J., Gleeson, J., Farhall, J., Lambrou, M., ... & Gumley, A. I. (2020). Perspectives of patients, Carers and mental health staff on early warning signs of relapse in psychosis: a qualitative investigation. *BJPsych Open,* 6(1) (Chapter 5)

Allan, S., McLeod, H., Bradstreet, S., Beedie, S., Moir, B., Gleeson, J., ... & Gumley, A. (2019). Understanding implementation of a digital self-monitoring intervention for relapse prevention in psychosis: protocol for a mixed method process evaluation. *JMIR research protocols*, 8(12), e15634 (Chapter 6)

Allan, S., McLeod, H., Bradstreet, S., Bell, I., Whitehill, H., Wilson-Kay, A., ... & Gumley, A. (2021). Perspectives of Trial Staff on the Barriers to Recruitment in a Digital Intervention for Psychosis and How to Work Around Them: Qualitative Study Within a Trial. *JMIR Human Factors*, 8(1), e24055 (Chapter 7)

Allan, S., O'Driscoll, C., McLeod, H. J., Gleeson, J., Farhall, J., Morton, E., ... & Gumley, A. (2022). Fear of psychotic relapse: exploring dynamic relationships with common early warning signs of relapse using once a day electronic self-reports. *Accepted for Publication to Psychosis* (Chapter 9)

1.9.1 Papers Under Review Resulting from this Thesis that are Reproduced Entirely in the Respective Chapters

Allan, S., Beedie, S., McLeod, H. J., Farhall, J., Gleeson, J., Bradstreet, S., ... & Gumley, A. (2022). EMPOWER in Daily Life: A Qualitative Investigation of End User Experience of a blended digital intervention for relapse prevention in schizophrenia in a cluster randomised controlled feasibility trial. (Submitted for Review - Chapter 8)

Allan, S., Mcleod, H., McGuire, .N, Torous, J., Bell, I., Alon, N., Mercurio, M., Matrunola, C., Jamieson, M., Syrett, S., Gumley, A., Use of theoretical frameworks in user-led digital interventions for psychosis: A systematic review. (Submitted for Review– Chapter 3)

1.9.2 Other Relevant Co-Authored Publications linked to thesis aims.

Zukowska, Z., Allan, S., Eisner, E., Ling, L., & Gumley, A. (2022). Fear of relapse in schizophrenia: a mixed-methods systematic review. *Social psychiatry and psychiatric epidemiology*, 1-14 (joint senior author)

Bradstreet, S., Allan, S., & Gumley, A. (2019). Adverse event monitoring in mHealth for psychosis interventions provides an important opportunity for learning. *Journal of Mental Health.*

Fortuna, K. L., Walker, R., Fisher, D. B., Mois, G., Allan, S., & Deegan, P. E. (2019). Enhancing standards and principles in digital mental health with recovery-focused guidelines for mobile, online, and remote monitoring technologies. *Psychiatric Services*, 70(12), 1080-1081

Chapter 1

1.10 General Introduction and Thesis Outline

1.10.1 Schizophrenia and why it matters

Schizophrenia is a severe mental illness, a global health concern, and a leading cause of disability worldwide (Vos *et al.*, 2017). The burden of schizophrenia is expected to increase worldwide because demographic changes in low-and-middle-income countries, such as decreasing infant mortality, mean more people are living to working age and developing schizophrenia (Charlson *et al.*, 2018). In addition, people diagnosed with schizophrenia are likely to experience stigma and discrimination (Thornicroft *et al.*, 2009). Over their lifetimes, people with schizophrenia only earn 14% as much as people without this condition (Hakulinen *et al.*, 2019). Additionally, estimates suggest that 10.29% of homeless people (95% Confidence Interval: 6.44%- 16.02%) have a diagnosis of schizophrenia (Ayano, Tesfaw and Shumet, 2019). The impact goes beyond individuals. It is claimed up to half of people diagnosed with schizophrenia will require the support of an informal caregiver such as a relative or friend (Kuipers, 2010) or social care workers (McGuire *et al.*, 2020). Informal carers of people diagnosed with schizophrenia are likely to experience burnout (Onwumere *et al.*, 2018) and negative impacts upon their wellbeing (Bonsu, Salifu Yendork and Teye-Kwadjo, 2020). At the societal level, schizophrenia is associated with high direct costs from treatment and high indirect costs from lost productivity (Jin and Mosweu, 2017).

1.10.2 History of schizophrenia

A brief historical overview of schizophrenia is presented next.

1.10.2.1 Kraepelin

Emil Kraepelin was the first to describe a recognisable schizophrenia-like condition, dementia praecox, as a distinct nosological entity in around 1896; he based his claims upon clinical observation. Kraepelin felt that course and outcome best-distinguished dementia praecox from manic psychosis; therefore, he identified dementia praecox based on its onset (in adolescence or early adulthood), course (chronic and deteriorating), and outcome (permanent and pervasive impairment in mental functions) (Mueser and Jeste, 2008). From this definition, it has been argued that Kraepelin’s description did not necessarily see schizophrenia as a psychotic illness but rather as a cognitive disorder (Lake, 2012).

1.10.2.2 Bleuler

Eugen Bleuler was the first to coin the term schizophrenia in 1908 (Berrios, Luque and Villagran, 2003). He defined a set of fundamental symptoms unique to schizophrenia and always present in those with this group of diseases. Unlike Kraepelin, who viewed dementia praecox as progressive, Bleuler considered schizophrenia to have a variable course and outcome. Bleuler assumed that the core symptoms of schizophrenia were not hallucinations and delusions (which he thought were accessory symptoms) but rather the disintegration of mental functions, which were: loosening of association, blunt or inappropriate affect, ambivalence, and autism.

While Kraepelin's dementia praecox and Bleuler’s schizophrenia are often conflated to the extent that dementia praecox is used interchangeably with schizophrenia within the literature, it is essential to note that they are based on different theoretical assumptions (Zajicek, 2018). For example, schizophrenia was never considered to be necessarily chronic and deteriorating, unlike dementia praecox.

1.10.2.3 Schneider

Neither Kraepelin nor Bleuler foregrounded psychotic symptoms in their formulations of schizophrenia. However, German Psychiatrist Kurt Schneider attempted to further refine schizophrenia by defining symptoms that could be considered integral to the diagnosis. This process resulted in a selection of second-rank symptoms. The first-rank symptoms are chiefly psychotic and include audible thoughts, arguing or commenting voices, feeling controlled or influenced by an external force, thought withdrawal, diffusion of thinking, and delusions (Mueser and Jeste, 2008). Second-rank symptoms include other forms of hallucinations, depressive or euphoric mood changes, emotional blunting, perplexity, and sudden delusional ideas (Lake, 2012).

1.10.2.4 Beyond “Western” Psychiatry

This brief overview has foregrounded the influence of key figures from the canon of “Western” Psychiatry upon our understanding of schizophrenia. The explanatory models proposed by critical figures like Schneider (and their continued influence upon modern thinking) likely reflect socio-political contexts rather than linear scientific progress. Psychiatrists such as Grunya Efmovna Sukhareva published work in the 1930s foregrounding the role of trauma in the development of schizophrenia (Sher and Gibson, 2021) which has much in common with modern research, proposing a link between the two (Longden *et al.*, 2020). Reasons for her contributions being historically erased are likely due to her being female and Jewish and her work not being translated into English (Sher and Gibson, 2021) Furthermore, people from other parts of the world, such as the Māori of New Zealand, hold their own longstanding explanations of what gets called schizophrenia, which persists despite colonisation (Taitimu, Read and McIntosh, 2018).

1.10.3 Modern Classifications of schizophrenia

In modern times, schizophrenia is not considered progressive but rather a condition with a heterogenous clinical course, with some people only experiencing a single episode, others episodic, and others experiencing continuous psychosis symptoms (Austin *et al.*, 2015). In terms of psychosis symptoms, schizophrenia is said to comprise positive symptoms because they are regarded as additional to 'normal' experience (American Psychiactric Association, 2013) including delusions or hallucinations. Negative symptoms are considered 'deficits' to 'normal' behaviour, characterised by a lack of fluency of thought and speech combined with difficulty carrying out goal-directed tasks (ibid). Kraepelin, Bleuler and Schneider provide markedly different criteria for determining schizophrenia. However, their influence is seen in modern diagnostic manuals containing Kraepelinian chronicity, Bleulerian negative symptoms, and Schneiderian positive symptoms (Tandon, Nasrallah and Keshavan, 2009). These current classifications will now be discussed. There are two critical diagnostic manuals for the diagnosis of schizophrenia, the International Classification of Mental and Behavioral Disorders (ICD) and the Diagnostic and Statistical Manuals (DSM) Psychiatric (American Psychiatric Association, 2013). The DSM is in its fifth edition, while the ICD is now in version eleven.

Table 1 Comparison of Schizophrenia Criteria Across Diagnostic Manuals - reproduced from Valle and colleagues (Valle, 2020).

The information in Table 1 charts a harmonisation process between the DSM and the newest edition of the ICD. For example, now, the ICD-11 and DSM-5 do not include subtypes; instead, for ICD-10, they do. In addition, while the ICD-10 used to emphasise the presence of First Rank symptoms for diagnosis, this is no longer the case for the ICD-11, again in line with the DSM-5. However, there are still marked differences between the systems. For example, the ICD-11 still does not include functioning criteria, while the DSM-5 does.

Aspects	**ICD-10**	**DSM-5**	**ICD-11**
Name of chapter	schizophrenia, schizotypal and delusional disorders	schizophrenia spectrum and other psychotic disorders	schizophrenia and other primary psychiatric disorders
First-rank symptoms	Emphasises first-rank symptoms	Does not emphasise first-rank symptoms	Does not emphasise first-rank symptoms
Duration of psychotic symptoms	Psychotic symptoms for at least one month	One month for section A. Symptoms of the disorder persists for at least six months	Psychotic symptoms for at least one month
Functioning criteria	It does not include functionality criteria	Criterion B: functioning at work, interpersonal or self-care level is well below the premorbid level	It does not include functionality criteria
SCH subtypes	Paranoid Hebephrenic Catatonic Undifferentiated Post-schizophrenic depression Residual Simple Other Non-specific	Does not include subtypes	Does not include subtypes
Symptom specifier	Does not include a symptom specifier	Hallucinations Delusions Disorganised course,	Positive symptoms Negative symptoms Depressive symptoms

Aspects	ICD-10	DSM-5	ICD-11
		abnormal psychomotor behaviour Negative symptoms Cognitive impairment Depression Mania	Manic symptoms Psychomotor symptoms Cognitive impairments
Cognitive damage criteria	It does not include the cognitive damage criterion	Included as a symptom specifier	Included as a symptom specifier
Course specifier	Continuous Episodic with progressive deficit Episodic with stable deficit Episodic remittent Incomplete remission Complete remission Other Uncertain course, very short observation period	The first episode is currently an acute episode. The first episode is currently in partial remission. The first episode, currently in full remission Multiple episodes, currently in acute episode multiple episodes, currently in partial remission multiple episodes, currently in full remission Continuous Unspecified	First currently symptomatic episode First episode, in partial remission First episode, in full remission First episode, Multiple unspecified episodes, currently symptomatic Multiple episodes, in full remission Multiple episodes, unspecified Continuous, currently symptomatic Continuous, in partial remission Continuous, in full remission

Aspects	ICD-10	DSM-5	ICD-11
			Continuous, unspecified other specified SCH Unspecified SCH

1.10.4 Problems Experienced by People Diagnosed with Schizophrenia

Regardless of the diagnostic manual used, the problems experienced by people with schizophrenia are not limited to the signs and symptoms contained in the ICD-11 or DSM-5. For example, schizophrenia is considered the most stigmatised mental health condition (Hazell *et al.*, 2022). Considering structural oppression, people diagnosed with schizophrenia can face discrimination when attempting to access insurance, employment and housing (Lauber, 2008). At the individual level, people with schizophrenia can experience many problems, including poor physical health (Firth *et al.*, 2019), depression (Li *et al.*, 2020), relapse (Ascher-Svanum *et al.*, 2010), and fear of relapse brought on by worrying about having another relapse event (Zukowska *et al.*, 2022). However, as will now be described, existing interventions for the many problems faced by people with schizophrenia can be poorly implemented which means people do not get the help they need. Therefore, it is important to understand why there is poor implementation of interventions that could help people diagnosed with schizophrenia with the many problems they face.

1.11 Implementation of Interventions and The Promise of User-led Interventions

The mainstay of schizophrenia treatment is antipsychotic medications (Leucht *et al.*, 2012). Antipsychotics are superior to placebo for relapse prevention (Tiihonen *et al.*, 2017) and are linked with improvements in positive and negative symptoms

(McCutcheon *et al.*, 2021). However, antipsychotics can even create or worsen the common problems experienced by people with schizophrenia, such as physical health problems. For example, antipsychotic medication can cause deleterious side effects such as weight gain (Firth *et al.*, 2019). It is evident that people diagnosed with schizophrenia need more than medication to be well, so psychosocial interventions are recommended in treatment guidelines worldwide (NICE, 2014). Even with complete adherence to antipsychotics, relapses can still happen (Rubio *et al.*, 2020) further demonstrating a need for support beyond medication.

For this reason, psychosocial interventions such as family therapy are recommended because these have demonstrated robust efficacy in reducing relapse within randomised controlled trials (RCT)s (Bucci *et al.*, 2016) . However, if we define implementation as family therapy at least being *offered* to patients, the pattern in routine mental health care is highly variable - with reported rates in mental health trusts ranging from none to just over half (0-53%) (Ince, Haddock and Tai, 2016). Other estimates suggest that implementation rates of family therapy (as received) were as low as 1.1% (Haddock *et al.*, 2014). Therefore, people are not currently getting access to evidence-based care.

1.11.1 Implementation Science: History and Definition

The problem of poor implementation of interventions is not unique to schizophrenia. While it is well known that James Lind (probably) invented the modern RCT when he compared whether soldiers given lemons had less scurvy than those given seawater, garlic paste or cider – what is less well known is that the navy did not implement the findings from his successful result for 42 years and many people died of scurvy during that time. Why? One key reason given is that while Lind had discovered a “cure” for scurvy, he had failed to provide this cure in the format of effective storable preserved citrus, which could be used on long journeys (Trohler, 2005; Baron, 2009). As a result, the navy could not implement his novel intervention into their routine everyday practice. Therefore, the evidence from the world’s first randomised control trial also seems to have demonstrated the need for implementation science (the study of how and why interventions do or do not become part of routine clinical care (Nilsen, 2015). Implementation science does not usually focus on developing interventions or proving their efficacy in evaluations but on increasing the uptake of effective and safe interventions in clinical practice (Dixon and Patel, 2020).

1.11.2 Psychosocial Intervention Uptake from an Implementation Science Perspective

Considering the family therapy example from an implementation science perspective, a definition of which is described in the previous paragraph, a lack of clinician training in family therapy, and a lack of clinical time, are likely contribute to the poor delivery of this psychosocial intervention. Indeed, the availability of trained clinicians to deliver psychosocial interventions to people with psychosis is limited, and patient need far outstrips the supply of clinicians (Bell *et al.*, 2020). Face-to-face mental health support typically requires someone to attend mental health services to meet a clinician, and this is usually for a specific number of sessions (Michie *et al.*, 2017). One way to deliver interventions to people with schizophrenia in a more accessible format is by using user-led digital interventions. User-led digital interventions provide interventions, at least in part, to patients outside of healthcare services. User-led interventions here are defined to include interventions which are solely user-led such as a patient completing an online course of cognitive behavioural therapy (CBT) all the way up to interventions that are used to supplement or enhance traditional face-to-face work. They can consist of computer programmes, website-based modules, or mobile phone apps. While some, such as avatar therapy (Garety, Edwards, *et al.*, 2021), use digital technology as part of the intervention, these are not considered user-led interventions because the patient does not engage with the digital intervention component in their own time. Moreover, digital phenotyping which involves passing data collection to detect changes (Henson *et al.*, 2020) cannot be considered user led. While it must be noted that there are still people who are digitally excluded (Greer *et al.*, 2019; Watson *et al.*, 2021) usage of digital technologies such as mobile phones is high in people diagnosed with schizophrenia (Gay *et al.*, 2016), which suggests they may be feasible for this group. Patients in rural areas may live too far away from a face-to-face service that could offer them the support needed (Anthes, 2016), and offer services for geographically excluded patients.

1.12 Current Advances in Digital User-Led interventions

The following section will broadly summarise what problems user-led interventions are tackling for people with schizophrenia, how much patients adhere to the intervention (defined here as the percentage of participants who completed the intervention or average completion) and to what extent participants drop out (defined here as a percentage of participants not completing trial follow up assessments). Additionally, this section will comment on current evidence regarding effectiveness. This is helpful information to summarise as it gives a broad overview of what clinical problems are being addressed. With the focus on implementation taken in this thesis, this section will also summarise how well interventions have been implemented in clinical trials. While not likely to be comprehensive, it can be argued that the extent to which participants do not complete follow up assessments (defined here as trial drop-out) and adherence (defined as how much a group of participants used an intervention on average) may provide useful information about the extent to which existing interventions are being engaged with. While a loss to follow up and trial dropout rates are considered distinct because dropout refers to officially dropping out and loss to follow up refers participants not completing follow up assessments (Dettori, 2011), they are conflated here because engagement in follows up is taken as a proxy for engagement.

1.12.1 Cognitive Deficits

Targeting cognitive deficits describes interventions focused on improving neurocognitive abilities such as attention, working memory, cognitive flexibility, planning, and executive functioning, leading to improved psychosocial functioning.

Usually delivered by computer programmes on laptops or via app on tablets (Pijnenborg *et al.*, 2010; Sablier *et al.*, 2012; Fisher *et al.*, 2015; Hargreaves *et al.*, 2015; Biagianti *et al.*, 2016, 2017; Roberts *et al.*, 2017; Donohoe *et al.*, 2018; Moura *et al.*, 2019). User led interventions targeting cognitive deficits can range from standalone interventions that are used entirely independent by patients (Roberts *et al.*, 2017) or alongside work with a clinical psychologist such as cognitive remediation homework in between weekly sessions (Moura *et al.*, 2019). Looking to the literature, drop-out rates can be as high as 68% (Donohoe *et al.*, 2018). Adherence appeared to range between 42.6%-84% (Sablier *et al.*, 2012; Fisher *et al.*, 2015; Hargreaves *et al.*, 2015; Biagianti *et al.*, 2016; Roberts *et al.*, 2017; Moura *et al.*, 2019). Of note, one study compared participants completing therapy remotely compared to those receiving treatment at mental health premises, with no significant differences in adherence (Biagianti *et al.*, 2017). There was evidence of improved cognitive functioning in two RCTs, but no linear association was observed between intervention usage time and cognitive gains.

1.12.2 Social Skills

Social skills interventions target outcomes linked to competence in facilitating interaction and communication with others where social rules and relations are created, communicated, and changed in verbal and nonverbal ways. Available stand-alone user-led interventions include a website-based intervention which delivered teaching sessions on recognising facial expressions, and two computer-based interventions used computer programmes to teach social skills with interactive exercises. In terms of blended interventions, a study conducted in the USA delivered twenty-four sessions of weekly group therapy where social skills were taught and supplemented this with between session prompting using a digital device (Nahum *et al.*, 2014; Vázquez-Campo *et al.*, 2016; Gülkesen *et al.*, 2017; Nahum *et al.*, 2020; Granholm, Holden, Dwyer and Link, 2020). Besides beta-testing the usability of the facial recognition website with patients (Gülkesen *et al.*, 2017), no social skills interventions described involving patients in intervention design. There seems to be variety in terms of clinical efficacy of existing interventions. For example, participating in an online social skills programme called SocialVille resulted in greater improvement on behavioural composite measures of social cognition compared to those given an active control (Nahum *et al.*, 2020). However, using a digital device to prompt homework adherence did not increase engagement in homework and improvements in social skills did not differ compared to participants attending therapy alone (Granholm, Holden, Dwyer and Link, 2020). Dropouts ranged from 16%-47% for those randomised to receive user-led interventions. For studies reporting adherence, this appeared to range from 58%-76.4%.

1.12.3 Self-Management and Recovery

Another key strand of user-led interventions are interventions which attempt to increase patient ability to self-manage psychosis and achieve recovery (Rotondi *et al.*, 2010; Alvarez-Jimenez *et al.*, 2013; Beebe, Smith and Phillips, 2014; Ben-Zeev *et al.*, 2014; Thomas *et al.*, 2016; Bucci, Barrowclough, *et al.*, 2018; Depp *et al.*, 2018; Ben-Zeev *et al.*, 2019; Krzystanek *et al.*, 2019; Hanssen *et al.*, 2020; Ludwig *et al.*, 2020; Steare *et al.*, 2020; Westermann *et al.*, 2020). Of these, seven interventions used mobile apps; three were websites, one was a website blended with a forum and another used SMS text delivery. Intervention duration ranged from 21 days to a year. Half of the self-management and recovery interventions described patient involvement in designing the interventions. Eight interventions were blended with human contact, and this ranged from a single therapy session forum moderators and patients being able to arrange a “tele-visit” with a mental health professional if they needed one. Dropouts ranged from 0%-33% for participants randomised to receive interventions. For the four studies (Ben-Zeev *et al.*, 2014; Depp *et al.*, 2018; Hanssen *et al.*, 2020; Steare *et al.*, 2020) reporting adherence, this ranged from 3.2%-86.5%, indicating a broad range. Preliminary evidence from two RCTs (Krzystanek *et al.*, 2019; Westermann *et al.*, 2020) shows self-management interventions may improve psychosis symptoms when compared to control.

1.12.4 Motivation

Problems with motivation was a target for one app-based intervention (PRIME), (Schlosser *et al.*, 2018) which blended app content with access to motivational coaches and peers. The intervention was 12 weeks in length. Adherence for logging into the app was 57.5% per week (SD=0.2), and 100% of participants messaged a coach at least once with a challenge completion rate of 91.47 (SD=12.2) % in those randomised to receive PRIME. The dropout rate was 13.6% for those randomised to receive PRIME.

1.12.5 Social Anxiety

Around 25% of people diagnosed with psychotic disorders will experience social anxiety (McEnery *et al.*, 2019) which may be maintained by feelings of shame (Aunjitsakul *et al.*, 2021). One existing eight-week-long intervention targeted social anxiety using an online website intervention with twelve modules underpinned by CBT principles with access to an interactive forum and comics (Mcenery *et al.*, 2019). Patients were extensively involved in designing this intervention. Participants demonstrated 75% mean completion of therapy modules, and dropout was 23%. The authors concluded the intervention is feasible, but the study was not designed to estimate a treatment effect size.

1.12.6 Medication Adherence

Improving medication adherence is another aim of some user led interventions (Granholm *et al.*, 2012; Montes *et al.*, 2012; Sibeko *et al.*, 2017; Xu *et al.*, 2019) which all involved sending text messages and ranged in duration from 12 weeks to six months. Two interventions targeted the behaviour of carers. Two interventions described involving patients in intervention design, and one of those also involved carers in the design process. Positive effects for improving medication adherence improvement were noted for the two non-feasibility RCTs (Montes *et al.*, 2012; Xu *et al.*, 2019). Dropouts ranged from 4.31%-59.5% for those randomised to receive interventions. One further study reported 1% dropout (Montes *et al.*, 2012) but excluded 19.4% of participants for not being exposed to the intervention. For the single study reporting adherence indicated rates of 83%–86% (Granholm *et al.*, 2012). However, there were reported issues in three SMS interventions. For example, in one study, 42% of participants did not receive texts due to a technological problem (Sibeko *et al.*, 2017) and only 54% of participants reported reading texts in another (Xu *et al.*, 2019). Additionally, 66 participants were removed from formal analysis because they did not receive texts for seven consecutive days (Montes *et al.*, 2012) which may bias the reported successful improvement in medication adherence.

1.12.7 Positive Symptoms

One blended intervention study using a mobile app and face-to-face therapy specifically targeted voice hearing (Bell *et al.*, 2020). Split into two phases, participants self-monitored voices and this information was then used for functional analysis, and then to identify and program individualised coping strategies into an app. This intervention then used the mobile app to deliver the coping strategies depending on the data inputted by the users. Participants responded to 72% of EMA prompts, and the authors state this is a feasible approach, but the study was not designed to estimate treatment effect sizes. Dropout was 8.8% in those randomised to the intervention. Another app-based study targeted the positive symptom of paranoia. SlowMo (Garety, Ward, *et al.*, 2021) combined one-on-one therapy to help people reduce fast thinking biases which were supported by in-between sessions usage of a mobile app which featured information and personalised “thought bubbles” where patients could tackle fast thinking in real time. In total 71.4% of participants were adherent to using the mobile app between sessions and 8.2% dropped out of the treatment arm.

1.12.8 Negative Symptoms

Negative Symptoms (described under section 1.10.3) comprise of five key constructs: blunted affect, alogia (not using many words when communicating), avolition (having lower goal-directed activity), asociality, and anhedonia (markedly decreased experience of pleasure) (Aleman *et al.*, 2017). From the patient perspective, negative symptoms have been described as pervasive causing real barriers to everyday functioning with tasks such as brushing teeth feeling like "climbing the biggest mountain" (Butcher, Berry and Haddock, 2020). Two user-led digital interventions targeted negative symptoms (Granholm, Holden, Dwyer, Mikhael, *et al.*, 2020; Luther *et al.*, 2020). One blended weekly therapy with a mobile app, and another used a blended approach with a single one-on-one goal-setting session supplemented with text message prompting. Intervention duration ranged from 8-24 weeks. Neither intervention was designed with patient involvement. Both interventions were feasibility RCTs, and the authors report that both appear feasible. Looking at the implementation intervention available, dropouts ranged from 7.4%-16.1% and adherence ranged from 19.2%-86.1%.

1.12.9 Patient Involvement in Shared Decision Making

Shared decision making describes where psychiatrists provide clear and complete information to patients about treatment options, and patients provide treatment on their preferences to come to a shared plan for care (Fiorillo *et al.*, 2020). One website-based intervention aimed to improve patient experiences of shared decision-making with clinicians in managing their mental health problems (Van Der Krieke *et al.*, 2013). Participants were given access to an online decision tool aimed to support patients in acquiring an overview of their needs and appropriate treatment options provided by their mental health care organization. In total, 55% of patients did not use the website decision aid tool, and no differences were found between the intervention and control conditions on perceived involvement in medical decision-making. Study dropout was 68% for those randomised to the intervention arm.

1.12.10 Engaging in Exercise

Many people diagnosed with schizophrenia are highly sedentary (Vancampfort *et al.*, 2017) so it is not surprising user-led interventions are attempting to encourage participation in physical activity. One intervention prompted engagement in physical exercise in between face-to-face group exercise classes using text message-based reminders (Chen *et al.*, 2016). Participants met 81% of the targeted weekly exercise duration of 90 minutes between classes and dropout was 31.25%.

1.12.11 Symptom monitoring

Another stand of user-led intervention was symptom monitoring where patients were given the opportunity to record the presence of various symptoms such as hearing voices. Five interventions monitored for changes in mental state using digital devices with information being passed to mental health staff (Španiel *et al.*, 2012; Kasckow *et al.*, 2016; Cullen *et al.*, 2020; Lewis *et al.*, 2020; Moitra, Park and Gaudiano, 2021). Four aimed to detect changes which could be associated with relapse using mobile phone apps or SMS texting, and one intervention focused on suicidal ideation using a device connected to a landline telephone. Intervention duration ranged from four weeks to one year. All interventions asked patients to self-monitor by replying to text messages or inputting data onto a mobile app or device attached to a landline telephone. In the ITAREPS (information Technology Aided Relapse Prevention programme in Schizophrenia) intervention (Španiel *et al.*, 2012), carers also reported on the patient's symptoms by responding to texts in addition to the patient. Most of these interventions were targeted for use after a recent hospitalisation or an episode of being more unwell. Reported dropouts ranged from 5.06% - 30.07% in intervention conditions. For studies reporting adherence, this ranged from 33% – 86.2% (Španiel *et al.*, 2012; Moitra, Park and Gaudiano, 2021). In the single RCT, despite over 80% of mental health monitoring texts being responded to by patients and/or carers, psychiatrists did not use the data in relapse prevention clinical decision making and the intervention reported a null result for relapse prevention compared to an active control (Španiel *et al.*, 2012).

1.12.12 Loneliness

Loneliness can be common in schizophrenia. For instance, a study found that 80% of people diagnosed with psychosis were lonely compared to just 35% of the general population with similar demographic characteristics (Badcock *et al.*, 2015) meaning loneliness is an important target for intervention. An existing user-led intervention targeted loneliness using a mobile app called +Connect (Lim *et al.*, 2019), which delivered positive psychology content daily for 6 weeks. Patients were involved in the design of the intervention. In total 95.47% of the 12 participants used at least 70% of the app content (*a priori* feasibility). Dropout was 16.6% and the authors concluded that the intervention was feasible.

1.12.13 Depression

Around 32% of people diagnosed with schizophrenia meet the criteria for major depressive disorder (Etchecopar-Etchart *et al.*, 2021). An existing user-led online CBT based modular intervention (Moritz *et al.*, 2016) which had no blended components targeted depression. All individuals in the intervention condition logged in to Help ID at least once and adherence was 88% (defined as completing at least one module). Dropout was 19.35%. Compared to wait-list control, the study reported a large reduction in depression symptoms.

1.13 Understanding the Implementation of User-Led Interventions

To summarise, user-led digital interventions have been developed for various problems impacting people with schizophrenia. Interventions ranged from fully standalone where participants completed the intervention without any human contact aside from partaking in clinical outcome assessments, to fully blended interventions where the user-led component meant a participant engaged in exercises between therapy sessions. Digital Interventions with a human interaction are associated with higher engagement of people with psychosis (Killikelly *et al.*, 2017) because these interactions can provide support and encouragement (Mohr, Cuijpers and Lehman, 2011). Therefore, when using trial intervention engagement as a proxy to predict implementation, it would be important to understand the impact of what human contact may offer.

Most studies are feasibility studies, so at this stage it is hard to tell if they will improve the lives of people diagnosed with schizophrenia. However, adherence to the interventions was variable, and some demonstrated high rates of dropout (some over 40%), suggesting there is much to learn about what makes a user-led intervention something people with schizophrenia will even want to use. A systematic review of 26 studies (Aref-Adib *et al.*, 2018), which summarised implementation barriers (things that discourage implementation) for digital interventions for patients diagnosed with schizophrenia and bipolar affective disorder, suggested that attitudes and beliefs towards interventions are important, with negative attitudes and scepticism potentially leading to a lack of motivation to engage with or complete assessments. Additionally, the complexity of interventions was stated to be off-putting to people struggling with psychiatric problems. However, implementation problems are not unique to digital interventions for psychosis.

Since many digital interventions struggle to be implemented into routine care, a team of researchers developed the Non-adoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies (NASSS) Framework (Greenhalgh *et al.*, 2017) to explore commonalities between technologies that experience implementation problems. Health conditions within the NASSS framework are described as simple (well-characterized, well-understood and predictable), complicated (not fully characterized, understood, or predictable) or complex (poorly characterized, poorly understood, and high risk), with the implication being that the more complex a health problem is, the harder it will be to implement new digital interventions. From the brief literature review, schizophrenia easily satisfies being a complex health condition, which makes it particularly important to conduct implementation research to understand why people do or do not engage with a digital intervention. It is possible to learn about implementation problems for psychosocial interventions from post-hoc analyses of RCTs with poor implementation (Španiel *et al.*, 2012; Thornicroft *et al.*, 2013). However solely relying on retrospective implementation research risks the loss of crucial knowledge that emerge during a trial which may not be recorded as the trial is occurring (Sutcliffe *et al.*, 2015; Medical Research Council (MRC) and National Institute of Health Research (NIHR), 2019). This potential loss of essential information suggests a need to conduct prospective and concurrent implementation research and generate appropriate evidence which can be used to understand implementation.

Implementation research is important because it helps understand not just barriers to implementation but also implementation facilitators – things which encourage the uptake of interventions (Lobb and Colditz, 2013). However, understanding and measuring implementation is complex. If data are collected without an overarching theory, the output may be a list of disconnected empirical findings, which do not help us know what to expect or not to expect (Muthukrishna and Henrich, 2019). In other words, there is a need to ensure that a theoretical framework is developed so the meaning of data can be interpreted. However, already existing implementation frameworks for digital mental health interventions have been critiqued for ignoring both rapidly changing technological environments and the varied and complex circumstances of individual patients' lives (Mohr *et al.*, 2017). This issue may have a historical precedent. For example, implementation science was developed to understand healthcare professionals' behaviour as opposed to other stakeholders such as patients. However, with the advent of "user-led" interventions for psychosis (wherein patients can use digital interventions in their daily lives (Alvarez-Jimenez *et al.*, 2014)), it makes sense to consider patients as implementation agents and try to understand behaviours from their point of view. While this has an intuitive appeal, the personal perspectives of staff and (especially) patients (Greenhalgh *et al.*, 2015) are typically considered to be low-quality evidence within the "hierarchy of evidence" underpinning evidence-based medicine (EBM). However, EBM is not restricted to pre-defined RCT outcomes and the results of meta-analyses. Evidence-based medicine means using the best external evidence to answer clinical questions, which can include the perspectives of patients and staff (Sackett *et al.*, 1996). When asking questions about the implementation of digital interventions, it becomes important to define what the best external evidence would mean within this context and how we value knowledge.

Researchers are recommended to base process evaluations upon implementation theories, frameworks, and models. However, implementation theories and frameworks can be chosen for various reasons. A survey of 223 researchers from 12 countries who use implementation theories and frameworks suggested the most popular reasons for using specific frameworks (Birken *et al.*, 2017) were the analytic level (e.g. focusing on the individual, organizational or system levels) (58%), logical consistency/plausibility (i.e. having good face validity) (56%), empirical support (other research has used the theory and the researcher will be able to do cumulative theory building) (53%) and description of the change process (54%). The criteria used by the fewest respondents included fecundity (hypothesis generation) (10%), uniqueness (does the framework address the evaluation needs of the intervention?) (12%), and falsifiability (are the findings resulting from using the framework verifiable with empirical data?) (15%). However, the authors noted that from the open text responses, such as “my PhD supervisor told me to!” and others expressed concern that frameworks and models were chosen for non-scientific reasons (Birken *et al.*, 2017). Additionally, the 223 respondents reported using over 100 theories, frameworks, and models. There is a clear and justified scientific need to understand implementation from the point of view of key stakeholders. However, as has been implicitly touched upon in the chapter so far, foregrounding the views of people who use interventions as scientific evidence is not without controversy.

Knowledge democracy recognises and respects the contributions to knowledge that communities make and that these may be shaped by unique epistemologies (Stern, 2019). However, as we have covered, evidence-based medicine does not currently function as a knowledge democracy, and clinical guidelines are hierarchal because this epistemology is suited to the RCT paradigm (mostly positivist or realist)

(Bonell *et al.*, 2018) are placed atop the hierarchy. The typical term applied to this approach is a technocratic approach to knowledge. One way to try and make medical research more democratic in the UK has been patient and public involvement (PPI). The National Institute for Health Research patient and public involvement advisory group (NIHR INVOLVE) (NIHR Involve, no date) defines PPI as 'research being carried out with or by members of the public, rather than to, about or for them. Doing PPI within implementation research is recommended in the MRC process evaluation guidelines (Moore *et al.*, 2015) and very strongly indicated in the new complex intervention guidance (Skivington *et al.*, 2021).

However, it can be argued that the concern that it is unclear "what PPI even adds" to clinical (or implementation) research and calling for it to be scrutinised and evaluated (Crocker *et al.*, 2017) is forcing it to adhere to the existing evidence hierarchy. As has been remarked (Williams *et al.*, 2020), while evaluation might be helpful for any number of reasons, it must be said from a knowledge democratic standpoint, doing user involvement in research and/or valuing stakeholder expertise does not require that user involvement has a sound evidence base. RCTs seem essential for determining cause and effect, but the hierarchy of evidence may be understood more as a hierarchy of power (O'Shea, Boaz and Chambers, 2019). Quite simply, some evidence is not considered as necessary as others. However, some of the authors involved in developing Grading of Recommendations, Assessment, Development and Evaluations (GRADE) welcome looking beyond the RCT and including expert evidence. In brief, expert evidence is not opinion and is described as either the observations or experience obtained from a person who is knowledgeable about a particular area (Schünemann, Zhang and Oxman, 2019). This approach is recommended if something is rare. Therefore, I propose that we consider patient expertise on par with the RCT outcome in terms of importance; it is just different and perhaps better for understanding implementation. Eliciting diverse stakeholder expertise and viewing contextual expertise as aspects of the 'bigger picture of the context of mental health organisations' appears essential. In sum, RCT methodologies alone may not answer research questions about implementation, and it seems valuable to use methodologies that more adequately assess stakeholder expertise.

Beyond a lack of focus on end-user perspectives, standard RCT reporting is also suboptimal for understanding trial recruitment and change mechanisms from an implementation science perspective which will now be discussed in turn.

1.14 Recruitment to Clinical Trials

Another overlooked area of research is the recruitment process for clinical trials. It is recommended that the recruitment of participants should be described in sufficient detail to enable readers who wish to contextualize or replicate the work. Feasibility studies help establish important parameters such as the willingness of clinicians to recruit patients and the willingness of participants to be randomized. Despite the importance of recruitment, the CONSORT (Consolidated Standards of Reporting Trials) statement does not require RCT reporting to describe recruitment in detail beyond documentation of participant flow (Glasgow, Huebschmann and Brownson, 2018). Reporting detailed examinations of recruitment processes with a particular focus on recruitment barriers would help interpret trial results and help develop strategies for improvement – particularly important in schizophrenia where recruitment to trials can be poor (Deckler *et al.*, 2022). For feasibility studies, there is a need to understand recruitment barriers so strategies can be put in place to mitigate them in a full-scale trial where meeting statistical power will be paramount (Moore *et al.*, 2015). Systems underpinning recruitment processes are likely to be complex and non-linear and bound up in human interactions. Therefore, standard RCT outcomes are unlikely to observe these processes well. To summarise, research which unpacks the processes underpinning successful clinical trial recruitment are likely to be beneficial for a holistic understanding of final trial outcomes from an implementation science perspective.

1.14.1 Black Box Reporting

Many clinical trials reports are considered a “black box” because the outcome measures do not include a meaningful examination on the relationships of specific mechanisms of change on specific outcomes. This is a problem because exploring the mechanisms by which complex interventions create change is important for understanding both the specific intervention effects (the final outcome measures) and also how these effects may replicate in future interventions (Skivington *et al.*, 2021). Additionally, participants in RCTs are typically selected for having specific diagnoses which means interventions are assumed to either target an underlying disorder or a specific set of symptoms in line with that diagnosis such as those found in the diagnostic manuals covered in section 1.10.3 . This means RCT outcome measures can demonstrate a lack of focus on how specific symptoms relate to each other or change over time. As highlighted in section 1.10.4 people diagnosed with schizophrenia experience many problems such as physical health complications which can often extend far beyond those described in diagnostic manuals. Therefore, detailed empirical exploration of change processes within RCTs may even contribute to understanding of transdiagnostic issues. Additionally, the theoretical assumptions underpinning how symptoms are expected to change in RCTs are often poorly articulated within published papers (Michie and Johnston, 2017) which means it can be unclear how best to understand empirical investigations of change processes within trials unless they are placed within an overarching theoretical framework. Therefore, research which attempts to understand symptom change processes and places the results within a theoretical framework is likely to advance implementation science and would be a worthwhile extension to standard RCT outcome evaluation.

1.14.2 A Young Field

One issue which is highly relevant to user-led digital interventions for psychosis is the relative youth of the field. Most user-led digital interventions for people diagnosed with psychosis have been tested in feasibility trials. Feasibility studies examine whether intervention development and research can be accomplished to inform implementation and support the design of more extensive studies, such as RCTs. The final goal of a feasibility trial is to recommend whether an intervention is feasible to be evaluated in an RCT. With the implementation of digital interventions being poor, there is a need to better anticipate implementation from the earliest stages of clinical research, which may include intervention refinement. This is explicitly recognised in the new complex intervention guidance states that feasibility trials can be used to generate ideas for intervention refinement (Skivington *et al.*, 2021). Therefore, the field of user-led digital interventions for psychosis presents a valuable opportunity for understanding implementation processes from the earliest stages of RCTs within an area of research. Conducting a process evaluation is a common strategy to understand implementation, and the next section will introduce process evaluations and why they are important before introducing the EMPOWER clinical trial.

1.15 Process Evaluations

As has been covered, complex interventions can be poorly implemented, and part of the problem might be that RCTs do not generate data or theories that are helpful to understand implementation. For instance, the final result of an RCT is considered to have emerged from a "black box" because clinical trial outcomes do not usually indicate how different mechanisms have interacted together to produce the observed effect. The final "black box" result of an RCT on its own does not appear to provide evidence on the general effectiveness of an intervention (whether it will work outside of a trial). Coming back to Lind's lemons that were discussed in section 1.10.11, having some lemons on hand to give to a small group of soldiers on a short journey is one thing – expecting this to scale up is quite another. One way in which researchers are advised to improve the quality of their reporting of trials for policymakers is to include economic and social analysis alongside a trial because this can help indicate how the results of a trial will translate into "the real world" (Whitty, 2015). Additionally, randomised designs are not suitable for answering questions about different intervention components or complexity. One recommended way to gather data during a trial, and to optimise the data gathered for use in making predictions about uptake into general practice (such as including social analysis), is to conduct implementation research such as a process evaluation (Bakker *et al.*, 2015).

While the James Lind trial arguably demonstrated the need for implementation research, this is only believed to have become a field of academic research in the 1980s with the publication of *Avoiding Type III Errors in Health Education Program Evaluation: A Case Study* (Basch *et al.*, 1985) was key in the development of process evaluation. This paper highlighted intervention results may not be accurate because they have not been implemented well, a problem distinct from the final empirical result being a false positive (Type I) or a false negative (Type II). In using the same nomenclature, they labelled this as a “type III error”. However, it was not until the early 2000s that process evaluation research began to become more popular. Linnan and Steckler (Steckler and Linnan, 2002) propose that implementation research was more widely used for the following reasons: 1) social and behavioural interventions became increasingly complex, and it was important for researchers to know the extent to which all intervention components are implemented 2) projects became more likely to be implemented at multiple locations, which makes process evaluation important for knowing if implementation differed between sites.

Policy changes have made conducting implementation research more appealing. For example, academic clinical researchers were once exclusively, and still are to a certain extent, evaluated by their abilities to conduct intervention studies and publish and disseminate the results in high impact journals (Simmons, Nelson and Simonsohn, 2011; Norris and O’Connor, 2019). Whether their findings translated into any actual impact on health had not traditionally been the responsibility of academic researchers (Bauer *et al.*, 2015). However, demonstrating real-world clinical impact is now considered to be important to the extent that the UK Department of Health now recommends the systemic use of implementation research (Department of Health, 2017) in their framework for mental health research. Moreover, even the “high impact journals” are now encouraging implementation research. The most pertinent example of this in relation to digital mental health is the Journal of Medical Internet Research (JMIR) (Buis, 2019) stating that while they still want to publish the outcomes of RCTs, they also want to publish research that is centred on complex implementation issues. Another key change is that the new MRC guidelines for evaluating complex interventions now recommend that “implementation questions should be considered alongside effectiveness ones from the outset. Moving away from a narrow ‘effectiveness’ focus should increase the relevance of the evidence produced by evaluation studies and increase the speed with which effective interventions can be implemented within policy and practice” (p.57) (Medical Research Council (MRC) and National Institute of Health Research (NIHR), 2019).

The MRC process evaluation guidelines were published in 2015 and are considered influential. There is no prescriptive process evaluation methodology, but the MRC guidelines stipulate that in order to carry out a process evaluation of a complex intervention, the following three key functions must be examined: i) implementation (identifying what was delivered and how this was done or achieved), ii) mechanisms of impact (factors that contributed to the delivered intervention producing or not producing change) and iii) context (contextual factors external to the intervention which affected implementation, intervention mechanisms, outcomes and vice versa) and are shown in Figure 1 below. Each will now be described:

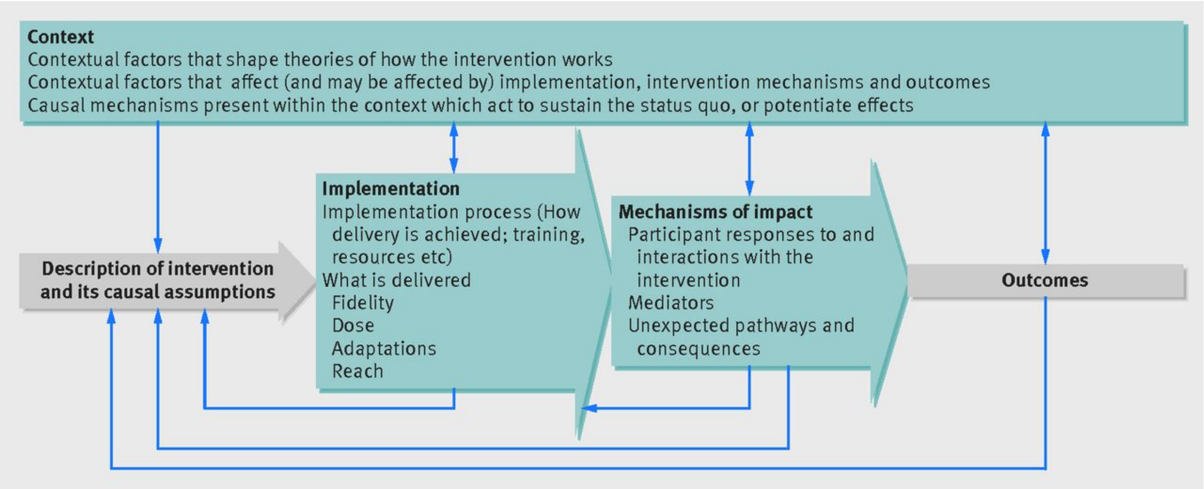


Figure 1 Diagram reproduced from Moore et al (2015) (Moore et al.*, 2015) showing how implementation, context and mechanisms relate to observed trial outcomes.*

1.15.1 Implementation

Implementation can refer to when an intervention is implemented within routine clinical practice and implementation science studies the processes which underpin how and why this happens. However, implementation of an intervention within clinical care can only be achieved once an intervention has shown efficacy in an outcome evaluation. For feasibility trials, it is important to understand how interventions are used, and the focus is on trying to understand the implementation process. In this case, implementation can be best described as the degree to which an intervention was delivered according to the study protocol and what was envisioned in advance. However, implementation goes beyond fidelity and can also be used to describe what was delivered and any emergent or unexpected processes. This would be best achieved by strongly assessing end-user perspectives and developing implementation theory.

1.15.2 Mechanisms

The MRC process evaluation guidelines (Moore *et al.*, 2015) describe two key approaches to understanding how interventions create impact: theory-based evaluation and realistic evaluation. Theory-based evaluation aims to examine how hypothesised intervention causal chains play out in practice. Researchers who are proponents of theory-based evaluation argue that this allows information to be gathered about the stages at which the causal chain might break down (Weiss, 1997). Theory based evaluation may focus on ‘intervention theory’ (the mechanisms through which intervention components produce change), ‘implementation theory’ (how successful implementation is achieved) or a combination of the two. However, because there is a somewhat interrelated relationship between intervention theory and process evaluation, the MRC process evaluation guidelines explicitly recommend that process evaluators base new process evaluations on what has come before and look at interventions based on similar theories. However, this is only possible with systematic searching and reporting. This would be optimised for interventions with at least one post-test efficacy measure (even if at the feasibility stage) to understand whether interventions create impact via proposed mechanisms of change which could be observed by changes in outcome measures.

Realistic evaluation also focuses on understanding the mechanisms of change. However, realist evaluation emphasises the contextually contingent nature of mechanisms. Based on a critical realist epistemology, interventions are viewed as “working” because they introduce mechanisms which are suited to their context and can produce change. In other words, evaluation through a realist lens aims to discover context-mechanism-outcome configurations, in order to understand what works, for whom, under what circumstances and why (Bonell *et al.*, 2012). The realist perspective is important to process evaluation because it examines how contextual factors (such as trial site) can influence intervention impact.

Complex interventions often have multiple components which means it can be difficult to understand change. Process evaluations present a unique opportunity to identify “active ingredients” which contribute to successful outcomes (Kan *et al.*, 2021). However, this will only be possible if interventionists clearly report the theory underpinning their intervention so other researchers can understand the likely mechanisms by which the intervention has produced change. If intervention components appear helpful, this information would be beneficial to share with the wider community to develop better interventions to address clinical need. An assessment of the current quality of intervention is warranted.

1.15.3 Mediators

Part of MRC guidance for conducting an analysis of impact is to assess the extent to which the causal assumptions underpinning the intervention can be tested through mediation analysis. Incorporating mediation into an intervention’s theory of change means designing research questions such as “if intervention X is implemented, this will lead to change in the mediating variable, which will then, in turn, lead to a change in outcome Y”.

1.15.4 Moderators

While mediation analyses explore emergent processes, trial participants arrive in the trial with varying demographics, which may impact the relationship between observed outcomes. For example, human support is a predictor of engagement with digital interventions (Arnold *et al.*, 2021) for people with psychosis, but this may be moderated by baseline levels of psychosis symptoms. Testing moderation means examining whether pre-existing demographics significantly interact in the relationship between the independent and dependent variables.

1.15.5 Network Analysis

While not referred to within the MRC guidance, network analysis (Fried *et al.*, 2017) appears a helpful addition to the researcher toolkit for understanding mechanisms in feasibility studies. Both mediation and moderator analysis, as described in the process evaluation guidance, are optimised for full-scale RCTs. Mediator and moderator analyses do not focus on the most appropriate level of analysis for a process evaluation in a feasibility study where there may still be uncertainties about how the theory or model underpinning the programme theory works. Programme theory describes how an intervention is expected to lead to impacts and under what circumstances. In terms of internal validity, there is a need for so-called “inward-looking” process evaluations that more fully explain how an individual intervention works. For feasibility trials, it is important to explore programme theory. Many existing analyses to determine mechanisms of change do not allow for relationships between multiple potential mechanisms. Network models allow for the inclusion of multiple potential mechanisms of change, which may act in parallel or have interactive and/or reciprocal effects and offer an added value for process evaluation research by giving the opportunity to test assumptions underpinning programme theory and open up the “black box” – a need highlighted in section 1.14.1.

1.15.6 Context

The final component is context, which refers to any factors external to the intervention that may have acted as a barrier or facilitator to the way it is implemented or to the outcomes. As mentioned, the uptake and use of psychosocial interventions for psychosis are dependent on context; therefore, understanding the context within a feasibility study seems crucial for interpreting the findings from the trial and thinking about adaptations. As covered in section 1.6.9, recruitment is seldom well described, which means it is an important area of enquiry to the foreground when trying to understand the context. This issue is particularly pertinent because recruitment into trials is often biased with marginalised groups being underrepresented (Morris *et al.*, 2022).

1.15.7 Logic Models

Logic models are recommended as a way of documenting the core functions of a process evaluation and providing a way to structure process evaluation findings which can often be complex. In particular, a logical model provides a theoretical framework for understanding the findings, Figure 1 is a basic example of a logic model.

1.15.8 Process Evaluations as an Opportunity for Learning in Feasibility Trials

As has been covered in section 1.3.9, RCTs cannot answer questions about everything that might be relevant for a feasibility study. Process evaluation is an opportunity to learn far more than what a standard RCT can provide. For example, the EMPOWER trial was a feasibility cluster randomised control trial of a peer worker-supported digital intervention. As discussed in Section 1.5, many digital interventions are not well implemented even if shown to be feasible and then effective in a full-scale trial. Therefore, formal guidance encourages process evaluations at the feasibility stage to explore factors influencing uptake and to inform the further development of interventions for people diagnosed with schizophrenia. Case study research is based on in-depth explorations of complex phenomena in real-life, settings. Empirical case studies typically enable dynamic understanding of complex challenges and provide evidence about causal mechanisms and the necessary and sufficient conditions (contexts) for intervention implementation and effects (Paparini *et al.*, 2020). The case study methodology is ideally suited to real-world, sustainable intervention development and evaluation because it can explore and examine complex phenomena, in depth, in numerous contexts and using multiple sources of data (Robinson, Schulz, Blank, *et al.*, 2020)

1.16 EMPOWER Background and Rationale

EMPOWER (Gumley *et al.*, 2022) was a user-led digital intervention trialled in Glasgow and Australia. The following section will introduce the EMPOWER clinical trial rationale before introducing and discussing how to understand implementation in the context of feasibility trials. EMPOWER was designed to prevent relapse; first, this introduction will briefly cover relapse.

1.17 Relapse in Schizophrenia

Relapse episodes in people diagnosed with schizophrenia reflect times when they are more unwell, and their symptoms are no longer viewed as in remission. As demonstrated in this figure from a 2020 overview paper published in the Journal of the American Medical Association (McCutcheon, Reis Marques and Howes, 2020), relapse events are a regular part of the clinical course of schizophrenia – shown in Figure 2.

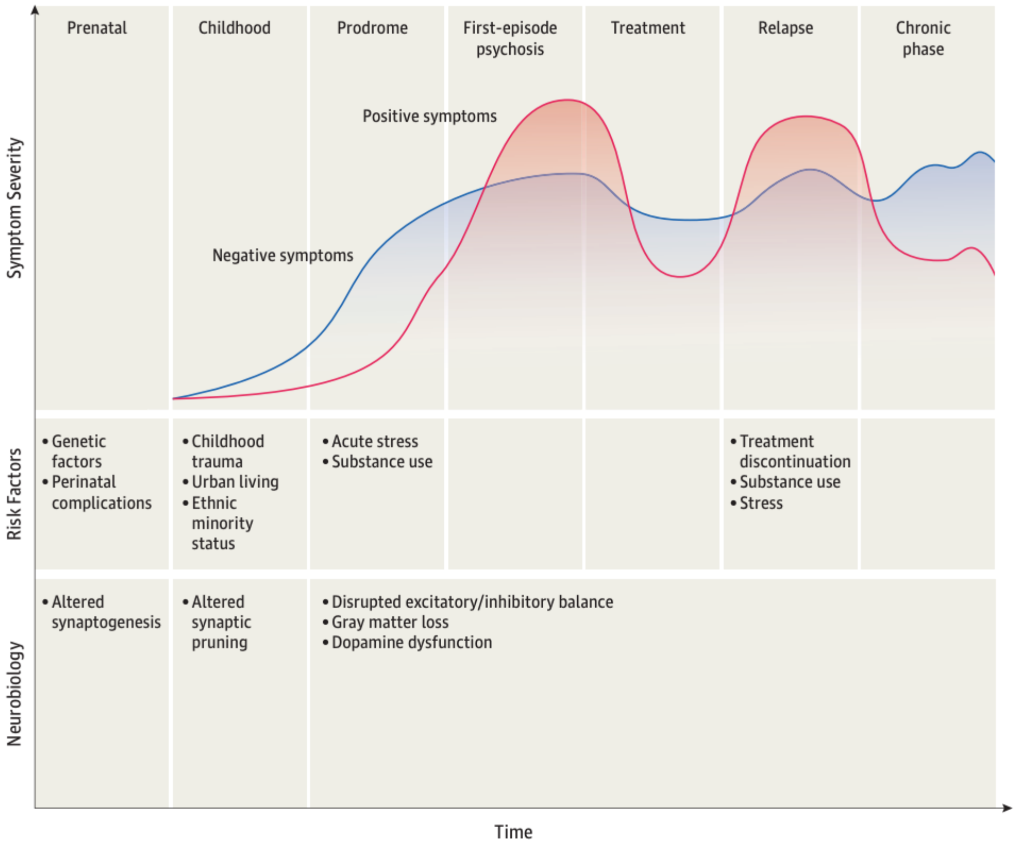


Figure 2 Course of schizophrenia - reproduced from (McCutcheon et al., 2020)

Relapse is common in schizophrenia, with one recent study reporting that 46.4% of people experience a relapse event involving hospital treatment five years post-diagnosis (Köhler-Forsberg *et al.*, 2019), and another reporting 64.1% of people will be re-hospitalised in the five years following discharge from psychiatric hospital (Hudson, 2019). It was important to highlight that there is not an agreed definition as to what relapse is and how to measure it (San *et al.*, 2015; Moncrieff *et al.*, 2020). For example, in a systematic review of relapse definitions it was reported that 62% of the 87 papers that operationally defined relapse utilised hospitalisation as a proxy for relapse (Olivares *et al.*, 2013) . Despite this lack of conceptual clarity as to what a relapse is, relapses are generally considered to be highly negative events and relapse prevention is a key recommendation within clinical practice guidelines worldwide (Hasan *et al.*, 2013), and in both the UK (NICE, 2014) and Australia (Galletly *et al.*, 2016) which are based upon the results of clinical trials research.

1.17.1 Assessment using Early Warning Signs

Symptoms are typically evaluated through clinical impressions, in-person interviews, or clinician-administered rating scales, which require direct contact with a trained assessor. EMPOWER is based on early warning signs monitoring, so this section will discuss that approach in some detail. Like a cough may be considered an early warning sign of a cold, relapse in schizophrenia is often preceded by so-called "early warning signs". Formal early warning signs monitoring approaches were pioneered in the 1980s by Max Birchwood. A long-standing definition of early warning signs is that they are "subtle changes in thought, affect and behaviour precede the development of frank psychosis" (Birchwood, Spencer and Mcgovern, 2000) p. 93. Historically, these early warning signs were constructed as a prodrome, but this went out of favour because this implied that someone experiencing these symptoms meant that this was the start of a disease process and relapse was inevitable and could not be prevented (ibid). Early warning signs monitoring approaches assume that if early warning signs of relapse can be identified, early intervention (such as by providing timely medication or psychosocial support) means relapse can be avoided.

Just as cough may proceed to a cold, it may be more concerning if the cough was an early warning sign for the coronavirus. However, if only observing that the person has a cough, it may be difficult to predict if the person will end up with just a cold or become unwell (or infect others) with coronavirus. Intervene as if it is coronavirus when it is just a cold (false positive), and you risk alarming someone unnecessarily, but equally, not intervening adequately (false negative) could run the risk of them spreading a potentially deadly virus to others. Early warning signs monitoring approaches in psychosis face similar problems of prediction. For example, a review of cohort studies (Eisner, Drake and Barrowclough, 2013) using common early warning signs monitoring approaches suggested that sensitivity (the ability of the early warning signs monitoring approach to identify people who actually will relapse) ranged from 10%–80% (median 61%) while the specificity (the ability to differentiate only those who will relapse) ranged from 38%–100%, (median 81%) which suggest current prediction accuracy is poor and requires improvement.

In addition to improving methodological rigour and accuracy, the field might be improved by improving what early warning signs are measured. In medical terminology, signs are distinct from symptoms because signs are what is observed by someone with clinical expertise, and symptoms are what patients experience subjectively and then may report to the clinician (Subotnik and Nuechterlein, 1988). Respectfully borrowing the ideas of Foucault that discourse (especially regarding terms used in psychiatry) is indicative of societal power relations (Roberts, 2005), the usage of “signs” may be a subtle yet important indicator that patient views are lower down the hierarchy of evidence than that of the clinical observer. Within schizophrenia research, it is always important to be mindful that people diagnosed with schizophrenia (Kamens, 2019) have been historically conceptualised as unreliable experts in understanding their wellbeing. In addition, mental health research has been critiqued for commonly committing a philosophical error of conflating the absence of knowledge with knowledge of absence (McPherson, 2020). In other words, by not measuring or enquiring about specific experiences or including certain types of evidence in analysis, we can falsely conclude that a phenomenon lacks certain facets. Concern has been raised that potentially useful early warning signs of relapse (Freeman, Morrison, *et al.*, 2019) have been missed and not included within research because the original early signs scale (ESS) was developed from analysing the views of carers about what they witnessed during their loved one’s relapse events (Birchwood *et al.*, 1989).

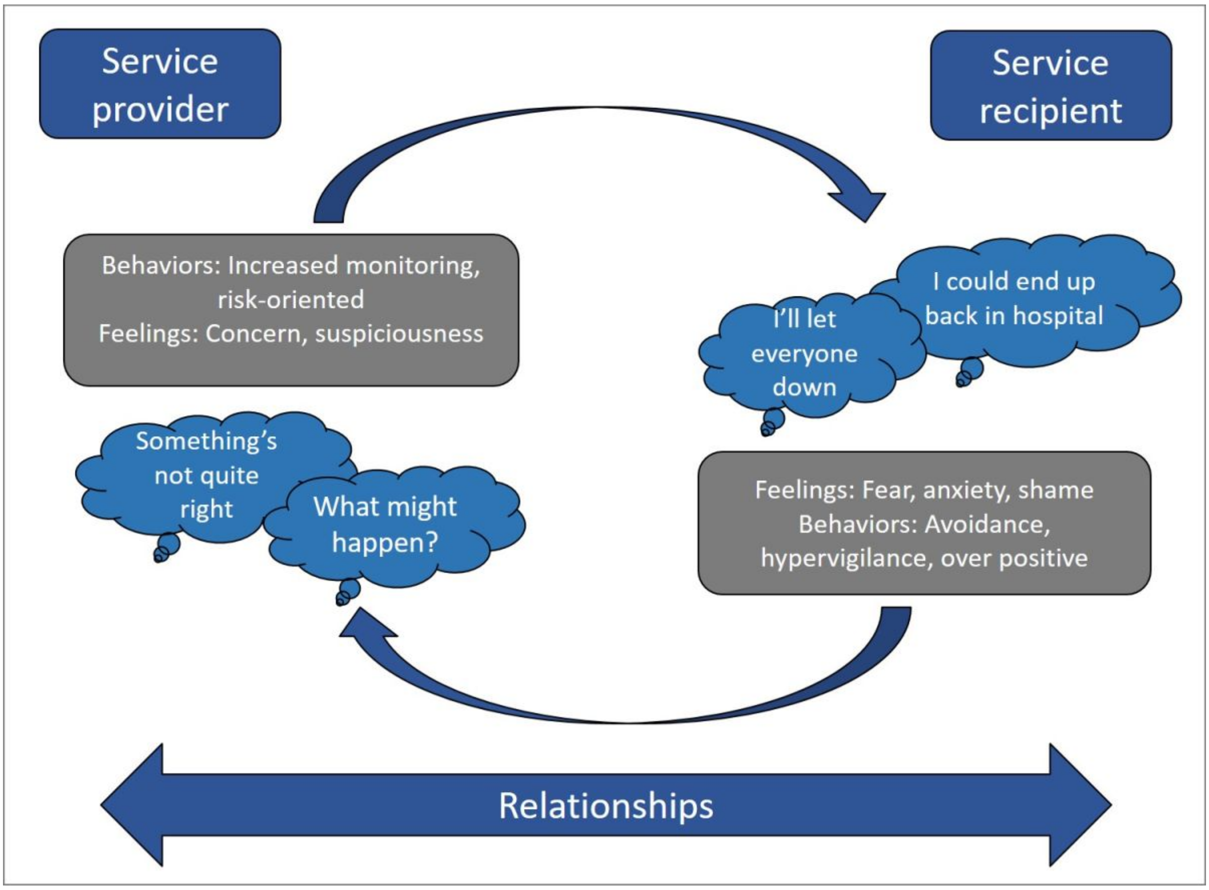
There is evidence that some early warning signs have been overlooked. For example, in a recent study, patients who had experienced a relapse were 16 times more likely to report basic symptoms (subtle differences in the perception of the world) in the run-up to their relapse event in an interview (where they were asked about them) compared to what was recorded in their case notes (Eisner *et al.*, 2018). Beyond suggesting that basic symptoms may be clinically meaningful early warning signs, this also suggests that the subjective experiences of patients may be overlooked, and clinicians are perhaps failing to enquire about (or at least record) potentially relevant early warning signs. The approach taken by the researcher of directly speaking to patients fits with the value of giving people the power to describe their experiences in their own words (Hughes, Hughes and Cocq, 2020). Another example of a potentially overlooked early warning sign is patients experiencing fear of relapse (Gumley *et al.*, 2015).

1.18 Fear of Relapse

The EMPOWER intervention is underpinned by a cognitive interpersonal model of fear of relapse. Before describing the model, this section will cover fear of relapse in some detail. Fear of relapse itself is not unique to schizophrenia and has been observed in multiple sclerosis (Khatibi *et al.*, 2020) and cancer (Mutsaers *et al.*, 2019). Fear of relapse in schizophrenia has been noted in published journals as far back as 1931 with patients who had previously received treatment for dementia praecox where it was described as fear of impending insanity (Paskind, 1931) “the patient has good reasons for the belief that insanity is impending, and this conviction is understandable; it has an obvious and palpable cause, and that cause is the misinterpretation of a sensation or experience”. It is of note that the clinical observations published in 1931 are very much in line with the cognitive, interpersonal model underpinning EMPOWER, which posits that appraisals of experiences and sensations can generate reactions such as catastrophic thoughts about relapse, increased fear, heightened vigilance and interpersonal threat sensitivity (Gumley *et al.*, 2006). In terms of clinical utility, fear of relapse appears a useful “early warning sign” as evidenced by fear of relapse independently predicting relapse (sensitivity=72%, 95% CI 52-86; specificity=46%, 95% CI 32-60) compared with other standard early warning signs (sensitivity=79%, 95% CI 62-89; specificity=35%, 95% CI 23-50) (Gumley *et al.*, 2020). Additionally, fear of relapse significantly predicted the time to relapse in one clinical trial, as demonstrated by a ratio of hazard rates of 1.20 (95% CI = 1.01–1.42) (Gumley *et al.*, 2015).

The available cross-sectional and prospective research evidence suggests fear of relapse is closely linked not only to the trauma of psychosis itself but also to treatment experiences and is associated with emotional distress (White and Gumley, 2009; Gumley *et al.*, 2015). However, this research does not account for how psychotic and affective experiences fluctuate over time in schizophrenia (Lecomte, Leclerc and Wykes, 2018). New developments in data collection have the potential to address this. Ecological Momentary Assessment (Stone and Shiffman, 1994) (EMA) allows participants to report their experiences in real-time (Mofsen *et al.*, 2019), facilitating insight into how symptoms occur within daily life and overcoming biases associated with methods based on retrospective recall (Myin-Germeys *et al.*, 2018). To our knowledge, no research has explored to what extent people experience fear of relapse on a day-to-day basis and to what extent fear of relapse co-occurs with previously described EWS such as disrupted mood or psychosis. Therefore, there is merit in exploring day-to-day reports of fear of relapse, utilising multivariate time series methods to explore interactions between fear of relapse and other symptoms and experiences. However, beyond typical EWS, there is recognition that positive well-being experiences such as self-esteem may also play a role, with low self-esteem predicting later relapse events (Holding *et al.*, 2013). Additionally, perceived social support may be protective against relapse events (Vázquez Morejón, León Rubio and Vázquez-Morejón, 2018). Therefore, a time series that includes protective factors would greatly enhance the current understanding of fear of relapse. The cognitive, interpersonal model below posits that fear of relapse would influence and be influenced by affective symptoms and psychotic experiences and would form the basis of further work.

Figure 3 The Cognitive Interpersonal Model Underpinning EMPOWER – reproduced from (Gumley et al.*, 2020)*



1.19 Overview of the EMPOWER trial

The EMPOWER trial has been described in some detail in the published protocol (Gumley *et al.*, 2020). However, a summary will be given here to situate the thesis. The EMPOWER trial was a 12-month cluster RCT with community mental health teams (CMHTs) as the unit of randomisation; the CMHTs were purposively selected for likely having five care coordinators who were likely to want to take part. The EMPOWER trial aimed to establish the feasibility of undertaking a definitive randomised controlled trial to determine the effectiveness of a blended digital intervention for relapse prevention in schizophrenia. The comparator was treated as usual (TAU). EMPOWER had three participant groups: care coordinators, patients, and carers. Patient participants were eligible if they were older than 16 years of age, had schizophrenia or related diagnosis confirmed via case records, were able to provide informed consent, had contact with community mental health teams (CMHTs), and had had a relapse within the previous two years. Researchers approached care coordinators and sought their consent to participate.

Before randomisation, consenting care coordinators provided researcher workers with an anonymised list of potentially eligible service users on their caseload. Care coordinators provided participants with an information leaflet about the study to facilitate the expression of interest in participating. Carers of people receiving support from participating services were eligible for inclusion if nominated by an eligible participant and were in regular contact with that participant. Participants were followed up at three months, six months, and twelve months.

CMHTs and the participants therein were randomised into one of two groups. EMPOWER (the intervention group), or treatment as usual. If participants in the intervention group did not already have a smartphone, they were provided with a smartphone for the duration of the study. EMPOWER employed Peer Support Workers who were staff with their own lived experience of mental health problems Peer Workers introduced participants to the ethos and principles of the EMPOWER stepped care approach and set up and personalised the app with participants. Participants were then asked to undertake daily monitoring for an initial four weeks to help establish their personal baseline. During this period, additional support was provided by peer support workers through weekly telephone follow-ups. This provided an opportunity to encourage engagement with the app, provide technical advice and assistance, and identify any adverse effects. At the end of the four weeks, a further meeting was arranged with the peer support worker or Mental Health Nurse to review monitoring and to discuss preferences for actions in response to changes in wellbeing picked up by the EMPOWER algorithm. All participants were offered ongoing contact with the Peer Worker, which was achieved mostly by phone calls with some text messaging and occasional in-person meetings. Ongoing support included generally checking in with participants and encouraging them to reflect on changes in wellbeing displayed through the charting function. Peer Workers continued to check on participant experiences of the app monitoring, review engagement and monitor and report any adverse experiences.

Daily monitoring of wellbeing was achieved via a mobile phone app developed for Android devices. Handsets were provided to participants as required. The app was developed in part through consultation with people using services, their carers, and mental health professionals. The questionnaire contains 22 items reflecting 13 “domains” (e.g., mood, anxiety, coping, psychotic experiences, self-esteem, connectedness to others, fear of relapse, and personalised EWS). Items included both positive (e.g., “I’ve been feeling close to others”) and negative (e.g., “I’ve been worrying about relapse”) content. Each item was completed using a simple screen swipe and was automatically scored on a scale of one to seven. If items scored more than three, patient participants were invited to complete additional probe questions. This meant there were up to a maximum of 56 questionnaire items. Other elements within the digital intervention included wellbeing and self-management-focused messages. Messages were triggered each time a questionnaire was used. Messages were designed to encompass the following domains: Generic, Psychosis, Anxiety and Coping, Mood, Fear of Recurrence and Activity/Activation. Messages were designed to encourage hopefulness, self-compassion and recovery, suggestions for coping and self-management, and signposting to online self-management resources. These messages were curated through consultation with a lived experience reference group, contributions from the peer support workers, an online survey, and consultation of online and written self-help resources. The App also contained a diary function to allow people to record their own experiences and included a charting function where people were able to monitor and review their wellbeing data over specified time periods – unlike the self-monitoring data the diary function was stored locally.

If participants’ response to EMA monitoring indicated a change in wellbeing, this could trigger either a tailored message (for a small change) or a check in prompt (ChiP) for a larger change. A clinical interface enabled staff to review participants monitoring data, identify and review ChiPs and update any actions in relation to these. The EMPOWER intervention was available to patients for up to twelve months. As can be seen from this long description, EMPOWER was a highly complex intervention with many components, which are summarised in Table 2.

Table 2 EMPOWER Components

Relevant intervention component	Rationale
Self-Monitoring	In terms of the underlying model, self-monitoring was designed both for patients to understand changes in their own wellbeing (possibly in a normalising way) but also to detect EWS
Peer Support	To provide ongoing tech support for using the app and share experiences of mental health
Diary	In addition to self-monitoring, a diary function existed wherein participants could keep a diary of their wellbeing.
Self-Management Messages	Following the input of data, patients were given a message tailored to their input. For example, a high score on “Sleep Change” would mean getting a message about sleep
Use of and sharing of graphs	The self-monitoring data created longitudinal graphs which participants could look at themselves and/or choose to share/discuss with others. Additionally, trial staff were able to look at these graphs to understand patient wellbeing.
“Ebb and Flow”	A philosophical approach to understanding the emotional wellbeing in daily life for people

	with psychosis. In EMPOWER, this means accepting that emotional states and changeable and may not herald relapse.

1.20 Process Evaluation of EMPOWER.

Parallel to the EMPOWER (Early signs Monitoring to Prevent relapse in psychosis and prOmote Well-being, Engagement, and Recovery) feasibility trial process evaluation was undertaken, following the guidelines recommended by the Medical Research Council's (MRC) framework on process evaluations of complex interventions (Moore *et al.*, 2015). EMPOWER is regarded as a complex intervention because it is composed of multiple components with the potential for interactions and several possible outcomes (Richards and Hallberg, 2015) The MRC guidelines stipulate that to carry out a process evaluation of a complex intervention, the following three essential functions mentioned in Section 1.4 must be examined: i) implementation (identifying what was delivered and how this was done or achieved), ii) mechanisms of impact (factors that contributed to the delivered intervention producing or not producing change) and iii) context (contextual factors external to the intervention which affected implementation, intervention mechanisms, outcomes and vice versa). The MRC process evaluation guidance does not say much about process evaluation within feasibility trials which requires the usage of exploratory research.

1.21 Summary and Thesis Outline

This thesis aims to address the following research aims:

1.1. To develop an initial process evaluation framework grounded in stakeholder expertise from qualitative data gathered from focus groups with mental health staff, carers, and patients to process evaluate the EMPOWER feasibility trial. Then to conduct relevant empirical research to generate process evaluation data to refine the initial logic model with the results from the process evaluation (triangulated with relevant aspects of main trial outcomes) to develop a process evaluation framework suitable for a potential full-scale clinical trial. Linked to the first aim, I also aimed to systemically review what interventions are user-led like EMPOWER, which will enable me to relate the findings to relevant literature and facilitate the future conduct of process evaluations by providing a database of intervention theories.

1.2. To explore the temporal dynamics of fear of relapse to enhance understanding of underlying intervention theory and to make recommendations for the refinement of intervention theory.

1.3. To produce a Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis of implementation for EMPOWER to suggest areas for intervention refinement.

1.22 Thesis Structure

This is a PhD by publication which means Chapters 3 – 9 were written for publication in academic journals. This means the empirical chapters are impacted by journal word count limits. Some further detail has been added in the methods sections which is not within the published papers to help the reader understand the work more completely.

A further introductory chapter (Chapter 2) sets out the epistemology and ontology for the rest of the work. In Chapter 3, a systematic review of the theory underpinning user-led digital interventions for psychosis was conducted – the empirical data was also used to create a taxonomy to understand what user-led interventions exist more fully for psychosis: Chapters 4 and 5 present qualitative data analysis conducted in advance of the trial. Chapter 6 presents the process evaluation methodology in the form of a published protocol. Chapter 7 presents an ethnographic study's results to understand trial recruitment better. Chapter 8 shows the results of qualitative interviews with EMPOWER end users. Chapter 9 presents a temporal network analysis to understand better the fear of relapse as an outcome of interest. The final chapter (Chapter 10) is a general discussion, which integrates the findings from this thesis’ empirical studies, drawing overarching conclusions about EMPOWER feasibility (in the form of a SWOT analysis) and identifying fundamental limitations and suggestions for future research.

2 Chapter 2 Epistemology and Ontology

2.1 Background

It is recommended that researchers highlight what assumptions they bring to the research process (Ocloo and Matthews, 2016). The cognitive, interpersonal model that underpins EMPOWER posits that different people who have different roles (patients or staff) experience the phenomena of monitoring for relapse in unique role and distinct ways. When engaging with such an intersubjective phenomenon, it is pertinent to discuss my philosophical underpinnings of relapse in psychosis and how this links with my approach to evaluation. Additionally, focusing on understanding implementation from the viewpoint of diverse stakeholders, I need to reflect upon my positionality within the research. Within research, there is stated to be a link between how we understand reality (ontology), the meanings we ascribe to the creation of knowledge (epistemology) and rationales for research design and methodologies (Humphrey *et al.*, 2016). The MRC guidance for process evaluations does not provide advice on dealing with this more philosophical side of the assessment. However, the direction has been critiqued by (Maar *et al.*, 2017) for having an implicit philosophical underpinning of realism (an assumption that reality is experienced the same way). This section contains relevant aspects of my background and beliefs that shaped my data collection, analysis, and interpretation approach. Haigh and colleagues recommend that healthcare research explicitly spell out their research paradigm (Haigh *et al.*, 2019):

Ontology – researcher's understanding of what reality is
Epistemology – how the researcher 'makes sense of the world
Methodology – approach to knowledge construction
Axiology – influence of researcher values on what is known and acquired. Axiology is particularly important as the influence of values is vastly overlooked in evaluation research (Gullickson and Hannum, 2019).

The ontology best suited to this thesis was critical realism. Critical realists perceive that reality consists of unobservable elements beyond our empirical realm that are still reachable by scientific inquiry. In arguing that social truth can be known, even though the social world is unpredictable and complex, critical realism offers a conception of the real fundamentally different from the empirical realism of the natural sciences. A central aspect of realism ontology is the distinction between three ontological domains: the observed, the actual, and the real (Eastwood *et al.*, 2019). The practical domain is what can be experienced and observed (a record of events, the actual domain is what happens beyond what can be shared and celebrated (events)). The existing domain is the deepest level of reality which contains all the mechanisms that have gone into an event.

In my PhD, I consider the domain of the “real” to be best captured by structural symbolic interactionism. Within this, the individual and the context where the individual exists are inseparable (Benzies and Allen, 2001). The symbolic interactionist perspective toward ontology comes from sociology. Research questions within traditional symbolic interactionism emphasise process rather than structure (Benzies and Allen, 2001). Therefore, it has been critiqued for not considering the impact of social structure. The original (Mead, 1967) stance on symbolic interactionism emphasised that social processes generated by society were critiqued by Stryker (Stryker, 2008), who puts forward that culture shapes the self, which then subsequently shapes social interaction (Hausmann, Jonason and Summers-Effler, 2011).

Structural symbolic interactionism states that conduct within relationships goes beyond individual contributions. The “structural” contribution (Stryker, 2008; Serpe and Stryker, 2011) privileges how sociodemographic factors and broad cultural and historical forces pattern relapse management in psychosis. For example, the therapeutic relationship between a member of staff and a service user will always be understood within the context of the relationship being a function of mental health services. The most crucial part of symbolic interactionism is that the individual and the context where the individual exists are inseparable (Benzies and Allen, 2001). The human experience is socially organised, not random. In early warning signs-based relapse prevention, patients and staff interact not by chance but because it has already been decided that the patient requires support in managing psychosis. Evidence suggests this is a normative way to prevent relapse. In other words, each person has a crucial role.

Role theory originates from sociology and deals with the organisation of social behaviour at both collective and individual levels (Turner, 2001). Individual behaviour in a social context acquires meaning in terms of roles. Versions of role theory that start at the collective level are known as structural theories. Structural interactionism posits that self-interest motivates human behaviour and takes social interactions as the unit of analysis (Stets and Serpe, 2013). Structural symbolic interactionism stresses a symbiotic relationship between structure and an individual (Stryker, 2008). Therefore, if society (or structure) can change, so can individuals. Structural symbolic interactionism appears to be a sound theoretical basis for process evaluation because it enables us to think clearly about broader social structures' impacts on individual implementation behaviours. While this may read as abstract, it aligns with current thought on the ontological exitance of complex interventions as attempts to create change within the healthcare systems (Moore *et al.*, 2019). Social structures define boundaries, meaning that those within social structures will likely have relationships with others and interact with those over specific issues and with specific resources (Stryker and Vryan, 2006). Stryker builds up from the person to the situation within the larger social structure, demonstrating the reciprocity of the individual and society. In every case, individuals identify themselves and others in the context of social structure. Individuals then reflexively apply what they perceive to be others' identifications of them that, over time, become internalised expectations for behaviour as part of the self and the role one plays in society (Carter and Fuller, 2015) —using structural symbolic interactionism as critical realist ontology provides a “dynamic bridge” between the cognitive, interpersonal psychological programme theory and the complex social world where EMPOWER resided when it was trialled.

The epistemology was social constructivist; constructivism posits that individuals and society construct knowledge. It has even been claimed that adopting a constructivist epistemology within evaluating interventions means that researchers do not accept that we should privilege one type of knowledge over another (Wilson *et al.*, 2020). While I am not sure I achieved this, we all have our own biases and blind spots; it was my goal to foreground end-user perspectives, and this seemed the best fit.

The methodology was interpretivism and aimed to understand implementation from various perspectives. As highlighted by Brockenhurst (Brocklehurst *et al.*, 2017), when it comes to evaluation, how much an intervention improves some clinical outcome measure in a clinical trial may be irrelevant because it is the meanings people ascribe to the intervention that will dictate how it is used which makes interpretive methodology key.

The axiology of this thesis (relevant values) is my position as a “critical friend”. Being based within the office that was the hub of the EMPOWER trial in Glasgow and being supervised by the chief investigator and a principal investigator meant it would have been challenging to remain fully independent. Therefore, my position as process evaluator could be considered a “critical friend”. I respectfully call on the framework proposed by Balthasar (Balthasar, 2011) that states quality evaluation requires both methodological soundness and practical relevance and that both things are embedded within a transparent evaluation process. Being a critical friend means accepting that I am not neutral; my PhD was funded to produce valuable data to help inform potential upscale decisions for EMPOWER. My critical friend positionality likely influenced my choices.

2.2 Quality and Credibility

Epistemology and ontology of research are closely linked to determining the quality and credibility of the analysis. The PhD was mixed methods and positioned within a constructivism epistemological framework and a critical realist ontology. Within the ontology proposed, I have accepted that any tools or techniques I use to improve the quality of analysis are not trying to get closer to a scientific “truth” (or, in other words, a true reflection of reality) but are trying to do a good job, nonetheless. I feel this is especially important within the PhD topic because decisions on whether to use interventions are socially constructed (Brocklehurst *et al.*, 2017). Even if, somehow, I was able to conduct research with no measurement errors or bias, decisions on how to interpret the evidence from my process evaluation would still be used in a socially constructed manner. I have adhered to "open science" principles by sharing my code on the open science framework and have made super explicit that my research was exploratory.

The thesis will now lead into the empirical chapters that address the aims in Section 1.21.

3 Chapter 3: Use of theoretical frameworks in user-led digital interventions for psychosis: A Systematic Review

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Title: Use of theoretical frameworks in user-led digital interventions for psychosis: A Systematic Review

Abstract:

Background and Hypothesis: User-led digital interventions may upscale effective mental health care for people with schizophrenia. Using theory to develop and evaluate interventions is likely to enhance the evidence base on which future interventions are developed. Clearly reporting intervention theory would improve the utility of existing research, and a review is required to evaluate the current quality of theory reporting.

Study Design: This study systematically reviewed the use of theory in user-led digital interventions for patients and developed a taxonomy of intervention types. PubMed, PsychINFO, Cochrane Trial Register and OVID Medline were searched for relevant literature published up to April 3rd, 2021. Methodological quality and risk of bias were assessed using the Downs and Black tool. Quality of theory reporting was assessed with an adapted version of the Theory Coding Scheme.

Study Results: Forty-six articles with data from 3038 participants were available for narrative synthesis. User-led digital interventions target: loneliness, cognitive deficits, social skills deficits, depression, sedentary behaviour, social anxiety, and positive and negative symptoms, and to monitor symptoms and provide access to self-management. Most were feasibility studies showing a high risk of bias. Only around half of studies reported being based on an overarching theoretical framework. The research team developed a multidimensional descriptive taxonomy to describe the interventions, which had six key factors: intended targets, facilitator involvement, the location where the intervention was used, intervention platform, intervention targets and degree of data ownership.

Conclusions: The taxonomy of types presents a new way to conceptualise a heterogenous research area.

3.1 Introduction

People diagnosed with schizophrenia face many challenges such as cognitive dysfunction (Thai, Andreassen and Bliksted, 2019), loneliness (Lim *et al.*, 2018), poor physical health (Firth *et al.*, 2019), depression (Li *et al.*, 2020), and distressing psychotic symptoms (Longden *et al.*, 2020). A lack of access to interventions for these problems worsens suffering, and evidence-based care for these problems is poorly implemented (Maj *et al.*, 2021). Digital interventions, broadly defined as those which promote the mental health of people with schizophrenia and are delivered via technology such as websites, smartphone apps or computer programmes have been heralded as a way to upscale the provision of evidence based-interventions (Aref-Adib *et al.*, 2018; Hariman, Ventriglio and Bhugra, 2019; Foley and Woollard, 2020). One subtype of digital health interventions that could enable upscaling of support involves user-led interventions

(Alvarez-Jimenez *et al.*, 2014) which deliver mental health interventions to patients outside of mental health services.

User-led interventions need to address clinical needs, be effective, safe, and be implemented into clinical practice. Digital interventions are typically complex (Murray *et al.*, 2017) and present unique evaluation challenges. Recent guidance has called for the identification of causal components and pathways in health interventions (Skivington *et al.*, 2021) to understand how and why interventions work. This can be achieved through explicit use of intervention theory. While there is debate over the definition of theory (Guest and Martin, 2020) in health research, it is typically agreed that it describes a set of ideas and principles that explain phenomena and interrelationships among a group of concepts (Michie and Prestwich, 2010). Theory-use enables researchers to develop digital interventions that are more explicitly targeted to the most relevant mechanisms of change, select the most robust evaluation techniques for those strategies, and understand if the intervention was delivered as intended (Horan *et al.*, 2021). Another key recommendation for developing effective digital interventions is co-designing with patients (Ng *et al.*, 2019). Patient involvement may influence choice of intervention theory. Therefore, there is a need to appraise the extent of user involvement alongside theory use.

Standard evaluation of complex interventions using randomised control trial (RCT) methods are described as a “black box”. In intervention research, this refers to two key issues (Baron *et al.*, 2018). First, interventions designed without theoretical basis are unclear about what outcomes they target, what processes interventions aims to change and the hypothesised mechanisms through which anticipated effects occur. The second issue is “black box” labelling which results in poor reporting of interventions within manuscripts. Incomplete reporting of intervention descriptions affects the building of an evidence base by making interpreting and replicating results more challenging. It is not known how well theory is used or reported in user-led interventions for psychosis which means a summary is needed.

Since the only common characteristic of user-led interventions is the ability of a patient to engage with it in their own time, these interventions are likely to be heterogeneous. Developing taxonomies is applicable within digital healthcare where there is heterogenous research because they can develop precise classifications on interventions which can then be used to make meaningful comparisons (Muñoz *et al.*, 2018). This review aimed to fill the knowledge gap about user-led digital interventions for people diagnosed with schizophrenia. The objectives were to: (a) summarise what problems the interventions are addressing and describe their preliminary efficacy and adherence; (b) review what theories have been applied in the development of these digital interventions and the extent of theory reporting; (c) construct a taxonomy of the main user-led interventions that are in use and discuss their respective features.

3.2 Methods

3.2.1 Protocol and Registration

This systematic review is prepared based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Liberati *et al.*, 2009). The protocol was registered on PROSPERO and can be accessed here: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=139797

3.2.2 Search Strategy and Information Sources

3.2.2.1 Definitions

3.2.2.1.1 User-led digital interventions

We define user-led digital interventions as programmes that are accessed and delivered via a digital medium such as a computer, website, SMS or mobile application that patients could use independently (at least in part) outside of formal mental health service encounters.

3.2.2.1.2 Adherence

We expected adherence would be reported in a variety of ways. We followed guidance from a previous review (Killikelly *et al.*, 2017) and defined the standardised adherence for the narrative synthesis as (1) the mean percentage of the intervention completed, and (if this was not reported) we considered (2) percent of participants that completed the intervention and we reported this in the summary table.

3.2.2.1.3 Dropout

We defined dropout as the percentage of participants who did not complete the final follow-up assessment.

3.2.3 Search methods

PubMed, Ovid MEDLINE, Cochrane Trials, and PsycINFO databases were searched from inception to 03/04/2021. Search terms used for the population were psychosis OR schizophr* OR psychotic, and interventions were digital OR internet OR Website OR Web-based OR smartphone OR text message OR SMS OR mHealth OR mobile OR eHealth OR computer.

3.2.4 Eligibility Criteria

3.2.4.1 Quality of Theory Reporting

The theory coding scheme (TCS) (Michie and Prestwich, 2010) provides a standardised tool to assess the quality of theory reporting in some detail. Existing reporting guidelines (Hoffmann *et al.*, 2014; Agarwal *et al.*, 2016) do not specify theory reporting in as much detail as the TCS, particularly whether patients are selected in line with theory. The original tool was developed for evaluating behavioural change interventions and has a behavioural focus. User-led interventions can target far more than patient behaviour, so we adapted the TCS for this review with an iterative process – the changes are summarised below:

Question 1 “Theory/Model mentioned” was not adapted.

Question 2: “Targeted construct mentioned as predictor of behaviour Intervention” was adapted. “Construct” referred to the construct that the study intervention is hypothesised to change. For example, appraisals of psychotic experience for a cognitive behavioural therapy (CBT) intervention.

Question 3 “was intervention based on a single theory?” was refined during the coding process to refer to an overarching theoretical framework. During initial coding rounds, many interventions were scored as “0”. However, if the intervention presented as an overarching theoretical framework for a complex intervention, then this was coded as being based on a single overarching theory.

Question 4: "Theory/predictors used to select recipients for the intervention” was largely retained and covered whether participants were selected for having a particular score on a theory relevant construct. For example, in a cognitive remediation intervention – did the researchers demonstrate that the participants had cognitive deficits?

Question 5: “Theory/ predictors used to select/develop intervention techniques” was largely retained and explored whether intervention techniques were based on the overarching theoretical framework

Question 6: “Theory/ predictors used to tailor intervention techniques to recipients” was adapted to assess whether the intervention techniques were adapted in line with overarching theory. For example, if a participant reported a distressing appraisal of a psychotic experience and the intervention delivered CBT based content to challenge this then it would be scored.

Question 9 was dropped as it was not of relevance to the original aims.

Questions 7,8,10 and 11 were largely retained and explored to what extent theory relevant constructs were linked to intervention techniques.

Three reviewers (two PhD students and a psychology professor who has developed and trialled digital interventions) independently. Due to the iterative adaptation of TCS we did modal reporting instead of interrater agreement. Where interventions were reported in multiple papers, we considered the information across all studies. The possible scores ranged from zero to ten.

3.2.4.2 Risk of Bias

Two reviewers independently assessed the risk of bias using the Downs and Black (Downs and Black, 1998) which was chosen because it can assess RCTs and feasibility studies. Disagreements were resolved by discussion.

3.2.5 Data collection and analysis

Search results were imported into EndNote, combined and then the “remove duplicates” function was applied. Following a title search led by SA. Next, SA, and MM, CM compared full texts against inclusion criteria resulting in a final set of included papers.

3.2.5.1 Inclusion Criteria.

(1) Study samples that comprised over 75% diagnosed with schizophrenia spectrum condition (including first episode psychosis); (2) Included at least one post-test clinical outcome; (3) published in a peer-reviewed journal

3.2.5.2 Exclusion Criteria.

(1) Literature reviews, case reports, book chapters or conference abstracts; (2) studies of mixed diagnostic samples that do not present data in sub-groups or only provide pooled or aggregated data (3) Not in the English language

3.2.5.3 Data Extraction

One author (SA) led on data extraction using an extraction template developed by IB, AG, JT, HM and SA. We extracted data concerning participant demographics, countries, intervention types, adherence and dropout, clinical outcomes, service user involvement and intervention theory.

3.2.6 Data Analysis and Synthesis

We planned a narrative synthesis due to the anticipated intervention heterogeneity. Narrative systematic reviews are useful for exploring the development of ideas (e.g., theoretical application) and for advancing the knowledge of a particular intervention, problem, or field of research. This was conducted in two stages:

Stage 1: The first stage involved a qualitative analysis using constant comparison of the completed data extraction template with a specific focus on research aims, clinical outcome measures, and the stated rationale for using a digital intervention. This allowed identification of the problems the user-led digital interventions were addressing. These were reviewed by the research team.

Stage 2: We looked both between and within studies and explored beyond specific clinical outcomes and considered where interventions were linked or disparate, and used the systematic review summary table data to develop the taxonomy of types (Steen *et al.*, 2018). Due to the exploratory nature of this study, there was no pre-existing codebook. Therefore, we used qualitative iterative and inductive content analysis to group intervention descriptions within the systematic review summary tables. The initial taxonomy was then presented to an independent team including psychiatrists, psychologists and service user researchers for critique who identified missing facets.

3.2.6.1 Reflexivity

Due to the interpretivist nature of creating the coding framework (Drisko and Maschi, 2015) in a team which included patient, clinician and carer perspectives, we present a reflexivity section. The research team brought a range of international clinical and academic expertise, including psychiatry and clinical psychology.

3.3 Results

3.3.1 Identification of Studies

A total of 20,344 articles were identified through database searching, 19,971 titles were screened, 661 papers were assessed for eligibility, 44 papers were identified, and a further two were added from hand searches. The final review included 46 papers (Pijnenborg *et al.*, 2010; Rotondi *et al.*, 2010; Granholm *et al.*, 2012; Montes *et al.*, 2012; Sablier *et al.*, 2012; Španiel *et al.*, 2012; Alvarez-Jimenez *et al.*, 2013; Van Der Krieke *et al.*, 2013; Beebe, Smith and Phillips, 2014; Ben-Zeev *et al.*, 2014; Nahum *et al.*, 2014; Fisher *et al.*, 2015; Hargreaves *et al.*, 2015; Biagianti *et al.*, 2016; Chen *et al.*, 2016; Kasckow *et al.*, 2016; Moritz *et al.*, 2016; Thomas *et al.*, 2016; Vázquez-Campo *et al.*, 2016; Biagianti *et al.*, 2017; Gülkesen *et al.*, 2017; Roberts *et al.*, 2017; Sibeko *et al.*, 2017; Bucci, Barrowclough, *et al.*, 2018; Depp *et al.*, 2018; Donohoe *et al.*, 2018; Schlosser *et al.*, 2018; Ben-Zeev *et al.*, 2019; Kidd *et al.*, 2019; Krzystanek *et al.*, 2019; Lim *et al.*, 2019; Mcenery *et al.*, 2019; Moura *et al.*, 2019; Xu *et al.*, 2019; Nahum *et al.*, 2020; Bell *et al.*, 2020; Cullen *et al.*, 2020; Granholm, Holden, Dwyer and Link, 2020; Granholm, Holden, Dwyer, Mikhael, *et al.*, 2020; Hanssen *et al.*, 2020; Lewis *et al.*, 2020; Ludwig *et al.*, 2020; Luther *et al.*, 2020; Steare *et al.*, 2020; Westermann *et al.*, 2020; Moitra, Park and Gaudiano, 2021) unique interventions due to interventions being trialled in different countries (Alvarez-Jimenez *et al.*, 2013; Ludwig *et al.*, 2020) or moving from feasibility testing (Ben-Zeev *et al.*, 2014; Nahum *et al.*, 2014; Hargreaves *et al.*, 2015) to RCT (Donohoe *et al.*, 2018; Ben-Zeev *et al.*, 2019; Nahum *et al.*, 2020). The details of the study selection process are provided in Figure 3.

3.3.2 Study and Participant Characteristics

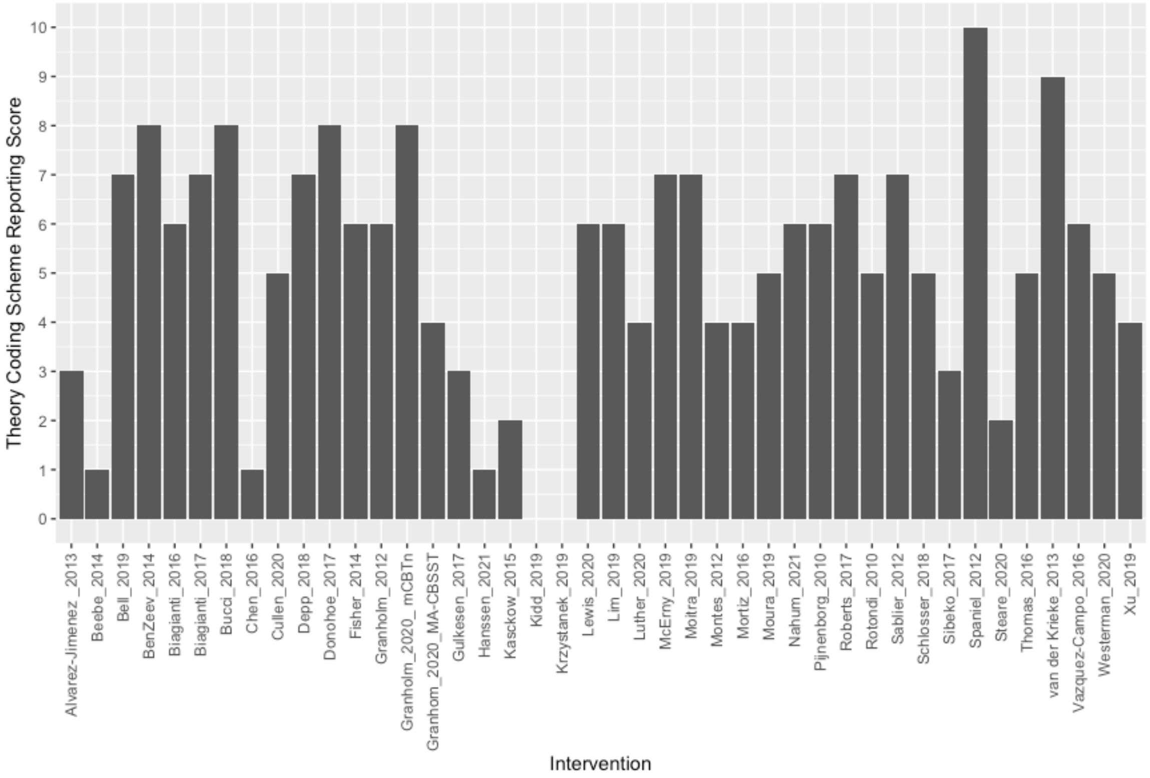
The weighted mean age of the 3038 participants for whom age was reported was 38.68 (study mean range 19.52 – 55.9), and 59.3% of people in studies that reported gender was male (n=1804). Interventions were tested in the USA (n=20), Australia (n=5), Netherlands (n=3), UK (n=3), China (n=2), Ireland (n=2), Spain (n=2) and a single study each from Canada, Czech Republic, France, Germany, Poland, Portugal, South Africa, and Turkey. One study obtained participants from two countries (Switzerland and Germany). The length of interventions ranged from 21 days to a year. In total, 23 (Pijnenborg *et al.*, 2010; Rotondi *et al.*, 2010; Alvarez-Jimenez *et al.*, 2013; Beebe, Smith and Phillips, 2014; Biagianti *et al.*, 2016; Chen *et al.*, 2016; Thomas *et al.*, 2016; Sibeko *et al.*, 2017; Depp *et al.*, 2018; Donohoe *et al.*, 2018; Schlosser *et al.*, 2018; Krzystanek *et al.*, 2019; Mcenery *et al.*, 2019; Moura *et al.*, 2019; Xu *et al.*, 2019; Bell *et al.*, 2020; Granholm, Holden, Dwyer and Link, 2020; Granholm, Holden, Dwyer, Mikhael, *et al.*, 2020; Luther *et al.*, 2020; Nahum *et al.*, 2020; Steare *et al.*, 2020; Westermann *et al.*, 2020; Moitra, Park and Gaudiano, 2021) interventions (reported across 26 manuscripts ((Pijnenborg *et al.*, 2010; Rotondi *et al.*, 2010; Alvarez-Jimenez *et al.*, 2013; Beebe, Smith and Phillips, 2014; Nahum *et al.*, 2014, 2020; Hargreaves *et al.*, 2015; Biagianti *et al.*, 2016; Chen *et al.*, 2016; Thomas *et al.*, 2016; Sibeko *et al.*, 2017; Depp *et al.*, 2018; Schlosser *et al.*, 2018; Krzystanek *et al.*, 2019; Mcenery *et al.*, 2019; Moura *et al.*, 2019; Xu *et al.*, 2019; Bell *et al.*, 2020; Granholm, Holden, Dwyer and Link, 2020; Granholm, Holden, Dwyer, Mikhael, *et al.*, 2020; Ludwig *et al.*, 2020; Luther *et al.*, 2020; Steare *et al.*, 2020; Westermann *et al.*, 2020; Moitra, Park and Gaudiano, 2021)) featured a degree of human contact and should be considered blended interventions. The earliest intervention was tested in 2005 but most are recent, with 19 papers published from 2020 onwards. As anticipated, there were many feasibility studies (n=30. 65.2%) where the main research question is whether an intervention can be feasibly evaluated in a full-scale trial. Based on the described intervention aims and clinical outcome measures, it appeared user-led digital interventions are being applied to diverse problems such as cognitive deficits, social deficits, depression, sedentary behaviour, social anxiety, loneliness, positive symptoms, negative symptoms, and motivation. They are also being used to monitor symptoms and provide access to self-management tools.

Study characteristics are summarised in the supplementary tables available on the Open Science Framework: https://osf.io/srk2m/

3.3.2.1 Use of Theory

TCS item 1 assesses whether a theory is mentioned (even if the intervention is not based on this theory). Of the 42 (Pijnenborg *et al.*, 2010; Rotondi *et al.*, 2010; Granholm *et al.*, 2012; Montes *et al.*, 2012; Sablier *et al.*, 2012; Španiel *et al.*, 2012; Alvarez-Jimenez *et al.*, 2013; Van Der Krieke *et al.*, 2013; Beebe, Smith and Phillips, 2014; Ben-Zeev *et al.*, 2014; Fisher *et al.*, 2015; Biagianti *et al.*, 2016; Chen *et al.*, 2016; Kasckow *et al.*, 2016; Moritz *et al.*, 2016; Thomas *et al.*, 2016; Vázquez-Campo *et al.*, 2016; Biagianti *et al.*, 2017; Gülkesen *et al.*, 2017; Roberts *et al.*, 2017; Sibeko *et al.*, 2017; Bucci, Barrowclough, *et al.*, 2018; Depp *et al.*, 2018; Donohoe *et al.*, 2018; Schlosser *et al.*, 2018; Kidd *et al.*, 2019; Krzystanek *et al.*, 2019; Lim *et al.*, 2019; Mcenery *et al.*, 2019; Moura *et al.*, 2019; Xu *et al.*, 2019; Cullen *et al.*, 2020; Granholm, Holden, Dwyer and Link, 2020; Granholm, Holden, Dwyer, Mikhael, *et al.*, 2020; Hanssen *et al.*, 2020; Lewis *et al.*, 2020; Luther *et al.*, 2020; Nahum *et al.*, 2020; Steare *et al.*, 2020; Westermann *et al.*, 2020; Moitra, Park and Gaudiano, 2021) unique interventions, 95% reported a reference to theory within a manuscript or referenced protocol. Item 3 assesses whether interventions are based on a single clear overarching theoretical framework, and 54.7% could be identified in this manner. Only 23.8% of interventions selected participants based on participants experiencing clinical problems that were in line with intervention theory. Moreover, there were very few cases where authors reported links between theory and intervention techniques. Further descriptions of theory reporting can be seen in Figure 1

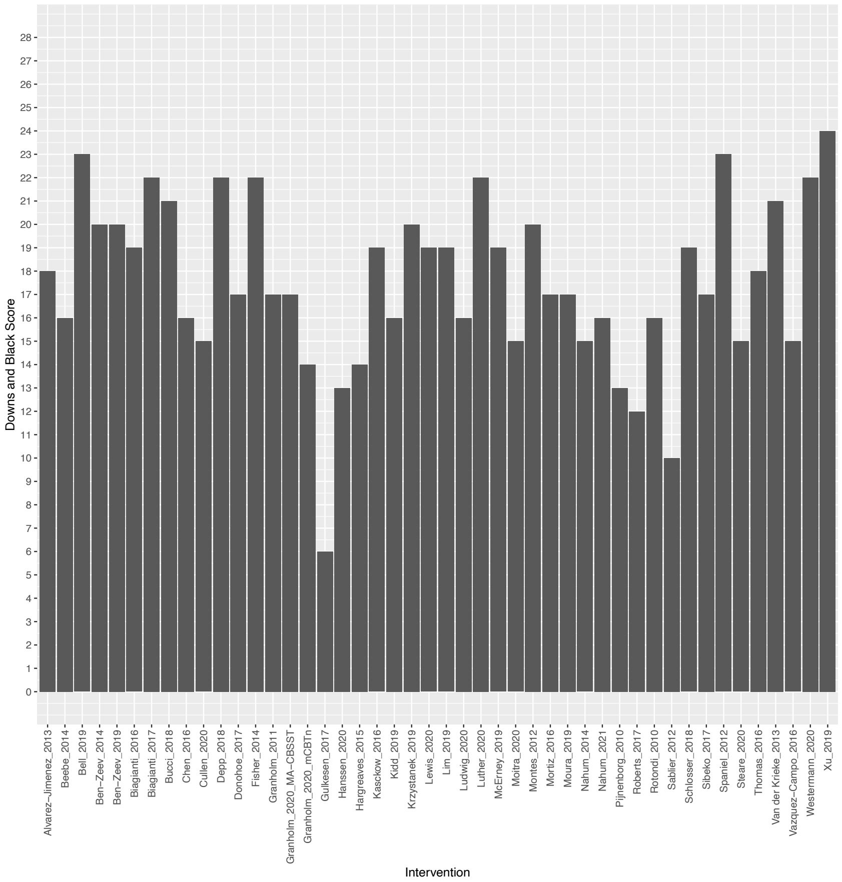
Figure 4: Overall Quality of Theory Reporting.



3.3.3 Methodological Quality

Using the Downs and Black checklist, the methodological quality of included studies, the initial independent risk of bias agreement was k=0.89, and disagreements were resolved via discussion. Over 60% of included papers reported on feasibility studies which reflect the relatively early stage of this field. On average, studies scored 17.5 (SD=3.64) out of 28 (Downs and Black, 1998). The risk of bias came from low levels of assessor blinding, low levels of randomisation and low levels of intent to treat analyses. Additionally, 70% of studies did not report information about adverse events – either if they occurred or did not.

Figure 5 Risk of Bias Assessed with Downs and Black



3.3.3.1 Service User Involvement

Of the 42 unique interventions, 29 interventions (Pijnenborg *et al.*, 2010; Rotondi *et al.*, 2010; Montes *et al.*, 2012; Sablier *et al.*, 2012; Španiel *et al.*, 2012; Van Der Krieke *et al.*, 2013; Beebe, Smith and Phillips, 2014; Fisher *et al.*, 2015; Biagianti *et al.*, 2016; Roberts *et al.*, 2017; Sibeko *et al.*, 2017; Depp *et al.*, 2018; Donohoe *et al.*, 2018; Schlosser *et al.*, 2018; Krzystanek *et al.*, 2019; Mcenery *et al.*, 2019; Moura *et al.*, 2019; Granholm, Holden, Dwyer and Link, 2020; Granholm, Holden, Dwyer, Mikhael, *et al.*, 2020; Hanssen *et al.*, 2020; Lewis *et al.*, 2020; Luther *et al.*, 2020; Nahum *et al.*, 2020; Westermann *et al.*, 2020; Moitra, Park and Gaudiano, 2021) (69%) did not describe any user involvement in the design of the intervention; we discuss service user involvement under each clinical problem heading.

3.4 Clinical Problems

3.4.1 Cognitive Deficits

This describes interventions focused on improving neurocognitive abilities such as attention, working memory, cognitive flexibility, planning, and executive functioning, leading to improved psychosocial functioning. Eight interventions (reported across nine papers) stated a main aim of targeting cognitive deficits (Pijnenborg *et al.*, 2010; Sablier *et al.*, 2012; Fisher *et al.*, 2015; Hargreaves *et al.*, 2015; Biagianti *et al.*, 2016, 2017; Roberts *et al.*, 2017; Donohoe *et al.*, 2018; Moura *et al.*, 2019). Intervention duration ranged from four weeks to six months. Five interventions (Fisher *et al.*, 2015; Hargreaves *et al.*, 2015; Biagianti *et al.*, 2016, 2017; Moura *et al.*, 2019) were cognitive remediation programmes delivered on computers or a website; two delivered cognitive training via an application on a tablet device. Two took a “cognitive orthotic” approach (Pijnenborg *et al.*, 2010; Sablier *et al.*, 2012) and delivered prompts to a mobile phone or personal digital assistant. Five interventions were blended and involved part of the intervention being delivered by mental health staff, and for one intervention, this was also supplemented by a group chat with peers. No patients were involved in intervention design.

3.4.1.1 Adherence and Preliminary Efficacy

Across all studies, dropouts ranged from 14.28% - 68% in those randomised to receive interventions. For the six studies (Sablier *et al.*, 2012; Fisher *et al.*, 2015; Hargreaves *et al.*, 2015; Biagianti *et al.*, 2016; Roberts *et al.*, 2017; Moura *et al.*, 2019) reporting adherence, this ranged from 42.6%-84%. Of note, one study compared participants completing therapy remotely compared to those receiving treatment at mental health premises, with no significant differences in adherence (Biagianti *et al.*, 2017). There was evidence of improved cognitive functioning in two RCTs, but no linear association was observed between intervention usage time and cognitive gains (Hargreaves *et al.*, 2015; Donohoe *et al.*, 2018) in either study.

3.4.2 Social Skills

This describes outcomes linked to competence in facilitating interaction and communication with others where social rules and relations are created, communicated, and changed in verbal and nonverbal ways. Four interventions targeted social skills development (Nahum *et al.*, 2014, 2020; Vázquez-Campo *et al.*, 2016; Gülkesen *et al.*, 2017; Granholm, Holden, Dwyer and Link, 2020). One website-based intervention delivered teaching sessions on recognising facial expressions (Gülkesen *et al.*, 2017). Two interventions (one reported across two papers) used computer programmes to teach social skills with interactive exercises (Nahum *et al.*, 2014, 2020; Vázquez-Campo *et al.*, 2016). One further intervention was blended and featured 24 sessions of weekly group therapy supplemented by a personal digital assistant, which prompted homework activities (Granholm, Holden, Dwyer and Link, 2020). Interventions ranged from four to 24 weeks; besides beta-testing the usability of the facial recognition website with patients, no social skills interventions described involving patients in intervention design.

3.4.2.1 Adherence, Dropout and Preliminary Efficacy

Dropouts ranged from 16%-47% for those randomised to receive the user-led intervention. For three studies reporting adherence, this ranged from 58%-76.4%. For two non-feasibility studies, in the blended therapy intervention, the PDA device designed to prompt homework adherence did not increase engagement in homework and improvements in social skills did not differ compared to participants attending therapy alone (Granholm, Holden, Dwyer and Link, 2020). Additionally, group participants receiving SocialVille (an online programme) showed greater improvement on independent behavioural composite measures of social cognition compared to those given an active control (Nahum *et al.*, 2020).

3.4.3 Self-Management and Recovery

Twelve papers included interventions with outcomes relevant to increasing patients' ability to self-manage psychosis and achieve recovery (Rotondi *et al.*, 2010; Alvarez-Jimenez *et al.*, 2013; Beebe, Smith and Phillips, 2014; Ben-Zeev *et al.*, 2014; Thomas *et al.*, 2016; Bucci, Barrowclough, *et al.*, 2018; Depp *et al.*, 2018; Ben-Zeev *et al.*, 2019; Krzystanek *et al.*, 2019; Hanssen *et al.*, 2020; Ludwig *et al.*, 2020; Steare *et al.*, 2020; Westermann *et al.*, 2020). Both FOCUS and HORYZONS are reported in two different studies. Seven interventions used mobile apps (Ben-Zeev *et al.*, 2014; Bucci, Barrowclough, *et al.*, 2018; Depp *et al.*, 2018; Ben-Zeev *et al.*, 2019; Kidd *et al.*, 2019; Krzystanek *et al.*, 2019; Hanssen *et al.*, 2020; Steare *et al.*, 2020); three interventions were websites (Rotondi *et al.*, 2010; Alvarez-Jimenez *et al.*, 2013; Thomas *et al.*, 2016), HORZYZONS was a website blended with a forum (Alvarez-Jimenez *et al.*, 2013; Ludwig *et al.*, 2020) and another used SMS text delivery (Beebe, Smith and Phillips, 2014). Intervention duration ranged from 21 days to a year. Half of the self-management and recovery interventions described patient involvement in designing the interventions. Eight interventions were blended with human contact, and this ranged from a single therapy session forum moderators and patients being able to arrange a “tele-visit” with a mental health professional if they needed one.

3.4.3.1 Adherence and Preliminary Efficacy

Dropouts ranged from 0%-33% for participants randomised to receive interventions. For the four studies (Ben-Zeev *et al.*, 2014; Depp *et al.*, 2018; Hanssen *et al.*, 2020; Steare *et al.*, 2020) reporting adherence, this ranged from 3.2%-86.5%, indicating a broad range. Preliminary evidence from two RCTs (Krzystanek *et al.*, 2019; Westermann *et al.*, 2020) suggests interventions may improve psychosis symptoms compared to control. Additionally, further post-hoc subgroup analyses suggests people diagnosed with schizophrenia suggest that self-management user-led interventions may reduce depression (Ben-Zeev *et al.*, 2019).

3.4.4 Motivation

Problems with motivation was a target for one app-based intervention (PRIME), which blended app content with access to motivational coaches and peers. The intervention was 12 weeks in length.

3.4.4.1 Feasibility and Adherence

Adherence defined as logging into the app was 57.5% per week (SD=0.2), and 100% of participants messaged a coach at least once with a challenge completion rate of 91.47 (SD=12.2) % in those randomised to receive PRIME. The dropout rate was 13.6% for those randomised to receive PRIME.

3.4.5 Social Anxiety

One eight-week-long intervention targeted social anxiety using an online website intervention with twelve modules underpinned by CBT principles with access to an interactive forum and comics (Mcenery *et al.*, 2019). Patients were extensively involved in designing this intervention.

3.4.5.1 Adherence and Preliminary Efficacy

Participants demonstrated 75% mean completion of therapy modules, and dropout was 23%. The authors concluded the intervention is feasible.

3.4.6 Medication Adherence

Improving medication adherence was an aim of four interventions (Granholm *et al.*, 2012; Montes *et al.*, 2012; Sibeko *et al.*, 2017; Xu *et al.*, 2019) which all involved sending text messages, duration ranged from 12 weeks to six months. Two interventions described involved patients in intervention design, and one of those also involved carers in the design process.

3.4.6.1 Adherence and Preliminary Efficacy

Positive effects for improving medication adherence improvement were noted for the two non-feasibility RCTs (Montes *et al.*, 2012; Xu *et al.*, 2019). Dropouts ranged from 4.31%-59.5% for those randomised to receive interventions. One further study reported 1% dropout (Montes *et al.*, 2012) but excluded 19.4% of participants for not being exposed to the intervention. For the single study reporting standardised adherence indicated rates of 83%–86% (Granholm, Holden, Dwyer and Link, 2020). However, there were reported issues in three SMS interventions. For example, in one study, 42% of participants did not receive texts due to a technological problem (Sibeko *et al.*, 2017) and only 54% of participants reported reading texts in another (Xu *et al.*, 2019). Additionally, 66 participants were removed from formal analysis because they did not receive texts for seven consecutive days (Montes *et al.*, 2012).

3.4.7 Positive Symptoms

One blended intervention study using a mobile app and face-to-face therapy specifically targeted voice hearing (Bell *et al.*, 2020). This intervention used a mobile app which provided tailored coping strategies depending on momentary ecological sampling (EMA) data entered into the app. Patients were involved in designing the EMA questionnaires.

3.4.7.1 Adherence and Preliminary Efficacy

Participants responded to 72% of EMA prompts, and the authors state this is a feasible approach. Dropout was 8.8% in those randomised to the intervention.

3.4.8 Negative Symptoms

Two interventions targeted negative symptoms (Granholm, Holden, Dwyer and Link, 2020; Luther *et al.*, 2020). One blended weekly therapy with a mobile app, and another used a blended approach with a single one-on-one goal-setting session supplemented with text message prompting. Intervention duration ranged from 8-24 weeks. Neither intervention was designed with patient involvement.

3.4.8.1 Adherence and Preliminary Efficacy

Both interventions were feasibility RCTs, and the authors report that both appear feasible. Dropouts ranged from 7.4%-16.1%. Adherence ranged from 19.2%-86.1%.

3.4.9 Involvement in Shared Decision Making

One website-based intervention aimed to improve patient experiences of shared decision-making (Van Der Krieke *et al.*, 2013). Participants were given access to an online decision tool aimed to support patients in acquiring an overview of their needs and appropriate treatment options provided by their mental health care organization. While the authors do not describe patient involvement, the intervention was based on work by a service user researcher.

3.4.9.1 Adherence and Preliminary Efficacy

In total, 55% of patients did not use the website decision aid tool, and no differences were found between the intervention and control conditions on perceived involvement in medical decision-making. Dropout was 68%. The authors report the intervention was not a good fit with clinical practice as indicated by the low usage levels and likely experienced poor implementation.

3.4.10 Engaging in Exercise

One intervention prompted engagement in physical exercise in between face-to-face group exercise classes using text message-based reminders (Chen *et al.*, 2016).

3.4.10.1 Adherence and Preliminary Efficacy

Participants met 81% of the targeted weekly exercise duration of 90 minutes between classes, but from the reporting it was not clear if text messages prompted increased adherence to the exercise programme. Dropout was 31.25%.

3.4.11 Symptom monitoring

Five interventions monitored for changes in the mental state using digital devices with information being passed onto mental health staff (Španiel *et al.*, 2012; Kasckow *et al.*, 2016; Cullen *et al.*, 2020; Lewis *et al.*, 2020; Moitra, Park and Gaudiano, 2021). Four (Španiel *et al.*, 2012; Cullen *et al.*, 2020; Lewis *et al.*, 2020; Moitra, Park and Gaudiano, 2021) aimed to detect changes which could be associated with relapse using mobile phone apps or SMS texting, and one intervention focused on suicide ideation using a device connected to a landline telephone (Kasckow *et al.*, 2016). Intervention duration ranged from four weeks to one year. All interventions asked patients to self-monitor by replying to text messages or inputting data onto a mobile app or device attached to a landline telephone. In the ITAREPS (information technology aided relapse prevention programme in schizophrenia) intervention, carers also reported on the patient's symptoms by responding to texts in addition to the patient. Most of these interventions were targeted for usage after a recent hospitalisation or an episode of being more unwell.

3.4.11.1 Adherence and Preliminary Efficacy

Reported dropouts ranged from 5.06% - 30.07% in intervention conditions. The studies reporting standardised adherence ranged from 33 – 86.2% [69]. In the single RCT, despite over 80% of mental health monitoring texts being responded to by patients and/or carers, psychiatrists did not use the data in relapse prevention clinical decision making and the intervention reported a null result for relapse prevention compared to an active control (Španiel *et al.*, 2012).

3.4.12 Loneliness

One intervention targeted loneliness using a mobile app (Lim *et al.*, 2019) which was available for six weeks. Patients were involved in the design of the intervention.

3.4.12.1 Adherence and Preliminary Efficacy

In total 95.47% of participants used at least 70% of the app content (a-priori feasibility). The authors conclude that the intervention was feasible. Dropout was 16.6%.

3.4.13 Depression

One intervention was an online CBT based modular intervention targeted depression (Help ID) (Moritz *et al.*, 2016) which had no blended components.

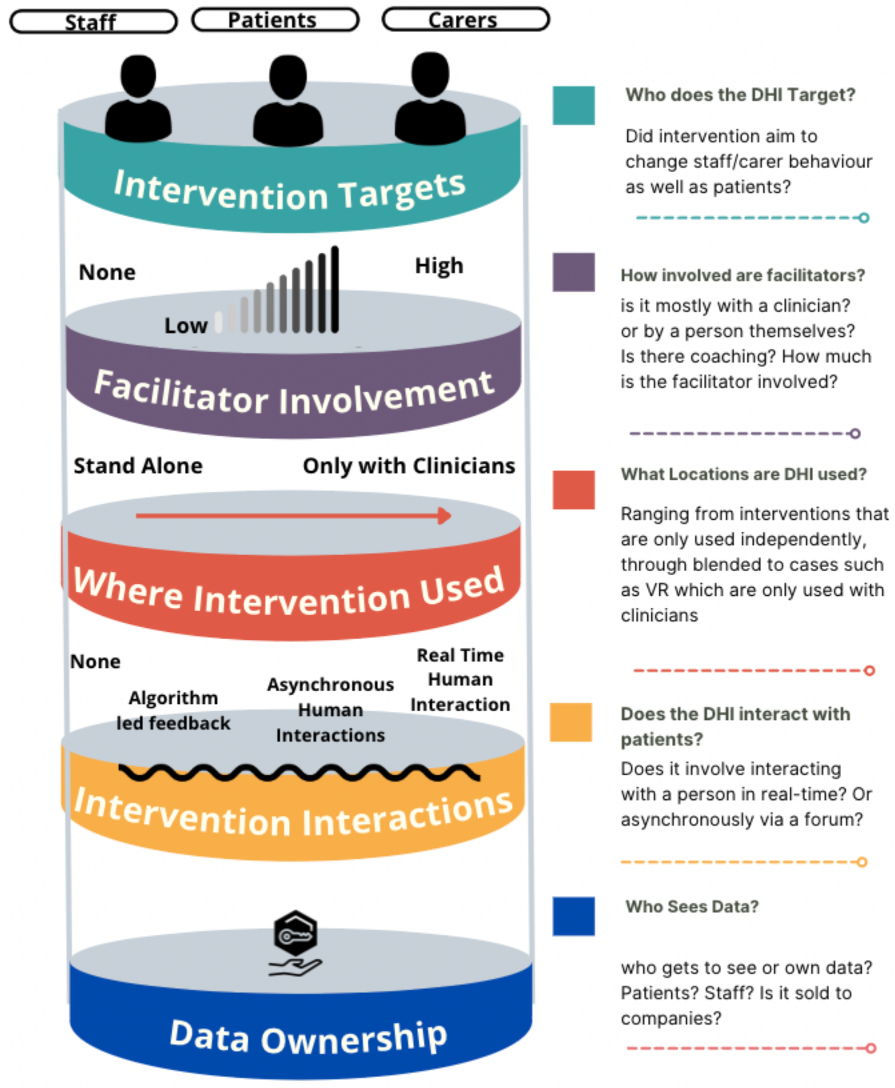
3.4.13.1 Adherence and Preliminary Efficacy

All individuals in the intervention condition logged in to Help ID at least once and adherence was 88% (defined as completing at least one module). Compared to wait-list control, there was a large reduction in depression symptoms. Dropout was 19.35%.

3.5 Taxonomy of Types

Despite the heterogeneity of user-led interventions, there were key similarities. We used interpretive content analysis to develop a multidimensional descriptive taxonomy with six factors: intended targets, facilitator involvement, location where the intervention was used, intervention interactions, intervention targets and degree of data ownership. Firstly, the intended targets addressed whether the intervention solely addressed patient behaviour or whether it also targeted the behaviour of other social actors such as carers or mental health staff. Secondly, facilitator involvement covered how much blending there was from another human, ranging from none up to numerous contacts and coaching. Thirdly, location described where patients accessed the intervention. Fourthly, intervention interactions covered what interactions the intervention affords patients was a functional category with some interventions offering sequential intervention access, while other interventions were responsive based on what the patient inputs into an intervention. This responsiveness could come from either a human, or automatically via the intervention. Lastly, data ownership addressed to what extent patients were given access to the data the intervention generated. The concepts measured by the typology (called the overarching concept in typological research) (Gasser *et al.*, 2020) is the purpose of a health technology; not its hardware or software. Therefore, this taxonomy of types can likely categorise emerging user led technologies and cover a range of clinical outcomes – both existing and future.

Figure 6 Taxonomy of Types



Who does the DHI Target?

Did intervention aim to change staff/carer behaviour as well as patients?

How involved are facilitators?

is it mostly with a clinician? or by a person themselves? Is there coaching? How much is the facilitator involved?

What Locations are DHI used?

Ranging from interventions that are only used independently, through blended to cases such as VR which are only used with clinicians

Does the DHI interact with patients?

Does it involve interacting with a person in real-time? Or asynchronously via a forum?

Who Sees Data?

who gets to see or own data? Patients? Staff? Is it sold to companies?

3.6 Discussion

User-led digital interventions are being used to target loneliness, cognitive deficits, social skills deficits, depression, sedentary behaviour, social anxiety, positive and negative symptoms, and to monitor symptoms and provide access to self-management. Most studies only report feasibility data but there was preliminary efficacy for self-management interventions reducing psychosis symptoms and remote cognitive remediation improving cognitive functioning. Most interventions were tested in feasibility studies and there is high risk of bias. Adherence to interventions was reported and measured in a variety of ways which made synthesis challenging. The available evidence suggests patient adherence to digital interventions is highly variable, dropout can be high and technological issues can block participants from being exposed to the intervention. Additionally, adverse events were poorly reported.

3.6.1 Quality of Theory Reporting

Complex interventions usually have multiple components (Craig *et al.*, 2008) which means theory is a useful framework to understand why interventions work and how components might interact to produce effects. Of the 42 unique interventions, 95% mentioned theory but only 54.7% were identified as being based on an identifiable overarching theoretical framework. Due to the typically poor quality of theory reporting it was difficult to determine to what extent interventions may be described as truly based on theory or whether they had incorporated some aspects. Most studies did not report details regarding the linkages between theory-relevant constructs and intervention components. Additionally, most did not reference the components of the selected theory when describing the interventions. These missing pieces are essential for informing modifications of existing interventions and the development of more effective interventions by identifying the essential active ingredients that work.

One further concern is that less than one in four studies reported sampling participants in a way which matched a mechanistic need (presenting problem) with a proposed mechanism of change. In other words, many participants seem to be recruited because they have a schizophrenia diagnosis and not because they met a particular score/level on a theory-relevant construct. Therefore, it is currently difficult to say whether user-led interventions are useful for people diagnosed with schizophrenia to address the specific problems highlighted in this review. As the field moves beyond feasibility studies and into more advanced testing, improved theory reporting will help identify what works for whom and why.

3.6.2 Taxonomy of Types and Its Implication

Over half of identified interventions were blended (i.e., included human contact) but this ranged from digital interventions that augmented traditional face-to-face therapy through to coaching. Additionally, the taxonomy suggests that many user-led interventions are created to support work that is led by clinicians and still require significant input from mental health staff. Digital interventions which feature some sort of human interaction are theorised to demonstrate higher patient engagement because social presence may positively influence expectations, accountability and bond (Mohr, Cuijpers and Lehman, 2011). Therefore, it seems likely that the blended approach taken in many user-led interventions is likely to be optimal.

While a range of problems are being addressed by user-led interventions, there may be gaps between user-led intervention treatment targets and what patients want help with. For example, sleep problems have been identified as a desired treatment targets by patients (Freeman, Taylor, *et al.*, 2019) and only formed part of one intervention identified within this review. Intervention guidelines recommend that patients are involved in intervention design (Skivington *et al.*, 2021). While most interventions did not involve patients in intervention design, this varied depending on intervention target. For example, half of self-management interventions described patient involvement while no cognitive remediation or social skills training interventions did. Involving patients in user-led digital intervention design may improve user engagement as well as addressing the problems patients want interventions to address.

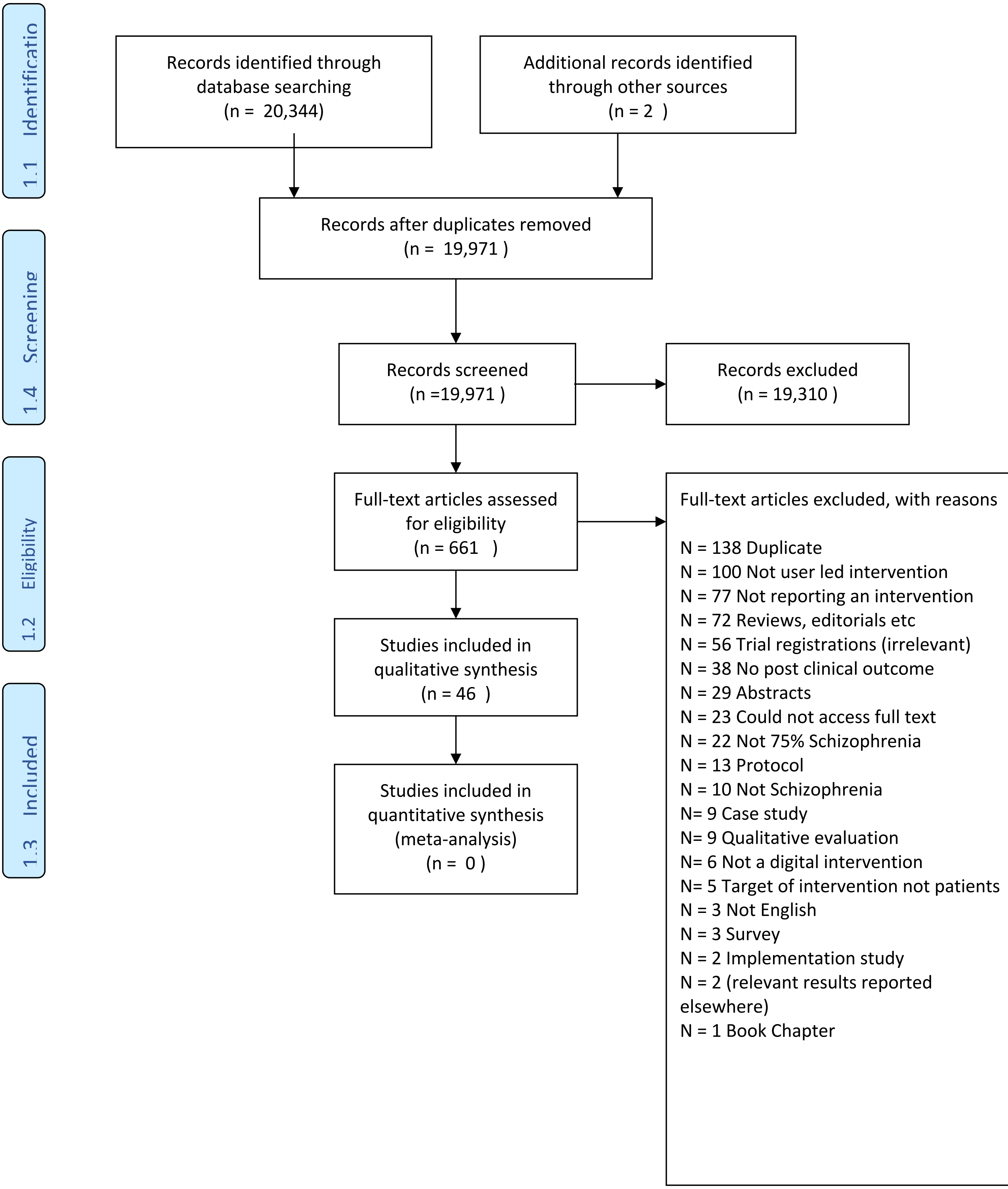
3.6.3 Strengths and Limitations

The strengths of this review lie in the reliance on standardized approaches to assess use of theory and intervention reporting quality, and in the involvement of independent reviewers to determine study inclusion and apply assessment tools. However, there are several limitations. For example, we limited our search to studies published in the English language and did not include grey literature which may significantly bias our results. We used qualitative methods to develop our typology which may introduce further interpretivist bias, in future methods using quantitative cluster analysis approaches which include variables such as behavioural and cognitive change techniques, digital devices used in combination with their theoretical underpinnings may be useful in developing a more meaningful taxonomy of types. A further limitation is that we only included interventions which have tested a clinical outcome which may have excluded interventions at an earlier stage of development. One further limitation is that we adapted the TCS for this review, this is frequently done (Stacey *et al.*, 2015; Horan *et al.*, 2021) because the tool has helpful general assessments items for theory reporting, the tool was originally developed for behavioural interventions and adapting it may have introduced bias (Pickering *et al.*, 2020).

3.6.4 Conclusions and Future Directions

User-led digital interventions exist for a variety of problems experienced by people with schizophrenia. This study suggests that existing evaluations of user-led digital interventions for psychosis remain mechanistically opaque due to the lack of clear reporting of intervention theory usage in published work. Greater reporting of theory use in the design and evaluation of trials of user-led interventions is recommended and will help reach a better understanding of the mechanisms through which these interventions achieve their effects. Combined with improved adverse events reporting, this could help identify if adverse events are related to underlying mechanisms. This would be particularly strengthened by going beyond guidelines such as the TIDIER template (Hoffmann *et al.*, 2014) and adhering to the Standards of Evidence for Efficacy, Effectiveness, and Scale-up Research in Prevention Science guidance by ensuring “a clear theory of causal mechanisms (including identification of mediators as well as outcomes) is stated” within manuscripts. The full articulation of intervention theory would be enhanced by including visual representation such as logic models – in line with recent complex intervention guidance (Skivington *et al.*, 2021). Strengthening the reporting of theory in user-led digital interventions for psychosis will likely improve the replicability and rigour of clinical trials.

Figure 7 PRISMA Flowchart



4 Chapter 4: Monitoring early signs of psychosis relapse using a Mobile App: Developing a Hypothetical Implementation Framework of Expectations for staff, carers and service users with Qualitative Methods.

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4.1 Abstract

Background: Relapse is a common experience for people diagnosed with psychosis, which is associated with increased service costs and profound personal and familial distress. EMPOWER is a peer worker supported digital intervention which aims to enable service users to self-monitor their mental health to encourage self-management and the shared use of personal data to promote relapse prevention. Digital interventions have not been widely used in relapse prevention and, therefore, little is currently known about their likely implementation – both within trials and beyond.

Objective: Seeking the perspectives of all relevant stakeholder groups is recommended in developing theories about implementation because this can reveal important group differences in understandings and assumptions about whether and for whom the intervention is expected to work. However, the majority of intervention implementation research has been retrospective. This study aimed to discover and theoretically frame implementation expectations in advance of testing and synthesise these data into a framework.

Methods: To develop a hypothetical implementation framework, 149 mental health professionals, carers and people diagnosed with psychosis participated in 25 focus groups in both Australia and the United Kingdom. An interview schedule informed by Normalisation Process Theory was used to explore stakeholders' expectations about the implementation of the EMPOWER intervention. Data were analysed using thematic analysis and then theoretically framed using the Medical Research Council guidelines for understanding the implementation of complex interventions.

Results: All groups expected EMPOWER could be successfully implemented if the intervention generated data which were meaningful to mental health staff, carers and service users within their unique roles. However, there were key differences between staff, carers and services users about what facilitators and barriers that stakeholders believe exist for intervention implementation in both the cRCT stage and beyond. For example, service user expectations mostly clustered around subjective user experiences, while staff and carers spoke more about the impact upon staff interactions with service users.

Conclusion: A hypothetical implementation framework synthesised from stakeholder implementation expectations provides an opportunity to compare actual implementation data gathered during an ongoing clinical trial giving valuable insights into the accuracy of these stakeholder's prior expectations. This is among the first studies to assess and record implementation expectations for a newly developed digital intervention for psychosis in advance of testing in a clinical trial.

ISRCTN: 99559262

4.2 Introduction

Relapse is common for many people diagnosed with schizophrenia (Robinson *et al.*, 1999). Relapses are linked to increased disability from loss of important relationships and reduced education and employment opportunities (Scottish Intercollegiate Guidelines Network (SIGN), 2013). One estimate suggests psychotic relapse costs £10,950 (at six months) compared to £2,532 for no relapse, with 75% of the difference in these costs coming from inpatient treatment (SANE, 2006). In the USA, excess costs from relapse range from $6033–$32,753 (Pennington and McCrone, 2017). Commonly, relapses are preceded by so-called Early Warning Signs (EWS) that reflect a combination of symptoms such as anxiety, depression, suspiciousness, plus uniquely personal experiences. EWS based prevention strategies assume that identifying relapse early enough enables preventative action and averts full relapse (Eisner *et al.*, 2014). Guidelines for psychosis in both Scotland, UK (Scottish Intercollegiate Guidelines Network (SIGN), 2013) and Australia (Galletly *et al.*, 2016) recommend early signs based strategies as crucial for relapse prevention in routine psychosis care.

Research into reliable and valid signs of relapse is essential for early intervention aimed at minimising the harms associated with relapse (Emsley *et al.*, 2013). A review (Eisner, Drake and Barrowclough, 2013) to determine the validity of early signs as predictors of relapse in people with non-affective psychosis found that the sensitivity (correct relapse prediction by staff) ranged from 10% to 80% (median 61%), and specificity (non-relapses correctly identified) ranged from 38% to 100% (median 81%). Therefore, existing systems used to identify EWS have an uncertain prognostic utility and may result in an unnecessary intervention that engenders fear of relapse in service users and carers (Gumley *et al.*, 2015). Delayed help-seeking narrows the window for timely intervention (Birchwood and Spencer, 2001) and can result in the use of coercive treatment measures which confirm negative expectations (Gumley *et al.*, 2006) and make disclosure of EWS more threatening for service users. Therefore, new interventions that address problems associated with help-seeking and disclosing EWS appear warranted (National Institute for Health and Care Excellence, 2014).

4.3 EMPOWER Description

One emerging application of technology in mental healthcare is remote self-monitoring (Rajagopalan *et al.*, 2017). Remote self-monitoring may improve upon traditional face-to-face monitoring by allowing more regular sampling of symptoms and, potentially, earlier detection of relapse signs. EMPOWER (Early signs Monitoring to Prevent relapse in psychosis and prOmote Wellbeing, Engagement and Recovery, ISRCTN: 99559262) aims to develop and evaluate a Mobile app for use with adults who experience psychosis. The app enables routine self-monitoring for a variety of different experiences, including psychosis (e.g. hearing voices, suspicious thoughts), anxiety, mood, self-esteem and interpersonal support. Furthermore, each time people complete an app questionnaire they receive an ‘EMPOWER message’, which (depending on user input) provides links to further relevant information, practical advice or helpful quotes. The EMPOWER algorithm aims to tailor these messages to individual changes in user wellbeing to promote a greater sense of control over mental health and to support self-management. EMPOWER participants will use the app for an initial twenty-eight-day baseline period to identify their typical variation in personal wellbeing. Significant changes from baseline will then be triaged by a clinician. Peer support workers will be involved in setting up and personalising the daily questionnaire, alongside regular fortnightly follow-up meetings where they will support service users in using the app.

4.4 Implementation of Digital Interventions

Digital interventions can help address clinical priorities in psychosis, such as increasing access to psychological interventions for symptoms such as paranoia (Garety *et al.*, 2017). However, many effective digital interventions have failed to generalise from clinical trials into clinical practice (Greenhalgh *et al.*, 2017; Aref-Adib *et al.*, 2018). Due to concerns about generalisation beyond trial contexts, the UK Department of Health (Department of Health, 2017) encourages systematic implementation research to increase understanding of how interventions are adopted or rejected. The effectiveness of interventions (including their success in reaching the target population) can be influenced by how an intervention interacts with the context in which it was implemented (Moore *et al.*, 2015; Petticrew *et al.*, 2015). When appraising the results of a clinical trial, it can be challenging to know whether the intervention will generalise into “real world” contexts of clinical practice. Process evaluations assess the implementation of interventions and help predict generalisability in different contexts. The MRC framework for process evaluation (Moore *et al.*, 2015) recommends clear descriptions of assumptions about how the intervention is expected to be implemented within a specific context. Additionally, consulting multiple stakeholder groups is recommended because this can reveal across group variance in understandings of what the intervention is and differences in assumptions about why and for whom the intervention is expected to work. Collecting data at different time points is also recommended to characterise changes in implementation factors such as participants’ attitudes towards an intervention.

Typically, the majority of implementation research on engagement with interventions has been retrospective (Sutcliffe *et al.*, 2015). The MRC framework for process evaluations recommends that implementation research should proactively include key stakeholders because those expected to engage with an intervention are likely to have relevant experiential knowledge, which is useful in understanding the implementation process during a trial (Moore *et al.*, 2015). Qualitative research carried out *during* a trial (e.g. asking service users about their experiences) can aid understanding of why an intervention might work and how context affects implementation (Bonell *et al.*, 2012). However, *befor*e interacting with an intervention, stakeholders may have pre-existing expectations regarding implementation that will shape how they interact with a planned intervention (hypothetical acceptability). Hypothetical acceptability is measured by key stakeholders' willingness to engage with a proposed intervention and in previous trials of digital interventions for severe mental health problems actual acceptability (assessed post-intervention) is typically higher than hypothetical acceptability (Berry *et al.*, 2016).

Theory in implementation science implies some predictive capacity (Nilsen, 2015). Typically, implementation theory aims to create conceptual tools which enable researchers to describe, identify and explain crucial elements of the implementation process and its outcomes (May, 2013). Developing implementation theories in advance of empirical testing provides a framework for developing predictions about how interventions will interact with the context in which they are tested. Furthermore, completing this work allows researchers to make informed predictions about what implementation barriers which might be reasonably expected (May, Johnson and Finch, 2016). One such implementation theory, Normalisation Process Theory (NPT) (May, Johnson and Finch, 2016) focusses on the work that groups and individuals do when interacting with an intervention and how they make sense of it, many intervention studies have successfully utilised NPT as a framework to guide research to more fully understand the implementation process (May *et al.*, 2018). Despite the recommended involvement of patients and members of the public within implementation research (Esmail, Moore and Rein, 2015) and widespread assumptions that consultation work can help researchers anticipate stakeholders' needs, capacities and priorities (Oliver, Kothari and Mays, 2019), there is little direct evidence about what this involvement brings to the research process (Gray-Burrows *et al.*, 2018). For example, the MRC guidelines on process evaluation (Moore *et al.*, 2015) report substantial empirical uncertainty regarding the value of Patient and Public Involvement (PPI) work. However, stakeholders are likely to offer insights beyond the acceptability of digital interventions (e.g. predicting intervention implementation barriers during testing) and arguably have a right to be involved in research, which impacts them. Adding the insight of carers, service users and mental health staff should lead to a clearer understanding of barriers and facilitators to implementation.

To the best of our knowledge, only one other study has (Huerta-Ramos *et al.*, 2016) explored staff, carers and service users' perspectives of acceptability and implementation of a digital intervention for psychosis before engagement. Inclusion of these stakeholders enabled potentially diverse perspectives to be integrated into system design requirements for a mobile intervention for people who were considered to have treatment-resistant schizophrenia. Although this study is in a different population, the inclusion of multiple perspectives is a strength that could be applied to the prospective investigation of stakeholder engagement with digital interventions. Additionally, there is little longitudinal research comparing stakeholder predictions pre-intervention with what happens when people interact with a digital intervention. Developing implementation theories for the EMPOWER intervention based on the expectations of staff, service users and carers within a longitudinal process evaluation will allow for the assessment of the accuracy and the changing nature of these predictions over time, potentially highlighting the value of contextual knowledge that comes from consulting with stakeholders. We anticipate that developing an *a-priori* implementation theory derived from stakeholder consultation will enhance implementation of the intervention in the context of a clinical trial and provide meaningful data to enable later generalisation into clinical practice, a clear priority for services (Department of Health, 2017; Greenhalgh *et al.*, 2017).

This study aimed to summarise the implementation expectations expressed within focus groups by mental health staff, carers and service users in consultation work before a clinical trial to be able to compare these to the actual experiences of implementation observed within a feasibility study.

4.5 Methods

4.5.1 Design

This study forms part of the qualitative phase conducted before a cRCT for the EMPOWER intervention (**ISRCTN**: 99559262). The methods are reported in line with the CORE-Q reporting recommendations for qualitative work (Tong, Sainsbury and Craig, 2007); a full checklist can be seen in supplementary materials. Prior to the study start, ethical approvals were provided by West of Scotland REC (16/WS/0042) and Melbourne Health (REC/15/MH/344). Managerial approval was given by NHSGG&C (GN14CP229) and North Western Mental Health Services (MH Project Number: 2015.286). The protocol is available via the National Institute of Health Research (NIHR) website (https://www.journalslibrary.nihr.ac.uk/programmes/hta/1315404#/).

4.6 Eligibility & Recruitment

All participants came from one health board area in the UK and one in Australia, where the intervention will be tested in a multisite clinical trial. Staff who support people with psychosis within Community Mental Health Services (CMHS) were invited to take part through initial researcher contact with clinical team leaders. Service user participants were invited to take part in focus groups through mental health staff and organisations providing support or representation to people with mental health difficulties. Service user participants were eligible if they were in contact with CMHS had experienced a relapse within the previous two years; had received a diagnosis of DSM-5 psychosis-related condition and were able to provide informed consent. People who identified as carers for someone with psychosis were recruited from both mental health services and support organisations.

4.7 Focus Groups

Using focus groups rather than individual interviews enabled respondents to interact with and respond to the ideas and comments of other participants with whom they shared a role (Kruger and Casey, 2014). Focus groups were held in private rooms (of either CMHS or support organisations) and conducted by members of the research team using a topic guide. We did not collect demographic data beyond whether the participant was a carer, service user or mental health staff. Following best practice guidelines (Moore *et al.*, 2015), we used an explicit theoretical framework to guide our focus group schedule. An interview schedule informed by NPT (May *et al.*, 2009) was developed to explore stakeholders' expectations. A copy of the Topic Guide for each of the Stakeholder Focus Groups is provided in Multimedia Appendix 1.

Twenty-five focus groups were held across Melbourne and Glasgow from 20th July 2016 to 9th September 2017. Participants were 88 mental health staff, either working in the NHS in the UK (n=54, 9 focus groups) or NorthWestern Mental Health (public run) services in Australia (n=34, 4 focus groups). Focus group length ranged from fifty-seven minutes to two hours and nine minutes. Twenty-one service users were recruited from the UK (n=5, 3 focus groups) and Australia (n=16, 4 focus groups) and forty carers from UK (n=20, 2 focus groups) and Australia (n=20, 3 focus groups). Carers and service users received £20/$40 for participation. Staff received no cash reimbursement and participated during their usual working day. All participants gave written consent before taking part. All focus group facilitators (AG, SB, AC, ML, JG, JH, JF & SA – a mix of genders) identified themselves as researchers to conduct the research and were transparent if they also held a clinical role. All participants received a presentation about the EMPOWER intervention. The focus groups were audio recorded and then transcribed verbatim. NVIVO software was utilised (QSR, 2015) to perform analysis.

4.8 Reflexivity

SA is a PhD student investigating the implementation of digital interventions for psychosis. Facilitating focus groups was a task shared by all co-authors. Data analysis was primarily completed by SA, who has previously utilised qualitative methods. Supervision and code checking for all analysis (including discussions about saturation) were provided by AG and HM, both of whom are Clinical Psychologists. AG is Chief Investigator for the EMPOWER study and was responsible for the overall design and conduct of the research.

4.9 Data Analysis

The analysis comprised two stages. Thematic analysis is a qualitative method used to construct, analyse, and report on patterns within text data (Braun and Clarke, 2006). This is commonly utilised within qualitative aspects of process evaluations to identify key barriers and facilitators for implementation of a diverse range of digital interventions (Maar *et al.*, 2017; Morton *et al.*, 2018; van Reijen *et al.*, 2018). In stage one, we performed an inductive thematic analysis (Braun and Clarke, 2006) for each unique stakeholder group in turn. This was justified because in a pilot clinical trials such as EMPOWER, study evaluators are encouraged to use exploratory research to identify facilitators and barriers to interventions so that strategies can be put in place in time for an evaluation of effectiveness (Moore *et al.*, 2015).

For stage 2 The MRC process evaluation framework (Moore *et al.*, 2015) was identified as a suitable deductive coding framework (Gale *et al.*, 2013) for placing the themes in an implementation theory context more relevant to the needs for a feasibility study where it may be too early to decide if normalisation should be the goal. This was the rationale for moving away from our original plan (EMPOWER **ISRCTN**: 99559262) to use the NPT (Murray *et al.*, 2010) framework for qualitative work. The MRC framework goes beyond barriers and facilitators to implementation and provides a taxonomy of implementation constructs. Expected barriers and facilitators (on their own) can be seen as singular aspects of a predicted overall process. However, during the analysis of focus group conversations, it was clear that barriers and facilitators were expected to *interact* together into an overall expected implementation process for EMPOWER. Therefore, we selected implementation constructs from the MRC process evaluation to structure our barriers and facilitators findings in a theoretically driven hypothetical implementation theory (presented as a deductive framework) for the EMPOWER trial:

- Reach (whether service users are expected to consent to take part)
- Fidelity (whether the intervention is expected to be used as described)

- Context (contextual factors expected to affect, or be affected by, the implementation process)
- Implementation (what successful implementation would look like in practice, beyond a trial)

Coding and analysing the data within this framework resulted in the implementation issues highlighted during inductive analysis being more meaningfully constructed as implementation barriers and facilitators. Through our initial thematic analysis, we developed sixteen themes (Table 3). The implementation diagram (Figure 8) represents implementation expectations for the EMPOWER intervention across staff, service users and carers with facilitators (green) and barriers (red) within the implementation framework. The framework analysis was completed across all stakeholder groups simultaneously.

Both stages of qualitative analysis were completed by SA and triangulated through discussion with AG and HM. Resource limitations meant that strategies such as member checking (where participants check over themes proposed by the researcher as an interpretation validity check (Doyle, 2007)) were not utilised. However, it has been highlighted that employing this technique may increase the validity of findings in qualitative research exploring user views of digital interventions in psychosis (Berry, Lobban and Bucci, 2019) and better ensure participant views have not been misrepresented.

4.10 Results

The first part of the results section introduces the inductive thematic analysis (as shown in Table 1) and offers example quotes as an attempt to illustrate our analysis transparently.

4.10.1 Inductive Results

4.10.1.1 Mental Health Staff Implementation Expectations

4.10.1.1.1 Implementation Facilitators:

4.10.1.1.1.1 Youth

Many staff predicted that young people (e.g. those accessing early intervention services for psychosis) were more natural consumers of digital interventions. Staff perceived young service users as being both familiar with and highly able to use digital technology. Staff also expected that older service users would find the intervention harder to use and to be too burdensome for this reason. These assumptions appeared commonplace throughout discussions in both the UK and Australia.

> *"I do think it's going to be a good thing in the long term, but there's going to be clients that don't fit into it now as well as. Because I think the next generation of people coming through are going to have been grown up with technology and are going to be okay with using it..."* (Participant 8, Staff Group 11, Australia)

4.10.1.1.1.2 Clinical Usefulness

Most staff appeared cautiously optimistic about the value of the data from the EMPOWER app and believed that it could be useful for their clinical practice by enabling staff to tune themselves into the changes in early signs and the broader context for these changes. In this particular illustrative quote, staff members highlighted how they expected EMPOWER data could draw their attention to patterns and links between stress and psychotic symptoms in the life of a service user.

> *"You see where the stressors are, what times, what the patterns are, the patterns would be so clear."* (Participant 1, Staff Group 2, UK)

4.10.2 Implementation Barriers:

4.10.2.1 Service users viewed as having "Chaotic Lives."

Staff reported that service users with a "chaotic" life would struggle to use the intervention. Staff viewed those individuals with chaotic lives as being the most vulnerable to relapse. "Chaotic lives" was a complex term referring to multiple factors including service users having difficulties with reflecting on their own experiences, having lack of insight, poor social or cognitive functioning, avoidance of services, or an inability to retain a mobile phone. These factors were considered in the context of the influence of a broader context of social deprivation or financial problems leading to users' selling a provided mobile phone for cash.

> *"It sounds like there'd be quite a specific group of patients that would benefit from this in terms of the people who are able to kind of reflect, who are you know, their lives aren't so chaotic that they can't keep hold of a mobile phone, you know, it doesn't end up somewhere else or in someone else's hands or whatever, and it's – I think it will be really useful for people who are functioning at that level and are able to reflect on things like that, but I guess it's – I suppose I'm just thinking it's a shame because it's often the people I suppose who I wonder might be at more risk of more kind of relapsing or being lost in the system somehow and becoming very unwell, are maybe already a bit too chaotic or functioning at too poor a level supposed to be able to make use of something as helpful potentially as this."* (Participant 1 Staff Group 7, UK)

4.10.2.2 Service User Paranoia

While the EMPOWER intervention was commonly described by staff to be an acceptable tool for managing relapse in at least some service users, they also perceived the intervention would not be acceptable to others. One common implementation barrier expected by staff was that service users with paranoid and/or delusional beliefs about technology would not engage with the intervention. This implementation expectation appeared grounded in expectations about how changing levels of paranoia will vary with technology affinity and competence. Conversations about service users who have technology focused beliefs were frequent throughout staff focus groups and can be exemplified in the quote below where a staff member wonders aloud if EMPOWER would work for someone who already has such concerns about digital technology. Furthermore, this staff member highlighted that these beliefs could become more pronounced in the context of relapse.

> *"I'm thinking about one of my service users in particular who, when he becomes unwell, his phone is actually part of his delusional belief system, and he becomes obsessive about certain part of it; so I'm wondering how that would work for him?"* (Participant 4, Staff Group 6, UK)

Uncertainty about whether EWS data are useful in EI services

4.10.2.3 Uncertainty about whether EWS data are useful in Early Intervention services

Despite the optimistic expectation staff held about younger service users engaging with the intervention, staff from early intervention services discussed some different implementation barriers not present in other focus groups. For instance, the early stages of psychosis can be an uncertain time for clinicians because EWS of relapse might not be established yet. As illustrated below, a staff member from an early intervention service within the UK highlighted that the EMPOWER intervention might face a different implementation barrier because the data gathered via the app might have limited utility for staff in predicting relapse.

> *"It's a trial but it is quite on the edge of relapse, which is risky. With our patient group, relapse signature is not that familiar because of early on. So, you've not got that history to learn from."* (Participant 2, Staff Focus Group 3, UK)

4.10.2.4 App Providing De-contextualised data

Many staff expressed the concern that the quantitative self-reported data gathered from service users through their usage of the app lacked the context that comes from typical interactions staff have with service users. In sum, data alone were understood as being potentially unhelpful without the clinical experience of staff members to interpret these data. Staff valued their knowledge and relationship-based experiences of service users as a basis for making decisions concerning the risk of relapse. There was an additional concern that the quantity of data could also potentially block effective decision-making. An example of this can be seen below where a staff member highlighted that if information from the EMPOWER app implies that a service user is relapsing, they would not feel comfortable acting on this information alone.

> Participant 3*: "a bit of an overload of information perhaps if we're getting like you know three or whatever plus messages from the app a day and we'd need to do a management plan around... at presentation and a big limitation in that sort of context is that you don't... it's difficult to get a feel from the person about what is happening for the person…*
> Participant 4*: "missing out on the interpersonal context"* (Staff Group 12, Australia)

4.10.2.5 Lack of staff time

Staff were concerned that using the intervention in practice might be difficult. Working with people with a diagnosis of psychosis was described as a time-intensive part of their role. Staff reported having many other competing demands on their time and limited resources to do their jobs. Staff frequently referred to a lack of capacity in the system and resource constraints. Several mental health Staff even related the lack of available resources within the mental health system and were concerned that digital technologies might one day replace their jobs. In the example below, the other participants in the focus group agree with Participant 1, expressing concern about the potential lack of staff capacity the implementation of EMPOWER.

> *"It definitely makes sense, in that my only worry about it is that thinking about my caseload at the moment and I just don't know where we'd have the capacity to be working with it. [Sounds of Agreement from Other Participants] Particularly because it's psychosis and schizophrenia illness and how disabling that is… erm, to people."* (Participant 1, Staff Group 2, UK)

4.11 Carers' Implementation Expectations

4.11.1 Implementation Facilitators

4.11.1.1 More attuned clinical responses

Many carers expressed the view that routine monitoring and access to chart data could result in more attuned responses from mental health services because the data would indicate when support was needed. They believed that this would result in their loved one engaging with services when necessary, and services having a response that was experienced by their loved ones to be more relevant, timely and acceptable. As demonstrated in the example below, carers state that they expect themselves to have a role in starting the help-seeking process.

> *"if the chart was, you notice yourself it's is negative, they are definitely going down the tube, you will encourage them, if they don't see their doctor on a regular basis, that we should go and visit a doctor"* (Participant 2, Carer Group 3, Australia)

4.11.1.2 Carer support for trying something new

Aside from reporting implementation concerns for EMPOWER, carers also said it was essential to try out new interventions aimed at improving the lives of people with psychosis. Throughout all focus groups, it seemed clear that carers valued that clinical researchers were attempting to introduce innovation and were supportive of the role of research. While carers were cautious about how successful their encouragement may be, nevertheless carers appeared keen to encourage ongoing usage of self-monitoring interventions by people whom they support.

"if we [as carers] had a good working understanding of it [EMPOWER] I'd find it easier to say to her "oh how are you getting on with the app?" and just encouraging her with it if she was happy to be encouraged, yeah. So, I think that'd be really good." (Participant 5, Carer Group 1, UK)

4.11.2 Implementation Barriers

4.11.2.1 Service user having previous negative experiences with mental health services

However, like staff, carers frequently expressed that they expected the intervention to face multiple implementation barriers. Carers were nearly unanimous that the previous experiences of people with psychosis accessing services are likely to shape the reach of the intervention. This can be seen in the example below, where a carer predicts that her son is unlikely to use the EMPOWER intervention because of his previous autocratic experience dealing with mental health services. However, she remains cautiously optimistic about the implementation potential for the intervention of service users with different experiences.

> *“I just...in my son's case, he wouldn’t use it. He just wouldn't use it. And that's down to the experiences he's had with what he says is the mental health authorities. He's really...but for people who are open to it, it would be terrific. [murmur of agreement from other participants*]” (Participant 7, Carer Group 5, Australia)

4.11.2.2 Service users inputting Inaccurate data

Carers reported widespread concern that their loved ones may inaccurately input data. Throughout focus groups, this was understood as a function of concerns that their loved ones would downplay or minimise their experiences to avoid unwanted responses and interventions from services that they believe could result from accurate data input.

> *“I suppose in some people if they are trying to be over positive and not give the truth”* (Participant 3, Carer Group 1, UK)

4.12 Service Users' Implementation Expectations

4.12.1 Implementation Facilitators

4.12.1.1 Having access to own data

Service users expected that having access to their data could be a useful source of learning about and becoming attuned to their wellbeing. Focus group discussions highlighted that psychotic experiences and general wellbeing are very changeable for service users. Data access appeared understood as a potential way to explore and learn about possible patterns, which might exist in these same wellbeing changes. In this particular example, a service user remarks that having data might encourage them to use the app because they feel that they are not currently aware of how their wellbeing fluctuates.

> *"I would use them to see what's making me happy, what's doing my head in. How is my sleep schedule, am I getting ill. It's just understanding your own mind better than when you're doing it yourself. Because you're not really aware of all these things. You forget what you done yesterday."* (Participant 1, Service User Group 1, UK)

4.12.1.2 Wanting own data to be accurate

Service users reported valuing having their data and expressed an awareness that for EMPOWER to work optimally, data entry will need to be accurate. In recognition of this, service user participants reflected on the importance of responding to the survey to the best of their ability. In the example below, a participant describes this being an implementation facilitator because inaccurate data would make the app data meaningless and would not confer any benefit.

> *"don't lie to yourself because if you lying to the app the you are lying to yourself and basically you are not doing anyone any favours".* (Participant 2, Service User Group 5, Australia)

4.12.1.3 Importance of App providing a good User Experience

Service users highlighted the importance of the app being appealing to use and the proposed message content being relevant and non-patronising. In the example below, a service user highlighted how they would feel infuriated if they were made to feel patronised. However, they stated that if they had control over what content they had to read this would improve acceptability. Discussions like this were commonplace and suggested that service users' perceptions of intervention content were a vital implementation expectation.

> *Participant 1: "Yeah. There's a risk that it might be a wee bit patronising. Just a risk, I don't know. I know that me personally if I was feeling down in the dumps and I got a message saying "go for a walk"... [laughs]*
> *Researcher 1: "Pull your socks up".*
> *Participant 1: Yeah. It may infuriate me. But maybe if I had the option to read the message, I was choosing to read the message, it wouldn't be so annoying."*
> (Service User Group 1, UK)

However, user experience conversations were not limited to intervention content. Discussions about the importance of how the app looks were common throughout focus groups. In the example below a participant highlighted the importance of the intervention providing good experience through aesthetics. Therefore, the importance of user experience seems to envelop both intervention content as well as the package in which the intervention is delivered.

> *"if it looks decent, if it doesn't look like a ten-year-old made it. Yeah. It has to be engaging and it look visually... that's pretty important to me. Not what I stand for, a ten-year-old"* (Participant 3, Service User Group 7, Australia)

4.12.2 Implementation Barriers

4.12.2.1 Data Privacy Concerns

Some service users stated that EMPOWER might be unacceptable to them because of expected paranoia. However, more common concerns were expressed regarding the privacy of data inputted into the app. The example below suggests that the service user is already concerned about threats to their privacy/autonomy and highlights that they are wary because their information will be sent to the treating team. While this specific example highlights concern about information going to mental health staff, the focus group conversations also revealed concerns about other people, such as government employees or hackers getting access to personal data. Therefore, this theme may reflect existing privacy concerns in the lives of service users. While service users were generally accepting of the intervention regarding its role in supporting self-monitoring, they were cautious and guarded about being monitored by others particularly mental health services

> *Participant 3: We know that nothing is essentially private, well I happen to know that nothing that you tell any counsellor or social worker, nurse, therapist, anything, everything you tell them can be transferred even if it's just in the lounge in the kitchen during lunchtime "oh blah de blah de blah". We know they share information about us. We know they… um there is no privacy. Well I know it.*
> *Participant 1: Uh what was the question again?*
> *Researcher 1: It's really about the security arrangements and confidentiality with app as we have explained it, if there is any concerns or comments about that?*
> *Participant 3: Totally, it's going to be sending information to the treating team*" (Service User Group 7, Australia)

4.12.2.2 Concern App will Replace Service Access

Service users throughout focus groups described accessing mental health services as a source of support in managing their wellbeing. The EMPOWER intervention was described as likely to encounter implementation barriers if the technical side of the intervention was perceived to be replacing "high touch" human connection. In the example below, a service user participant highlighted that the digital intervention on its own would be a poor substitute for dealing with a person who knows them.

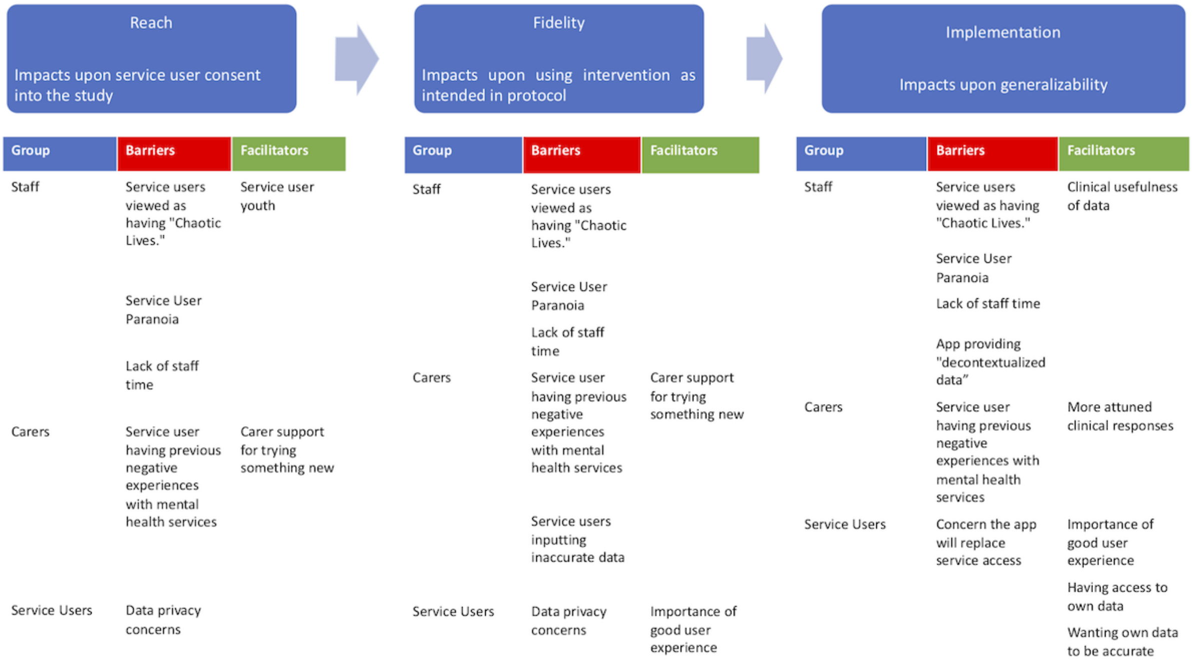
“seems a poor substitute for seeing a person that knows you “(Participant 2, Service User Group 1, UK)

4.13 Deductive Results

Barriers impacting upon reach (who consents to participate in the trial) are expected early in the implementation process. For example, carers expect that service users with previous negative experiences such as coercive treatment will be less likely to consent into the study (a reach barrier). Mental health staff expected service users who have low general levels of functioning and/or high levels of paranoia would not consent or struggle to use the app if they do. However, mental health staff expected that younger service users would be more likely to be willing to participate in a digital intervention study because their generation are "digital natives". Implementation issues, which impact upon fidelity (such as service users inputting inaccurate data) are expected slightly later in the implementation process. However, even if the implementation is successful (with service users completing daily self-monitoring) and the data is perceived to be an accurate reflection of their mental state – problems using EMPOWER data for relapse prevention are still expected. For example, staff predicted that EMPOWER data will not be applicable within the context of early intervention services because EWS of relapse will still be unclear for people experiencing first episode psychosis (an implementation barrier). Barriers such as a lack of staff time were constructed as a predicted barrier across all levels (i.e., expected to impact upon everything from service user consents into a feasibility study all the way up to generalising into clinical practice if clinical outcomes in a definitive RCT were favourable). The results of this deductive analysis can be seen in Figure 8.

Table 3 presents the themes as barriers and facilitators constructed during the inductive analysis.

Stakeholder Group	**Expected Implementation Barriers**	**Expected Implementation Facilitators**
Staff	Service users viewed as having "Chaotic Lives."	Service user youth
	Service user paranoia	Clinical usefulness of data
	Uncertainty about whether EWS data are useful in Early Intervention services	
	App providing "decontextualized data”	
	Lack of staff time	
Carers	Service user having previous negative experiences with mental health services	More attuned clinical responses
	Service users inputting inaccurate data	Carer support for trying something new
Service Users	Data privacy concerns	Having access to own data
	Concern the App will replace service access	Wanting own data to be accurate
		Importance of good user experience



Reach

Impacts upon service user consent into the study

Group	Barriers	Facilitators
Staff	Service users viewed as having "Chaotic Lives." Service User Paranoia Lack of staff time	Service user youth
Carers	Service user having previous negative experiences with mental health services	Carer support for trying something new
Service Users	Data privacy concerns	

Fidelity

Impacts upon using intervention as intended in protocol

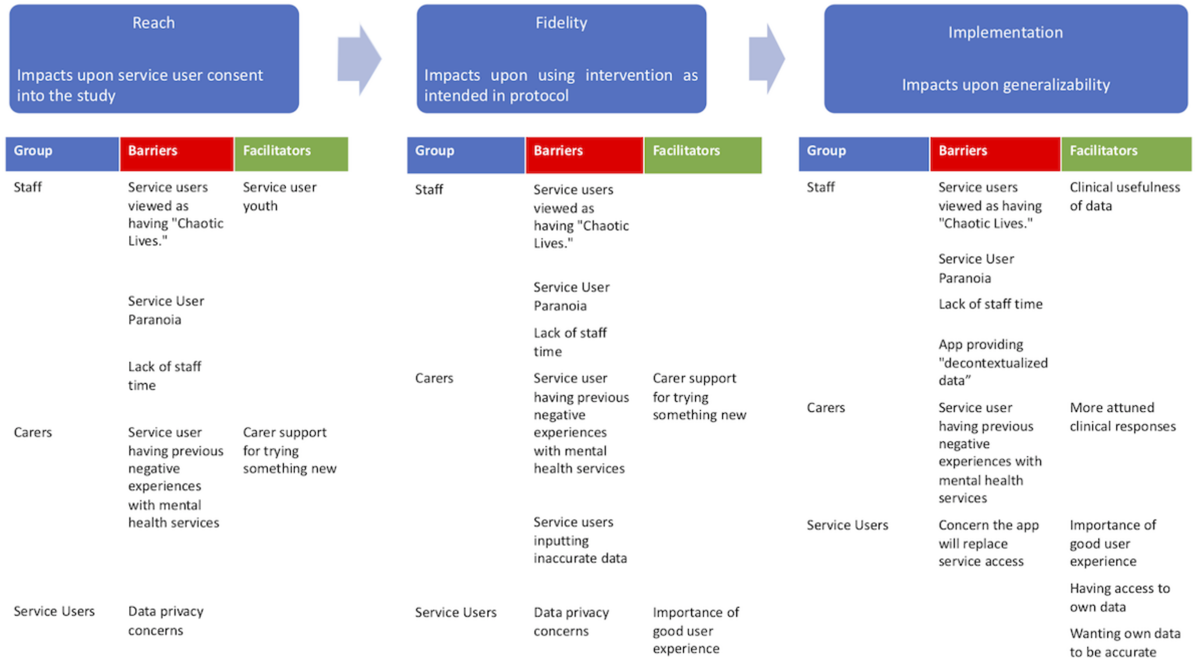
Group	Barriers	Facilitators
Staff	Service users viewed as having "Chaotic Lives." Service User Paranoia Lack of staff time	
Carers	Service user having previous negative experiences with mental health services Service users inputting inaccurate data	Carer support for trying something new
Service Users	Data privacy concerns	Importance of good user experience

Implementation

Impacts upon generalizability

Group	Barriers	Facilitators
Staff	Service users viewed as having "Chaotic Lives." Service User Paranoia Lack of staff time App providing "decontextualized data"	Clinical usefulness of data
Carers	Service user having previous negative experiences with mental health services	More attuned clinical responses
Service Users	Concern the app will replace service access	Importance of good user experience Having access to own data Wanting own data to be accurate

Figure 8 presents the hypothetical implementation framework which scaffolds both barriers and facilitators themes that came up during focus group discussions. The diagram shows Throughout all stages, barriers and facilitators reach, fidelity and implementation we



Reach

Impacts upon service user consent into the study

Group	Barriers	Facilitators
Staff	Service users viewed as having "Chaotic Lives." Service User Paranoia Lack of staff time	Service user youth
Carers	Service user having previous negative experiences with mental health services	Carer support for trying something new
Service Users	Data privacy concerns	

Fidelity

Impacts upon using intervention as intended in protocol

Group	Barriers	Facilitators
Staff	Service users viewed as having "Chaotic Lives." Service User Paranoia Lack of staff time	
Carers	Service user having previous negative experiences with mental health services Service users inputting inaccurate data	Carer support for trying something new
Service Users	Data privacy concerns	Importance of good user experience

Implementation

Impacts upon generalizability

Group	Barriers	Facilitators
Staff	Service users viewed as having "Chaotic Lives." Service User Paranoia Lack of staff time App providing "decontextualized data"	Clinical usefulness of data
Carers	Service user having previous negative experiences with mental health services	More attuned clinical responses
Service Users	Concern the app will replace service access	Importance of good user experience Having access to own data Wanting own data to be accurate

4.14 Discussion

This is among the first studies to assess and record implementation expectations across mental health staff, carers and service users for a newly developed digital intervention for psychosis in advance of testing in a clinical trial, building on previous multi-stakeholder work (Huerta-Ramos *et al.*, 2016). We have identified and theoretically framed the most common implementation expectations expressed by mental health staff, service users and carers in advance of the EMPOWER clinical trial. Understanding the context behind empirical outcomes from novel digital mental health interventions is key in deciding if an intervention can be easily implemented within current practice (Aref-Adib *et al.*, 2018), or will require significant resources and effort to do so (Torous and Firth, 2018). Within a standard implementation science approach, context is defined as a shared environment, which can provide either barriers or facilitators for implementation. However, within a complexity science-informed understanding, context is defined by an intervention interacting with multiple enacted environments of different social actors (Braithwaite *et al.*, 2018). While the MRC process evaluation framework provides a theoretical framework, creating the framework shown in Figure 8 means that it is more tailored to the clinical context of relapse management as reported by carers, mental health staff and service users. Our findings provide a complexity science-informed account of how different stakeholders expect EMPOWER to interact within the multi-stakeholder actions that already occur during routine relapse prevention.

Key to the proposed framework (Figure 8) is a similarity between groups regarding expectations of what would constitute successful implementation. For successful implementation, it was agreed EMPOWER must enable service user participants to self-monitor, to a level of granularity which results in data allowing for visualisation of potential personal indicators of relapse while also giving a comprehensive insight into overall service user mental health. Despite this implementation expectation appearing similar across groups, there were some role differences between staff, service users and carers. The context of healthcare settings is constructed as being institutionalised (Greenhalgh *et al.*, 2018) because behaviours by social actors are described in terms of the roles people are expected to act out. Our findings suggest that implementing the use of EMPOWER data in relapse prevention is only expected to be successful if the data is symbolically meaningful (Greenhalgh *et al.*, 2017) to each stakeholder's role. For example, in the case of staff, this means having data, which enables them to understand better how a participant feels and can help them differentiate early warning signs of relapse from a false alarm. For carers, useful data was constructed as staff becoming more attuned and being able to differentiate relapse signals from false alarms. While both staff and carers emphasised data access as being an implementation facilitator that could improve service responses, service users were more curious about the impact of having access to a record of their self-reported day-to-day wellbeing. Previous qualitative research conducted with service users exploring potential (Huerta-Ramos *et al.*, 2016; Bucci, Morris, *et al.*, 2018; Berry, Lobban and Bucci, 2019) and actual (Eisner *et al.*, 2019) acceptability of digital self-management interventions for psychosis has reported that having access to personal data may have positive impacts such as enhancing self-management. However, this previous work also highlights more negative impacts reported by service users such as creating concerns about data privacy (Berry, Lobban and Bucci, 2019), paranoia (Eisner *et al.*, 2019) and concern that using digital interventions may eventually lead to a reduction in mental health services (Berry, Lobban and Bucci, 2019). Therefore, the mixed findings from our study appear mainly in line with previous research.

Like previous work exploring hypothetical implementation expectations held by staff, service users and carers for a digital intervention for an online portal for schizophrenia (Huerta-Ramos *et al.*, 2016), we found key differences in implementation expectations across staff, service users and carers. Service user implementation expectations for both barriers and facilitators most frequently focused on individual experience. For example, the importance of EMPOWER providing a good user experience was highlighted as a key implementation facilitator throughout all stages of the implementation process and will be very important for sustained intervention use. User experience has been described as a neglected area within digital intervention research (Michie *et al.*, 2017) and psychosis more specifically (Bell *et al.*, 2017). A recent study examining a mobile health platform for clinical monitoring in psychosis indicates that implementation was low because of the app frequently crashing (Kumar *et al.*, 2018), perhaps highlighting the importance of exploring user experience in implementation research. Carers (similar to findings from previous qualitative work (Lal, Daniel and Rivard, 2017)) and staff generally reflected how they foresee EMPOWER influencing service user interactions with staff. Furthermore, staff foreseeing digital interventions having an impact on staff roles and responsibilities is similar to previous qualitative research work conducted with mental health staff (Huerta-Ramos *et al.*, 2016; Berry, Bucci and Lobban, 2017). Carers expected that previous negative experiences of mental health care could act as a barrier towards initial engagement with the app. For carers, this expectation appeared to be related to a fear that EMPOWER would come to emulate existing dynamics within relapse prevention that can block timely communication of EWS. These findings are in line with previous research demonstrating that different stakeholders can hold different perspectives on digital mental health interventions (Carper, Mchugh and Barlow, 2013; Huerta-Ramos *et al.*, 2016; Strand *et al.*, 2017) and suggest value in seeking out all relevant stakeholder perspectives.

This consultation work was helpful to the EMPOWER study because it highlighted key concerns of key stakeholders. For example, staff reporting a concern that app-generated data would be de-contextualised data which may not be useful for clinical decision making. Going forward into the feasibility study, the role of a clinician in triaging data from the intervention to place app data within a meaningful context was emphasised to staff during recruitment.

4.15 Limitations

This study has several limitations. First, focus groups may result in some participants feeling reluctant to share their views fully. Secondly, the implementation barriers and facilitators highlighted in this paper were those that were most commonly discussed throughout the focus groups. However, the quantity of discussion of barriers and facilitators may not equal their importance or relevance (Kooij, Groen and Van Harten, 2018). Thirdly, participants were given a *presentation* which covered the EMPOWER rationale and how the intervention works. Participants might have formed different expectations if they were presented with an *actual* prototype. A recent recommendation for undertaking complexity science-informed implementation research within healthcare services is to abandon attempts to simplify implementation research, but rather to explore implementation more inductively from multiple perspectives (Greenhalgh and Papoutsi, 2018). Therefore, there is a concern that adopting existing implementation taxonomy from the MRC process evaluation framework (Moore *et al.*, 2015) within our analytic approach may have overly simplified construction of the hypothetical implementation framework. Moreover, following the NPT framework in designing research questions may have minimised the range of potential responses from participants. Lastly, PPI can range from consultation to stakeholders having decision making over the aims and conduct of a study (Greenhalgh *et al.*, 2019). Therefore, these findings should be considered in light of them coming from consultation and not direct stakeholder involvement.

4.16 Conclusions

The field of digital self-monitoring interventions in psychosis is rapidly expanding (Bell *et al.*, 2017; Eisner *et al.*, 2019), and there is a need to optimise interventions for implementation. One critical implementation focused strategy is intervention co-design with stakeholders in order to develop digital psychosis interventions more suitable to the needs of end users (Hardy *et al.*, 2018; McClelland and Fitzgerald, 2018). After completion of the EMPOWER feasibility trial, we will utilise observations amassed during the trial to base comments on how stakeholder expectations identified from this analysis compare to actual trial implementation. This qualitative work done in advance of the EMPOWER trial provides insight into very early implementation expectations that form when people are first told about a digital intervention. These implementation expectations seem associated with the role that a person plays in managing a health problem (such as being a patient, or a carer) as well as their previous experiences. Furthermore, these expectations extend across different levels of implementation (McGinn *et al.*, 2011), from early engagement to post-trial implementation - indicating expectations are complex and wide-ranging. Our results suggest that potential participants may quickly form implementation related expectations about interventions and make predictions about how they (and others) will interact with the intervention. These findings indicate that potential participants do not arrive at interventions in a naïve state and may develop expectations and assumptions about new technology before they even use it for themselves.

4.17 Acknowledgements

We thank all the participants who agreed to take part in the study. This study was supported by NHS Research Scotland, through the Chief Scientist Office and the Scottish Mental Health Research Network. This project was funded by the National Institute for Health Research Health Technology Assessment programme (project number 13/154/04) and the National Heath Medical Research Council (APP1095879). It will be published in full in the Health Technology Assessment. The research was supported by NHS Research Scotland (NRS), through NHS Greater Glasgow & Clyde (NHSGG&C) and of the Mental Health Network (MHN). SA was funded by the Cremore Research Fellowship. The views and opinions expressed are those of the authors and do not necessarily reflect those of the Health Technology Assessment programme, National Institute for Health Research, the NHS, The Department of Health, NorthWestern Mental Health Services, The Cremore

Research Fund or the National Health Medical Research Council. We also wish to thank Jennifer Hargrave who volunteered in co-facilitating two of the focus groups in Glasgow.

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4.18 Conflicts of Interest

None

4.19 Abbreviations

UK: United Kingdom
NHS: National Health Service
EI: Early Intervention
cRCT: Cluster Randomised Controlled Trial
MRC: Medical Research Council
EWS: Early Warning Signs

5 Chapter 5: Service Users, Carers and Mental Health Staff understandings of early warning signs of relapse in psychosis: A qualitative investigation.

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5.1 Abstract

Background: Relapse prevention strategies based on monitoring of early warning signs (EWS) are advocated for the management of psychosis. However, there has been a lack of research exploring how staff, carers and service users make sense of the utility of EWS, or how these are implemented in context.

Aims: To develop a multi-perspective theory of how EWS are understood and used, which is grounded in the experiences of mental health staff, carers and service users.

Methods: Twenty-five focus groups were held across Glasgow and Melbourne. Participants comprised of 88 mental health staff, 21 service users and 40 carers from United Kingdom and Australia, for a total of 149 participants. Data were analysed using constructivist grounded theory.

Results: All participants appeared to recognise EWS and acknowledged the importance of responding to EWS to support relapse prevention. However, recognition of and acting on EWS were constructed in a context of uncertainty, which appeared linked to risk appraisals which were dependent on distinct stakeholder roles and experiences. Within current relapse management, a process of weighted decision-making (where one factor was seen as more important than others) described how stakeholders weighed up the risks and consequences of relapse alongside the risks and consequences of intervention and help-seeking.
Conclusions: Mental health staff, carers and service users speak about using EWS within a weighted decision-making process, which is acted out in the context of relationships that exist in current relapse management, rather than an objective response to specific signs and symptoms.

5.2 Introduction

Relapse influences the long-term course of psychosis with rates following a first episode accumulating to 54% at three years (Alvarez-Jimenez *et al.*, 2012) and 80% at five years (Robinson *et al.*, 1999). The economic costs of treating relapse are significant (Pennington and McCrone, 2017). Furthermore, relapse increases psychological distress and demoralisation in service users (Gumley and MacBeth, 2006), and disrupts important interpersonal relationships such as those with carers (Tempier *et al.*, 2013). Lack of acceptance of treatment and unplanned discontinuation of antipsychotics are predictors of relapse (Alvarez-Jimenez *et al.*, 2012) reflecting poorer engagement with mental health staff (Lambert *et al.*, 2010). One way of addressing risk of relapse is monitoring Early Warning Signs (EWS). EWS monitoring is well established for the detection of relapse, but evidence for routine implementation is poor (Morriss *et al.*, 2013). This may in part be due to the relatively poor sensitivity of formal EWS monitoring (median sensitivity = 61%) (Eisner, Drake and Barrowclough, 2013) and fear of relapse (Gumley *et al.*, 2015) leading to avoidance of help-seeking (Gumley and MacBeth, 2006; Gumley *et al.*, 2010) (Farrelly *et al.*, 2016). Therefore, successful implementation of early signs monitoring to detect and prevent relapse not only rests on being able to accurately predict relapse, but also on the quality of interpersonal interactions, communication and shared decision making, including with families and carers (Onwumere, Shiers and Chew-Graham, 2016).

5.3 Study Aims

The primary aim of this study was to develop a multi-perspective theory of how EWS are utilised by service users and carers to inform the future implementation of a clinical trial of digital technology for relapse detection and prevention (EMPOWER Trial, ISRCTN: 99559262). The selection of research questions followed the Medical Research Council (Moore *et al.*, 2015) framework for developing and evaluating complex interventions.

5.4 Methods

5.4.1 Design

A qualitative focus group design was chosen to gain insight into participants' perspectives, experiences and expectations (Braun and Clarke, 2019). Using focus groups enabled respondents to interact with and respond to the ideas and comments of other participants (Kruger and Casey, 2014). Following best practice guidelines (Moore *et al.*, 2015), we used a theoretical framework to guide our focus group schedule. An interview schedule was informed by Normalisation Process Theory (an implementation theory that helps model the attitudes, behaviours, and reflections that affect the integration of new complex interventions into routine care) (May *et al.*, 2009) was developed to explore stakeholders' expectations. We planned to use NPT to explore how mental health staff, carers and service users made sense of EWS, how they engaged with them, the actions they took in relation to EWS and how effective they thought EWS were in managing relapse. However, due to the lack of available knowledge on the topic and the focus group conversations not necessarily sticking to pre-defined topic areas, it was decided to analyse the data with a more exploratory stance and NPT was not used to analyse the data.

5.4.2 Sampling and Recruitment

Staff who support people with psychosis were recruited from Community Mental Health Services (CMHS) in Glasgow, UK and Melbourne, Australia. Staff were invited to take part through the research team making contact with clinical team leaders in all eligible CMHS within both health boards. Service users were recruited to take part in focus groups through direct approach by mental health staff and posters placed in support organisations for people affected by mental health problems. Service user participants were eligible if they were in contact with a local CMHS; had experienced a relapse in the past two years; had a diagnosis of a psychosis-spectrum condition and were able to provide informed consent. Self-identified carers for people with psychosis were recruited by the research team advertising through posters and word of mouth in mental health services and support groups. Participants included eighty-eight mental health staff, either working in the National Health Service (NHS) in the United Kingdom (n=54, 9 focus groups) and NorthWestern Mental Health service in Australia (n=34, 5 focus groups). Twenty-one service users were recruited from local mental health services in the United Kingdom (n=5, 3 focus groups) and Australia (n=16, 4 focus groups) and forty carers from United Kingdom (n=20, 2 focus groups) and Australia (n=20, 3 focus groups). To maximise participant anonymity, we did not collect any demographic data beyond whether the participant was a carer, service user or mental health clinician.

5.5 Procedure

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All procedures involving patients were approved by West of Scotland (REC/16/WS/0042) and Melbourne Health (REC/15/MH/344) Ethics Committees. Written informed consent was obtained from all participants. Carers and service users received £20/$40. Staff received no financial reimbursement and participated during working hours. Following a short presentation about EMPOWER which covered trial rationale, design and key aspects of the intervention, twenty-five focus groups were conducted locally following the topic guide by researchers trained in qualitative methods between 20th July 2016 to 6th September 2017. Focus group length ranged from fifty-seven minutes to two hours and nine minutes. Focus group schedules are publicly available in the appendices 2-3 of (Allan, Bradstreet, *et al.*, 2019).

5.6 Analysis

Constructivist grounded theory assumes that the phenomenon in question is inter-personally constructed and context dependent (Charmaz, 2017). The analysis followed the constructivist grounded theory approach as outlined by Charmaz (Charmaz, 2017). Our philosophical stance was influenced by Structural Symbolic Interactionism, which posits that context is closely linked to how social or organisational roles of each stakeholder influences their daily life (Stryker, 2008). For example, being a mental health professional comes with a set of normative expectations regarding the nature of their mental health expertise, expected actions and role-driven behaviours (Farrelly *et al.*, 2016). This was considered important as different stakeholders may have different perspectives on psychosis management (Stovell *et al.*, 2016). Constructivist grounded theory posits (Charmaz, 2017) that themes do not emerge from the data but are constructed as part of a reflexive analytic process. Therefore, themes will be reported as such.

Focus group transcripts were coded line-by-line through an inductive process, developing open codes that summarised the transcripts. The original open code stage resulted in 1246 codes. Following the open code stage, categories were then formed by repeatedly comparing open codes to see if these could be linked together in terms of shared meaning. During the final theoretical coding stage, data from all three groups were repeatedly compared to see if categories could be linked together as a higher order unifying or overarching theme, or if there were differences between groups. During all stages of coding, SA reflected about the data.

There is no prescriptive method for ensuring quality in qualitative analysis (Noble and Smith, 2015), therefore, reporting of results followed good practice guidelines (Tong, Sainsbury and Craig, 2007). For example, we made our philosophical position (constructivism) clear for the reader and our intentions behind the study (exploring existing context in advance of implementing an intervention) transparent.

Furthermore, SA kept reflexive memos throughout the study, which recorded how the influence of researcher characteristics and experiences may have shaped analysis. Analysis was triangulated by discussion with academic clinicians (AG & HM). Only data relevant to the aims of study (understanding how EWS management is currently sustained in context by three stake-holding groups) were included in this paper. The quotes chosen are illustrative of the most common constructions within the data. See Appendix for an overview of the overarching themes and subthemes.

5.7 Results

5.7.1 Weighted Decision-Making

We constructed an overarching theme termed *Weighted Decision-Making*, reflecting a process acted out by different stakeholders' responses to the uncertain context of EWS. Throughout all groups, weighted decision-making was constructed as a process that emerged from interactions between service users, staff and carers (if a person had one). Weighted decision-making was strongly linked to risk appraisal, with each group having their own distinctive (and sometimes shared) experiences of the harms and benefits of acting on EWS as a strategy to prevent relapse. This overarching theory comprised of four key themes; each is now described and explained in turn:

5.7.2 The Apparent Consensus Around EWS

There was consensus across stakeholders that EWS were experiences or behaviours that are taken to indicate risk of relapse, and that identifying EWS was a potentially useful way to understand changes in wellbeing and to allow for early intervention. Service users described a variety of personal experiences labelled as EWS. Their descriptions suggested that EWS function as a barometer for recognising changes in wellbeing.

> *Researcher 2: And how helpful would you say it is to kind of monitor early warning signs?*

> *Participant 2: It's important. It's important for your wellbeing. See how you feel the next morning. See how your health is, your mindset. It's very important.* (Service User Group 6, Australia)

Carers reflected on the function of EWS as a means to identify and act in order to avert mental health crises. Carers valued monitoring early signs as a basis for preventing a potential relapse.

> *"You can stop it from escalating and into a full-blown episode. You can see when it's coming on. They can increase the medication or encourage them to see the doctor or something like that. There's lots of things you can do. But, you know, once they get too sick, then it gets more difficult, they get more suspicious."* (Participant 6, Carer Group 4, Australia)

Mental health staff reported that EWS offered an indicator that things were starting to break down for a service user and signalled when staff believed that intervention was needed. Staff believed that if EWS were noticed and acted upon, then there was an opportunity that relapses could be managed.

> *"I think it's their behaviours; you know, if there's a sudden change or you know, that if you've done your relapse prevention and they have identified relapse triggers, then the person's starting to do them."* (Participant 1, Staff Group 7, UK)

5.7.3 Meaning and Consequences of EWS Identification

While there was broad agreement by stakeholders on the function of EWS as a tool to detect and ameliorate risk of relapse, each group articulated distinctive expectations regarding the possible sequence of events following the recognition of EWS. These distinctive expectations were closely linked to the meanings of relapse for each stakeholder group. Carers generally valued EWS, however our analysis suggested that the benefits of identifying EWS came with the possible consequence that a loved one could feel harmed from subsequent interventions. Many carers described traumatic experiences connected to relapse (such as a hospitalisation) and their reluctance to involve services. While carers recognised the value of recognising and acting on EWS, they also feared the potential impact of acting on these in terms of the impact on their relationship with their loved one or the impact of experiences such as being put in hospital upon their loved ones themselves.

> *"I don't want to do anything that's going to push her, you know because there's already part of that whole sectioning process, and that is a huge thing to go through that in a family dynamic."* (Participant 5, Carer Group 2, UK)

Many service users spoke in great detail about the personal distress caused by experiences of psychosis in the context of a relapse. Such experiences were commonly described by service users, which suggested that relapse represented a threat to personal wellbeing. Service users often feared that relapse would also be associated with a series of consequences including the expectation that letting others know about EWS could result in a potential threat to their autonomy such as being made to go to hospital.

> *"Sometimes you don't want to say anything in case you get a negative response. I don't want to go back to the hospital."* (Participant 2, Service User Group 2, UK)

A sense of relapse being somewhat inevitable was observed across the staff focus groups.

Staff recognised that identification of EWS and relapse prevention was an expected part of their role as clinicians. Therefore, the importance of EWS monitoring as a basis for minimising the impact of relapse was generally seen as an essential part of staff responsibilities. However, staff were open to the possibility that foregrounding relapse prevention in such a risk averse manner might not accord with how service users want to manage their own wellbeing.

> *“You are not going to prevent relapse - relapse is always going to be there. On some sort of scale, even people who are well have momentary relapses.”* (Participant 1, Staff Group 1, UK)

> *"I reckon like this is a massive generalisation but I think we [staff] are probably more conservative in the sense that we would probably do more to prevent a relapse but sometimes maybe you can see the consumers’ situation where they will entertain a few more risks, you know - around the potential for relapse if they think that some other benefit like they get to do something else in their life - whereas we are probably a bit more conservative”* (Participant 5, Staff Group 12, Australia)

5.7.4 Experience as Expertise

The nature of risk appraisals linked to EWS expressed by different stakeholders appeared distinctive and reflected contrasting concerns and different types of knowledge and experience. Service users described a dual process of making sense of their own experiences and of how others (particularly mental health staff) would interpret their experiences. This was heavily influenced by their own risk assessment: acknowledging the personal threat a relapse posed and then assessing the external threat of how other people would respond. Service users embedded their appraisals in their previous experiences when appraising EWS disclosure risk. In addition, service users perceived that their experiential expertise in appraising the risk of EWS could be downplayed by staff.

> *“We hate hospital, but we also want to be as honest as we can and often we want to be able to manage our own symptoms too. We don’t want to be medicated up to our eyeballs.”* (Participant 1, Service User Group 5, Australia)

For carers, their expertise in assessing the EWS risk in this context came from knowledge gained through their close contacts. Carers often described themselves as being able to successfully contextualise the risk of EWS through knowing their loved one.

> *“my sister's now, what, fifty-two, so she was diagnosed when she was twenty-one. And why I say I'm her carer, is I recognise the signs.”* (Participant 3, Carer Group 4, Australia)

Carers also reported frustration that staff sometimes did not value carer assessment of the risk posed by EWS. Many carers believed that staff did not recognise the value of their knowledge, experience and expertise.

> *“Well I don't like the fact that I get told "your son is doing really really well, really really really" and I phone up and say "I'm really concerned.”* (Participant 2, Carer Group 2, UK)

Staff reflected on their expertise in recognising and acting upon EWS. This appeared formalised in professional mental health guidelines and policies reflecting both their broader clinical expertise and also their more intimate knowledge of a service user. They reflected on the uncertainty and complexity of acting in response to early signs and the importance of being able to personalise their response to EWS.

> *Participant 2: we’re kind of conscious that we’ll be trying to fit it to the individual. Obviously, people’s experiences with something might work better for some people. But I’d imagine it’d be pretty similar with a few provisions maybe.*
> *Participant 3: There an Integrated Care Pathway and kind of all those guidelines. (Staff Group 7, UK)*

> *“you can only do what you can do as a key clinician in terms of you know those policy procedures we've just discussed* and *there's a whole other gamut of influences that might impact on a consumer that are out of our scope to influence I guess. So, um, I think that's... it's tricky and every consumer is completely different and has different warning signs based on potentially their diagnosis or potential harm so it's yeah. I guess when you are actually*

> *addressing those EWS - it really just depends."* (Participant 1, Staff Group 12, Australia)

Staff valued their individualised knowledge built up through their relationships with service users. In the absence of this, staff then placed their expertise in a team context, utilising colleagues' insights and case notes for developing and evidencing their risk assessment of EWS. The actions reported by staff implied that broader staff knowledge was regarded as a reliable and trustworthy source of information.

> *"I'm just thinking, what would I do in a crisis phone call? So, I would look at notes, try and speak to the person. I would go to that team and say, "who knows this person?" So, I would be trying the collective formal and informal consciousness of the team. Because I don't know all the answers."* (Participant 1, Staff Group 3, United Kingdom)

If staff recognised behaviours they believed were EWS (without a service user reporting EWS experiences to staff) then this appeared to be taken as a "lack of insight" and an indicator of increased risk of a relapse occurring. This commonly resulted in staff believing they needed to take ownership of clinical risk assessment, which appeared to impede sharing decision-making.

> *"There's Staying Well plans and stuff like that. People, we get to sit down and talk about that side, and what happens when they become unwell and things like that. But I've never really had a patient phone me saying "listen, I've referred back to this plan, and I'm starting to get some of these symptoms". You know. It's usually way past that and you pick it up yourself because they just don't have the insight to notice.*" (Participant 4, Staff Group 9, United Kingdom)

5.7.5 EWS Decision-Making Processes

For staff, intervention decisions were based upon a risk gradient. For example, if EWS were perceived to be low risk (in this context – a threat to service user wellbeing but which could not be ruled out as a false positive), then staff interventions focused on helping the service user manage their experiences. If the risk was perceived to be greater (in this context risk being severe detriment to service user wellbeing and more indicative of a relapse event), then the staff role shifted from relapse prevention to relapse management where intervention options included enforced treatment.

> *"there will be steps to take to ensure the consumer isn't getting to the point where they are really unwell - being able to prevent that pretty much - most of it, all of it, getting in contact, you know. Getting input from the medical team- even using legal measures such as a temporary community treatment order or a system those things…, yeah. It's different for everybody, but there are ways where we can really try and manage someone."* (Participant 3, Staff Focus Group 12, Australia)

Decisions were contextualised by constraints on mental health service provision particularly responsibilities for large caseloads. Staff reported having to invest more time with service users who they perceived to have the greatest likelihood of experiencing relapse and feeling dissatisfied with routine practice. This was felt to impact on the quality of working relationships and the ability to respond proactively to EWS.

> *“What we find difficult as nurses is massive caseloads and trying to maintain quality of care trying to make sure things like that are all up to date so it's hard it’s nice in theory to say “oh this is what happens and this always happens” but we’d love it to always happen but sometimes we don't have time to do that and it’s there chasing you every day and you’re thinking oh my god. Best practice. Core standard. Every patient would have that, but reality is we don't often get the time to do it for everybody.”* (Participant 1, Staff Centre 1, United Kingdom)

Decision-making for service users was constructed as a process of weighing up the personal benefits and risks of disclosure of EWS. The expectation that other people would overreact was frequently described as a barrier to help-seeking. Service users described how their decision-making processes were shaped by these sources of uncertainty associated with disclosure.

> *“I get a bit scared to tell people about the early signs. Because you don't want people to blow it out of proportion and then they're staring at you and watching your every move. I don't like that; I like my privacy. And so I like...I don’t know.”* (Participant 1, Service User Group 1, UK)

Some service users spoke about times when staff responses did not result in an expected level of support to help them manage distress. This meant that service users were left to manage distress alone, left them feeling dejected and less incentivised towards future help-seeking.

> *“it's really hard to get to help when you're in psychosis, people don't want to take on the responsibility of helping you and it's not always very easy to ring triage and then get the appropriate response that you want”* (Participant 3, Service User Group 4, Australia)

The struggles expressed by service users with respect to the personal risks of help-seeking were also reflected by carers who did not believe staff were likely to have access to all the relevant information needed for optimal decision-making. Carers reported that they could provide context and detail especially in response to non-disclosure by service users.

> *Participant 2: We often have the feeling that we want to ring them up and up "but all this is going on, and you probably don't know about it" or "she's probably not telling you the history of what's happened beforehand."*
> *Participant 4: Yeah. That's why it's really important to say "This is what's really going on".* (Carer Group 4, Australia)

5.8 Discussion

This study aimed to create a multi-perspective theoretical account of how EWS are experienced and acted out in routine practice. Relapse into psychosis has major ramifications for everyone involved. However, to the best of our knowledge, the context in which EWS are identified and acted on has not previously been described in detail from the perspectives of mental health staff, service users and carers. Self-management interventions for severe mental illness have been reported to generally improve mental health outcomes but the evidence is mixed for relapse prevention (Lean *et al.*, 2019). However, this was noted to be in contrast to a previous meta-analyses which focused on schizophrenia (H. *et al.*, 2013) where self-management interventions (including EWS monitoring) were associated with a significant reduction in relapse events. A call has been made for research that is focused on how to understand and overcome barriers to the implementation of self-management interventions (Lean *et al.*, 2019). This study represents the first large-scale qualitative investigation of how EWS are understood and experienced by staff, service users, and carers across two geographically distinct healthcare systems.

5.8.1 Weighted Decision-Making

Relapse was described as a negative event throughout the focus groups with no stakeholders in these specific focus groups describing relapse as potentially positive, which may imply relapse is perceived as a persistent and ongoing threat. All groups seemed to recognise EWS and emphasised their possible value for relapse prevention. However, recognition of and acting on EWS were constructed in a context of uncertainty. Within current relapse management, a weighted decision-making process described how stakeholders weighed up role congruent (Stryker and Burke, 2000) consequences of relapse alongside role congruent risks and consequences of intervention and help-seeking. A key finding from our qualitative analysis was that responses to EWS appeared linked to risk appraisal and there are differences in how risk is appraised by staff, carers and service users which are closely related to participants' previous experiences and for staff, their professional role.

Similar to findings from previous research (Lal *et al.*, 2017), carers seemed concerned about relapse. Carers weighed the risk posed by EWS of a potential relapse within the context of their close personal knowledge about the person they care for. Carers described wanting to provide supplementary or countervailing information to predict relapse and improve clinical decision-making. However, they reported that their expertise and EWS assessment were often dismissed and devalued by staff. These findings resonate with previous research showing that carers believe they have excellent knowledge of the EWS of relapse from close relationships, but do not feel staff value their knowledge as clinically relevant (Olasoji, Maude and McCauley, 2017). Furthermore, carers disclosing EWS to staff may come with a risk of undermining relationships with service users.

The uncertainty about the degree to which staff may respond was a key factor, which weighed into service users' decisions about help-seeking. This was in contrast to staff expectations that failure to help-seek arose from a lack of insight. For some service users, the potential losses arising from seeking help (such as loss of autonomy) outweighed the potential gains in terms of preventing a deterioration in well-being – echoing previous work by Sibitz (Sibitz *et al.*, 2011). However, some service users also spoke about not receiving adequate support from mental health services when they were struggling, despite promptly reporting EWS.

Broader contextual factors influenced decision-making. Staff spoke about EWS as an important opportunity to prevent or minimise relapse, but felt that in reality they were constrained by high caseloads and inadequate resources - leading to an emphasis on crisis interventions at the cost of developing close working relationships, critical to anticipating and supporting relapse prevention. Lower staff continuity has been linked to worse clinical outcomes in schizophrenia (Macdonald *et al.*, 2018), and inadequate staffing appears linked to increased use of restrictive practices over de-escalation techniques, because these are considered more time efficient in poorly staffed wards (Price *et al.*, 2018). Research on clinical decision making is stated to be difficult to conduct because of the dynamic environment of applied settings (Muntean, 2011). This analysis suggests EWS are utilised within a particularly dynamic and intersubjective decision-making process, with stakeholders valuing different outcomes. For example, service users may value personal autonomy over clinical stability typically valued by staff. While these findings are from qualitative data and should be interpreted with caution, they may offer a theoretical basis for exploring applied clinical decision making further. For example, discrete choice experiments (Ryan, 2004) would allow the relative value of costs and benefits for different stakeholders to be empirically tested.

5.9 Limitations

With qualitative research it is not possible to make comment on the generalisability of any findings. Furthermore, all participants volunteered to take part within focus groups, which raises the possibility that we may have missed important perspectives from those who did not participate. While focus groups allowed for participants to interact together and discuss topics, it may be the case that some participants could feel uncomfortable contributing contradictory viewpoints. The real-world clinical context of EWS usage comes from interactions between mental health staff, carers and service users. However, we spoke to these groups in isolation from each other which may have impacted upon the results. Finally, while at a conceptual level we observed no differences in how people understood and use EWS between Australia and UK, we did not explicitly explore the way in which the distinctive health systems which contextualise practice might influence stakeholders' views and experiences. Additionally, staff, carer and service user participation are unbalanced, with lower numbers of service users participating. Our approach to recruiting mental health staff enabled us to systematically approach all local community mental health services in our two study sites. However, we were unable to have such a systematic approach to user and carer participation and our lower rates of participation reflect this. Furthermore, it should be acknowledged that many service users live alone in the community without support from a carer. While not collecting demographic data was important to better protect participant anonymity and this was a pragmatic methodological choice, the authors acknowledge it is a limitation for readers in interpreting the data.

5.10 Implications for Mental Health Practice

Qualitative methods have been found to be helpful in uncovering "ruptures in communication", wherein differences in how doctors and patients understand medical problems can lead to distress and dissatisfaction with care (Braun and Clarke, 2019). In highlighting how mental health staff, service users and carers described their experiences, it seems EWS are utilised within a weighted decision-making process, which is acted out in the context of relationships, rather than an objective response to specific signs and symptoms. However, there were marked differences in how groups spoke about this decision-making process. Service users and carers reported that staff sometimes did not appear to value their knowledge about EWS and self-management. This may be part of a broader issue, where the subjective experiences of service users and carers are perceived to be less clinically useful because these are perceived to be at risk of bias (Greenhalgh *et al.*, 2015). These findings echo previous qualitative research examining implementation of Joint Crisis Care Plans, which found that staff prioritised risk assessment in accordance with their professional roles at the cost of addressing service users' priorities for their treatment and care (Farrelly *et al.*, 2015).

EWS-based intervention development and implementation may be enhanced by better utilising the knowledge of carers and service users who bring expertise to shared decision making. For example, interventions which gather data from service users and/or carers may reduce clinical uncertainty by placing EWS in a meaningful context. The sharing of data showing temporal wellbeing changes within this weighted-decision making process could influence interactions with key clinicians and reduce uncertainty about potential negative impacts of help-seeking (for all groups) by allowing for predictable alerting of EWS.

Relationships appear the context in which weighted decision-making involving EWS is both acted out and understood. These results suggest that uncertainty of how others will behave may create a barrier to early intervention. EWS based interventions may be better implemented if they address this uncertainty by providing a clearer stepped care pathway, for example through a focus on Shared Decision Making (Slade, 2017). In order for EWS based interventions to be a "good fit" within context of current relapse management, interventions should aim to change the interpersonal inter-relationship behaviours of staff, service users and carers (where applicable), rather than targeting a single social actor.

Table 4 List of Themes from Chapter 5

Dominant Theme	Subthemes
1. Weighted Decision Making	1.1 The apparent consensus around early warning signs
	1.2 Early warning signs decision making processes
	1.3 Experience as expertise
	1.4 Meaning and consequences of early warning signs identification

5.11 Acknowledgements:

We thank all the participants who agreed to take part in the study. This study was supported by NHS Research Scotland, through the Chief Scientist Office and the Scottish Mental Health Research Network. This project was funded in the UK by the National Institute for Health Research Health Technology Assessment Programme (project number 13/154/04) and in Australia by the National Heath Medical Research Council (APP1095879). It will be published in full in the Health Technology Assessment. The Health Services Research Unit is funded by the Chief Scientist Office of the Scottish Government Health Directorate. SA was funded by the Cremore Research Fellowship. The views and opinions expressed are those of the authors and do not necessarily reflect those of the Health Technology Assessment programme, National Institute for Health Research, the NHS, The Department of Health, NorthWestern Mental Health Services, The Cremore Research Fund or the National Health Medical Research Council. We also wish to thank Jennifer Hargrave who volunteered in facilitating two of the focus groups in Glasgow.

6 Chapter 6: Understanding Implementation of a Self-Monitoring Intervention for Relapse Prevention in Psychosis: Mixed-Methods Process Evaluation Protocol

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6.1 Abstract

Background: Relapse is common in people who experience psychosis and is associated with many negative consequences, both societal and personal. People who relapse often exhibit changes ("early warning signs" (EWS)) in the period before relapse. Successful identification of EWS offers an opportunity for relapse prevention. However, several known barriers impede the use of EWS monitoring approaches. EMPOWER is a complex digital intervention that uses a mobile app to enhance the detection and management of self-reported changes in wellbeing. This is currently being tested in a pilot cluster randomized control trial (ISRCTN99559262). Because digital interventions have not been widely used in relapse prevention, little is known about their implementation. Process evaluation studies run in parallel to clinical trials can provide valuable data on intervention feasibility.

Objective: To transparently describe the protocol for the process evaluation element of the EMPOWER trial. We will focus on the development of a process evaluation framework sensitive to the worldview of service users, mental health staff and carers, the aims of the process evaluation itself, the proposed studies to address these aims and a plan for integration of results from separate process evaluation studies into one overall report.

Methods: The overall process evaluation will utilise mixed-methods across four sub-studies. Three will use qualitative methodologies, and one will use quantitative methodologies. Three of the studies will run in parallel to the EMPOWER pilot trial, and one will occur post-trial.

Results: The results of all studies will be triangulated into an overall analysis and interpretation of key implementation lessons.

Conclusions: Findings from this study will help identify implementation EMPOWER facilitators and barriers. These insights will inform both upscaling decisions and optimisation of a definitive trial.

Ethics & Dissemination: Ethical approval has been received from West of Scotland REC (16/WS/0042) and Melbourne Health (REC/15/MH/344) plus managerial approval from NHSGG&C (GN14CP229) and North Western Mental Health Services (MH Project Number: 2015.286).

Trial Registration: ISRCTN99559262

6.2 Background

Psychotic disorders are common (Jongsma *et al.*, 2019), and schizophrenia is one of the top fifteen leading causes of disability worldwide (Vos *et al.*, 2017). Relapse is common in schizophrenia, with up to 80% of people experiencing one five years after onset (Emsley *et al.*, 2013). Relapse is associated with increased costs to mental health services, with 70% of the UK mental health care costs being for unplanned inpatient hospital care for relapses (Fitzgerald *et al.*, 2009; Ascher-Svanum *et al.*, 2010) with a similar picture reported in Australia (Morgan *et al.*, 2012). Relapse is associated with unwanted outcomes, such as reduced social functioning (Emsley, Chiliza and Asmal, 2013). Relapse also reduces the quality of life of both people with psychosis and their carers (Koutra *et al.*, 2015). More frequent hospitalisations due to relapse are associated with reductions in relationship quality between service users and staff (Gumley *et al.*, 2014). Staff wanting to intervene during early relapse report that they often struggle to engage with service users who have become mistrustful of services (Loft and Lavender, 2016). In summary, relapse is associated with high financial and human costs, so detecting and intervening promptly to prevent the negative consequences of relapse is a crucial goal for schizophrenia care (Munro *et al.*, 2011).

Relapse is the culmination of a process of changes which commence days and sometimes weeks before psychosis symptoms re-emerge or are exacerbated (Birchwood *et al.*, 1989; Eisner, Drake and Barrowclough, 2013). These early warning signs (EWS) include affective changes and incipient psychosis. Although a Cochrane Review of interventions targeting recognition and management of EWS of relapse in schizophrenia found significant effects for reduced relapse and re-hospitalisation rates (Morriss *et al.*, 2013), trial quality was poor regarding randomisation, concealment and blinding. Therefore, these interventions need to be more rigorously evaluated using high quality randomised control trial (RCT) methodologies. Until this happens, relapse prevention interventions based on EWS cannot be recommended for routine implementation within health services (Morriss *et al.*, 2013).

Further barriers to implementation of approaches focused on EWS include their uncertain diagnostic utility (Eisner, Drake and Barrowclough, 2013), which may result in unnecessary intervention from mental health staff (false positives). Furthermore, in mental health services, the delivery of treatment through scheduled and routine appointments can result in EWS being missed because these experiences may not coincide with scheduled visits, reducing the opportunity for detection during times of actual need (Bucci, Barrowclough, *et al.*, 2018). Finally, service users can be apprehensive about telling staff how they feel because this could trigger unwanted interventions such as hospitalisation (Farrelly *et al.*, 2016), which may act as a barrier to help-seeking. Fear of relapse is linked to more traumatic experiences of psychosis and hospital admission and greater fear of symptoms such as voices and paranoia (White and Gumley, 2009), and experiencing fear of relapse appears linked to actual relapse events (Gumley *et al.*, 2015).

Digital interventions may enhance relapse prevention through the prompt identification and communication of EWS of relapse. Use of, and enthusiasm for digital interventions for psychosis is reasonably high in service users (Firth *et al.*, 2016; Gay *et al.*, 2016; Bonet *et al.*, 2018), and current evidence of digital interventions acceptability and adherence rates suggest that these approaches are feasible (Killikelly *et al.*, 2017). Therefore, multiple strands of evidence suggest that it is time to develop a digital intervention to enhance relapse prevention and to test using RCT methodology. Implementation research explores the transfer of interventions from clinical trials into general usage (Nilsen, 2015). While randomized controlled trials (RCTs) are considered to be the most rigorous way of evaluating effectiveness in the medical context by providing substantial rigour and strong internal validity; in contrast, external validity (i.e. implementation outcomes such as whether the intervention will become utilised within routine clinical practice) is often compromised (Noyes *et al.*, 2016). Therefore, RCT methodologies alone may not answer research questions about implementation.

6.3 The EMPOWER Study

Early signs Monitoring to Prevent relapse in psychosis and prOmote Wellbeing, Engagement and Recovery (EMPOWER; ISRCTN: 99559262) is a proof of concept cluster randomised controlled trial (c-RCT) is to establish the feasibility of conducting a definitive RCT comparing EMPOWER against Treatment as Usual (TAU). This aim will be addressed by establishing the parameters of the feasibility, acceptability, usability, safety and outcome signals of an intervention as an adjunct to usual care that is deliverable in UK and Australian community mental health service settings. Specific aims of EMPOWER are to:

(i) enhance the recognition of EWS by service users and their carers;

(ii) provide a stepped care pathway, that is either self-activated or in liaison with a carer and/or community healthcare professional, which then

(iii) triggers a relapse prevention strategy which can be stepped up to a whole team response to reduce the likelihood of psychotic relapse.

EMPOWER is a Just In Time Adaptive Intervention (JITAI) (Nahum-Shani *et al.*, 2016). JITAI is a term used to describe intervention design that aims to address the dynamically changing needs of individuals via the provision of the type/amount of support needed, at the right time, and only when needed (Nahum-shani *et al.*, 2014). The EMPOWER app is a key part component of the EMPOWER intervention, the app prompts people with psychosis to input data once a day (through pseudo-random mobile phone invitations) via repeated sampling method known as ecological momentary assessment (EMA) (Stone and Shiffman, 1994). There are 22 questions which correspond to thirteen different domains, illustrated in Figure 9 below:

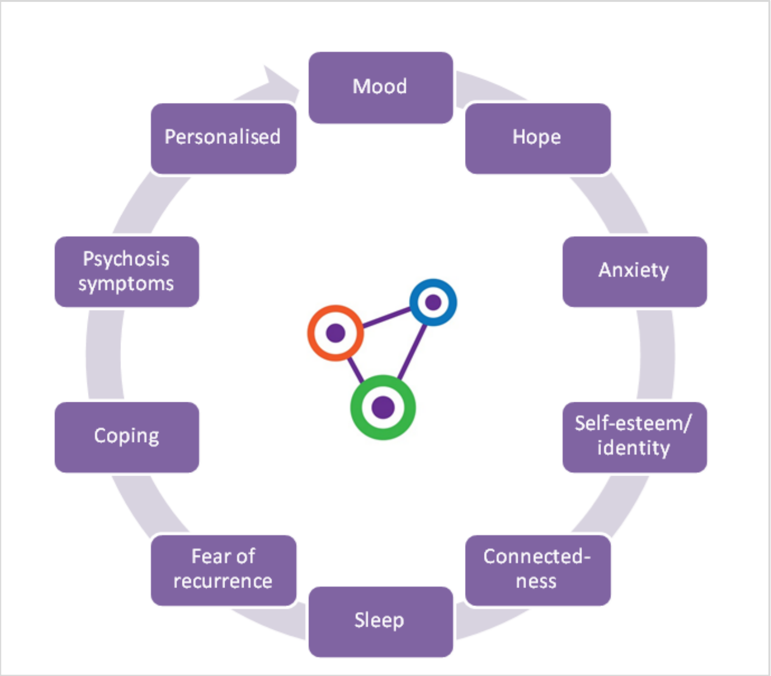

Figure 9 diagram showing the different EMPOWER Monitoring Domains available on the app

During the first four weeks of app usage a baseline is established which enables the EMPOWER algorithm to calculate the magnitude of future changes to support decision making (see below). After this, the potential for EMPOWER resulting in a response (decision-point, in JITAI taxonomy) every time a participant responded to an EMA prompt, or else failed to respond to a prompt for several days. Data entered by the participant responding to an EMA prompt were analysed by the algorithm resulting in one of the following responses: i) if the algorithm detects no overall change in well-being, a generic message is randomly generated ii) if the algorithm detects a small change (defined as an increase of over one standard deviation from baseline) then a message tailored to the specific domain breach was generated. For example, if a one standard deviation change in sleep was detected then the message will feature sleep content iii) if the algorithm detected a higher change (defined as an change of over 2 standard deviations away from baseline over three days) then resulted in a check-in prompt (ChiPs - described further in the EMPOWER protocol; (Gumley *et al.*, 2020).

The EMPOWER system also allowed participants to use the app to view periodic graphs of their reported data (raw EMA data) and keep a diary of how they are feeling, and why (stored locally only). Peer Support workers helped set up and individualise the app for users and facilitated information exchange through their own lived experience of mental health problems to augment the individualised self-management aspect of support available via the app. Service users could review their app data with peer support workers as a means of promoting curiosity and reflection on patterns of wellbeing over time. Regular telephone contact from Peer Support Workers for the duration of the study aimed to maintain participant motivation for continued engagement with the app. Peer Support Worker calls also provided an opportunity for routine troubleshooting of any technical issues that arose with the app and for the identification of any adverse effects from the intervention.

The EMPOWER study aimed to recruit up to 86 service users between participating community mental health services in Glasgow (United Kingdom) and Melbourne

(Australia) along with staff members and relatives or carers (if the participant wished this) who supported a service user. EMPOWER met the Medical Research Council definition of a complex intervention (Craig *et al.*, 2008); it had various components, was being tested across two international sites and included mental health staff and carers as participants in addition to service users.

Mental health service users' perspectives about interventions are rated low in the evidence hierarchy, with RCT evidence (especially in systematic reviews) coming out on top (Faulkner, 2015). However, even with strong RCT evidence, no relapse prediction system for schizophrenia will be useful if it is not able to be integrated into clinical care and actually used by clinicians and patients (Torous *et al.*, 2018). Furthermore, a recent proof-of-concept trial for a digital intervention in psychosis concluded that more research was needed to understand service users' and other stakeholders' perspectives on digital health systems to maximize implementation (Bucci, Barrowclough, *et al.*, 2018). The design of digital interventions for mental health problems such as psychosis could be optimised if interventions are both valued by staff and patients and therefore compatible for long-term use as well as meeting clinical and scientific standards (Biagianti, Hidalgo-Mazzei and Meyer, 2017). Use of current RCT methodologies in understanding complex interventions falls short of comprehensively explaining interventions (Deaton and Cartwright, 2018) – with qualitative research being recommended (Thirsk and Clark, 2017) to enhance understanding. The benefit of qualitative implementation research exploring user experiences is illustrated by the identification of barriers and facilitators to implementation for a digital intervention for bipolar disorder (Dodd *et al.*, 2017) which would have been missed if the focus was only on pre-defined outcome measures using a standard RCT approach. Service users reported that they felt motivated to use the intervention because of their positive relationships with the research team delivering the intervention.

Process evaluations are studies which run alongside a clinical trial, earning them the nickname of *trial siblings* (Cargo *et al.*, 2018). Process evaluations look into the different components of a complex intervention, how it is delivered, and what happens when people interact with an intervention (Maar *et al.*, 2017). Process evaluations can improve the validity and interpretation of outcomes, help refine the intervention, and provide necessary information to help inform upscaling decisions for digital interventions. Therefore, a process evaluation will help answer questions about implementation which the EMPOWER c-RCT alone cannot (Noyes *et al.*, 2016). In a pilot study such as EMPOWER, process evaluators are usually interested in facilitators and barriers to implementation, so that strategies to ensure quality implementation can be put in place in time for a definitive evaluation (Moore *et al.*, 2015). A process evaluation can also support the development of implementation theories (Moore *et al.*, 2015), which provide conceptual tools for researchers to understand, describe and explain key aspects of dynamic and emergent implementation processes observed during a trial (May, 2013; O'Connor *et al.*, 2019).

A process evaluation with a key focus on the usage of qualitative methods can enhance understanding of the implementation process during the EMPOWER trial and illuminate user perspectives on key implementation issues identified within the trial protocol (under review) such as acceptability, feasibility and deliverability as highlighted within their literature review of process evaluation frameworks. Marr and colleagues (Maar *et al.*, 2017) express concern that there is a common assumption within process evaluation frameworks that the experience of interacting with an intervention is experienced in much the same way by different stakeholders and across different settings. We argue that given the complex and multi-component nature of the EMPOWER intervention, the targeting of service users, carers and mental health staff within the intervention programme theory, and the intervention being tested across two international sites – it is doubtful that a process evaluator could identify key evaluation domains utilising a pre-defined framework. Therefore, it was considered necessary to develop a process evaluation framework suited to the needs of trialists who wish to make decisions about potential upscaling and also to better ensure that the needs of service users, carers and mental health staff are addressed.

6.4 EMPOWER Process Evaluation Aims

In no particular order of importance, we aimed to use the process evaluation to:

1. Understand the feasibility process of recruitment into the EMPOWER c-RCT by mapping out barriers and facilitators which may be useful learning for a future full scale trial.
2. Use data collected after recruitment is completed to develop a deep understanding of the experiences of the diverse group of stakeholders involved in the EMPOWER c-RCT, including members of the research team. A particular focus will be on identifying barriers and facilitators for implementation, acceptability, and feasibility.
3. Develop an implementation theory to understand and explain important aspects of the implementation process during the trial, including the impact of context (including psychological changes) on observed implementation outcomes.

We will now describe how the process evaluation aimed to address these key aims through the development of a process evaluation framework and several key studies.

6.5 Methods

6.6 Process Evaluation Paradigm and Design

The MRC framework for process evaluations (Moore *et al.*, 2015) highlights the importance of integrating mixed-methods results from process evaluations to better understand what is observed within clinical trials. An explicit epistemological stance is also recommended as a way of reconciling the paradigms of quantitative and qualitative approaches within a single process evaluation (Cheng and Metcalfe, 2018). However, our literature review suggests that epistemological positions invoked within process evaluations are rarely reported within published protocols. We present a brief description of how we arrived at our epistemological stance and how this shaped methodological choices.

Conjunctive theorising (aiming to create appropriately complex rather than simplified abstractions of organisational phenomena) (Tsoukas, 2017) is a recommended approach within implementation research (Greenhalgh and Papoutsi, 2018), because such an approach situates implementation as subject to multiple interacting influences. With this in mind, it was decided to approach our process evaluation by choosing a research paradigm, which focuses on understanding implementation from multiple stakeholder viewpoints. Constructivism presents such a paradigm (Mills, Bonner and Francis, 2006). Constructivism, while commonly assumed to be associated with qualitative enquiry is not necessarily aligned with any particular methodological stance (Morgan, 2014) and therefore provided no prescriptive guidance for methods chosen within our process evaluation. However, adopting a constructivist paradigm was critical in thinking about how best to develop research questions and choose methods that would maximise understanding of participant experiences and develop a theory for interpreting these. This approach has been successfully used by Maar and colleagues (Maar *et al.*, 2017). They reported that their approach resulted in process evaluation data which were relevant to their stakeholders and allowed for emergent understandings of implementation throughout the trial.

6.7 Designing the EMPOWER Constructivist Approach to Process Evaluation

Following the selection of an epistemological paradigm, the development of our process evaluation framework (Figure 10) was achieved through the following steps:

1. A process of mapping out key EMPOWER components as listed in the trial protocol
2. Analysis of key implementation themes constructed from formative qualitative work involving twenty-five focus groups held with mental health

staff, carers and service users across both international sites in both the United Kingdom and Australia (Allan, Bradstreet, *et al.*, 2019).

3. A literature review of digital health evaluation issues, particularly those relevant to psychosis
4. Choice and application of a process evaluation framework
5. A final process of validity checking, where the proposed process evaluation framework developed from steps 1-3 was presented to researchers who had developed EMPOWER.

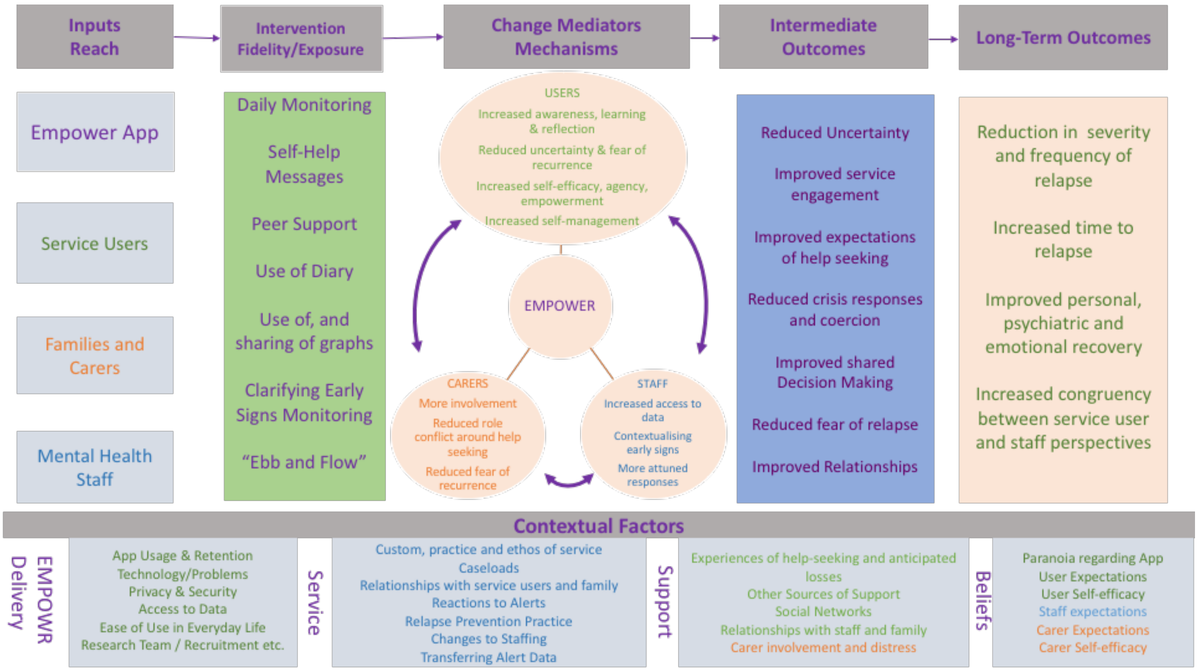

Figure 10 The logic model based process evaluation framework for EMPOWER.

6.8 Formative Qualitative Work

Following mapping out key EMPOWER components as described in the protocol (step 1), our formative qualitative work conducted in advance of the trial (Allan, Bradstreet, *et al.*, 2019) was key to developing the process evaluation framework (step 2 of our process) and will be described briefly. The person-based approach to intervention evaluation (Yardley *et al.*, 2015) provided a useful guide for utilising our qualitative work as the process evaluation framework was developed. Qualitative research is valued within the person-based approach because it allows exploration of participants' understandings of factors or processes that might be involved in intervention implementation. In a pilot study, process evaluators are usually interested in facilitators and barriers to implementation, so that strategies to ensure quality implementation can be put in place ahead of a definitive trial (Moore *et al.*, 2015).

Application of the person-based framework (Yardley *et al.*, 2015) to our formative qualitative work was vital in understanding implementation factors and processes from the worldview of mental health staff, service users and carers across the United Kingdom and Australia. The formative qualitative work guided the process evaluators to develop process evaluation domains (based upon expected implementation facilitators and barriers), relevant to mental health staff, service users and carers and is published elsewhere (Allan, Bradstreet, *et al.*, 2019).

6.9 Brief Literature Review of Psychosis Specific Evaluation Issues

Our formative qualitative work also suggested both carers and service users (but especially service users) feel that they are in a disempowered position compared to staff within current relapse management (will be published elsewhere). Our literature review (step 4) identified that structural symbolic interactionism (Stryker, 2008) had been used as a constructivist theoretical framework to understand power differences in interactions between mental health staff and service users in psychosis research (Farrelly *et al.*, 2015). When mental health staff believe someone diagnosed with a psychotic disorder is experiencing relapse, they prioritise their "risk management" role which has more positional power than role enactments focused on service user experiences (Farrelly *et al.*, 2015). In other words, service users reported feeling unable to influence decisions made by staff about treatment during this time and reported that their views of the situation were not valued.

Structural symbolic interactionism posits that individuals adopt positions, which are recognised social categories (e.g. being a carer). According to structural symbolic interactionism, a role is a set of expectations associated with a position, such as service user expecting a mental health professional to have a specific set of skills to manage relapse in psychosis (Farrelly *et al.*, 2015). At its heart, structural symbolic interactionism posits that people in their roles have agency when they interact both with each other and with interventions, but social structure always constrains interactions. For example, service users interactions are constrained by being in a relatively disempowered social role compared to staff. In sum, while constructivism invites researchers to consider that all experiences are constructed, it falls short at explicitly considering how different people in their roles interact together and how existing power differentials might shape these interactions. Therefore, we used structural symbolic interactionism to enable us to think critically about power and ensuring the subjective views, and implementation experiences of relatively disempowered groups such as service users are valued in this process evaluation.

6.10 Choice and Application of a Process Evaluation Framework

Our brief literature review also revealed a tension in process evaluation research, where research could be focused on implementation outcomes valued by mental health staff, service users and carers (Maar *et al.*, 2017) , or be focused on addressing implementation outcomes valued by clinical researchers (Moore *et al.*, 2015). This was an important consideration because the overall aim of our process evaluation is to make an evidence-based comment on the acceptability, feasibility and deliverability of the EMPOWER intervention. While stakeholder implementation outcomes are important, they are not the whole story, and data need also to be suitable for researchers who work in clinical trials. Our attempt to address this tension within our constructivist paradigm is discussed next.

A logic model is a diagrammatic representation of an intervention, describing anticipated delivery mechanisms (e.g. how resources will be applied to ensure implementation), intervention components (what is to be implemented), hypothesised mechanisms of impact (the mechanisms through which an intervention will work) and intended outcomes Moore et al (2015, p. 8) (Moore *et al.*, 2015). Logic models are recommended as a way of documenting the core functions of a process evaluation and providing a way to structure process evaluation findings. The logic model presented here (Figure 2) represents a process evaluation framework developed to be sensitive to the unique worldview of staff, service users and carers. Choosing to incorporate the MRC process evaluation framework ensures that data generated during our process evaluation are valid for making scientific decisions about intervention implementation, improvement and also in contributing to the implementation research field more generally. In line with our constructivist paradigm, this pragmatic step reflected our view that trial researchers and staff are an active part of the enquiry and that process evaluation outcomes are not objective data but are shaped by researcher choices.

A lack of shared terminology within process evaluations can produce challenges when comparing process data from similar interventions across different trials (Noyes *et al.*, 2018; Rapport *et al.*, 2018). This reduces the opportunity for inclusion of process data within systematic reviews. Utilising the MRC process evaluation framework (enhanced by including the construct of 'exposure' from Matthews and colleagues (Matthews *et al.*, 2017) to explicitly foreground the views of end-users) provided the following taxonomy of key process evaluation terminology:

- *Fidelity* - The extent to which the EMPOWER intervention is delivered as intended.
- *Exposure* - The extent to which participants received and understood the different elements of the intervention and whether these were implemented as intended.
- *Reach* - The extent to which the target audience is reached by the intervention.
- *Context* - factors external to the intervention which may influence its implementation or whether its mechanisms of impact act as intended.
- *Mechanisms of Impact* - The intermediate mechanisms through which an

intervention creates an impact. This information is used to develop theories to understand why interventions reach implementation outcomes observed in trials.

In sum, our process evaluation framework builds upon the definition of context utilised
within the MRC framework by considering what aspects of context are important for mental health staff, carers, service users and researchers within the EMPOWER study and valuing each group. Therefore, we hope that our process data will be specific enough to be relevant to the unique perspectives of our diverse stakeholders but general enough to allow for the inclusion of process characteristics within implementation evidence synthesis (Harris *et al.*, 2018).

6.11 Finalisation of Process Evaluation Framework and Validity Checking

The validity of relationships posed within a logic model is reported to be strengthened through triangulation (Cooksy, Gill and Kelly, 2001). Therefore, the finalisation of process evaluation (step 5) domains and the construction of the logic model (Figure 10) was facilitated through discussion between process evaluators and the research team. The final step was an iterative process involving critical feedback from members of the EMPOWER research team (including investigators and trial managers) working in both the United Kingdom and Australia. Ultimately, this step served as a final validity check to ensure that the proposed framework also made sense to the research team who had designed the intervention.

6.12 Planned Process Evaluation Studies

The next subsection describes the planned process evaluation studies and their intended integration. As per MRC process evaluation guidance (Moore *et al.*, 2015), all studies are based upon key areas of interest within our process evaluation framework (Figure 10) which is briefly described for each study in turn. The process evaluation studies were or will be carried out by a PhD student (SA), a clinical psychology trainee (SB) and a Masters student (BM) who are semi-independent from the research team. SA and SB are supervised by the Chief Investigator of the EMPOWER trial (AG). BM is supervised by SB2 and SA. For all studies, the process evaluators will be blind to any c-RCT outcome until it is published. Each study maps onto a specific area of the process evaluation framework (Figure 10) and is described in turn.

6.12.1 Study 1A: In-Depth Ethnographic Exploration of Recruitment

Background: Developing an understanding of the context of the recruitment process is important in understanding implementation feasibility (Montgomery *et al.*, 2018). Ethnography is recommended within process evaluation of complex interventions because this method enables process evaluators to understand process data within its social context, and can produce internally valid data which can enhance the development of implementation theories (Morgan-Trimmer and Wood, 2016). Beyond standard ethnographic observations of how the researcher team carries out implementation processes, trial documents such as protocols and minutes of meetings are recommended as an essential source of ethnographic enquiry to understanding implementation more thoroughly (Murdoch, 2016).
Aim: To provide an account of the context in which recruitment to the trial occurred (Process Evaluation Aim 1).
Process Evaluation Framework: Contextual Factors
Ethnography: SA will complete a detailed analysis of minutes from meetings held in both the UK and Australia to provide a detailed account of recruitment concerning implementation feasibility and lessons for potential upscaling.

6.12.2 Study 1B: Focus Group of Researcher Recruitment Experiences

Aim: To create an in-depth understanding of researcher insights about the recruitment process beyond what can be observed in ethnography (Process Evaluation Aim 2).

Process Evaluation Framework: Contextual Factors / EMPOWER delivery

Focus Group: After initial recruitment, UK and Australian focus groups were run with Research Assistants, Trial Manager and Chief Investigator to enquire about their experiences of the recruitment process. A focus group schedule can be seen in the supplementary materials (will be uploaded).

Analysis: Focus groups will be transcribed verbatim. Post-transcription, the focus group data will be analysed inductively utilising a thematic analysis approach (Braun and Clarke, 2006). All qualitative data will be stored in the latest version of NVIVO, providing a transparent audit trail.

6.12.3 Study 2A: Qualitative Interviews with Service Users, Carers and Staff

Aim: To explore participants' experiences of implementing and trialling the EMPOWER intervention including their perceptions of any barriers and facilitators (Process Evaluation aim 2). Qualitative process data were collected through individually based in-depth interviews.

Process Evaluation Framework: All

Interviews: An interview guide was developed for each stakeholder group: mental health staff, carers and service users. The Service User interview schedule was developed to explore service user experiences of key components of the EMPOWER intervention (including "non-digital' areas such as interacting with peer support workers) as listed in the process evaluation framework. Mental health staff and carer interview schedules were developed to explore how these groups interacted with the intervention both directly and indirectly through interactions with a service user enrolled in the study. Furthermore, all interview schedules were designed to explore further anticipated mechanisms of change developed from formative qualitative work – all schedules can be seen in supplementary materials. We aimed to interview participants at different time points (following completion of baseline and during the 12-month follow-up period). This was in order to capture the varied and evolving experiences of participants over time

Participants: Staff, Service Users and Carers in the UK and Australia.

Recruitment and Procedure: Within the UK, we purposively recruited a sub-sample of service users who provided their informed consent to participate in the

EMPOWER study and who were randomised to the EMPOWER Intervention arm. The purposive sampling strategy for approaching service user participants was developed from early-stage ethnographic observations constructed during Study 1A. These early observations suggested that the following features might be relevant implementation factors: service user gender, service users inputting the same score every day which would impact on the ability of the intervention to detect change, frequency of engagement with peer support workers, whether a participant had experienced a relapse and/or an adverse event during intervention usage (Bradstreet, Allan and Gumley, 2019). Therefore, we aimed to speak to participants who demonstrated the aforementioned characteristics to understand their experiences.

After careful ethical consideration it was decided that because interviews with mental health staff and carers linked to a service user would involve them reflecting upon the service user's experiences, that mental health staff and carers will only be invited to participate in qualitative interviews if a service user provides their informed consent for this.

If a participating service user gave consent to interview staff, we approached mental health staff who had been involved in responding to EMPOWER app prompts associated with changes in early warning signs or relapse episodes (as defined by the programme theory) during their involvement in the study. If the service user provided consent to interview a carer, their carer was invited to participate soon after the service user was interviewed. SB and SA completed interviews with staff, while SA completed interviews with carers and service users. No limit was placed upon the number of participants.

Analysis: Interviews will be transcribed verbatim. Post-transcription, the interview data will be analysed inductively utilising a thematic analysis approach (Braun and Clarke, 2006).

6.12.4 Study 2B: Qualitative Interviews with EMPOWER trial staff

Aim: To explore trial staff experiences of implementing key EMPOWER intervention components (peer support work and ChIPs), including their perceptions of any barriers and facilitators (Process Evaluation aim 2). Qualitative process data was collected through individually based in-depth interviews.

Process Evaluation Framework: Contextual Factors / EMPOWER delivery

Participants: Peer support workers, trial staff involved in developing the peer support role within EMPOWER, and trial staff responsible for ChIPs.

Interviews: Interview schedules were developed for peer support workers and staff who are responsible for ChIPs. The interview schedule for peer support workers explores the delivery of peer support from the perspective of peer support workers by exploring their interactions with service users, which can include discussing EMPOWER app data. The interview schedule for trial staff involved in developing the peer support worker role explores their perceptions of how the peer support worker role has emerged from conception to delivery within the trial. Finally, the interview schedule for staff responsible for ChIPs explored the delivery of this intervention component from the perspective of trial staff involved. All interviews schedules are available in Appendix A.

Recruitment and Procedure: All relevant trial staff members in both the UK and Australia were invited to take part in one to one interviews.

Analysis: Interviews will be transcribed verbatim. Post-transcription, the interview data will be analysed inductively utilising a thematic analysis approach (Braun and Clarke, 2006).

6.12.5 Study 3A: Development of Network Models

Background: The EMA data (daily ratings on a 1 to 7 Likert scale) generated through intervention usage was available to service users in its raw form via the graph function, who could view and opt to share their data with others. However, the same data may also reveal important relationships between the 13 well-being domains, which EMPOWER assesses. In network models, mental disorders such as schizophrenia are not conceptualized as common causes of symptoms, but as conditions that arise from the interaction between symptoms (Isvoranu *et al.*, 2016). Moreover, symptoms of psychosis and other indicators of well-being (nodes) are connected by their associations, which are determined by their correlations or regression coefficients. Based on these associations, the importance of individual nodes in a network is expressed via network parameters, including measures of centrality. A highly central node is one that is likely to spread activation throughout the network via the edges that connect it to other nodes (Lutz *et al.*, 2018).

An important aspect of network research is the prediction of the course of mental distress from network characteristics of groups of individuals (Fried *et al.*, 2017). Network patterns may demonstrate *early warning signals* – patterns of connectivity, which may indicate the upcoming onset of relapse for a specific individual (Fried *et al.*, 2017). Therefore, network models may present a useful means to quantify and understand the context of service user wellbeing during intervention usage and the relative influence of the thirteen different wellbeing domains. In line with EMPOWER programme theory as defined in the protocol which will be published elsewhere (and is currently under review), we are particularly interested in fear of recurrence (Gumley *et al.*, 2015). Little is known about such early warning signals in a relapse in psychosis, and it is hoped exploring routine EMA data collected during the trial may provide insight into the general phenomenology of wellbeing over time.

Aim: To better understand the context of service user wellbeing during intervention usage by building network models of psychosis during stable, early warning signs phase and clinical relapse – with the three states defined as per EMPOWER programme theory (Process Evaluation Aim 2&3).

Process Evaluation Framework: Change mechanisms / Contextual Factors

Network Analysis: Exploratory network analysis will be performed using relevant packages on the most recent version of R.

6.12.6 Study 3B: Exploratory Analysis of User Engagement

Background: Previous digital schizophrenia research studies use an EMA response rate of 33% for data to be considered reliable (Myin-Germeys *et al.*, 2003; Kimhy *et al.*, 2006). While acknowledging criteria for determining EMA response feasibility varies in the literature (Bell *et al.*, 2017), it is vital to determine what factors are associated with opportunities to maximise engagement. To the best of our knowledge, there are no guidelines for defining a required level of engagement with peer support. For example, participants meeting a peer support worker three times was considered to be sufficient (Johnson *et al.*, 2018) but was not based on firm guidance. Therefore, there is a need to develop summary statistics about levels of peer worker engagement.

Aim: To summarise and describe engagement with key components of the EMPOWER intervention and place these within a meaningful context (Process Evaluation Aim 2 & 3). Response to daily EMA prompts will be taken as a proxy for app usage. Additionally, engagement with peer support will be defined from the number of actual peer support contacts compared to potential peer support worker contacts. Data will be analysed retrospectively following completion of the trial.

Process Evaluation Framework: Fidelity / Change Mechanisms

Analysis: Descriptive statistics of engagement levels (with both app and peer support) which will be triangulated with contact notes and qualitative process evaluation interviews.

6.13 Results

At the time of writing, data collection has ended for studies 1B, 2A and 2B (details will be reported elsewhere), and no analysis is complete for any study.

6.14 Integration of Results

There is currently no consensus on what information is best for making decisions on whether an intervention is feasible for upscaling into a definitive trial (Hallingberg *et al.*, 2018). Therefore, we recognised that data from the EMPOWER process evaluation could address a fundamental research question posed by Matthews and colleagues: *are identified barriers and challenges to implementation of the intervention planned for and surmountable?* (Matthews *et* *al.*, 2017). In line with Matthews et al.'s recommendations, the triangulated overall interpretation resulting from these studies will be presented as a SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) (Valentin, 2001) which will list identified implementation barriers and challenges encountered during the EMPOWER intervention c-RCT, whether these were expected/unexpected and if the process evaluation data suggests these are surmountable within an upscaled definitive clinical trial. This final result will be presented as an independent report to relevant decision-making parties with recommendations for adaptations.

6.15 Discussion

This protocol describes four studies which utilise mixed-methods to generate process evaluation data for the EMPOWER trial. The process evaluation data will be utilised to develop a SWOT analysis to more fully understand what occurs in the EMPOWER pilot c-RCT through implementation outcomes constructed as being meaningful for mental health staff, carers and service users. Ultimately, the findings from this process evaluation will provide evidence not available from other sources of evaluation within the trial to help inform upscaling decisions. Furthermore, the pilot c-RCT will allow the process evaluators to test the validity of the process evaluation framework by allowing for the emergence of unexpected outcomes within the implementation process. Any such implementation outcomes which deviate from the proposed framework will be used to restructure and refine the logic model to build a process evaluation framework which is more valid for understanding the actual implementation process.

While the process evaluation framework was developed to be highly relevant to the process evaluation requirements for the EMPOWER study, this process evaluation may nonetheless provide data which is useful to other researchers. Theoretical understandings of how digital interventions create change are in their infancy; therefore it is recommended that researchers prioritise qualitative methods (Michie *et al.*, 2017) which foreground the discovery of how participants (in their own words) utilise interventions. Any potential benefit of digital interventions depends on users engaging with an intervention (Yardley *et al.*, 2016). Engagement with digital interventions consists of two definitions: firstly, the extent to which an intervention is actually used (indicated by non-subjective quantitative measures such as passively recording frequency of intervention usage) and secondly as a subjective experience characterised by attention, interest and affect (usually indicated through subjective measures such as questionnaires or interviews) (Perski *et al.*, 2017), concerningly, substantial heterogeneity in use of measures has been noted (Ng *et al.*, 2019). Little is currently known about what aspects of a digital intervention are relevant for user engagement for a digital intervention for psychosis. This process evaluation will integrate non-subjective measures (usage statistics) with subjective measures of engagement (through qualitative interviews) to develop a theory for understanding behavioural mechanisms underpinning engagement (or non-engagement) in people with psychosis.

To be suitable for fully informing behavioural change, theories need to capture individual differences and also changes over time (Hekler *et al.*, 2016). Most existing behavioural change theories lack utility for JITAIs because their static nature fails to capture the temporal dynamics of intervention usage over time (Nahum-Shani *et al.*, 2016). Nahum-Shani and colleagues recommend that scientific understandings of JITAIs can be enhanced through i) developing a richer theoretical understanding of the everyday experiences of inputting user data and ii) developing theoretical models of usage and user experience when an intervention usage results in response (Nahum-Shani *et al.*, 2016). Little is known about the subjective user experience of using JITAIs for psychosis. Therefore, the EMPOWER process evaluation provides an opportunity to develop an internally valid theory to better understand relationships between observable and objective measures of intervention usage with the subjective experiences of self-monitoring in people with psychosis. Such an understanding has broader implications for the management of psychosis and can inform the development of digital interventions for people with similar mental health problems, building on learning from previous qualitative work (Huerta-Ramos *et al.*, 2016; Berry, Bucci and Lobban, 2017; Bucci, Morris, *et al.*, 2018; Williams *et al.*, 2018; Berry, Lobban and Bucci, 2019; Eisner *et al.*, 2019).

Utilising EMA data within network analysis may make it possible to develop insight into previously implicit patterns of experiences and behaviours. A recent network analysis case study utilising EMA methodology suggests that paranoia becoming a central node in a complex network was associated with a service user being in a state of relapse (Bak *et al.*, 2016). However, no studies that we are aware of have explored how psychosis network structure presents when EMA data is collected as part of a JITAI. We believe that this is an essential distinction in terms of implementation outcome because EMA data is not merely being gathered to map out service user wellbeing but could trigger a decision point resulting in an active response from mental health services. The findings from Study 3A will be useful for understanding the implementation process because this will map out the context of service user wellbeing during the trial. Results from all network analysis within this process evaluation will be exploratory.

6.16 Limitations

This research should be considered within its limitations. The formative qualitative work used to develop our framework included a large sample size for qualitative research. However, it is still not possible to make any claims about generalisability and because this formative research was based on consultation and not user-led (Rose, 2020), its relevance to end users may be limited. Furthermore, there is a risk that important implementation outcomes were not uncovered through our prior qualitative work because of issues such as participants not feeling comfortable speaking within a focus group environment. Therefore, while the process evaluation framework appeared relevant to stakeholder needs constructed from focus group data, this may not be a complete picture of actual stakeholder needs.

Participation within qualitative process evaluation interviews has been suggested (Greenwell *et al.*, 2016) to represent a highly motivated group of service user participants who are not necessarily representative of the target population as a whole. Therefore, while discovering user insights in their own words is a key aspect of our constructive process evaluation approach, we may miss important user insight from this methodological choice. Furthermore, because staff and carer participation in interviews is determined by service user consent – we may miss insight from mental health staff and carers who interact with service users who choose not to participate in process evaluation interviews. Furthermore, trial staff (who are members of the EMPOWER research team) may feel uncomfortable speaking freely within interviews because of the limited pool of participants meaning it may be possible to identify participants from quotes within qualitative data. A further important limitation is that data collection ended for several studies before this protocol could be submitted for publication. However, formal data analysis was not initiated until finalisation of the protocol for publication.

6.17 Conclusions

There are strengths to the research. By transparently stating our process evaluation development, aims and proposed studies , we hope to contribute to good practise within this field (Mann *et al.*, 2016) and share learning. Publication of the protocol does not prohibit further process evaluation studies but ensures clarity that any such further study will be to explore unexpected consequences that were not anticipated within our pre-defined process evaluation framework. In line with recent recommendations to improve implementation research (Rapport *et al.*, 2018), the development of our constructivist process evaluation framework explicitly aimed to explore understandings between stakeholders and also implementation science researchers.

7 Chapter 7: Trial staff views on barriers to recruitment in a digital intervention for psychosis and how to work around them: A qualitative study within a trial

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7.1 Abstract

Background: Recruitment processes for clinical trials of digital interventions for psychosis are seldom described in detail within the literature. While trial staff have expertise in describing barriers and facilitators to recruitment a specific focus on understanding recruitment from the point of view of trial staff is rare.
Methods: We applied pluralistic ethnographic methods including analysis of trial documents, observation and focus groups explored the recruitment processes of the EMPOWER feasibility trial (ISRCTN: 99559262).
Results: Recruitment barriers fell into two main themes; service characteristics (lack of time available to mental health staff to support recruitment, staff turnover, patient turnover (within Australia only), management styles of community mental health teams, physical environment) and clinician expectations (filtering effects and resistance to research participation). Trial staff negotiated these barriers through strategies such as emotional labour (trial staff managing feelings and expressions in order to successfully recruit participants) and trying to build relationships with clinical staff working within community mental health teams.
Conclusions: Researchers in clinical trials for digital psychosis interventions face numerous recruitment barriers and do their best to work flexibly negotiate these barriers and meet recruitment targets. The recruitment process appeared to be enhanced by trial staff supporting each other throughout the recruitment stage of the trial.

Trial Registration: (ISRCTN: 99559262).

7.2 Introduction

To better understand how interventions could be developed, evaluated, and implemented into routine care, it is important to fully understand which aspects of randomised control trials (RCT) implementation are most challenging (Kannisto *et al.*, 2017). All RCTs must recruit participants for interventions to be tested (Deaton and Cartwright, 2018). However, recruitment into RCTs can be very difficult and is possibly the biggest challenge within clinical research (Tudur Smith *et al.*, 2014) with many RCTs failing to reach their recruitment targets (Walters *et al.*, 2017). Delayed recruitment can lead to additional costs (Liu *et al.*, 2018) and underpowered clinical trials can threaten the empirical value of intervention research (Halpern, Karlawish and Berlin, 2002). Systematic reviews of recruitment barriers have helped uncover specific barriers for recruiting ethnic minority populations (Heller *et al.*, 2014), within HIV trials (Mills *et al.*, 2006) and cancer trials (Fayter, McDaid and Eastwood, 2007). However, reviews are only possible if primary data are collected and shared. Digital interventions are becoming popular for increasing access to treatments, but little is known about the nature of specific recruitment barriers in these trials (O'Connor *et al.*, 2016). Beyond widespread societal concern about the negative impacts of digital technology within daily life (Orben and Przybylski, 2019), there may be recruitment challenges in mental health care research such as concerns patients may struggle to use a digital device (Allan, Bradstreet, *et al.*, 2019). However, systematic review evidence suggests that these effects are not yet understood because trial recruitment is not covered in depth in studies of implementation barriers for digital interventions for psychosis(Aref-Adib *et al.*, 2018).

Trial staff responsible for recruiting participants must implement something novel (in this case, the recruitment process for a new intervention) within a healthcare system which comes with existing norms, knowledge and social practices. Trial recruitment involves interacting with diverse groups (Finley *et al.*, 2018) including patients, clinical staff, clinical leaders and other members of the trial team. The healthcare system can be described as a context in which the recruitment process must fit. Process evaluations use qualitative research to develop an understanding of how trial processes such as recruitment were delivered and received by participants and trial staff (Moore *et al.*, 2015; Cheng and Metcalfe, 2018). Context in process evaluation terms is defined as factors external to an intervention that influence clinical trial processes delivery (Moore *et al.*, 2015) such as recruitment. Therefore, understanding the context of recruitment is important for understanding what factors may act as barriers and facilitators in enrolling participants within a clinical trial.

Usage of and interest in digital interventions is high in people diagnosed with schizophrenia (Firth *et al.*, 2016) and digital interventions for psychosis are growing in popularity (Bell *et al.*, 2017; Bucci, Schwannauer and Berry, 2019). Currently, the ongoing Covid-19 pandemic has seen a surge in interest in using digital technologies to support people with mental health problems (Torous *et al.*, 2020). However, the willingness of patients to be recruited into digital intervention clinical trials is poorly understood (Lim and Penn, 2018; Torous and Firth, 2018). People diagnosed with schizophrenia are described as a difficult to recruit population more generally within clinical trials (Jørgensen *et al.*, 2014). Recruitment for service users diagnosed with schizophrenia often involves approaching patients via staff; therefore, it seems particularly important to consider the role of staff within study recruitment. For example, a recent study reports that one in five mental health staff report having never recruited a service user into a research study (Carmichael *et al.*, 2016).

Within trials of digital interventions, it is recommended that the recruitment of end users should be described in sufficient detail to enable readers who wish to contextualise or replicate the work (Agarwal *et al.*, 2016). Feasibility studies help establish important parameters such as willingness of clinicians to recruit patients and willingness of participants to be randomised (Arain *et al.*, 2010). Despite the importance of recruitment, CONSORT statements(Campbell *et al.*, 2012) do not require RCT reporting to describe recruitment in detail beyond documentation of participant flow (Kearney *et al.*, 2018; Montgomery *et al.*, 2018). Proposed CONSORT extensions (Glasgow, Huebschmann and Brownson, 2018) recommended qualitative data be collected so context can be more fully understood so future researchers may recognise what relevant contextual elements (such as settings and stakeholder participation) which are necessary for the replication of findings observed within a particular trial. Reporting a more detailed examination of recruitment processes (particularly recruitment barriers (Harris *et al.*, 2018)) is suggested to be useful in interpreting trial results and developing strategies for improvement (Grant *et al.*, 2013). Moreover, failure to report recruitment experiences risks significant loss of a key source of knowledge. Additionally, it is important to note that detailed reporting of recruitment into digital intervention studies using mobile apps is noted to be scarce (Druce *et al.*, 2017).

Trial staff are responsible for meeting recruitment targets and interact with potential participants in order to do so. This places them in a unique position to comment on the overall recruitment process and provide a narrative on 1) what happened during trial recruitment; and 2) make informed comment on why. Identifying barriers to recruitment has been identified as a strength of qualitative research within clinical trials (O'Cathain *et al.*, 2013; Hennessy *et al.*, 2018). Furthermore, qualitative research could also describe what strategies trial staff utilise to negotiate around recruitment barriers. However, to the best of our knowledge there is little empirical exploration of the trial recruitment process directly from the point of view of trial staff.

7.3 Study Aims

This qualitative study within a trial (SWAT: (Treweek *et al.*, 2018) aimed to gather and analyse data to more fully understand barriers and facilitators encountered by trial staff during the recruitment process for the EMPOWER study (described in more detail below), and to facilitate learning ahead of a full trial. Previous qualitative work conducted with carers, mental health staff and service users suggested that recruitment barriers were hypothesised within the EMPOWER trial (Allan, Bradstreet, *et al.*, 2019) such as service users feeling paranoid in response to digital technology and a lack of staff time to support the recruitment process. Therefore, this study aimed to explore recruitment issues in some depth but was not limited to the a priori issues identified within our previous research.

EMPOWER (Early signs Monitoring to Prevent relapse in psychosis and prOmote Wellbeing, Engagement and Recovery (Gumley *et al.*, 2020), ISRCTN: 99559262) aimed to develop and evaluate a Mobile App for use with adults who experience psychosis. The EMPOWER App is a digital self-management tool (augmented with peer support) to enhance the identification of, and communication about early warning signs of relapse in people diagnosed with schizophrenia. The app enables routine self-monitoring for a variety of different experiences, including psychosis (e.g. hearing voices, suspicious thoughts), anxiety, mood, self-esteem and interpersonal support. EMPOWER participants used the App for an initial twenty-eight-day baseline period to identify their typical variation in personal wellbeing. Significant changes from baseline are then triaged by a clinician and, if necessary, mental health staff notified. EMPOWER was tested in a cluster randomised control trial (cRCT). Since EMPOWER was trying to enhance communication and shared decision making between multiple stakeholders, mental health staff, service users and carers (if relevant) were all potential participants. The feasibility of the EMPOWER intervention and study procedures were tested in a multisite trial in both Australia and the UK. The initial recruitment target was 120 service user participants (and any linked carers) and 40 mental health staff from 8 Community Mental Health Services (CMHS) before randomisation of the clusters (services). During the course of the study 8 CMHS were recruited and randomised however a revised recruitment target of n=86 was agreed and met.

In cluster trials, outcomes are usually measured at the level of the individual but trial procedures (such as recruitment) are applied by the research team at the level of the cluster (in this case, adult community mental health teams) (Mann *et al.*, 2016). When recruitment for EMPOWER began, research assistants within EMPOWER electronically screened medical records of local community mental health services for potentially eligible participants and then approached keyworkers employed within adult community mental health teams (the cluster) who had potentially eligible participants on their case load. Therefore, developing an understanding of recruitment both within and across sites appears important in contextualising the recruitment process in a cRCT like EMPOWER. Full details of the intervention are reported in the protocol (Gumley *et al.*, 2020). In a feasibility study such as EMPOWER, process evaluators are usually interested in facilitators and barriers to implementation so that strategies to enhance implementation of key processes such as recruitment can be put in place for a definitive trial (Moore *et al.*, 2015).

7.4 Methods

In line with the EMPOWER process evaluation protocol (Allan, Mcleod, *et al.*, 2019) the theoretical framework for this study was constructivism (Cheng and Metcalfe, 2018) which posits that knowledge is created through social interactions. The processes that occur during intervention implementation need to be understood in ways that are responsive to the complexities and intricacies of programs, people, and places (Thirsk and Clark, 2017). Recruitment in clinical trials is a complex social action so there is unlikely to be one definitive methodology (qualitative or otherwise) that can allow us to theorise recruitment in sufficient depth (Snowdon, 2015).

The primary focus of the analysis was on achieving the *a priori* study aims (understanding the context of recruitment during the feasibility trial stage to refine recruitment in a full trial). Particular attention was paid to the reporting of barriers and facilitators to recruitment because this helps understand the context of recruitment. We now describe the two methods of the study in line with the key aim:

7.4.1 Ethnography

Ethnography refers to both a process and outcome of research that produces rich descriptions and interpretations of a social system from the point of view of its key social actors, including their behaviours, roles and methods of interaction (Palinkas and Zatzick, 2019). Ethnography is useful for theorising implementation processes like recruitment because ethnographic narratives pay attention to interconnectedness while building a holistic understanding of how systems come together as a whole (Reynolds, 2017; Greenhalgh and Papoutsi, 2018). Furthermore, ethnography is useful for developing internally valid theory by focusing on describing how people behave in the real-world context of doing clinical trial recruitment. Taking an ethnographic stance is advantageous in process evaluation research because it can help develop implementation theory of key trial processes with good internal validity (Morgan-Trimmer and Wood, 2016).

SA was based within the main office base for the EMPOWER trial for the full duration of recruitment. While ethnography commonly involves a researcher directly observing social processes, the examination of administrative data and study documents are important within process evaluation research (Murdoch, 2016). Therefore, the minutes of team meetings were seen as sites for ethnographic enquiry beyond what SA recorded from observation.

7.4.2 Trial Staff Focus Groups

To triangulate findings from the observation-based ethnography, focus groups were held with members of trial staff who were involved in the recruitment process. The use of qualitative methods (Kitchen *et al.*, 2017), and in particular, focus groups within an RCT facilitates understanding of the recruitment process (Rick *et al.*, 2018). Exploring recruitment from the point of view of the research team who experienced directly is noted to be useful because it gives insight into reasons behind what can be observed (Hennessy *et al.*, 2018). Ethics approval for the study was received from West of Scotland Research Ethics Service (GN16MH271 Ref: 16/WS/0225) and Melbourne Health (HREC/17/MH/97 Ref: 2017.010.

7.5 Procedure

7.5.1 Ethnography

SA (who was based in the UK office for the EMPOWER study) was present at the majority of weekly team meetings in the UK that were held during the recruitment process and had access to the minutes of the meetings from this time. All members of the EMPOWER team who were based in Glasgow attended these meetings with the focus of discussion being on general trial business. Recruitment procedures for both the UK and Australia were discussed in these meetings. Beyond formal meetings, SA was able to observe the work of the trial staff within the office and was privy to their discussions and reflections on the matter for the duration of trial recruitment SA recorded reflective rough notes during the recruitment process from observations at both formal meetings and more informal daily work and consolidated these into reflective memos once the recruitment period was over. SA revisited meeting minutes (n= 50) for the period from 03/08/2017, when recruitment started, until 05/07/2018, when the recruitment target was achieved (n= 86) to refresh their memory and wrote reflective ethnographic memos. Relevant ethnographic reflections are reported in addition to analyses from the focus groups. Observational data from meeting recordings and field notes are anonymised.

7.5.2 Trial Staff Focus Groups

Both focus groups were facilitated by SA (independent of research team). One focus group was facilitated in person in Glasgow in the UK and another facilitated remotely with the Australian team in Melbourne who all remoted in individually via secure telephone interface. Verbal informed consent was taken before the start of each focus group. Each focus group followed a schedule of questions designed to explore barriers and facilitators to recruitment in some depth. A semi-structured interview schedule was developed for broad exploration of the recruitment process from the perspective of trial staff (see supplementary materials) Both focus groups were audio recorded and then transcribed verbatim. Focus groups lasted for an hour. All focus groups were held during the typical working day for trial staff and participation was voluntary. Data have been anonymised to protect confidentiality; all participants are simply referred to as “Participant” with numbers being used for clarity when a textual extract has data from more than one participant.

All participants in this SWAT (through observation focus group participation or both) were employed in the EMPOWER trial and were involved in trial recruitment (either directly or indirectly).EMPOWER was a feasibility study so the numbers reflect the relatively small pool of trial staff which is highlighted in Table 5. NVIVO (QSR, 2015) software was used for all analysis.

Table 5 Participant Characteristics

Location	Attendees	Roles
UK	6 (out of a possible 7)	Researcher, Chief Investigator and Trial Manager
Australia	3 (out of a possible 5)	Principal Investigator, Researchers and Trial Manager

7.6 Reflexivity

SA is a PhD student working on a process evaluation for the EMPOWER cRCT (Gumley *et al.*, 2020). The PhD funding SA receives is independent of any funding associated with the trial. Following observations of trial staff during the recruitment process, it seemed as though the recruitment process was a key site of enquiry to more fully understand full trial feasibility. Therefore, a decision was made to undertake a small qualitative SWAT. Supervision and finalisation of the coding process was done in conjunction with HM and AG who are academic clinical psychologists, academic supervisors to SA and investigators on the EMPOWER trial.

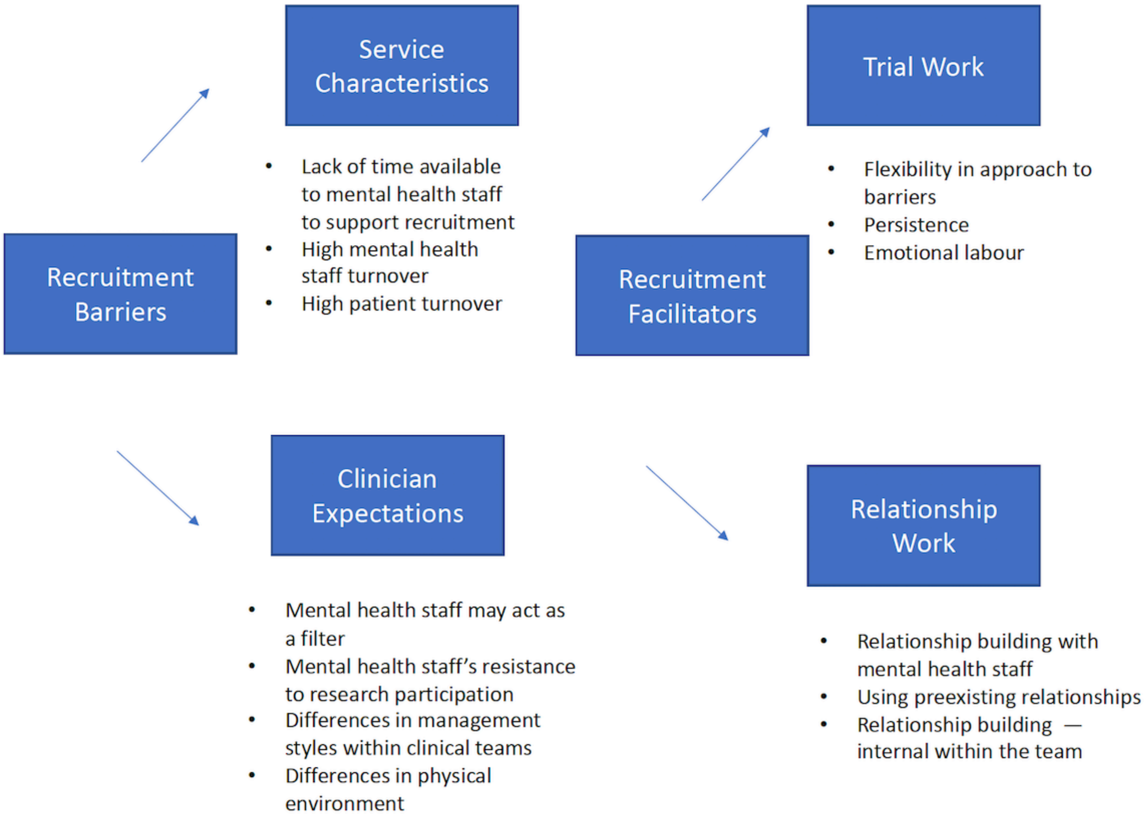
7.7 Analysis

All data including ethnographic observations and focus group transcripts were analysed thematically by SA using thematic analysis, a qualitative method used to identify, analyse, and report on patterns constructed within text data (Braun and Clarke, 2006). The first stage comprised of line-by-line coding (descriptive) moving onto the second stage of coding where descriptive codes were thematically linked together into a final set of themes. Constructivist qualitative research assumes that themes do not emerge from the data but are constructed as part of a reflexive analytic processes (Charmaz, 2006) Therefore, themes will be reported as being constructed. Trial staff provided critical feedback on the rigour and validity of the thematic analysis – similar to member checking (Doyle, 2007).

7.8 Results

Following thematic analyses of ethnographic observations and focus groups, it seemed that there were several key recruitment barriers encountered by the research team during the process of recruitment to the trial. Beyond simply listing recruitment issues, trial staff discussed how these issues were addressed and what work was done to best negotiate these issues. In order to frame these discussions as distinct from merely reporting key issues, the concept of *trial work* (Skea, Treweek and Gillies, 2017) was utilised within a qualitative framework analysis (Gale *et al.*, 2013). Trial work is a broad concept related to the work done to overcome barriers during the recruitment process engagement, 'buy in' to the trial across a range of stakeholders as well as work involved in managing the organisational complexity necessary to reach recruitment targets (Skea, Treweek and Gillies, 2017). Trial work appeared highly relevant to the aims of this study in terms of maximising learning and understanding from the EMPOWER recruitment process. The reporting will highlight the key *recruitment barriers* and then the *trial work* utilised to facilitate recruitment. We summarize the themes in Figure 11 and then describe the themes and provide portions of raw data to make the analysis more transparent.

Figure 11 Thematic map of recruitment themes.



7.8.1 Key Recruitment Barriers

The key barriers described by trial staff into trial recruitment broadly fell into three main themes; service characteristics (lack of time available to mental health staff to support recruitment, staff turnover, patient turnover (within Australia only), management styles of community mental health teams, physical environment) and clinician expectations (filtering effect and resistance to research participation)

7.8.1.1 Service Characteristics

7.8.1.1.1 Lack of Time available to Mental Health Staff to Support Recruitment

Research trial staff frequently spoke about mental health staff not having much time to engage within the recruitment process. The research team were highly aware of the broader social context of low staff capacity in the face of high numbers of patient referrals in routine care with limited staff to meet demand. Trial staff in both sites made empathetic references to being aware of mental health staff working within a context of immense pressure with a lack of resources and support. During the analysis by SA, it was constructed that the trial staff in EMPOWER felt it was inevitable that structural barriers that lead to mental health staff not having much spare time would inevitably be a barrier to trial recruitment.

Participant 1: *I don't think you can relate how busy they are. And much pressure they're under. Some of the numbers we heard about in terms of new referrals into teams were quite staggering.*
Participant 2: *Forty. Forty referrals a week, yeah. And there doesn't seem to be any sort of throughput to accommodate that additional pressure being moved around (UK)*

7.8.1.1.2 High Mental Health Staff Turnover

Closely linked to a lack of staff time was high staff turnover, which appeared to be systemic across both trial sites. Meeting notes and focus group data from both the UK and Australia indicated that high clinical staff turnover became a challenge to recruitment. Practically, this led to issues such as new clinical staff not being aware of the study because they were not employed when staff teams were initially told about it. Clinical staff changing jobs or being off sick also appeared to be systemic issues within mental health services and was a macro level recruitment challenge. In this example below, a member of the EMPOWER team reflects on the impact of high staff turnover.

"*What we're seeing is the key workers [mental health staff] are very fluid, there's loads of movement, there's massive changes as to who your key worker is, there's lots of staff turnover.* " (Participant, UK)

7.8.1.1.3 High Patient Turnover

A related sub theme (which was exclusive to Australia) was patient turnover because patients are discharged back to general practice (as evidenced in the quote below where participant alludes to "*it's not only a high turnover of consumers [patients]*"*)* following the end of an acute episode of psychosis, unlike in the UK where clinical support is generally more long term for people diagnosed with schizophrenia. This was a particular barrier to recruitment because if patients were no longer in the service, they simply could not be recruited. However, this issue intersected with high clinical staff turnover to result in a complex barrier to recruitment into the study because the high clinical staff turnover within mental health services blocked the ability of trial staff to build relationships with clinical staff to build trust in the team and the project.

"*I think it's also worth noting that in public mental health services it's not only a high turnover of consumers [patients] but there's also a pretty high turnover of staff in some places, so you would have some clinicians that hadn't heard of it or you know were quite new around that time and that kind of translates to recruiting consumers as well in terms of the discharges and the change in people being part of the service* (Participant, Australia)

7.8.1.1.4 Clinician Expectations

7.8.1.1.5 Mental health staff may act as a filter

Within the team meeting notes and articulated within focus groups, the research team were concerned that mental health staff sometimes acted as gatekeepers for some service users. This *"gate keeping"* behaviour appeared expressed when mental health staff assumed a potential participant would be unable to take part in the study, resulting in a filtering effect which biases what participants are invited to take part. Trial staff constructed that the concept of gatekeeping extended beyond participating in clinical research and was perhaps linked to mental health staff feeling protective over patients in their caseload. In the example below, a researcher reflects on how mental health staff appeared to very quickly decide on whether or not a service user could cope with the intervention.

We found that cases [mental health staff] were really quick to say I've got this person or this person specifically on my list who would be good and kind of having that conversation about the systematic approach that we wanted to have to recruitment was a bit of a hard sell because cases were saying well this person would never be able to use a phone and this person will sell it for drugs or will lose it immediately, too disorganized to use a mobile intervention (Participant, Australia)

Even when you approached them with eligible participants, they [staff] were maybe more likely to discount them straight away. Just say "no, they're not suitable," or "I don't think they want to take part. (Participant UK)

7.8.1.1.6 Mental Health Staff Resistance to Research Participation

Within the UK and Australian sites, it was remarked that while mental health staff may have consented to take part within the study, this did not necessarily reflect their active involvement as participants within the study. Trial staff observed that mental health staff could engage in behaviours indicating resistance to the study.

Participant 1: *because I don't think that looking at consent figures for key workers reflects the buy into the study. …If someone asked you to sign one of these things [consent form] you'd sign it, and then you'd employ your tactics of trying to avoid having to doing anything about it.*
Participant 2: *You either cooperate or don't cooperate.*
Participant 1: *…that's a better way of putting it. [laughs]* (UK)

Research staff working on EMPOWER theorised that mental health staff resistance to research participation emerged because mental health staff believed that they were expected to participate within clinical research as part of their role as mental health clinicians. There was some concern expressed that if mental health staff felt that their participation within the project was mandatory, this may have limited their motivation and commitment resulting in resistance to participation. In the following example, a member of the EMPOWER trial reflects on an encounter with a clinician who stated that they had to become involved because of expectations from management. This appeared linked with hierarchal relationships within mental health services. Therefore, clinical staff participating within research appeared to be a role expectation for clinical staff.

I remember one staff member talking about whether he agreed to be involved and he said "oh, do I really have a choice?" kind of saying "well, we've heard about it from, you know, management" and I got the sense he was communicating there was an expectation to get involved but that was just one thing I picked up about that kind of involvement. Yeah. (Participant, Australia)

7.8.1.1.7 Differences in Management Styles Within Clinical Teams

In both the UK and Australia there were discussions about differences in management style between the different mental health teams. In the first example, a trial team member explicitly stated that while participant numbers between sites may not have appeared too different, this obscured the challenges of having to adapt to different leadership styles across mental health teams. This was a viewed as a key determinant of recruitment success.

I think at the big picture level the rate of recruitment wasn't particularly different and you know, [other named research assistants] might be able to say a bit more about the style of how it happens etc., there are certainly very different personality styles of managers so in terms of us managing the managers, we had *to take into account that there are very different people who had a very different styles* (Participant, Australia)

However, as pointed out in the UK site, it was not always the case that managers were those who were “pulling the strings” in terms of creating barriers to recruitment.

Leadership’s hugely important in this. And always underestimated how much influence it has in any field, but this one no less. That the messages and the values and the attitudes that are being shared by the person who’s pulling the strings is really, really important. And that person who’s pulling the strings isn’t necessarily always the person who is supposed to be pulling the strings (Participant, UK)

As indicated by the memo below, there was a real sense from the trial staff that differences in management styles were a particularly key recruitment barrier and that this should be given more emphasis within the analysis.

When I initially presented my analysis to trial staff, it was remarked that differences in management styles could be a key determinant of recruitment success and some trial staff members felt that this was underemphasised. (Researcher’s Reflective Memo)

While in the example below, two UK team members theorise how leadership within clinical teams may impact upon recruitment by discussing contrasts between a site where recruitment was easier and one where recruitment was perceived to be more challenging. From the perspective of trial staff (and aligning with ethnographic observations) differences in leadership style between managers were a very important factor in determining recruitment success because leadership shaped everyday dyadic interactions between clinical staff and trial staff during the recruitment process.

Participant 1:. The staff were able to take that sort of leadership role.
Participant 2: So. There's quite a different style I think of leadership and management there that's permissive.
Participant 3: Yeah.
Participant 4: Facilitating versus one that's more "we're doing this." (UK)

7.8.1.1.8 Differences in Physical Environment

A further important recruitment challenge stemmed from the layout of the physical premises of mental health services themselves. While this may be unique to a particular centre, the impact upon recruitment was constructed by trial staff to be large. For example, two researchers recalled the impact of the physical layout of premises, which hindered their ability to develop relationships with staff and acted as a significant block to successful social interactions.

Participant 1: *The physical environment's really problematic there [named recruitment site] as well, because they're all in small, separate offices, so it doesn't really feel like a team. So individual and…*
Participant 2: *There's nowhere to circulate and to talk to the nurses.*
Participant 1: *There's nowhere to chat amongst yourself, just to build the rapport with nurses. It was like, everyone's all huddled away in separate offices.* (UK)

7.8.1.2 Trial Work Used to Facilitate Recruitment

Trial staff used several trial work strategies to facilitate recruitment in face of barriers including flexibility in approach to barriers; persistence and emotional labour (trial staff managing feelings and expressions in order to successfully recruit participants) in addition to building relationships (using pre-existing relationships with clinicians and utilising supportive research team relationships).

7.8.1.2.1 Flexibility in Approach to Barriers

Regardless of how barriers to recruitment were negotiated, something which stood out in both the minutes and the focus groups was the need for trial staff to be flexible in their approaches. Discussions around the benefits of flexible approach were common throughout both the Australian and UK focus groups. In the example below, a team member from Australia highlights that being flexible (and not rigid) in their approach to recruitment enabled staff to work through problems as they occurred.

I think that one of the real strengths in our research team has been how flexible and adaptive we've been when these challenges have come up, everyone involved in the process has been really thinking about ways to problem solve these things and coming up with suggestions (Participant, Australia)

One example trial staff provided which illustrates taking a flexible approach was in their discussions with clinical staff surrounding the trial protocol. Within a feasibility study, information about recruitment process is a key outcome. Therefore, when encountering potential staff 'paternalism' towards patients on their caseload, trial staff could emphasise that knowing how many people would refuse to take part was an important trial outcome. Explaining to trial staff that the protocol required that all relevant participants should have the opportunity to be approached, to discover numbers of patients who did not want to take part, was described as a it could circumnavigate the perceived filtering behaviours by clinical staff. In the example below, a principal investigator also describes how being flexible could enable trial staff to resist or negotiate staff paternalism, without it seeming like a direct challenge to clinical judgement.

…and our primary method of trying to get around that was to blame a third party to blame the protocol which says we needed to screen everyone and invite everyone rather than, you know directly, it feeling more like a direct challenge to the judgement of the key clinicians. (Participant, Australia)

The researcher noted in their reflective memo that flexibility appeared a key process that emerged from the very beginning of recruitment when trial staff were working to build relationships and engage with the staff. Trial staff did not appear to rigidly stick to one recruitment approach.

When looking through minutes from the start of the trial. I am struck by how apparent flexibility was from the early stages of recruitment. For example, working around the availability of clinical staff as much as was possible. Furthermore, it feels important to note that because clinical staff are so busy that being flexible appeared essential in moving recruitment forward. However, in later stages flexibility involved clinical trial staff (Researcher's Reflective Memo)

7.8.1.2.2 Persistence

Within EMPOWER, *trial work* was characterised not only by flexibility but also by persistence. This could be seen in accounts of trial staff constantly trying to contact mental health staff. The practical work of chasing up mental health staff was readily apparent from analysis of meeting minutes and reflective accounts of the recruitment process recorded in both focus groups. Chasing up could involve telephone calls, email or visits in person to community mental health teams. This was often due to systematic issues such as a lack of staff time to support the intervention but could also be due to local factors such as mental health staff feeling pressurised into taking part by management and then resisting against participation. However, linked to staff describing their need to be persistent there was acknowledgement that chasing up mental health staff could be a time-consuming part of trial work.

It depended quite a lot on the key workers that were involved within teams. How open they were to the study, and how much they followed through on things they said they were going to do. So, a lot of the time was spent chasing up key workers who said they would do something, and then didn't (Participant, UK).

7.8.1.2.3 Emotional Labour

While the need to be persistent in chasing up mental health staff and trying different recruitment strategies was apparent from both the minutes of meetings and focus groups, the focus groups foregrounded an important role for the emotional aspects of recruitment within a clinical trial. In the example below, it is clear that simply being persistent is not enough and that it is important for it not to be obvious that the research team experienced frustration. Indeed, the need to portray constant positivity in order to get the work done appeared to be considered key in successfully recruiting participants. Therefore, there appeared to be an important role for *emotional labour* within trial work.

Participant 1: *Persistence. Always smiling. Always the utmost professionalism*
Participant 6*: Sometimes it's fake. [shared laughter]* (UK)

To the best of my knowledge, no trial staff used the term emotional labour to describe the maintaining professionalism during interactions with mental health staff, carers and patients. However, when reflecting on my observations of the research process, emotional labour appeared a highly relevant interactional framework for understanding the actual work underpinning trial staff describing the competency of staying polite and professional even when faced with potentially stressful challenges. Emotional labour seemed especially pertinent because trial staff are trying to invoke positive feelings within clinical research staff to build trust in both the project and the research team themselves. (Researcher's Reflective Memo)

7.8.1.2.4 Building Relationships

Trial work appeared to be sustained and facilitated by relationship building. When trial staff described the work that they performed throughout the recruitment process, at all stages the work appeared to be underpinned by trial staffs' ability to successfully build and utilise relationships. In the absence of the ability to tap into existing relationships, trial staff had to be able to quickly build working relationships with clinical staff to facilitate the recruitment process. Reflecting on the overall emergent process, trial staff centred the importance of building relationships with clinical staff in both the UK and Australia. One key change that came from this was trial staff becoming trusted to make direct approaches to patients instead of always having to go through mental health staff.

I think the reason that it became more possible was um that the services got used to the research team and got confident in the research team, or at least management did, so I think there's something about us building the relationship that enabled us to move into a different way of doing it (Participant Australia)

From appraising the minutes of the team meetings, it is clear that trial staff initially had to go almost entirely through mental health staff. However, if a good relationship was built – this was perceived as helpful for recruitment because the staff were generally more engaged with the team.

Recruitment did not start at the four randomised mental health teams at exactly the same time. From analysing the minutes of meetings for the period October 26th to December 21st (all 2017), it appeared that initially members of the research team met with key clinicians to screen for eligible participants together and then this built up to the team making direct approaches for one of the community mental health teams. This process continued into early 2018. Moreover, from observations it was apparent that an enthusiastic key clinician or manager with whom the team had a good relationship appeared to be helpful in terms of recruitment. (Researcher's Reflective Memo)

Within two months, trial work moved on to the establishment of relationships between mental health staff and the research team. In this stage, the EMPOWER staff became trusted to make direct approaches. Linked to the process of building relationships over time with mental health staff, in both Glasgow and Melbourne, a clinical team member (Research Nurse and Peer Support Worker, respectively) became involved in trial recruitment. Both teams reflected upon this positively because both of these clinical team members brought their pre-existing *relationships with clinical staff. While the earlier stages of recruitment may have seemed slow, it appears productive in terms of carrying out trial work that built relationships and trust with clinical staff, ultimately moving trial recruitment forward.* (Researcher's Reflective Memo)

However, the barriers to recruitment could nonetheless block trial staff from using relationship building strategies. For example, the issues discussed by staff covered under the *Differences in Physical Environment* theme appeared to be a particular barrier to the ability of the trial staff to develop positive working relationships with trial staff.

From my observations of trial recruitment within EMPOWER it really did appear that idiosyncratic issues (of which physical layout was one) could nonetheless seriously constrain the recruitment process. The recruitment processes appeared to be constrained because it blocked the ability of trial staff to utilise their dynamic relationship building strategies (Researcher's Reflective Memo)

7.8.1.2.5 Utilising Pre-Existing Relationships

While building relationships underpinned all aspects of trial work, pre-existing relationships were described as helpful in establishing clinician trust. The "trial work" here is the insight and ability of the trial staff to utilise those pre-existing relationships in the service of recruitment. In this example, a research assistant stated that clinical staff felt more comfortable communicating negative feelings about the recruitment process to the peer support worker (part of the EMPOWER trial team) because of pre-existing ease and trust that comes with already knowing someone. The research team were then able to use this information and adapt the approach taken to recruitment to be less aversive for clinical staff.

I think the real turning point where [peer support worker who participated in recruitment process] was speaking to somebody perhaps because she has that more casual kind of pre-existing relationship with some of these people where they were explicitly saying "I'm a bit sick of this EMPOWER stuff" and that's when *you know, that sent out the message we need to pump the brakes hard in terms of how much we are asking clinicians to do here.* (Participant Australia).

7.8.1.2.6 Relationship building – internal within the research team.

Relationships appeared to serve important internal functions within the EMPOWER team. Across both the UK and Australia, trial staff made reference to the importance of having a team who understood the challenges associated with clinical trial recruitment. Furthermore, the importance of having space to be open about difficulties encountered so that discussions were focused around how best to move forward was described.

Because I think at times it is quite demotivating. And particularly if you've got that third [unanswered] phone call and think "please just answer the phone." I think we [trial recruitment staff] do try and support each other through those times (Participant, UK)

From the meeting minutes, being part of the UK meetings while recruitment was on-going and appraising themes constructed during the focus groups, it seemed as though having a space within the trial team to discuss and share frustrations that were inevitable from negotiating the various recruitment barriers. From my observations of actual meetings and continued within the focus groups, there appeared to be lots of in-jokes within the teams about the recruitment process including challenging aspects. For trial staff, this appeared to provide camaraderie and support (Researcher's Reflective Memo)

To summarise, relationship building internally within the team appeared to be just as important in facilitating the recruitment process as building external relationships with mental health staff. Trial staff were there for each other throughout recruitment challenges and provided a supportive space for each other to discuss problems.

7.9 Discussion

This study explored recruitment from the point of view of trial staff working on a digital intervention for psychosis. By examining the recruitment process in EMPOWER using ethnography supplemented with focus groups, we demonstrate the kind of recruitment barriers encountered by trial staff and what strategies trial staff utilise to overcome them. Recruitment barriers appeared to span macro (structure and systems; for example – lack of staff time), meso (roles; for example – staff leadership), and micro (idiosyncratic; for example – physical layout of community mental health premises) levels. The findings from this qualitative study suggest that simply reporting the number of participants recruited (n=86) clouds a highly complex social process underpinning trial recruitment. Taken together, the findings from this study can start to theorise the recruitment barriers and facilitators within the recruitment process for the EMPOWER trial.

While it has been recommended research exploring recruitment barriers should go beyond reporting a lack of staff time (Glasgow, Huebschmann and Brownson, 2018), it appeared a systemic problem within this trial that trial staff found difficult to negotiate. Lack of staff time has been reported as a recruitment challenge in many mental health studies (Jones and Cipriani, 2019).Therefore, our results support those of Skea (Skea, Treweek and Gillies, 2017) who suggested that researchers should take into account how essential trial recruitment processes fit in with the reality of clinical practice. The non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) framework (Greenhalgh *et al.*, 2017) provides a framework for understanding challenges encountered in the implementation of digital technologies. NASSS frames challenges as being simple (straightforward and predictable), complicated (multiple interacting components) or complex (unpredictable and hard to reduce down into linear components). NASSS addresses challenges and complexities that occur in different domains when implementing health care technologies, including the health condition being intervened on, value proposition, technology, adopter system, organisation, wider social context and changes across time. When framing the recruitment process via healthcare organisations in the UK and Australia, it appears the macro level recruitment barriers pose particularly complex challenges because of severe resource pressures with staff struggling to find time to support research, noted by other clinical trial researchers (Sheard and Peacock, 2020). However, even more idiosyncratic challenges such as differences in leadership between cluster sites were noted by trial staff to have complex, unpredictable and sometimes large impact upon recruitment – supporting the need to understand contextual differences across clusters in cRCTs (Mann *et al.*, 2016).

In order to negotiate complex recruitment barriers, trial staff put significant amounts of work in to engaging mental health staff during the recruitment process. Trial work is multifactorial and comprises of emotional labour, social and professional competencies. Initially, in performing trial work, staff in EMPOWER reported the importance of persistence, being flexible in trying different approaches and always being professional in their interactions with staff. Previous research on clinical trial staff has suggested emotional labour is a key part of trial work when staff are working to meet recruitment targets (Lawton *et al.*, 2015). In the face of stresses and strains created by recruitment barriers, trial staff have a duty to maintain an ethos of professionalism. Coming from the field of sociology, emotional labour is described as the silent work of evoking feelings in others and managing ones' own emotional expressions to do so (James, 1989). Emotional labour appeared a key strategy when dealing with barriers such as having to pursue contact with very busy staff while maintaining good working relationships by not letting frustrations show. Relationships between trial staff and clinicians (and the ability to quickly build and rapport) appeared essential to successful recruitment. However, barriers existed in the recruitment process which could make relationship building difficult. While a lack of clinical staff time is well reported in the literature, factors such as the layout of buildings making it impossible to have a private conversation also acted as a relationship building block.

Clinicians' exclusion of people independent of trial protocol criteria is noted to be a key challenge in mental health intervention recruitment (Bucci *et al.*, 2015). In the case of EMPOWER, it appeared that clinicians did regularly seek to exclude participants for reasons not stated in the protocol. Trial staff were given the impression that this was due to clinical staff having concerns about a service user's ability to cope with study participation. However, trial staff sometimes seemed able to negotiate this challenge by invoking the trial protocol and reminding staff that determining directly from the service user their willingness (or not) to participate was an important outcome within a feasibility study. Mental health staff filtering what patients ended up being approached for recruitment was a key theme identified in previous research exploring barriers to recruitment to non-digital psychosis studies (Bucci *et al.*, 2015). Excluding participants for reasons not contained in the protocol likely has implications for the replicability and robustness of research findings because the selection criteria are obscured (Pinfold *et al.*, 2019) and samples likely become biased. Therefore, there is need to learn more about why this apparent "filtering" happens (from the perspective of mental health staff) – particularly in digital interventions for psychosis where little is currently known (Aref-Adib *et al.*, 2018) and there may be assumptions about ability of people with psychosis to use technology (Allan, Bradstreet, *et al.*, 2019).

Mental health staff have perceptions of what is required from them professionally, and these perceptions seemed to cause tension and role conflict during the recruitment process. For example, clinical staff may not feel that they have the autonomy to decline participation because participating in research is a role expectation for clinical staff. Previous oncology research has indicated that nurses involved in conducting research describe a role conflict, where duty of care to the patient can sit uncomfortably with *feeling like a salesperson* when encouraging patient participation within trials (Tinkler *et al.*, 2018). Enhancing collaborations with key stakeholders such as mental health staff is stated to be important in developing better digital interventions for psychosis (Bucci, Schwannauer and Berry, 2019). Therefore, it seems pertinent to understand issues such as role conflict from the perspective of trial staff and co-design recruitment procedures around the needs of mental health staff.

Persistence and flexibility of approach was important in negotiating everything from macro level barriers, such as a lack of staff time, to more micro level issues, such as community mental health centre managers having different styles. One key element of the flexible approach to recruitment that emerged during the EMPOWER trial was a peer support worker (a person with their own experiences of psychosis employed to support people in their use of the intervention) advising how to approach recruitment challenges. A review concluded that patient involvement in clinical research may be associated with increased recruitment (but not retention) to clinical trials (Crocker *et al.*, 2018). However, the mechanisms of why this effect might exist are still unclear. Within EMPOWER, actively transforming the peer support role to encompass involvement in recruitment was reported by trial staff to have been very useful for recruitment because the peer support role brought pre-existing relationships with staff and fresh insight on how best to approach recruitment challenges. While this may be very specific to EMPOWER, it nonetheless demonstrates that experiential knowledge and enhanced capacity for relationship building with clinical staff may be important mechanisms to consider when theorising mechanisms of patient and public involvement (PPI) in trial recruitment.

7.9.1 Future Research

The research team reported that conveying to staff that discovering rates of participant refusal helped negotiate filtering behaviour by clinical staff. Future research could explore this observed phenomenon further, perhaps using relevant behavioural change theories as a theoretical framework (Musker *et al.*, 2020). Emotional labour in the context of clinical trials has previously been theorised in recruitment research involving direct interaction with patients (Lawton *et al.*, 2015). However, these findings suggest emotional labour may be as relevant in the everyday work of keeping clinical staff engaged in the recruitment process. The EMPOWER trial was conducted simultaneously in Australia and the United Kingdom. Therefore, it is perhaps unsurprising that a specific recruitment issue unique to one healthcare system were observed (high patient turnover within Australia) was apparent. However, there were some marked similarities across countries such as a lack of staff time. Clinical trials that are conducted across multiple countries may benefit from providing some context on differences between mental health care systems to contextualise recruitment results. Additionally, a Delphi study (Hasson, Keeney and Mckenna, 2000) could expand upon the barriers identified here to see if they are more widespread in trials of similar interventions.

7.9.2 Limitations

EMPOWER was a feasibility study which means there were a limited number of trial staff to observe and speak to. Beyond the small sample, findings from this study should be considered in light of several key limitations. Ethnography is an opportunistic methodology (Conte *et al.*, 2019) so researchers are limited by what they can or are allowed to observe. In regards to research methods, we did not believe that the focus group conducted remotely was any less rich than the focus group that was conducted in person in terms of the transcripts produced However, we cannot rule out that conducting one focus group in person and another remotely may have impacted upon both the conduct of the research and analysis. Moreover, while Australian recruitment was discussed at UK based meetings and was recorded in the minutes there, SA did not attend any Australian recruitment meetings due to being based in the UK and did not directly observe Australian staff during the recruitment process. While this study has identified barriers and suggested potential ways to optimise recruitment, the potential positive impact of qualitative research in trial recruitment research needs to be further researched (Hennessy *et al.*, 2018) before any comment can be made about potential utility. Furthermore, we have not focused on retention which is also an important issue in its own right (Eysenbach, 2005; Skea, Newlands and Gillies, 2019). Additionally, this study focused on barriers and facilitators experienced by trial staff during the recruitment phase of the trial, which related primarily to working with mental health staff. Facilitators addressing ongoing *Service characteristics* such as staff turnover and physical environment may have emerged if the study had been widened to include service managers or other informants. Furthermore, there was not much focus on the experiences of service user participants throughout the focus groups. Future research understanding barriers and facilitators to recruitment from the point of view of service users within clinical trials, building upon previous work exploring what service users think about digital interventions for psychosis in general (Berry, Lobban and Bucci, 2019; Eisner *et al.*, 2019). Another key limitation is that recruitment within EMPOWER occurred in public mental healthcare systems in both Australia and the UK, recruitment in private healthcare systems or recruitment processes conducted remotely through the internet may have unique challenges. Lastly, the focus of this study was to empirically explore recruitment from the point of view of trial staff, but it is of course important to highlight that future research would benefit from exploring recruitment from the perspectives of clinical staff and service users which will develop a more ecologically valid overview of the recruitment process.

7.9.3 Conclusions

Exploring recruitment from the perspective of trial staff provides rich insights into barriers and facilitators to recruitment within clinical trials of digital intervention. For example, rather than people with schizophrenia diagnoses being a monolithic “hard to reach group”, it seems that difficulties in recruiting people diagnosed with schizophrenia to clinical trials emerge from complex dynamic interactions within healthcare systems. This study suggests that performing recruitment in a clinical trial of a digital intervention for psychosis is complex. Barriers to recruitment exist at micro, meso and macro levels and trial staff must negotiate these barriers within their role to meet recruitment targets to the best of their abilities. Key competencies observed during the recruitment process included flexibility, persistence, and emotional labour. As discussed in focus groups and aligned with ethnographic observations, it was important for trial staff to work within a team that understood that recruitment to clinical trials could be challenging and appreciated having access to peer support from other trial staff. People responsible for managing staff who recruit into clinical trials may wish to consider these factors when deciding how best to supervise staff and design effective and resilient teams. One key conclusion from this study is that learning about what works along the way is important, as is providing a space for trial staff to discuss the recruitment process and both learn from and support each other during recruitment. Relationship building with clinical staff appeared to help facilitate the recruitment process which may have important implications for credentialing, training and supervising staff who work within clinical trials.

7.9.4 Acknowledgements

The authors are grateful to all the service users, carers and mental health staff, and community mental health services who gave their time and resources to contribute to the development of the EMPOWER study during the consultation phase. This was critical in developing the process evaluation (of which this study is part). They are grateful to all the service users, carers and mental health staff and community mental health services who gave their time and resources to contribute to the c-RCT and the process evaluation.

Funding

This study was supported by NHS Research Scotland, through the Chief Scientist Office and the Scottish Mental Health Research Network. This project was funded in the UK by the National Institute for Health Research Health Technology Assessment Programme (project number 13/154/04) and in Australia by the National Heath Medical Research Council (APP1095879). It will be published in full in the Health Technology Assessment. The Health Services Research Unit is funded by the Chief Scientist Office of the Scottish Government Health Directorate. S.A. was funded by the Cremore Research Fellowship. The views and opinions expressed are those of the authors and do not necessarily reflect those of the Health Technology Assessment programme, National Institute for Health Research, the National Health Service, the Department of Health, NorthWestern Mental Health Services, the Cremore Research Fund or the National Health Medical Research Council.

8 Chapter 8: Using EMPOWER in Daily Life: A Qualitative Investigation of Implementation Experiences

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Abstract:

Objectives: To study the implementation process of a cluster randomised controlled feasibility trial testing the feasibility of a blended digital intervention for relapse prevention in schizophrenia from the perspective of end-users.
Design: A qualitative interview design with thematic analysis was used
Method: A subsample of EMPOWER participants comprising of 16 patients, 5 mental health staff and one carer were interviewed one-on-one.
Results: Two overarching themes were constructed that were germane to understanding implementation within the EMPOWER trial which were *Affordances* and *Change Processes*. Affordances described the processes underpinning how and why participants interacted with or avoided the various components of the intervention. Affordances spanned all EMPOWER components including self-monitoring, peer support workers, clinical triaging, wellbeing messages and diary function. The affordances were Access to Social Connection, Access to Digital, Access to Mental Health Support, the Ability to Gauge Mental Health and Access to Mental Health Information. The affordances framework helped explain the multitude of engagement trajectories featured within the qualitative interviews. If participants sustained usage, affordances acted as a springboard for change

processes including increased self-confidence that patients could self-manage, noticing patterns and changes, and using EMPOWER as a conversation starter. **Conclusions:** The implementation process of EMPOWER was emergent and was best described by the intervention offering a range of affordances which could act as implementation barriers or facilitators depending on individual needs and wants.

8.1 Background

Almost half of all people with schizophrenia will relapse within 5 years post-diagnosis. Because standard treatment with antipsychotics does not entirely prevent relapse (Rubio *et al.*, 2020) adjunctive psychosocial approaches are recommended (NICE, 2014). A common psychosocial approach to relapse prevention is to detect and respond to early warning signs (EWS) (Eisner, Drake and Barrowclough, 2013; Morriss *et al.*, 2013) but the demand for this type of psychosocial support typically outstrips mental health service capacity (Kingdon and Turkington, 2019). Digital interventions provide one way to upscale access to psychosocial interventions and offer more autonomous service engagement options for people diagnosed with schizophrenia (Torous *et al.*, 2019).

Early Signs Monitoring to Prevent Relapse in Psychosis and Promote Well-Being, Engagement, and Recovery (EMPOWER, ISRCTN: 99559262) (Gumley *et al.*, 2022) was a feasibility cluster randomised controlled trial of a digital EWS self-monitoring app blended with peer support and clinical triage for people diagnosed with schizophrenia spectrum disorders. As described in the trial protocol (ibid, p.8): “EMPOWER was developed as a flexible user-led tool to (1) daily monitor the ebb and flow of changes in [patient] well-being which incorporated, (2) personalized EWS items, (3) enabled the delivery of EMPOWER (self-management) messages directly to patients and, (4) provided a mobile phone user interface to enable patients to review their own data and keep a diary of their experiences.” Three peer support workers (one in Australia and two in Glasgow) were employed to help set up the app for participants and provide regular fortnightly telephone support. If participants were digitally excluded and did not already own a smartphone, they were supplied with a phone and data. Participants had access to EMPOWER for up to 12 months.

Primary trial outcomes (Gumley *et al.*, 2022) indicated that overall EMPOWER was feasible, acceptable and safe. However, to understand how and why participants engaged with the intervention and the implementation process we explored participants' experiences. Implementation behaviours describe what people do when exposed to a new intervention, and understanding implementation behaviours require consideration of context and influences on behaviour (including subjective experiences) (Atkins *et al.*, 2017). It is possible to learn about implementation barriers for psychosocial interventions by studying interventions that were poorly implemented (Thornicroft *et al.*, 2013), but relying on retrospective data might miss key information about relevant factors that emerge *during* the implementation process (Sutcliffe *et al.*, 2015; Medical Research Council (MRC) and National Institute of Health Research (NIHR), 2019). Furthermore, conducting implementation research during feasibility trials means that strategies to overcome problems can be identified before progression to a full-scale trial. Implementation research has historically focused on the experiences of healthcare staff (Gray-Burrows *et al.*, 2018), but current guidance is that researchers should access the experiences of all relevant stakeholders (Medical Research Council (MRC) and National Institute of Health Research (NIHR), 2019). This is especially pertinent for interventions used independently by patients. Qualitative research exploring the experiences of end-users in daily life can provide information on complexity, context and mechanisms for understanding how and why interventions are implemented (Paparini *et al.*, 2020). Furthermore, qualitative research alongside feasibility studies can give important insights into adaptations to intervention design which may be necessary to improve participants' experiences.

Process evaluations are studies that investigate the different components of a complex intervention, how it is delivered, and what happens when people interact with an intervention. Process evaluations conducted in feasibility trials can improve the validity and interpretation of outcomes, help refine the intervention, and provide necessary information to help inform upscaling decisions or outline the need for intervention refinement (Moore *et al.*, 2015). The aim of this study was to understand implementation from the point of view of EMPOWER end-users including mental health staff, patients and carers using inductive qualitative methods.

8.2 Methods

Study Design

This qualitative study was embedded within the EMPOWER trial and received ethical approval from West of Scotland Research Ethics Service (16/WS/0225) and Melbourne Health Human Research Ethics Committee (HREC/15/MH/334). All participants provided their informed and written consent before participating in the process evaluation. Participant information sheets and ethical approval can be seen in Appendix B-D.

8.3 Theoretical Framework

We wanted to develop a deep understanding of how participants experienced using EMPOWER in daily life with a particular focus on identifying processes relevant for implementation. Linked to feasibility, we wanted to record and share improvement suggestions participants recommended – to this end research was conducted in a critical realist paradigm. Further information on the development of interview schedules can be seen in the pre-published protocol (Allan, Mcleod, *et al.*, 2019). Reporting follows guidelines for qualitative research (Tong, Sainsbury and Craig, 2007).

8.3.1 Reflexivity

SA is a PhD student interested in understanding the implementation of EMPOWER with a particular focus on foregrounding end-user experiences, this has come from the recognition that testimonial injustice (Crichton, Kidd and Carel, 2017) is commonly enacted against people diagnosed with schizophrenia and their supporters (including mental health staff|) which can mean their views are understood as “low quality” and “high risk of bias” within the technocratic hierarchy of evidence.

8.3.2 Data Collection

EMPOWER participants were invited to take part in interviews to understand their experiences. Service user participants were purposively sampled with reference to gender and intervention engagement. The two process evaluation interviewers (SA and SBe) were experienced in qualitative methods and had no existing relationships with participants. All participants gave written and informed consent. Interviews with UK-based participants were conducted face-to-face with patients (n=12) and a carer (n=1) and interviews with UK-based staff (n=5) were conducted by SBe as part of her doctoral training in clinical psychology. Interviews with Australian patient participants (n=4) and a mental health staff member (n=1) were conducted by SA over the telephone. To minimise retrospective recall biases or loss of recall detail, everyone was interviewed during trial participation. All interviews were audio-recorded and then transcribed verbatim. Transcripts were not returned to participants.

8.4 Analysis

All transcripts were analysed using thematic analysis (Braun and Clarke, 2013) by SA. SA was a PhD student interested in understanding these implementation issues. Descriptive “lumper” (Guest, MacQueen and Namey, 2012) codes were initially constructed during inductive coding. After the descriptive stage, thematic analysis was performed and guided throughout by the research aims (to understand implementation) and was an iterative process that involved comparing and contrasting codes both between and interviews to construct themes. Data were managed with NVIVO (NVivo, 2018) software and written notes. Constructivist qualitative research assumes that themes do not emerge from the data but are constructed as part of a reflexive analytic processes (Charmaz, 2017). Therefore, themes were always considered as constructed. To improve rigour, themes were discussed in supervision where the aim was to raise potentially different interpretations. During the thematic analysis, SA kept reflective memos for each participant interview which detailed the development of the final analysis. Trial staff commented on whether they felt themes were an appropriate fit and the results represent consensus.

8.5 Results

Participants

In total, 16 patients (38% of people randomised to receive EMPOWER), 6 mental health staff (all psychiatric nurses – 27% of staff responsible for EMPOWER participants), and one carer (14%) completed one-on-one qualitative interviews. To protect anonymity given the small sample, demographic details are limited. Differences between interviewed patients and the rest of the randomised EMPOWER sample are in Table 6. The single carer participant did not consent to quotes being used, so SA presents reflections from that interview and has withheld all demographic details. Three further patient participants and one carer who were approached declined participation.

Table 6 Demographic comparison of interviewed and main trial participants

	Process Evaluation Interview Sample (n=16)	Participants not interviewed (n=26)	P value for test statistic
Age	47.2 (SD = 11.3)	39.5 (SD = 13.3)	0.05
Gender	56.25% female	46.1% female	0.75
	75% UK	69.2% UK	0.95

Trial Site (UK or Australia)			
Duration of contact with mental health services (months)	164.4 (SD=124) (two missing values)	148.1 (SD = 122) (two missing values)	0.69
PANSS*Positive subscale (Kay, Fiszbein and Opler, 1987)	14.6 (SD=5.2)	15.0 (SD = 6.4)	0.8
PANSS Negative Subscale	11.8 (SD=3.4)	15.2 (SD=6.0)	0.02
Mean days inputting self-monitoring data into app per participant	218.56 (SD = 76.7)	79.23 (SD = 95.0)	<0.001
Mean number of peer support worker contacts per participant	21.75 (SD= 7.5)	11.50 (SD=7.7)	<0.001

*Positive and Negative Syndrome Scale (Kay et al., 1987)

8.5.1 Overview of Implementation Themes

Two overarching themes were constructed that were germane to understanding implementation within the EMPOWER trial which were *Affordances* and *Change Processes*. Affordances were the engine house of implementation within the EMPOWER intervention. Affordances, first theorised by Gibson (Gibson, 1979) describe the process by which people perceive possibilities for action from an object in their environment (Rietveld and Kiverstein, 2014). When applied to interventions like EMPOWER, this describes the processes underpinning how and why participants interacted with the various components of the intervention. Affordances spanned all EMPOWER components including self-monitoring, peer support workers, clinical triaging, wellbeing messages and diary function. The affordances were Access to Social Connection, Access to Digital, Access to Mental Health Support, the Ability to Gauge Mental Health and Access to Mental Health Information. The affordances framework helped explain the multitude of engagement trajectories featured within the qualitative interviews. Affordances helped circle the complex relationships between intervention capabilities and envisioned usage by participants. Affordances could be present at initial contact or developed over sustained engagement and act as a springboard for change processes.

Change Processes describes the impact EMPOWER had upon participants and was underpinned by Increased Self-Confidence that Patients could Self-manage, Noticing Patterns and Changes, Using EMPOWER as a conversation starter and Appraising Engagement Value.

Because qualitative research can yield important insights into adaptations to intervention design which may be necessary to improve participants’ experiences we asked participants for suggestions, and their ideas for improvement have been summarised in an appendix.

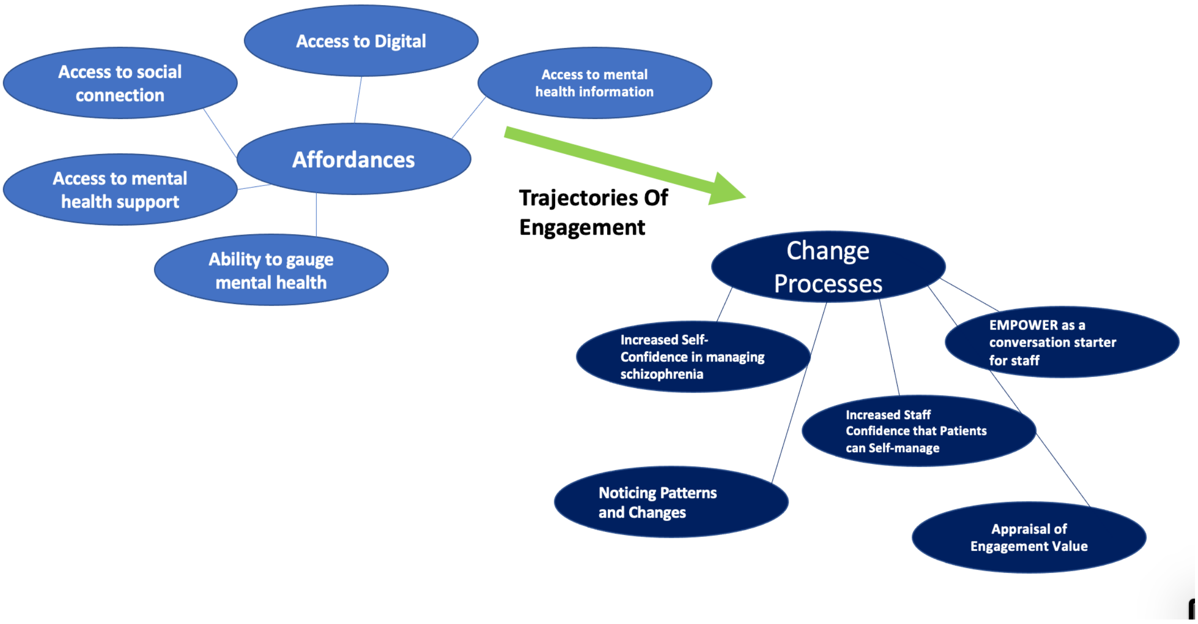

Figure 12 shows the relationship between the Affordance and Change themes

8.5.2 Affordances of EMPOWER

8.5.2.1.1 Affording Access to Social Connection

Many participants positively reflected upon their perception that EMPOWER afforded them access and the opportunity to have social connections with other people, this was typically expressed when discussing interactions with the peer support workers on the trial.

> *"I'm happy someone [peer support worker] phoned me and saying my problems, listening to my problems, and talking together"* (Alesha, UK)

Moreover, the app itself was perceived as providing a sort of social connection even if people were not up for talking to a person directly. This seemed to be an important affordance and suggests the intervention could work for people with a range of communication styles who were driven by a need for connection.

"I live on my own, I don't see people. Apart from if I go out to the shops. I find that the app helps.… I like being asked how I'm doing every day. It's because of the illness I've got, I can't concentrate around other people. I go into a shell" (Alesha, UK)

8.5.2.1.2 Affording Access to Digital

For participants who had already have a smartphone it was clear that EMPOWER was perceived as affording access to the digital world which could be a very new experience. Quite beyond EMPOWER components which the interview schedule was designed to explore, it was clear throughout the interviews that there had been an unexpected consequence of using the intervention. This was a clear example where an affordance emerged throughout a participant's engagement in the trial and was best constructed as a process of discovery. In the example below, a participant described how the smartphone they had borrowed also meant they could now access things such as Google alongside the intervention.

"Using Google and all these kinds of things, looking at websites and… weather… it's opened up a whole load of new things" (Matilda, UK)

Mental health staff also perceived that EMPOWER afforded access to the opportunity to develop skills and confidence in using technology even among people who are digitally excluded. In the example below, a staff member reflects surprise that the participant responded so well to using a digital device.

"I couldn't have been more wrong. [named patient] is probably the person you would think - out of all the people who attend this service, would be the least likely to use a mobile phone app. You know, I mean she has [not] got a mobile phone … it surprises me that she can even use that, you know. (Staff member 3, UK)

However, the digital nature of EMPOWER could be an implementation barrier depending on the context of a participant's life. In this example,

> *"I'm off work just now it's all right, but before it goes off when I'm at work. So, I'm either having to put it off till I get home, sometimes you miss it, or doing it in work, which is quite a private thing, you don't really want to be doing it in your work"* (Keith, UK)

8.5.2.1.3 Affording Access to Mental Health Support

EMPOWER clinical triage meant that if a change in a participant's data suggested possible relapse, a clinical member of the EMPOWER team would check in with them. In practice, this meant that patients had access to clinicians beyond the scope of their standard mental health care. When considering implementation, this could be an especially important facilitator because it meant participants could access timely support. This is exemplified below where a participant shares how it was helpful to check out a negative change in their wellbeing in a timely manner rather than waiting to see their usual clinician.

> *"We tried to get my mental health nurse. Couldn't get them. They weren't working Monday or Friday so it would be the following Tuesday before I would be able to get them. So, we phoned up [named clinician who provided clinical triage to trial participants] and spoke to them."* (Matilda, UK)

However, the affordance of access to mental health support was dependent on how positive patients perceived mental health support to be. A participant who reported more difficult experiences with mental health services reflected that EMPOWER affording access to clinicians was aversive and acted as an implementation barrier. This participant had particularly low levels of engagement with the intervention, and this seemed to be explained by the triage process and speedier access to care not being perceived as helpful.

> *"I don't want people to cause a fuss over me…. I don't need people phoning me up all the time and pestering me"* (Jay, UK)

The diary function was designed for self-reflection which means the data was not accessible by clinicians and therefore did not result in a response from them. It followed that if a participant was motivated to engage with EMPOWER because it afforded access to mental health support then they would not be likely to want to engage with components which did not have this feature. Indeed, this was suggested to be the case and the quote below highlights the importance of understanding affordances.

> *"But nobody seen them. CPN, nobody seen them… So, no need to fill up the diary"* (Darius, UK)

8.5.2.1.4Affording a Means to Gauge Mental Health

Beyond providing access to mental health support, the EMPOWER intervention afforded a means to gauge mental health in a more general way through components such as the charts and the diary.

"It's quite good actually. I've done, I think I'm up to forty days in a row now. And that was what was good with EMPOWER especially when I was studying, and I wasn't working. I would say a little diary entry each day just to sort of see how I was, and that was helpful too" (Leonie, Australia)

However, it should be noted that while EMPOWER afforded an opportunity for gauging mental health – trial staff such as the peer support workers had an essential role as data interpreters and were a key reason for why participants understood EMPOWER as a means to gauge mental health. In the example below, a participant highlights the key role of the peer support worker in placing the participant self-monitoring data in a format the participant could understand.

"I never used to understand charts, how they work. It's not my type of thing. So, it's hard to understand charts, for me. So [named peer support worker] was very helpful in explaining what it's showing and what the projection is and the decline, and what it's showing really, what's happening" (Sandy, Australia)

However, in this contrasting example a participant who stated they were not interested in gauging their own mental health and rather saw that task as something that should be done by a clinician describes how they were not interested in this affordance for themselves and therefore would not engage in looking at the charts, they nonetheless believed it could afford mental health staff an ability to gauge how they are.

"I wouldn't use the charts, really, you know what I mean? That would be something for my nurse to see or something, or my doctor" (Alexander, UK)

8.5.2.1.5 Affording Access to Mental Health Information

EMPOWER was seen as a source of potentially helpful mental health information, this could come from either accessing the wellbeing messages or through conversations with peer support workers.

"[named peer support worker] talked to me about like mindfulness and meditation and stuff like that, and that's something I've been looking into. So, I did find that quite useful. And talking to me about like, you can go and do group things and stuff. I don't know how I'll follow that yet, but he did suggest it to

me. So, there are good things [the peer support worker] brings to the table” (Keith, UK).

8.5.2.2 Change Processes

Affordances provided the engagement “hook” which made engagement possible. Change was embodied through interaction with the EMPOWER intervention and described the impact which EMPOWER had on participants.

8.5.2.2.1 Noticing Patterns and Changes

If EMPOWER afforded an opportunity to gauge mental health through self-monitoring, diary keeping and conversations with peer support workers, this could start a change process of patients noticing patterns in their own wellbeing. Participants made explicit links between the intervention and noticing patterns and changes in their own wellbeing. Some participants appeared to have utilised the intervention to increase awareness about dynamic changes within their own mental health and sometimes reached profound realisations. In this example, a participant described how using the intervention helped her to notice how changes in her mental health were linked in with her menstrual cycle.

“It was even good the graphs when it was, you know, female time of month or anything I might be feeling a bit crappier. And just being able to look at the graphs and go ’well actually, that’s why I was feeling a bit crappy’” (Leonie, Australia)

“I mean, the bad days, they showed me how I am. So yeah, literally bad days, you know what I mean? I’m back on my feet, what was better in the day before that. I look at the charts and see how they go, see the difference and say what do I do different” (John, Australia)

The change process of noticing patterns and understanding change in wellbeing was not just limited to patients on their own – but also extended to whom they shared these insights with. This process can be seen in this excerpt where a participant reflected how the charts not only enabled them to see when they were "slipping" but this individual noticing of a change became a joint understanding of patient wellbeing. This person's process is demonstrated in this excerpt where a participant reflected how the charts help them see that they are becoming unwell but then help mental health staff understand also.

"It's just, I think the charts help me see where I've been slipping. That's all I would say about that, just, yeah, the charts would help me notice when I'm slipping. And they help my CPN notice as well, yeah, when I was slipping down the charts as well" (Agatha, UK)

8.5.2.2.2 Change in appraisals of relapse

The programme theory was underpinned by an assumption EMPOWER would create change by reducing participants' worries about having a relapse. While it is important to remain mindful that these qualitative interviews represent a cross-sectional snapshot of participant experiences, nonetheless a major theme was that fear of relapse varied, and while some participants seemed to report feeling less concerned about relapse, this varied.

"Sometimes I do [worry about relapse], but I sort of think about it and go "well, it might never happen again." Like you I'm stable, I've got good accommodation, I've got a good job, things are okay. So, I accept that it could happen in the future, but it's not something I think about." (Leonie, Australia).

Relapse could even become a more frightening prospect when people were further along a recovery journey and the potential consequences and losses arising from a relapse increased.

> *"I dread it more. …how far I've come, I think, to relapse now would just be a crying shame."* (Michaela, UK).

8.5.2.3 Differing Trajectories of Engagement Underpinned by Changes in Appraisal of Engagement Value

Affordances shaped intervention engagement. For example, participants demonstrated different engagement trajectories which were linked to their appraisal of need for continued use of EMPOWER.

When speaking with patient participants, it seemed that sustained engagement was underpinned by whether the participant perceived value in doing so. Perceiving a positive value was an implementation facilitator, whereas no longer perceiving a positive value or never having had perceived a positive value acted as an implementation barrier. Taken further, this suggests engagement with EMPOWER is best understood as an interactional process determined by participants balancing the value of continuing. For example, here a participant states that “I’m a bit over it now” as they no longer feel they are gaining positive benefit from being involved and continuing to use EMPOWER continuously does not make sense.

“For want of a better phrase I’m a bit over it now. I think it was really, really good to start with, but I think as I’ve gotten more well and as I’ve got back to the workforce and things like that, I haven’t needed as much support…. I think in the long term, once patients became more stable, I think the need for it decreases.” (Leonie, Australia)

In further support of this, there were examples of participants who reported that their appraisal of engagement value was still on a positive trajectory, and they had not yet experienced the change process described in the account above which was leaning towards a termination of engagement:

“One thing that I have worried about is when this finishes, I’ll miss it and I hope I’ll continue to reflect each day, to invest a bit of time in myself, how I’ve

been feeling, what the day's been like, or what the week's been like." (Matilda, UK)

Self-reporting mental health data every day could be tedious for participants, however if participants still perceived a positive benefit from engagement, it seemed that this made them motivated to keep going.

> *"Just force of habit, you know. Just like taking medication…. It's a bit tedious, you know. Sometimes you can't be bothered going through it all because it's the same every day, you know. I can do it quite quickly now, so I can get the answers up quite quickly, you know."* (Nancy, UK).

8.5.2.3.1 Increased Self-Confidence in Managing Schizophrenia

When speaking to some patient participants, it was clear that some participants appeared to have developed confidence that they could self-management their condition a bit better through their experiences of implementing EMPOWER.

> *"[EMPOWER] means that I'm not hiding away from my illness and I'm not ignoring it and I'm not pretending it's not happening and carrying on regardless … since I've started using the App it's made that pathway to recovery much quicker."* (Emily, UK)

But this varied, here a participant states that while they feel they have improved – it is not at all attributed to using the intervention.

> ***SA:*** *"So, since you've started using EMPOWER, have you noticed any changes in how you manage your own wellbeing?"*
> ***Participant:*** *"I'm getting better. I've been getting better for the last year but it's not your fault, it's my medicine's fault."* (Seumas, UK)

8.5.3 Staff

8.5.3.1.1 EMPOWER as a Conversation Starter

A change process for mental health staff was EMPOWER functioning as a conversation starter. The main trial findings demonstrated that data sharing between patients and mental health staff was not routine. For staff, a key change process was that staff used the fact the participant was part of the EMPOWER study and self-monitoring their mental health to open conversations about wellbeing – rather than looking at charts:

> *“So, generally I guess I use the app just to start discussions around… you know, how she is feeling really.”* (Edith (Staff) UK)

> *“I sort of shy away from using the data in a sense, I really want to keep it - I didn’t want [named patient] to feel I was looking at her data and making a judgement… I tended to ask her how she was going rather than “I looked at your data and thought... as it takes it away from a personable experience.” (Philippa (Staff),Australia)*

8.5.3.1.2 Increased Staff Confidence that Patients can Self-manage

Beyond using EMPOWER participation as an opportunity to open up conversations about patient mental health status, across all six staff interviews it was constructed that the very fact patients were engaged in the trial meant staff were afforded confidence patients could self-manage to a degree and they could simply let the participant get on with it. This change process is exemplified by member of the community mental health team reflecting their trust in the patient engaging with EMPOWER had engendered staff confidence in the ability of patients to self-manage.

> *“But knowing that the app’s there, knowing that she’s responding to that… knowing that she’s the support from EMPOWER itself, getting phone calls from the*

Peer Support workers - the nurse, it's made me more confident in her ability to do it." (Gary (Staff), UK)

8.6 Discussion

The purpose of this study was to conduct a process evaluation of the EMPOWER trial. Evaluating complex psychological interventions such as EMPOWER is difficult and traditional RCT evaluations do not typically assess what it feels like to use an intervention. Moreover, user perspectives are devalued within their hierarchy of evidence (Faulkner, 2015). This process evaluation study used qualitative analysis to holistically understand EMPOWER participants' experiences of implementing the intervention by using and interacting with it. The analysis identified several key themes that appear germane to understanding the mechanisms underpinning the implementation process within EMPOWER (Moore *et al.*, 2015), and will likely be of interest to researchers looking to develop digital interventions for people who experience psychosis.

EMPOWER was well implemented and the key mechanism underpinned this was affordances. EMPOWER affordances can be described as offerings which may or may not be in line with how participants (patients, staff, and carers) envision how and why they will interact with the intervention (Bygstad, Munkvold and Volkoff, 2016). The affordances lens assumes that everyone including people with schizophrenia are goal-orientated actors, which means our findings are at odds with empirical research that portrays people diagnosed with schizophrenia as having deficiencies in the ability to perceive affordances (Kim and Kim, 2017). However, this research assessed whether patients were able to correctly identify what a range of objects were supposed to be used for. Our qualitative work strongly challenges the notion that people with schizophrenia are inherently deficient and rather will come to an object (in this case, an intervention) with their own individual perceptions about how and why they might come to use it. Social media giants such as Facebook are understood to have such high usage rates because they provide a wide range of affordances to their end-users. For example, someone could use solely Facebook to keep in contact with friends and another could use it to play games (Kaun and Stiernstedt, 2014). In other words, engagement is high because Facebook is perceived by users as being able to satisfy their individual needs and wants to a significant degree. The high engagement observed in the EMPOWER trial appeared best explained by the intervention offering a range of potential affordances that were personally meaningful to participants. For example, participants who were isolated were afforded human contact, in contrast, participants who did not want to speak to people were also afforded the opportunity to communicate how they were feeling via self-monitoring without talking to another human. Due to the flexibility of EMPOWER, both distinct affordances could be satisfied resulting in engagement.

Mental health staff, carers and patients have unique roles in the application of non-digital EWS monitoring approaches in clinical practice (Allan *et al.*, 2020), so it is not surprising there appeared to be role-linked differences in EMPOWER affordances for staff. While there were rare examples in the interviews of patients sharing data with mental health staff to develop a shared understanding of wellbeing, typically mental health staff opted to use the fact the patient was part of the study to open conversations rather than relying on data to understand how a patient was doing. Staff not feeling comfortable using data generated by digital interventions is a common implementation barrier (Greenhalgh *et al.*, 2017) and staff discomfort may explain the low levels of data sharing between patients and staff observed in the main trial. Moreover, staff appeared to develop trust that patients using EMPOWER could self-manage which may have led to staff taking an even more hands-off approach with the intervention and further discouraging data sharing.

Patients reported that taking part in the intervention afforded them increased access to information about psychosis generally through conversations with peer workers or wellbeing messages as well as direct support from trial staff during crisis events. Previous research has indicated that people diagnosed with schizophrenia perceive that digital interventions can afford them another source of support (Eisner *et al.*, 2019; Jonathan *et al.*, 2019; Valentine *et al.*, 2020). Expanding upon these previous findings, this research suggests mental health staff believe digital interventions can afford increased access to information and support for their patients, with this being generally being perceived positively and leading to staff taking a more hands-off approach. “Face-to-face” components of blended interventions has been an implementation facilitator noted in other qualitative research with people who experience psychosis (Moore *et al.*, 2020) and bipolar disorder (Dodd *et al.*, 2017). The current analysis builds on this and suggests mental health staff also viewed the increased human contact available to people they support in a positive light.

Affordances also presented a useful framework for understanding cases where users did not implement the EMPOWER intervention. For example, a participant who had experienced difficulties with mental health services reported that the intervention afforded access to a mental health professional contacting them during triage which was perceived negatively and acted as an implementation barrier. EMPOWER was available to participants for up 12 months but there were many different usage trajectories, sustained engagement appeared linked to whether patients believed the intervention was still affording them something of value. This supports a call for researchers to further understand engagement in relation to the purpose of digital interventions (Yardley *et al.*, 2016) and suggests affordances are a useful framework for achieving this.

8.6.1 Limitations

Interviews were conducted with a small sub-sample of end-users and several patients dropped out of the trial before process evaluation interviews began. Therefore, the results likely present factors which are more relevant to patients who had more positive experiences and people we spoke to had engaged significantly more with both self-monitoring and peer support. Furthermore, since all interviewees were already participants in a trial, their views may not be representative of how EMPOWER would be used within routine mental health care settings. Only one carer participated. Carers reported feeling relatively uninvolved within routine relapse management (Allan *et al.*, 2020) and it may be the case that low carer participation within EMPOWER reflects this. Carer views on taking part in dyadic research are much needed.

Going forward, patient public involvement work with carers within future process evaluation research (especially exploring best recruitment practices) may be of merit here. The Interview schedules were created by mapping closely to the process evaluation framework, which may have limited the quality and breadth of the qualitative data. All interviews with Australian patients and staff were conducted via telephone which may have negatively impacted upon the richness of the qualitative data. Additionally, member checking (where participants comment on the accuracy of the analysis) would likely have enhanced the research and minimised the risk of researchers misunderstanding participant views (Bucci, Schwannauer and Berry, 2019).

8.6.2 Clinical and Research Implications

The EMPOWER trial itself had pre-defined criteria for determining intervention acceptability and feasibility (Gumley *et al.*, 2020). The qualitative process evaluation added to the consideration of acceptability and feasibility by highlighting intervention adjustments suggested by stakeholders (O'Cathain *et al.*, 2015). This is important because intervention participants have valuable insight into what feasibility means for them (Fortuna *et al.*, 2019) – key in interpretivist research. While some participants found the intervention difficult to use at first, patient-participants generally expressed confidence in using the mobile phone-based intervention components. This is noteworthy because some had never used a smartphone before, and there was concern expressed before the EMPOWER trial that older and digitally excluded people may struggle to use an app-based intervention (Allan, Bradstreet, *et al.*, 2019). As identified in previous qualitative research with people who experience psychosis (Bucci, Morris, *et al.*, 2018), participants spontaneously identified potential solutions to problems they encountered with digital interventions that would make using them more acceptable for them.

Interventions which are flexible and empower participants to discover affordances which are personally meaningful to them are likely to be well implemented. Affordances are an interaction between a person and an object in their environment, with this in mind one key recommendation from our research is that future interventions work closely with patients to discover what would drive them to engage rather than assuming patients will necessarily have deficits. Co-design and user engagement is in line with current guidance from the MRC complex intervention development framework (Skivington *et al.*, 2021)

8.6.3 Conclusion

EMPOWER shows promise as a relapse prevention intervention which could be implemented and tested in a full-scale clinical trial. The implementation observed in the trial appeared to be best explained as EMPOWER offering a range of affordances which could act as implementation barriers or facilitators depending on individual needs and wants. If the engagement was sustained, EMPOWER created change by increasing confidence that patients could self-manage and opening conversations about wellbeing. However, sustained engagement was dependent on patients continuing to see value from the intervention which suggests there may be optimal engagement periods. The affordances framework proposed will likely be of interest to trialists looking to develop digital interventions. Future research would be greatly enhanced by discovering why the intervention was less suitable for some people than others, and by conducting more interviews with people who drop out of studies early or decline to take part in a digital intervention trial in the first place.

9 Chapter 9: Fear of psychotic relapse: exploring dynamic relationships with common early warning signs of relapse using electronic once-a-day self-reports

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9.1 Abstract:

Background: Fear of relapse is an independent risk factor for future relapse events indicating its importance as a novel intervention target.

Methods: 25 participants responded to daily ecological momentary assessment prompts assessing common early warning signs of relapse and self-reported positive experiences like feeling supported by others. We conducted multilevel vector auto-regression using common symptoms assessed in early warning signs monitoring relapse prevention while controlling for positive self-reported experiences like feeling supported by others to estimate three networks (to explore concurrent, temporal, and overall relationships).

Results: Reporting fear of relapse was positively associated (within the same cross-sectional time window) with hearing voices, alongside anxiety, negative affect, and sleep change. Fear of relapse appeared to predict anxiety, negative affect, and greater fear of relapse on the next consecutive day. However, none of the common early warning signs predicted fear of relapse within the temporal window and observed relationships were small.

Discussion: Early warning signs themselves appeared to be poor predictors of experiencing fear of relapse in this study. Fear of relapse predicts later anxiety and negative affect and may be a valuable intervention target within the daily life of people diagnosed with schizophrenia.

9.2 Introduction

Fear of relapse describes distress and worry about experiencing a relapse of psychosis and is closely linked to the trauma of psychosis and experiences of psychiatric treatment (White and Gumley, 2009). The cognitive interpersonal model of relapse (Gumley *et al.*, 2020) states fear of relapse is associated with emotional, cognitive and behavioural avoidance and delayed help-seeking. Relapses may be preceded by so-called “early warning signs” (EWS), which are subtle changes in affect, thoughts and behaviour that occur before relapse evens (Birchwood, Spencer and Mcgovern, 2000). Monitoring for EWS and intervening when they occur is a common relapse prevention strategy. (NICE, 2014) Fear of relapse is an independent predictor of relapse itself, which makes it a potential EWS and a promising intervention target (Gumley *et al.*, 2015). Beyond typical EWS, such as sleep changes and paranoia (Eisner, Drake and Barrowclough, 2013) there is recognition that positive wellbeing experiences such as self-esteem may also play a protective role against relapse (Holding *et al.*, 2013). Additionally, perceived social support may buffer against relapse (Vázquez Morejón, León Rubio and Vázquez-Morejón, 2018)

Current research suggests fear of relapse is positively associated with depression and anxiety (Zukowska *et al.*, 2022). In addition, fear of relapse may be a self-fulfilling process which triggers further anxiety (Jamalamadaka *et al.*, 2020). However, due to the cross-sectional nature of existing research, little is known about what might influence fear of relapse because these methodological approaches do not account for how psychotic and affective experiences fluctuate over time (Lecomte, Leclerc and Wykes, 2018). Uncovering variables that influence daily fluctuations in fear of relapse using time series methods may give insight into what mechanisms drive fear of relapse and map out potential intervention targets. For example, identifying what predicts fear of relapse at the next time point may uncover possible maintenance cycles. EWS are important within the cognitive interpersonal model because fear of relapse may both influence and be influenced by other EWS which means it is important to understand how common EWS relate to fear of relapse. Therefore, there is merit in using multivariate approaches to explore relationships between fear of relapse and other symptoms and experiences, and the validity of a time series model would be enhanced by including protective factors.

Constructing models to understand natural daily fluctuations requires intensive longitudinal data. Network analysis is a statistical framework particularly suited to understanding potential maintenance cycles in longitudinal data because this identifies relationships between variables that are observed repeatedly over time and estimates the temporal order of relationships (Epskamp, Borsboom and Fried, 2018). In network analysis, relationships between variables (nodes) are represented as “edges” in a graph. This approach generates three types of networks: a temporal network, which estimates if symptoms predict one another over time (indicating potential maintenance cycles); a contemporaneous network, which shows if symptoms predict one another in the same window of measurement when controlling for previous time points (indicating what fear of relapse typically co-occurs with); and a between-subjects network, which is a cross-sectional between persons model and can indicate, for example, whether people who experience fear of relapse are, on average, also more likely to experience anxiety.

This study aimed to conduct a time series on an ecological momentary assessment (EMA) dataset collected from people who have experienced a relapse within the preceding two years using network analysis. The EMA protocol includes EWS that have been previously demonstrated to occur before a relapse (Eisner, Drake and Barrowclough, 2013) (paranoia, anxiety, negative affect, sleep changes, fear of relapse, and voice hearing) and includes protective factors (feeling confident and perceived social support). Due to existing cross-sectional research evidence, we were particularly interested in relationships between fear of relapse, low mood, and anxiety. While these should not be considered hypotheses, to explore whether these identified factors were associated with fear of relapse and whether there were indications for temporal relations (potential maintenance cycles) in this sample we:

1) Examined the consecutive (lagged) relations between fear of relapse and the same variables with a temporal network.
2) Examined the concurrent relations between fear of relapse and common EWS and protective factors by estimating a contemporaneous network.
3) Examined general relationships between mean scores of fear of relapse and common EWS and protective factors variables across time by estimating a between-subjects network.

We pre-stated our intention to study how these relationships varied during both stable phases and relapse (Allan, Mcleod, *et al.*, 2019), but there were concerns about obtaining sufficient power to do so (i.e., >30 observations; (Howe, Bosley and Fisher, 2020)) because so few relapse events occurred (n=7 when exposed to the intervention). We report one case study where a participant consistently supplied EMA data in the 30 days before a relapse event.

9.3 Methods

9.4 Data Sources and Participants

Data were collected in the UK and Australia as part of a cluster randomised controlled trial (EMPOWER ISRCTN99559262) (Gumley *et al.*, 2022) . The West of Scotland Research Ethics Service (GN16MH271 Ref: 16/WS/0225) and Melbourne Health Human Research Ethics Committee (HREC/15/MH/344) approved the study. All participants met the criteria for schizophrenia spectrum diagnosis using the ICD-10 with diagnosis established from clinical notes. Recruitment occurred via community mental health teams.

9.5 Measures

The EMPOWER platform was used to collect participant responses. EMA prompts appeared at a pseudo-random moment once a day; this meant that an alert would appear on the app inviting a participant to complete a questionnaire at a randomly selected time between 10am and 6pm. Pseudo-randomisation was chosen as there is less chance for memory distortion than when people are asked to summarise information from longer periods. Additionally, time of day may influence feelings (Napa Scollon, Prieto and Diener, 2009) which the pseudorandomised design helps to control. When the app was set up, participants were instructed to answer questions reflecting on what they felt at that moment. All EMA questions asked participants to rate themselves between 1 (lowest) and 7 (highest). The 22 questionnaire items completed by participants reflected different domains (e.g., mood, anxiety, coping, psychotic experiences, self-esteem, and fear of relapse). Out of the original 22 items, all participants were asked to respond to 16 core items, with the additional 6 items allowing for tailoring of questions. Participants could use the app for up to twelve months. By June 2019, the server was shut down, and EMA data were available for analysis.

Responses to EMA prompt questions were nodes for the network analysis. With sixteen questions, the core EMA set is large. However, networks with eight or more nodes are considered “highly dense” (Jordan, Winer and Salem, 2020), so to be parsimonious, we selected eight variables to function as nodes within this analysis – shown in Table 7. This is in line with good practice within the field, which recommends researchers start simple with variables based on existing research evidence (Jongeneel *et al.*, 2020) which can then be refined in later research, as opposed to initially constructing complicated and explorative models which may be difficult to interpret.

Due to the high potential for analytical flexibility, we have been transparent about our variable choices (Flake and Fried, 2020) and a full list which includes reasons for inclusion and non-inclusion of all 16 original variables (including item wording) can be seen in Table 8, we summarise this in more detail in the supplementary materials.

9.5.1 Group Level

9.5.2 Multiple Vector Autoregression (VAR)

Data were analysed on R Studio version 4.0.2. All analysis code can be seen at: (https://osf.io/6gbs5/files/).

To estimate temporal relationships between fear of relapse and other variables of interest with multilevel VAR, we utilised the R package mlVAR (version 0.4.4) to estimate networks (Epskamp, Borsboom and Fried, 2018). mlVAR generated temporal networks that predicted each variable from its previous value (autocorrelation) and all other variables during the last measurement window (time-lagged effects) while controlling for all other network variables. We used a lag of one day. Next, mlVAR constructed the between-subjects network that represents the mean mutual regression of all variables in the form of a cross-sectional analysis. An edge that connects two nodes in a between-subjects network represents the mean of two regressions that are calculated using both nodes once as predictor and once as outcome. This way, between-subjects networks can be interpreted as cross-sectional associations between variables over the assessment period. From the residuals of the previous models, mlVAR generated a contemporaneous network representing the relationship between two nodes at the same time point, controlling for all other nodes in the network and temporal effects, indicating what variables occurred simultaneously.

To minimise bias, we did not impute any missing data because we were not confident data were missing at random (Ono *et al.*, 2019). To reduce the risk of false positives, we visualised the estimated networks using qgraph (version 1.6.5) (Epskamp *et al.*, 2012) where we utilised the “and” rule, which requires both edge relationships are significant in both potential directions. We applied a Bonferroni correction to determine edge statistical significance; this only reflects adjusting for multiple comparisons and is somewhat arbitrary (Lutz *et al.*, 2018) which results in a sparse network with somewhat increased edge likelihood (Costantini *et al.*, 2015). Due to the study's exploratory nature, we included all significant edges.

Positive relationships in Figures 13-17 are blue and red relationships indicate negative relationships. In terms of effect size interpretation, we used the same definition as Jongeneel and colleagues, who used Cohen's definition for standardised partial correlations where r=0.1 is small, r=0.3 moderate, and r=0 .5 is large (Jongeneel *et al.*, 2020).

9.5.3 Individual Level

9.5.4 Graphical Vector Autoregression

Relapse was an outcome measure for the EMPOWER trial. Relapses were identified by research assistants completing an analysis of case notes - defined as (1) a return or worsening in psychotic symptoms of at least moderate degree; (2) where symptoms lasted at least one week, (3) there was evidence of a decline in functioning and/or an increase in risk to self or others; and (4) there is evidence of clinical response from services. From these, the research assistants gave a date of relapse onset. In addition, one participant used EMPOWER during a relapse event, so we were able to estimate idiographic lagged (lag 1 autoregressive) and contemporaneous (concurrent) graphical VAR models for the 30 days before relapse using the graphicalvar package (version 0.2.4). The results indicate lagged partial correlations between observed responses to EMA prompts (Epskamp, Borsboom and Fried, 2018). The mean variable scores for the case study (both during a relapse and in their overall usage period) are in Tables 12 and 13.

9.6 Results

9.7 Descriptive Statistics

Recruitment occurred between the 19th of January and the 8th of August 2018. In total, 42 participants were randomised to receive EMPOWER and 41 completed app installation. Missing data are expected in EMA studies (Palmier-Claus, Haddock and Varese, 2019) and in the absence of clear guidance on how much data are sufficient, we included participants who met the criteria of having completed at least 30 EMA questionnaires (Howe, Bosley and Fisher, 2020) and who had answered at least 33% valid prompts (Gumley *et al.*, 2020), and had completed a 4-week baseline – meaning 25 participants included in this network analysis.

A recent review suggested age, gender, education, duration of illness, depression, positive symptoms and negative symptoms may impact digital intervention engagement (Arnold *et al.*, 2021) so we explored baseline differences between the groups. There were no significant differences between groups on baseline demographics (gender, years of education, trial site, age and duration of contact with mental health services) or baseline scores on clinical assessment measures, including the positive, negative subscales, and total scores of the Positive and Negative Syndrome Scale (Kay, Fiszbein and Opler, 1987; van der Gaag *et al.*, 2006) (PANSS), or total scores on the Calgary Depression Scale (Addington, Addington and Maticka-tyndale, 1993). Additionally, there were no differences in the Fear of Relapse subscale on the Fear of Relapse Scale. Therefore, we report baseline characteristics differences for those included (n=25) and not included (n=17) in Table 9.

The final dataset for the 25 included participants consisted of 6529 measurement occasions, of which 4928 (75.4%) were a complete set of EMA questions. Participants reported fear of relapse (defined as a score of more than 1) on 60.1% of complete responses to EMA prompts (individual range 0.45%-100%) which indicated that at least some level of fear of relapse was present. However, multilevel VAR uses only consecutive responses because the temporal network explores relationships between consecutive prompts and the contemporaneous network is estimated from temporal residuals. Therefore, when removing non-consecutive responses (where there was at least one missing EMA prompt following a completed prompt), there were 4660 prompts, meaning the data utilised in this analysis represent 71.3% of possible measurement occasions for the 25 participants. Therefore, all further descriptive statistics are based upon consecutive responses to prompts. The descriptive statistics for responses to EMA prompts can be seen in Table 10.

The mean lag between the 4660 consecutive prompts was 23.99 hours (SD=0.21). Therefore, the temporal network estimates how people respond around 24 hours after their previous questions. The shortest lag between consecutive beeps for a participant was 17.9 hours, and the longest was 30.87 hours. We will now describe the network analysis results and further sensitivity and stability tests.

9.8 Assumption checks

Both the group level and case study methods have assumptions, including stationarity and multivariate normality (Epskamp *et al.*, 2018). Kolmogorov-Smirnov tests and visual inspection of density plots were done to assess the multivariate normality assumptions. According to the Kolmogorov-Smirnov tests, residuals of the multilevel VAR model were not normally distributed for any variable (all $p < .001$). The stationarity assumption is that the conditional probability distributions do not depend on time and are thus stable over time. To explore stationarity, we used the Kwiatkowski-Phillips-Schmidt-Shin unit root test; all variables were stationary for all participants ($p > 0.002$, which was our Bonferroni corrected alpha level). To increase our confidence in this result (Jordan, Winer and Salem, 2020), we also conducted an Augmented Dicky-Fuller test which indicated variables were not stationary ($p > 0.002$). Due to these inconsistent results, we chose to run all network analyses (both group level and case study) on detrended data (with each participant detrended for their usage period using ordinary least squares regression). This is in line with the exploratory research aims of the study because we are interested in what factors are associated with fear of relapse at a given time point for future theory development, rather than changes in the processes that have resulted in observed values (Piccirillo, Beck and Rodebaugh, 2019). Group-level and individual network estimation methods are underpinned by the assumption of granger causality (Granger, 1969), where causes occur before any observed effects.

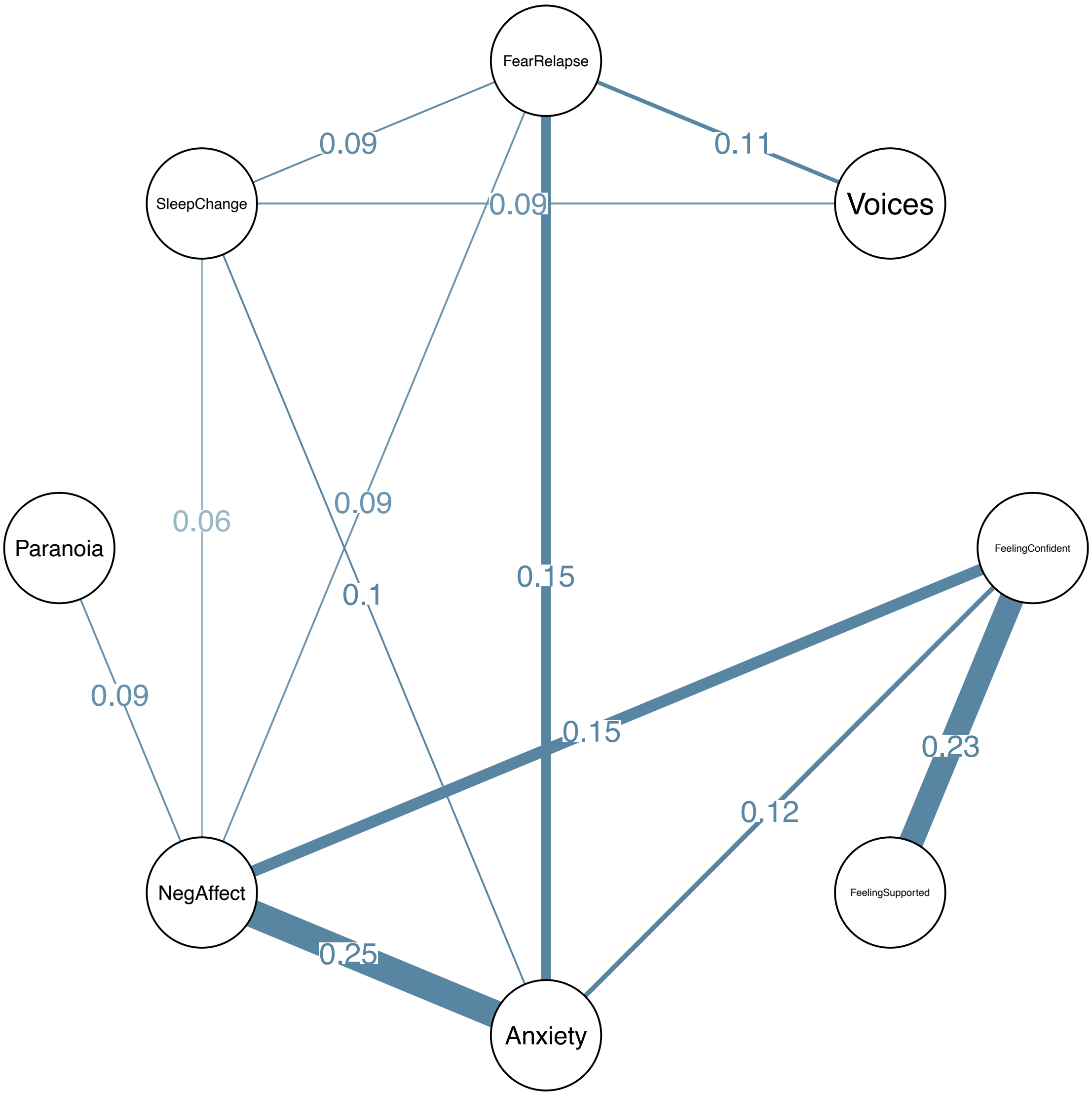
9.9 Sensitivity Analyses

We ran two further supplemental analyses on the detrended data and another on the non-detrended data (results and rationale are in the appendix).

9.10 Group Level Results

9.11 Contemporaneous Network

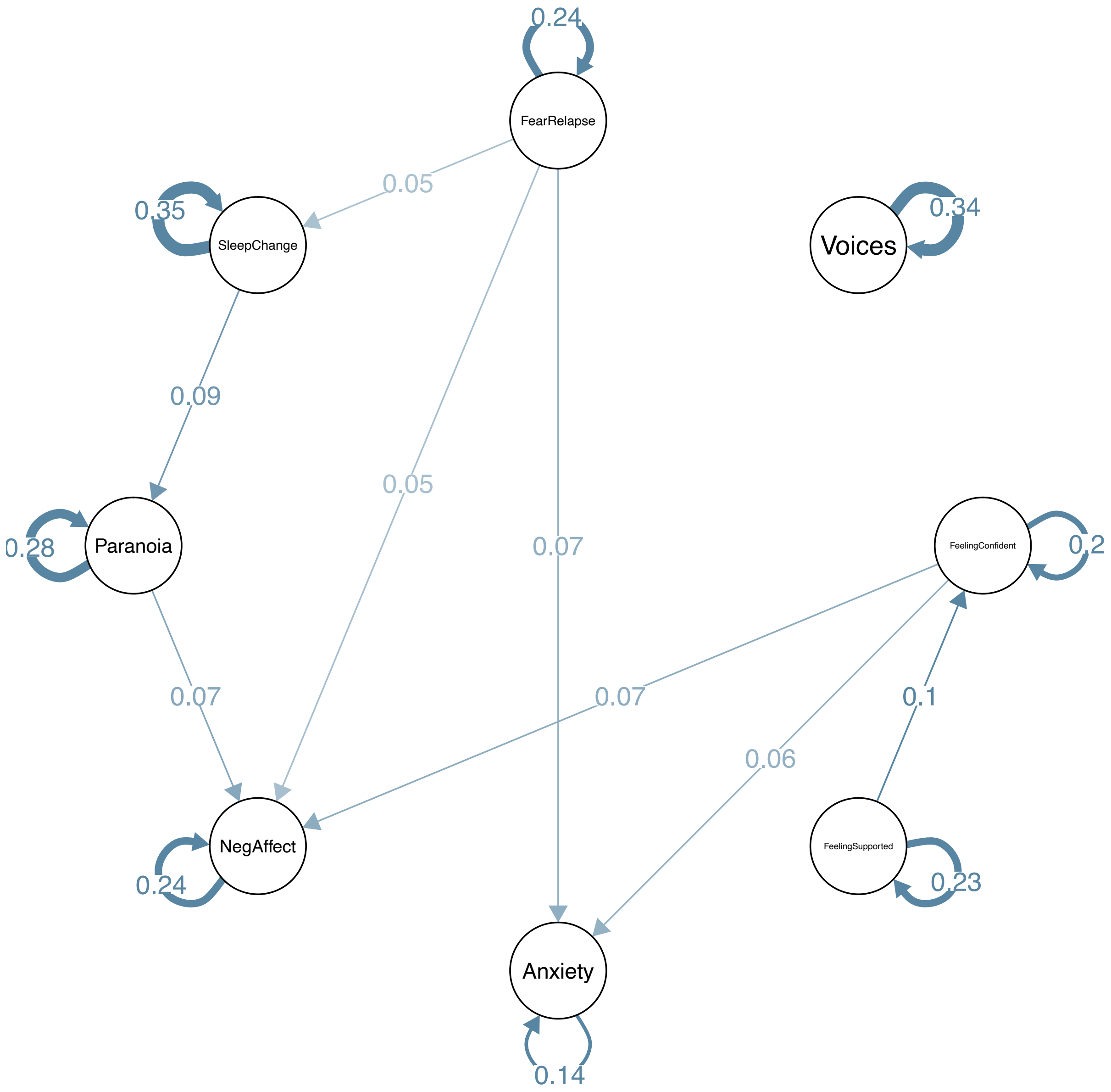
Figure 13 Contemporaneous Network Graph



The contemporaneous network shows variables that tended to co-occur, at the same time controlling for all other variables. For example, within the contemporaneous network, fear of relapse showed positive relationships with (in decreasing order of partial correlation strength) anxiety (0.15), voices (0.11), sleep changes (0.09) and negative affect (0.09). Other relationships were observed between feeling confident and feeling supported (0.23), negative affect and anxiety (0.25), and feeling confident and anxiety (0.12) and negative affect (0.15).

9.12 Temporal Network

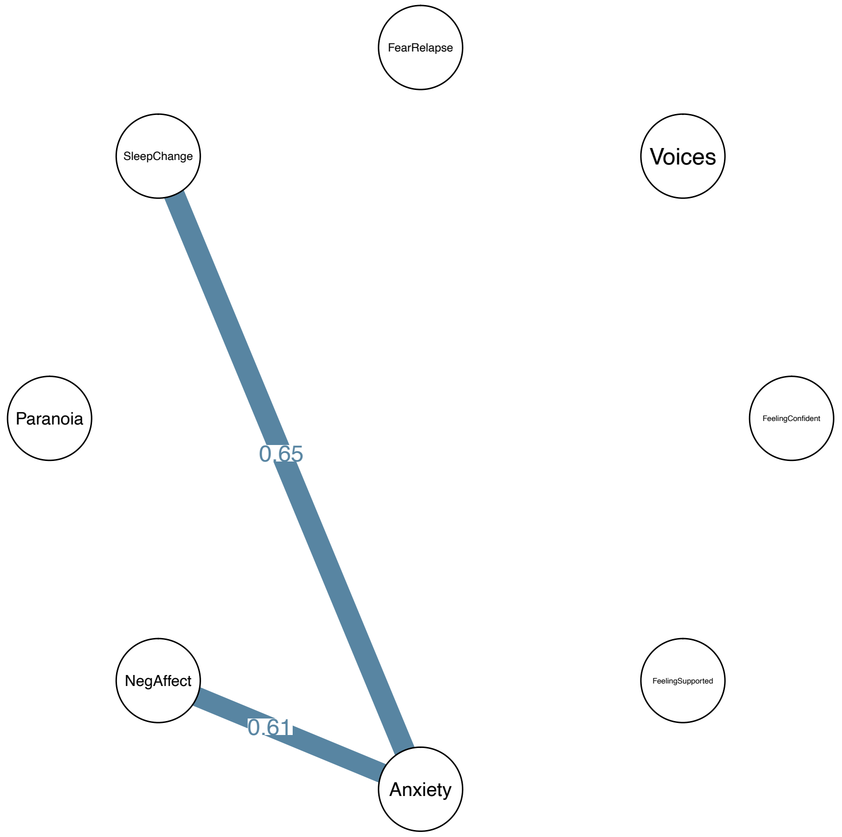
Figure 14 Temporal Network Graph



The temporal network highlights variables that predicted themselves and each other across time. In the temporal network, fear of relapse had directed relationships with negative affect (r=0.05,95%CI=0.02,0.08), anxiety (r=0.07,95%CI=0.03,0.10) and sleep change (r=0.08,95%CI=0.02,0.11). Fear of relapse showed a positive autoregressive co-efficient (r=0.24,95%CI=0.16,0.32), indicating that reporting fear of relapse in a single time window was significantly positively associated with reporting fear of relapse in the next time window. However, none of the other variables predicted fear of relapse. Autocorrelation was observed for all variables. Other significant relationships of note included feeling supported predicting increased self-confidence (r=0.10,95%CI=0.04,0.11) and sleep change predicting persecutory paranoia (r=0.08,95%CI=0.03,0.14).

9.13 Between Participants Partial Correlations Network

Figure 15 Between Participants' Network



The between-subjects partial correlations show partial correlations among the stationary means of participant EMA responses (when controlling for the mean levels of all other variables). In other words, this network suggests that people who generally reported having changeable sleep also reported experiencing higher anxiety (r=0.65). Additionally, anxiety was positively associated with negative affect (r=0.61) – large effect sizes. We did not observe any relationships that were statistically linked to fear of relapse. The means of the within-person standardised mean levels used to create the between-subjects network can be seen in Table 11.

9.14 Individual Case Study of Relapse

In the 30 days prior to relapse onset, the contemporaneous network demonstrated a moderate positive partial correlation between fear of relapse and persecutory paranoia (0.23) and a very weak positive correlation between fear of relapse and negative affect (0.02). The temporal network did not demonstrate any significant relationships, and since this was a fully sparse network, we have not visualised the resulting graph. For comparison, we present the contemporaneous network for the overall usage period (280 days, 62.8% adherence) where fear of relapse shows a very weak (0.01) positive relationship with anxiety and no apparent link with paranoia.

Figure 16 Contemporaneous Network of 30 days prior to a relapse event

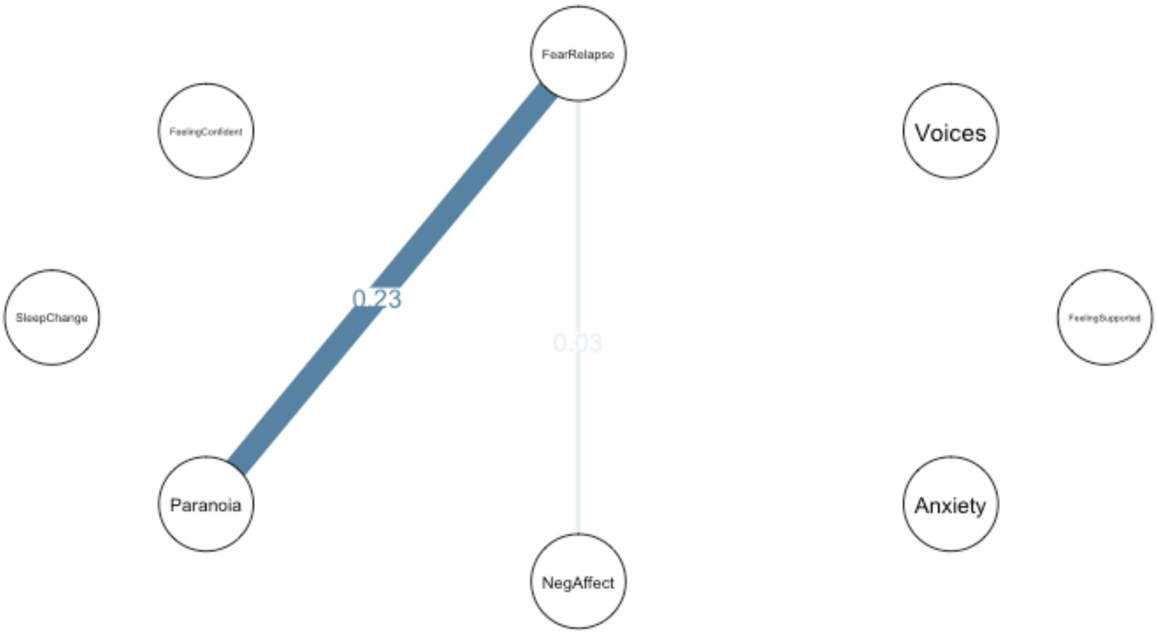
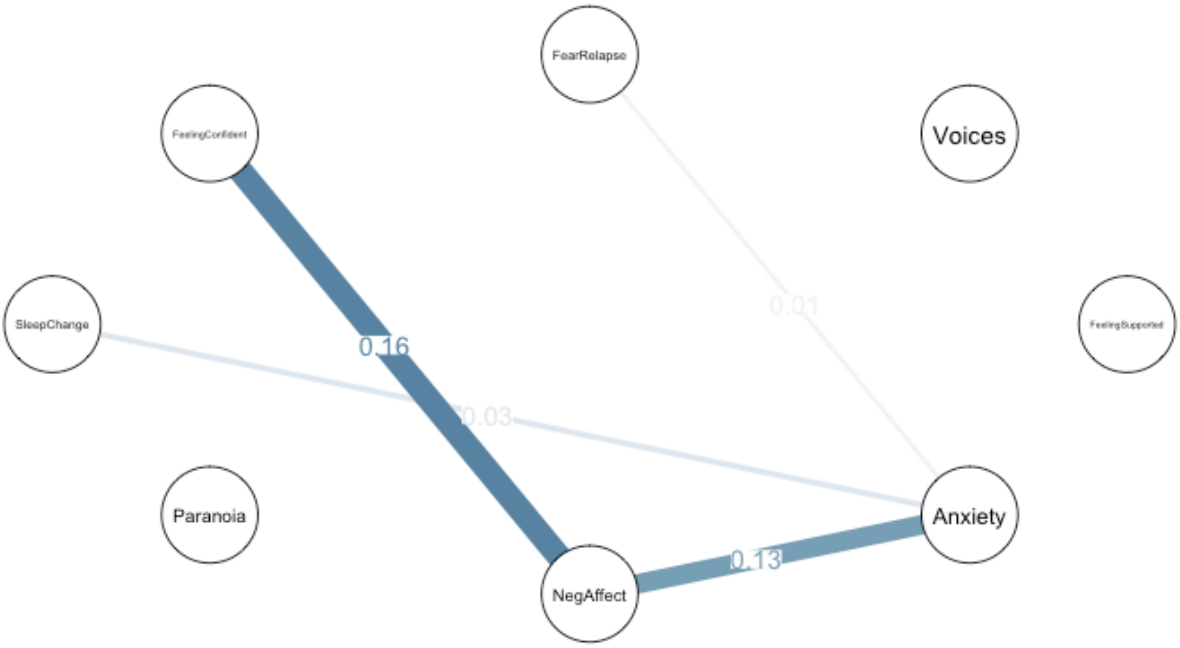


Figure 17 Contemporaneous Network of the same participant over the whole time period.



9.15 Sensitivity Analyses

We discuss sensitivity analyses in detail in the supplementary materials on the Open Science Framework: https://osf.io/6gbs5/

9.16 Discussion

In the current study, we investigated dynamic network associations between fear of relapse, protective factors and common EWS, including negative affect and anxiety. The cognitive interpersonal model (Gumley *et al.*, 2020) assumes that fear of relapse may lead to the development of schemas which influence meaning ascribed to psychotic or other personally salient EWS experiences. Although this study was preliminary, our main aim was to examine networks in line with this model. Findings indicate that fear of relapse demonstrated temporal and contemporaneous associations with anxiety and negative affect – even when controlling for all potential relationships between variables. Additionally, fear of relapse demonstrated additional positive relationships with voices and sleep changes in the contemporaneous network only. No significant associations were observed between fear of relapse and any variables in the between subjects' network, which suggests that people who report fear of relapse did not generally tend to experience high levels of any included variable.

In terms of potential maintenance cycles, fear of relapse appeared to predict greater fear of relapse at the next time point and appears self-sustaining. However, none of the included variables predicted next-day fear of relapse, suggesting common EWS alone did not predict and may be unlikely to be useful intervention targets for fear of relapse. However, fear of relapse predicted next-day anxiety and negative affect – expanding upon previous cross-sectional work (Jamalamadaka *et al.*, 2020). Intervening on fear of relapse may reduce anxiety and break the fear of relapse self-sustaining maintenance cycle. The effect sizes for the observed positive relationships between fear of relapse, voices, anxiety and negative affect were small; it may be the case that on a day-to-day basis fear of relapse results in later anxiety, which may have a cumulative effect over time (Funder and Ozer, 2019).

In the case study, fear of relapse demonstrated a positive contemporaneous relationship with persecutory paranoia before a relapse event, which may indicate heightened sensitivity to potential interpersonal threats (Meisel *et al.*, 2018) – in line with the cognitive interpersonal model (Gumley *et al.*, 2020). However, like the group-level analysis, no significant temporal relationships were observed, meaning none of the included variables predicted fear of relapse even before relapse. Our overarching interpretation of the three group networks and the single case study is that in daily life, fear of relapse is positively associated with negative emotional experiences, which may include persecutory paranoia before relapse. Consistent with the cognitive interpersonal model, the models suggest fear of relapse (perhaps triggered by a contextual factor) leads to negative experiences, rather than having high general fear of relapse being generally associated with low mood and anxiety given the lack of relationships between these variables in the between subjects’ network.

Beyond fear of relapse, other significant group-level relationships in the temporal network were apparent. For example, feeling supported was positively associated with increased self-confidence the next day. Low self-esteem is something many people diagnosed with schizophrenia want treatment and support for (Freeman, Taylor, *et al.*, 2019), finding ways to help people feel that they are supported may be a useful target to increase everyday self-confidence. Additionally, sleep changes predicted later persecutory paranoia, supporting research linking the two (Waite *et al.*, 2020). Finally, some observed relationships were unexpected. For example, the small positive partial correlation between negative affect and feeling confident and anxiety in the contemporaneous network may indicate that people feel confident despite negative emotional experiences.

These results must be interpreted considering several limitations. Firstly, we are reporting a subsample of a small number of people in a feasibility study. As the study was exploratory, we estimated edges conservatively, and the findings should be considered preliminary. Secondly, multilevel VAR assumes time lags between prompts are equal but EMPOWER participants responded to pseudorandomised prompts. Exactly how departure from this assumption may impact network structure is still unknown (Oreel *et al.*, 2019). Edges cannot be interpreted as authentic causal relationships because edges can arise from different unobserved factors that might influence daily fluctuations. While variable choices included common EWS that patients diagnosed with schizophrenia are advised to monitor for themselves (Morriss *et al.*, 2013), the symptoms and experiences that get called EWS may only function as actual EWS before a relapse event and those included might not be sensitive enough or specific enough for predicting fear of relapse. Therefore, the group-level analysis will likely have missed specific phase changes when someone moves from a stable to a pre-relapse and relapse state – noted elsewhere (Bak *et al.*, 2016). Finally, the data were skewed, which is common in psychosis studies assessing psychotic experiences in people diagnosed with psychotic conditions (Weijers *et al.*, 2018) which led to non-normality. Nonparametric alternatives to network modelling (Aalbers *et al.*, 2018) may be beneficial for research in the field of psychosis.

Network models only demonstrate potential connections between variables included within the network (Ryan, Bringmann and Schuurman, 2019). For example, we have not included data on how participants appraised the impact symptoms, which would be more informative and point to understanding the function of fear of relapse. Appraisal theories posit that emotional experiences emerge from the continuous evaluations of encountered stimuli on dimensions such as novelty and agency but also compatibility with a person's values and experiences (Lange *et al.*, 2020). Future work should consider operationalising aspects of the cognitive interpersonal model, such as differentiating cognitive triggers (for example, appraisal of psychosis) and contextual triggers (such as interpersonal encounters). Additionally, the single ESM item used to measure fear of relapse, "I have been worrying about relapse", presents a psychological formulation for fear of relapse, which, as a construct, features behavioural components like avoidance (Zukowska *et al.*, 2022) . Additionally, the item wording is potentially biased as it refers to worry. Measurement refinement options to be considered in future studies would be to separate affect domains (such as anxiety) and cognitive domains (I am thinking about my illness) and behavioural (I am avoiding other people) separately and to involve patients' perspectives in the prototyping of EMA measures. Finally, the EMA protocol was delivered only once daily, so it may have missed fast-acting processes. Research with more frequent observations is now needed to explore how long fear of relapse persists and what contextual factors are associated with longer duration and/or intensity of fear of relapse.

9.17 Conclusions

Fear of relapse appeared to be a relatively common experience in the day-to-day life of people diagnosed with schizophrenia. This study was the first to use network models to explore the relationships between fear of relapse and common EWS as anticipated by an existing psychological model. Network analysis suggested that fear of relapse was positively associated with negative affect and anxiety within the same time window and directionally predicted later experiences of fear of relapse, anxiety, and negative affect. However, no standard EWS variables appeared to predict fear of relapse, which suggests a need for revisions to the cognitive interpersonal model. Confirmatory hypothesis-driven research is now needed to explore the extent to which the relationships observed here (found to be generally small) in an independent sample.

Table 7 Items and associated constructs included in the analysis

Construct	**Item Wording**
Fear of Relapse	I have been worrying about relapse
Feeling Supported	I have been feeling supported
Paranoia	I have felt like someone, or something has meant me harm
Feeling Confident	I have been feeling confident
Negative Affect	I have felt sad
Voices	I have heard voices
Sleep Change	My sleep has changed
Anxiety	I have felt worried nervous, or anxious

Table 8 Items and associated constructs not included in analysis

Construct	**Item Wording**	**Why did we not use this**

Visions	I have been seeing things	Voices (45.9%) were more prevalent than visions (39.3%)
Stress	I have been feeling stressed	Demonstrated high collinearity with anxiety as determined by a high partial correlation in an original network estimation in between subjects' network (r=0.64). (Jongeneel *et al.*, 2020)
Activation	I have been putting myself under more pressure than usual	Construct did not fit with cognitive interpersonal model
Paranoia (alterative)	I have felt I cannot trust other people	Persecutory paranoia is more relevant to cognitive interpersonal model
Hope	I have felt upbeat about the future	Low factor loading
Coping	I have been managing well today	Low factor loading
Feeling Connected	I have been feeling connected to others	Low factor loading
Positive Affect	I have been enjoying things	Low factor loading

Table 9 Characteristics of randomised sample at Baseline (Means and Standard Deviations)

	Network Analysis Sample (n=25)	**Participants not in Network Analysis Sample (n=17)**	**p-value for test statistic**
Age	43.3 (12.0)	41.1 (14.7)	0.6 (t-test)
Gender (Female) %	52%	47%	1 (chi-square)
Trial Site (Australia) %	24%	35%	0.7 (chi-square)
Years of Education	12.52 (3.25) * 4 missing values	11.92 (2.37) * 3 missing values	0.5 (t-test)
Months since first contact with mental health services	153.78 (118) * 2 missing values	155 (131) * 2 missing values	0.9 (t-test)
Days inputting data into EMPOWER app	203 (85)	28.11 (37.6)	< 0.0001 (t-test)
PANNS Positive	15.1 (5.0)	14.5 (7.2)	0.8 (t-test)
PANNS Negative	13.2 (4.83)	14.9 (6.2)	0.4 (t-test)
PANNS Total	58.88 (14.6)	65.4 (22.3)	0.3 (t-test)

Calgary Total Score	7.12 (5.49)	6.64 (5.27)	0.8 (t-test)
Fear of Relapse Subscale	16.66 (5.77)	15.64 (4.89)	0.5 (t-test)

Table 10 Mean scores for responses to EMA prompts used in analysis

Construct	**Mean**	**SD**
Fear of Relapse	2.55	1.72
Paranoia	2.51	1.82
Anxiety	3.31	2.03
Voices	2.54	2.09
Feeling Confident	3.57	1.94
Negative Affect	3.07	1.89
Feeling Supported	2.76	1.78
Sleep Change	2.61	1.90

Table 11 Means of Intra-Individual data that forms Between-Subjects Network

Construct	**Mean**	**SD**
Fear of Relapse	2.48	1.10
Paranoia	2.61	1.43
Anxiety	3.31	1.54
Voices	2.34	1.73
Feeling Confident	3.60	1.47
Negative Affect	3.01	1.38
Feeling Supported	2.85	1.58
Sleep Change	2.68	1.56

Table 12 Means Scores for Relapse Case Study in 30-day period prior to relapse

Construct	**Mean**	**SD**
Fear of Relapse	1.33	0.71
Paranoia	1.33	0.80
Anxiety	2.23	1.28
Voices	3.27	1.26
Feeling Confident	2.83	1.39
Negative Affect	1.97	1.10

Feeling Supported	2.33	1.52
Sleep Change	2.87	1.68

Table 13 Means Scores for Relapse Case Study for overall usage period.

Construct	**Mean**	**SD**
Fear of Relapse	1.21	0.75
Paranoia	1.31	0.88
Anxiety	2.05	1.51
Voices	2.46	1.49
Feeling Confident	2.47	1.67
Negative Affect	2.31	1.60
Feeling Supported	1.71	1.33
Sleep Change	2.13	1.57

Data related to this research will be made available as soon as possible based upon reasonable request to the study chief investigator.

Declaration of competing interest

None.

Table 14 Items and associated constructs not included in analysis

Construct	**Item Wording**	**Why we did not use this**
Visions	I have been seeing things	Voices (45.9%) were more prevalent than visions (39.3%)
Stress	I have been feeling stressed	Demonstrated high collinearity with anxiety as determined by a high partial correlation in an original network estimation in between subjects network (r=0.64). (Jongeneel *et al.*, 2020)
Activation	I have been putting myself under more pressure than usual	Construct did not fit with cognitive interpersonal model
Paranoia (alterative)	I have felt I cannot trust other people	Persecutory paranoia is more relevant to cognitive interpersonal model
Hope	I have felt upbeat about the future	Low factor loading
Coping	I have been managing well today	Low factor loading
Feeling Connected	I have been feeling connected to others	Low factor loading
Positive Affect	I have been enjoying things	Low factor loading

Table 15 Characteristics of randomised sample at Baseline (Means and Standard Deviations) for Network Analysis Study

	Network Analysis Sample (n=25)	**Participants not in Network Analysis Sample (n=17)**	**p-value for test statistic**
Age **M (SD)**	43.3 (12.0)	41.1 (14.7)	0.6 (t-test)
Gender (Female) %	52%	47%	1 (chi-square)
Trial Site (Australia) %	24%	35%	0.7 (chi-square)
Years of Education **M (SD)**	12.52 (3.25) * 4 missing values	11.92 (2.37) * 3 missing values	0.5 (t-test)
Months since first contact with mental health services **M (SD)**	153.78 (118) * 2 missing values	155 (131) * 2 missing values	0.9 (t-test)
Days inputting data into EMPOWER app **M (SD)**	203 (85)	28.11 (37.6)	< 0.0001 (t-test)
PANSS Positive **M (SD)**	15.1 (5.0)	14.5 (7.2)	0.8 (t-test)

PANSS Negative **M (SD)**	13.2 (4.83)	14.9 (6.2)	0.4 (t-test)
PANSS Total **M (SD)**	58.88 (14.6)	65.4 (22.3)	0.3 (t-test)
Calgary Total Score **M (SD)**	7.12 (5.49)	6.64 (5.27)	0.8 (t-test)
Fear of Relapse Subscale **M (SD)**	16.66 (5.77)	15.64 (4.89)	0.5 (t-test)

Table 16 Mean scores for responses to EMA prompts used in analysis

Construct	**Mean**	**SD**	**Max**
Fear of Relapse	2.55	1.72	7
Paranoia	2.51	1.82	7
Anxiety	3.31	2.03	7
Voices	2.54	2.09	7
Feeling Confident	3.57	1.94	7
Negative Affect	3.07	1.89	7
Feeling Supported	2.76	1.78	7
Sleep Change	2.61	1.90	7

Table 17 Means of Intra-Individual data that forms Between-Subjects Network

Construct	Mean	SD	Max
Fear of Relapse	2.48	1.10	4.81
Paranoia	2.61	1.43	4.89
Anxiety	3.31	1.54	6.42
Voices	2.34	1.73	6.74
Feeling Confident	3.60	1.47	6.20
Negative Affect	3.01	1.38	5.29
Feeling Supported	2.85	1.58	6.99
Sleep Change	2.68	1.56	6.77

Table 18 Means Scores for Relapse Case Study in 30-day period prior to relapse

Construct	Mean	SD	Max
Fear of Relapse	1.33	0.71	4
Paranoia	1.33	0.80	4
Anxiety	2.23	1.28	5
Voices	3.27	1.26	7
Feeling Confident	2.83	1.39	6
Negative Affect	1.97	1.10	4
Feeling Supported	2.33	1.52	7
Sleep Change	2.87	1.68	7

Table 19 Means Scores for Relapse Case Study for overall usage period.

Construct	Mean	SD
Fear of Relapse	1.21	0.75
Paranoia	1.31	0.88
Anxiety	2.05	1.51
Voices	2.46	1.49
Feeling Confident	2.47	1.67
Negative Affect	2.31	1.60
Feeling Supported	1.71	1.33
Sleep Change	2.13	1.57

Data related to this research will be made available as soon as possible based upon reasonable request to the study chief investigator.

Declaration of competing interest

None.

10 Chapter 10 Overall Discussion

There are key uncertainties about what might impact the implementation of user-led interventions for psychosis. The overarching aim of this thesis was to conduct implementation research to more fully understand the implementation of the EMPOWER intervention which was a mobile app-based peer worker supported digital self-monitoring intervention. This chapter concludes the thesis by summarising and integrating the findings of each study and their contributions to the thesis as a whole.

The more specific research aims highlighted in Chapter 1 are repeated again:

1.1. To develop an initial process evaluation framework grounded in stakeholder expertise from qualitative data gathered from focus groups with mental health staff, carers, and patients to process evaluate the EMPOWER feasibility trial. Then to conduct relevant empirical research to generate process evaluation data to refine the logic model with the results from the process evaluation (triangulated with relevant aspects of main trial outcomes) to develop a process evaluation framework suitable for a potential full-scale clinical trial. Linked to the first aim, I also aimed to systemically review what interventions are user-led like EMPOWER, which will A) enable me to relate the findings to relevant literature and B) facilitate the future conduct of process evaluations by providing a database of intervention theories.

1.2. To explore the temporal dynamics of fear of relapse to enhance understanding of underlying intervention theory and to make recommendations for the refinement of intervention theory.

1.3. To produce a Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis of implementation for EMPOWER to suggest areas for intervention refinement.

This chapter begins with a brief recap of the main findings from each study, followed by an evaluation of the results of each of the overall thesis aims. While the main EMPOWER study outcomes were not one of the PhD papers, it is given a summary here so that the other findings can be placed within context. It then finishes by discussing the main strengths and limitations of the thesis and identifying implications for research and practice.

10.1 Chapter 3 Systematic Review

Access to evidence-based care for schizophrenia can be poor, and user-led interventions can potentially allow patients to access interventions. The systematic review results suggest that user-led interventions have been developed for various clinical problems. Four databases (PubMed, PsychINFO, Cochrane Trial Register and OVID Medline) were searched for relevant literature up to April 3rd, 2021. Forty-six articles were available for narrative synthesis, which covered forty-two unique interventions.

Around half (54%) of identified user-led interventions featured a degree of human contact and should be considered blended interventions. The blending components included clinicians, peer support workers and sometimes carers involved in task shifting. No papers were based on a cognitive interpersonal model of EWS, which further justifies the development of the bespoke implementation framework seen in Chapter 4. Additionally, the quality of theory reporting was found to be poor when assessed with an adapted version of the theory coding schemes, which means it is currently challenging to base process evaluations upon existing interventions because reporting is opaque. It appeared patients were rarely selected for having a theory-relevant measure of the problem of interest. For example, in cognitive remediation studies, it was not clear that patients were experiencing cognitive problems which is another limitation of the field.

10.2 Chapter 4

Mental health staff, carers and patients appeared to recognise EWS and acknowledged the importance of responding to EWS to support relapse prevention. However, recognition of and acting on EWS were constructed in a context of uncertainty, which appeared linked to risk appraisals that were dependent on distinct stakeholder roles and experiences. Within current relapse management, a process of weighted decision-making (where one factor was seen as more important than others) described how stakeholders weighed up the risks and consequences of relapse alongside the risks and consequences of intervention and help-seeking.

10.3 Chapter 5 Hypothetical Implementation Paper

All groups expected that EMPOWER could be successfully implemented if the intervention generated data that were meaningful to mental health staff, carers, and service users within their unique roles. However, there were key differences between staff, carers, and service users about what facilitators and barriers that stakeholders believe exist for intervention implementation in both the cluster randomized controlled trial stage and beyond. For example, service user expectations mostly clustered around subjective user experiences, whereas staff and carers spoke more about the impact upon staff interactions with service users.

10.4 Chapter 6 Process Evaluation Protocol

A logic model (Figure 10) was developed by mapping out the key EMPOWER components as listed in the trial protocol, analysing key implementation issues from studies 2 and 3, reviewing literature on digital evaluation issues (covered in Chapter 1), and creating an initial framework and then getting feedback from the EMPOWER study team. The logic model identified key uncertainties surrounding recruitment addressed in Chapter 5, key uncertainties surrounding user experiences discussed in Chapter 6 and uncertainties surrounding the fear of relapse addressed in Chapter 7. Additionally, the MRC process evaluation guidance recommends basing process evaluations upon interventions with similar programme theory, which I found challenging, resulting in the systematic review and Chapter 2.

10.5 Main EMPOWER trial paper

The main trial outcomes paper (Gumley *et al.*, 2022) concluded EMPOWER was feasible. The research team identified and randomised eight CMHTs (six in Glasgow, UK and two in Melbourne, Australia), resulting in 47 mental health staff participants, 86 patient participants and 17 carer participants. Chapter 5 describes in detail the processes underpinning recruitment. In total, 42 patients were randomised to receive EMPOWER. Of those randomised to EMPOWER, 30 (71%) met the a-priori criterion of more than 33% adherence to daily monitoring that assumed feasibility. However, self-monitoring data was not routinely shared between patients and mental health staff. There were 29 adverse events in the EMPOWER group and 25 in the treatment as usual group. Fear of relapse was lower in the EMPOWER group than in the treatment as usual group at 12 months (mean difference –7·53 (95% CI –14·45 to -0·60; Cohen’s d –0·53).

10.6 Chapter 7 Recruitment Paper

The main trial outcomes paper indicated EMPOWER recruited a satisfactory number of participants. This study was a qualitative observational study using both ethnography and focus groups with clinical trial staff featuring a range of perspectives from research assistants to principal investigators. Recruitment barriers were categorized into two main themes: service characteristics (lack of time available for mental health staff to support recruitment, staff turnover, patient turnover [within Australia only], management styles of community mental health teams, and physical environment) and clinician expectations (filtering effects and resistance to research participation). Trial staff negotiated these barriers through strategies such as emotional labour (trial staff managing feelings and expressions to recruit participants successfully) and trying to build relationships with clinical staff working within community mental health teams.

Status: Published

10.7 Chapter 8 Qualitative Interview Paper

This study was qualitative and designed to understand the point of view of 16 patients, six mental health staff and one carer about their experiences engaging with EMPOWER in everyday life. Two overarching themes were constructed relevant for understanding end-user experiences within the EMPOWER trial: Affordances and Change Processes. Affordances described the processes underpinning how and why participants interacted with or avoided the various components of the intervention. Affordances spanned all EMPOWER components, including self-monitoring, peer support workers, clinical triaging, self-management messages and diary function. The affordances were Access to Social Connection, Access to Digital, Access to Mental Health Support, the Ability to Gauge Mental Health and Access to Mental Health Information. The affordances framework helped explain the multitude of engagement trajectories featured within the qualitative interviews. If participants sustained usage, affordances acted as a springboard for change processes, including increased self-confidence that patients could self-manage, noticing patterns and changes, and using EMPOWER as a conversation starter. Taken together, EMPOWER implementation was best understood as a process of affordances which sparked engagement and then change processes. Affordances describe the impact intervention properties (either real or assumed) have upon end users because they present possibilities that may result in engagement. It is also of note that participants appeared to self-terminate engagement when they felt that the intervention was no longer of value.

10.8 Chapter 9 Network Analysis Paper

This study was quantitative, and part of the process evaluation based on the MRC process evaluation guidelines. Twenty-five EMPOWER participants inputted enough data to complete a temporal network analysis. The code used to analyse the data is freely available on the Open Science Framework and the analysis was explicitly pre-registered as being exploratory in the pre-published process evaluation protocol. The 25 participants whose data formed part of the analysis did not significantly differ from the 17 who did not input enough data in terms of gender, duration of contact with mental health services, depression, psychotic symptoms, or fear of relapse.

Fear of relapse demonstrated positive temporal relationships with anxiety and sleep change. Moreover, fear of relapse showed contemporaneous relationships with anxiety, sleep change and low mood. While this study is exploratory, it provides evidence that fear of relapse has a small but negative impact on daily mental health. While participants' self-confidence predicted lower levels of anxiety and low mood on the next day, this did not predict lower levels of fear of relapse.

11 Chapter 11 Contributions of Findings to Overall Aims

This thesis concludes by considering the findings of the empirical studies to make recommendations for refinement of intervention theory and implementation in a full-scale trial with a revised logic model, and finally, the EMPOWER intervention itself (in the form of a SWOT analysis). The findings from this thesis also contribute to generalizable knowledge by sharing methodological lessons learned from conducting this work. Additionally, the process evaluation data is reported in line with the MRC process evaluation framework (Moore *et al.*, 2015) terminology to maximise the utility of the work conducted in this thesis to researchers in the future who will conduct literature reviews. Each section will now be discussed in turn.

11.1.1 Recommendations for refinement of intervention theory

Complex interventions such as EMPOWER are often underpinned by an assumption of how problems are sustained ("intervention theory" (Skivington *et al.*, 2021) and form an essential part of understanding how an intervention works. One key aspect of intervention theory is developing a detailed understanding of the problem of interest. Despite arguably being described in 1814 as "fear of impending insanity" (Hill, 1814) a recent systematic review (Zukowska *et al.*, 2022) found that only nine papers have explicitly researched fear of relapse as a phenomenon in schizophrenia. The existing cognitive interpersonal model of EWS which underpinned EMPOWER describes fear of relapse as a driver of feelings of anxiety which is triggered by traumatic memories of past psychotic experiences (both from psychosis and iatrogenic harm caused by medical intervention) (Gumley *et al.*, 2020). Cross-sectional research suggests that fear of relapse is associated with depression and anxiety, but as covered in section 1.5 there is limited knowledge on whether fear of relapse does trigger anxiety as is assumed due to a lack of longitudinal research methods application. Additionally, using temporal methods afforded another opportunity to extend the theory by exploring if several candidate mechanisms predicted fear of relapse. This research aim is particularly relevant because EMPOWER was a feasibility study, and there was limited evidence available on temporal patterns of fear of relapse. The assumption that fear of relapse would be temporally associated with later experiences of anxiety was supported by the findings from Chapter 9 which supports the existing intervention theory. Fear of relapse predicted experiencing more fear of relapse, anxiety, and depression the next day – even when controlling for protective factors such as feeling supported and connected to others. However, none of the candidate mechanisms (sleep change, low mood, paranoia, or voices), which are all common EWS, predicted experiencing fear of relapse. Nevertheless, experiencing fear of relapse did indicate more fear of relapse, which suggests it maintains itself over time which is also in line with the underlying programme theory. These findings expand knowledge about fear of relapse by providing a temporal perspective and controlling for positive experiences.

However, there is room for further refinement and information from Chapter 9 and Chapter 8 informs this recommendation. The study in Chapter 9 did not consider the role of triggers (such as an upcoming appointment) which may prime participants to experience fear of relapse. Additionally, the role of mental health professionals has not been considered. Going forward, exploring triggers and safety behaviours with an approach using causal manipulations may allow an understanding of the mechanisms of change and improve theoretical knowledge. While this is a significant limitation, the study nonetheless enhanced the understanding of intervention theory by using a temporal method. Additionally, from Chapter 8 patients displayed a range of different personal meanings about what fear of relapse meant for them which suggests more research is needed to map out the concept further. To summarise, this thesis expands upon knowledge of fear of relapse as a problem of interest in schizophrenia both conceptually (how it should be measured) and in a limited way expands upon knowledge of how it impacts upon the daily lives of people diagnosed with schizophrenia. Chapter 3 suggests that intervention theories are often poorly reported which means a theory based comprehensive evaluation of a problem of interest within a clinical trial is likely to be novel.

11.2 Improving the understanding of implementation in a potential future full-scale trial with a revised logic model

Prior to conducting the process evaluation, a logic model (Figure 10) was developed to highlight the anticipated mechanisms of the implementation process. The final core aim of this thesis was to refine the existing logic model and create a new one which can be used to anticipate the mechanisms of implementation in a potential full-scale clinical trial. The revised logic model can be seen in Figure 18 and was developed using data from Chapter 6.

The logic model will be discussed using the following key terminology from the MRC process evaluation guidelines:

- Reach: The extent to which the intervention reached the target audience.
- Fidelity: The extent to which the EMPOWER intervention was delivered as intended.
- Exposure: The extent to which participants received and understood the different elements of the intervention.
- Mechanisms of impact: The intermediate mechanisms through which an intervention creates an impact.
- Context: Factors external to the intervention that appear to have influenced its implementation or whether its impact mechanisms acted as intended.

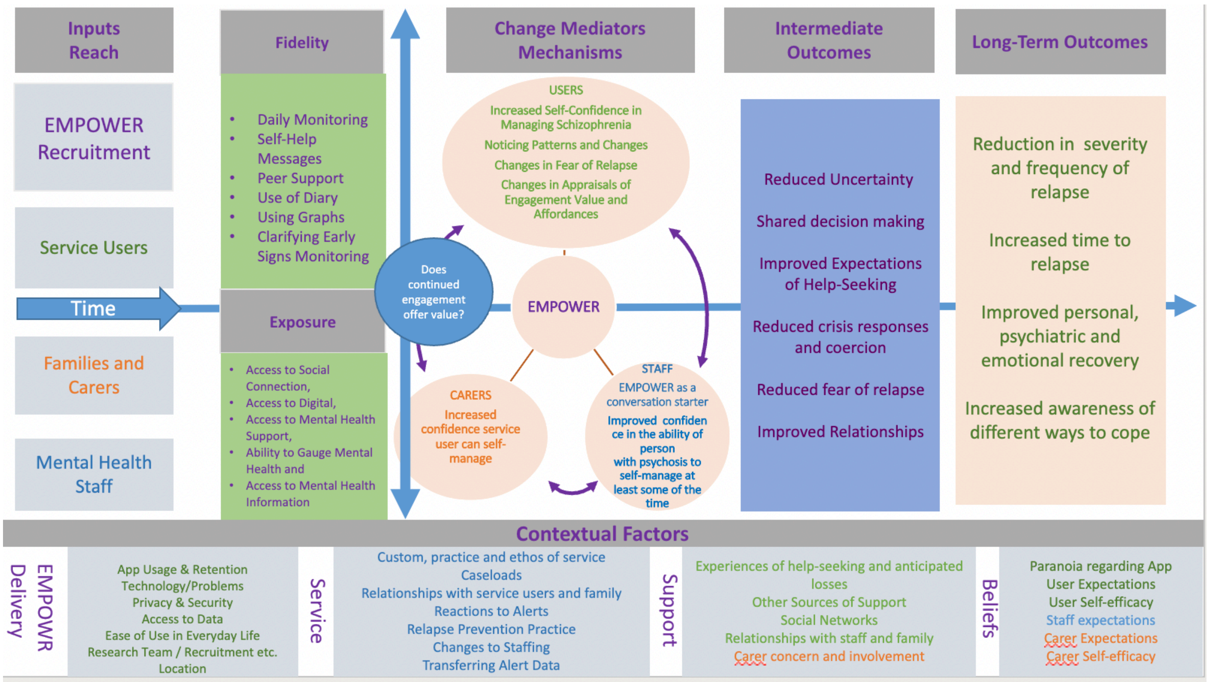


Figure 18 Revised Logic Model

11.2.1.1 Reach

Recruitment to EMPOWER was a key data source for understanding reach. One key aspect of the recruitment paper was that the patient participants who took part in EMPOWER are likely to be a biased sample. For example, Chapter 7 suggested that mental health staff acted as a filter for patients who took part in the trial due to staff expectations, such as assuming patients on their caseload may be too unwell to take part or could not cope using a smartphone. Additionally, Chapter 7 suggested systemic issues such as mental health staff not having enough time to support clinical research also acted as a block to patient recruitment. In addition, there was high staff turnover, which made it difficult for trial staff to establish working relationships with staff to facilitate referrals. Finally, there were some site-specific differences between Glasgow and Melbourne. For instance, Australian patients are often only with a community mental health team during the acute phase of their psychosis, and they are then typically discharged to a GP which meant the possible recruitment window for welcoming these patients into the trial was quite small compared to Glasgow where people diagnosed with schizophrenia are typically kept under the care of a community mental health team for more extended periods. To summarise, the findings from the thesis suggest the characteristics of the patients who took part in EMPOWER may not be truly representative of those who experienced a relapse within the past two years. Unfortunately EMPOWER is not unique and concerns about the representativeness of clinical samples are common in the literature. For example, a recent analysis of 25, 259 people diagnosed with schizophrenia in Finland and Sweden found that around four in five patients would not be eligible to take part in clinical research, and those excluded had a higher chance of being hospitalised for psychosis (Taipale *et al.*, 2022).

11.2.1.2 Fidelity

One key change to the revised logic model is that mental health staff are no longer assumed to regularly look at and use patient data within their clinical decision-making regarding early warning signs detection and managing relapse risk. This has important implications for the underlying programme theory because the EMPOWER trial was a cluster randomised control design due to the assumption that mental health staff would use patient data within their clinical workflows and the mechanism of change would be at the level of the custom and practise of the community mental health team. However, the tradition and practice of the community mental health team for managing relapse did not appear to be influenced by EMPOWER at all, with staff instead trusting that the patients on their caseload could get on with self-managing and staff could then take over in the face of any actual or perceived risk. Another change to the logic model, which was not predicted in advance, was that the mental health staff would use the fact that they knew the participant was self-monitoring and taking part in the EMPOWER study to open general conversations about mental health. This was in contrast with the assumption in the *a priori* logic model which assumed mental health staff would explicitly use the data generated from patient self-monitoring within their clinical workflows. Going forward, having EMPOWER be used to open conversations could be considered part of the logic model in addition to key intervention components such as usage of the diary and daily self-monitoring.

11.2.1.3 Exposure

Exposure assessed the extent to which participants made sense of various intervention components. Considering EMPOWER overall, exposure appeared best understood through a framework of affordances and a summary is given because these have been used to adapt the logic model. Affordances describe the interactions between a designer's intentions for how an intervention should be used and an end user's perception (defined further in Chapter 8). However, because there is debate on how affordances should be best described, Evans and colleagues (Evans *et al.*, 2017) provide a list of appropriate boundary conditions (Scheel et al., 2021) - where researchers are clear about the conditions where a phenomenon such as affordances are expected to hold. These are:

1. The affordance is neither the object (EMPOWER component) nor a feature of the object
2. The proposed affordance is not an outcome but an interactional process
3. The proposed affordance has variability; in other words, different people will experience EMPOWER in different ways.

In the context of EMPOWER exposure, from speaking with end users, it appeared the intervention afforded the following things for patients that were in line with the Evans criteria:

11.2.1.4 Access to Social Connection

Many patient participants positively reflected upon their perception that EMPOWER afforded them access and the opportunity to have social connections with other people. This was typically expressed when discussing interactions with the peer support workers on the trial. However, some participants reported feeling that the self-monitoring questions alone made them feel someone cared about how they were doing and inspired connection. These findings are in line with a review of affordances offered by digital interventions (Wong *et al.*, 2020) and support that the exposure section of the logic model should include a specific focus on social connection.

11.2.1.5 Access to Digital

For patient participants who did not already have a smartphone and were supplied with one to facilitate trial engagement, it was clear that EMPOWER was perceived as affording access to the digital world, which made a real impact on their lives. Participants shared how they now had access to search engines such as Google, could text friends and could check when local shops were open. Digital inequality has several aspects (Deursen et al., 2019), including a lack of actual access to technology but also a lack of skills in how to use digital tools such as smartphones. The findings derived from the interviews suggest participants received and understood EMPOWER as an opportunity to develop digital skills, which went beyond simply having access to a smartphone but the chance to master its use and in line with the affordance framework for this to be utilised in divergent ways across participants.

11.2.1.6 Access to Additional Mental Health Support

EMPOWER clinical triage meant that if a change in a participant’s data suggested possible relapse, a clinical member of the EMPOWER team would check in with them. In practice, this meant that patients had access to clinicians beyond the scope of their standard mental health care. When considering implementation, this could be a crucial engagement facilitator for patients because it meant participants could access timely support. However, this seemed to depend on how helpful patients perceived mental health support to be, and there were cases where patient participants were ambivalent or negative about this aspect of the intervention, which is in line with affordances.

11.2.1.7 Access to Mental Health Information

EMPOWER was seen as a source of potentially helpful mental health information; this could come from either accessing the self-management messages or conversations with peer support workers who shared information. Cognitive affordances describe using interventions to expand one’s learning (Moreno & D’Angelo, 2019), and in this case, cognitive affordances appeared to be a particular strength of the EMPOWER intervention because it exposed patient participants to information that they often did not know already such as availability of local services or self-management advice.

11.2.1.8 Ability to Gauge Mental Health

Beyond providing access to mental health support, the EMPOWER intervention afforded a means to gauge mental health in a more general way through components such as the charts and the diary. Additionally, patient participants even used the intervention in ways that were not envisioned by the developers, such as using the fact a branch question had appeared as an indicator of change without them ever looking at the charts. Peer support workers and other trial staff had were key in assisting patient participants to make sense of their self-monitoring data when it was presented in chart form. This finding is in line with a review of digital interventions' affordances, which highlighted that digital interventions can influence how end users make sense of their health (Wong *et al.*, 2020).

11.2.1.9 Mechanisms of impact

The relationship between affordances and engagement appeared to be reciprocal. To continue using EMPOWER and start a change process, participants first had to perceive that the intervention did afford them something worthwhile. If participants did engage, results from the qualitative analysis suggest EMPOWER created impact by the following processes:

11.2.1.10 Noticing Patterns and Changes

Suppose EMPOWER allowed gauging mental health through self-monitoring, diary keeping and conversations with peer support workers. In that case, this could start a change process of patients noticing patterns in their own wellbeing. Participants made explicit links between the intervention and detecting patterns and those changes in their own wellbeing. Some participants appeared to have utilised the intervention to increase awareness about dynamic changes within their own mental health and sometimes reached profound realisations. This growing awareness and reflective capacity are sometimes referred to as metacognition. Metacognition is broadly defined as thinking about thinking (Zohar and Barzilai, 2013) and, in particular, metacognitive knowledge (Cotterall & Murray, 2009), which describes the knowledge base that people draw upon as they make decisions about what to do with what they have learned may present a useful theory of change for understanding this observation. EMPOWER did not measure metacognitive change, so it is important to be cautious when theorising about the meaning of this observation; nonetheless, for patient participants, it appeared that looking at the charts either on their own or with support from someone like a peer support worker or a family member was the knowledge base that they drew upon. From observation, this may have been helpful in increasing self-awareness and reflective ability.

11.2.1.11 Changes in Fear of Relapse

The EMPOWER programme theory was underpinned by the cognitive interpersonal model of relapse, and it was assumed that patients using the intervention would experience reduced fear of relapse. This was considered because patient emotional awareness would be enhanced via self-monitoring and mental health staff being aware of how a patient was doing (via data sharing) would change negative interpersonal cycles. However, even with mental health staff not typically using patient self-monitoring data in their workflows, it did seem that patients were less worried about relapse. However, there were cases where patients reported worrying about relapse more because they felt they had more to lose because they were at a more advanced stage of recovery – a concern noticed in other qualitative work exploring fear of relapse in patients diagnosed with schizophrenia (Baker, 1995).

11.2.1.12 Increased Patient Confidence that Patients could demonstrate self-management abilities

From Study 6, it was clear some participants appeared to have developed confidence that they could better manage their condition through their experiences of using EMPOWER and that this sense of self-efficacy seemed to increase over time. This was evidenced by references to confidence in their ability to manage their mental health – in line with Bandura's conceptualisation of the concept (Bandura, 1977), referring to patients believing that they could face the challenges of self-managing their mental health.

11.2.1.13 Appraising Engagement Value

When speaking with patient participants, it seemed that sustained engagement was underpinned by whether the participant perceived value in doing so. Sensing a positive value of EMPOWER as a self-management tool was an implementation facilitator, whereas no longer perceiving a positive value or never having perceived a positive value acted as an implementation barrier. Taken further, this suggests an engagement with EMPOWER is best understood as an interactional process determined by participants balancing the importance of continuing to engage with EMPOWER or whether the intervention was no longer helpful. For some participants, choosing to disengage with EMPOWER was a sign they felt that they were now doing well, and the intervention was no longer required.

11.2.1.14 Using EMPOWER as a Conversation Starter

A key change process for mental health staff was EMPOWER functioning as a conversation starter. The main trial findings demonstrated that data sharing between patients and mental health staff was not routine. A fundamental change process was that staff used the participant's participation in the EMPOWER study and self-monitoring their mental health to open conversations about wellbeing-rather than looking at charts. It appears that EMPOWER being a conversation stater was a functional affordance (Hartson, 2003) which describes when interventions assist staff to do their usual role, in this case, having conversations with patients about their wellbeing.

11.2.1.15 Increased Staff Self-Confidence that Patients could Self-manage at least some of the time

The staff used EMPOWER participation as an opportunity to open conversations about patients' mental health status. However, from the six staff interviews, it also appeared that staff had developed confidence that patients could self-manage to a degree. This change process is exemplified by members of the community mental health team reflecting their trust in the patient engaging with EMPOWER had engendered staff confidence in patients' ability to self-manage. Other efficacy (Morrison and Lent, 2018) in contrast to self-efficacy, is dyadic and refers to how different relationship partners appraise the efficacy of an other partner in a relationship. From the staff interviews, it appears staff had increased other-efficacy for patients' ability to self-manage their mental health up to but not including the point of crisis and relapse when staff felt they needed to take over.

11.2.2 Context

The systematic review (Chapter 3) highlighted that contextual factors could significantly impact the implementation of user-led interventions, such as technical problems, meaning participants could not access intervention components. Unsurprisingly, this common finding was reflected in this thesis with the qualitative interviews conducted in Chapter 8 demonstrated that technical problems such as mobile phone having a short battery life created barriers to patient engagement. Further contextual factors impacted upon implementation. For example, participants in employment reported that self-monitoring personal mental health data did not feel appropriate at work. Contextual factors influenced engagement beyond the individual level, for example Chapter 5 highlighted that the current management of EWS-based relapse prevention was a complex social practice underpinned by local health policies and norms that would likely influence and be influenced by EMPOWER.

There was an assumption that EMPOWER would challenge current clinical practice because staff would use the data from patient self-monitoring within their clinical workflows. However, staff did not use data in this way but EMPOWER was nonetheless well implemented. The theme of *Increased Patient Confidence that Patients could demonstrate self-management abilities* appeared to explain this unforeseen process because EMPOWER was not seen by mental health staff as a challenge to traditional practice because they could observe that patients on their caseload were self-monitoring and engaging in the intervention without using the data within clinical workflows. This social practice account is in line with recent intervention conceptualities, which invite us to think of implementation as adding a complex intervention into a complex system in an attempt to invoke system change in that complex system (Moore and Evans, 2017). Within this conceptualisation, the intervention and the complex system affect each other in potentially subtle and nonlinear ways, with changes potentially reverberating throughout the system. Taken together, it is fair to say EMPOWER was acceptable within the context of EWS management because it did not challenge current practice. While conducted in the confines of a clinical trial, these findings contribute to knowledge about the successful uptake of psychosocial interventions for psychosis within routine clinical practice.

11.2.3 Summary

This chapter presents a framework of empirically grounded factors that influenced the implementation of EMPOWER within a feasibility cRCT and what will likely be relevant to include when trying to understand implementation within a full-scale trial. The findings from Chapter 8 discussed here under “Exposure” and “Change Mechanisms” are similar to implementation constructs from normalisation process theory (NPT) which is a theoretical framework often used to understand the experiences of implementing interventions for chronic illness (Huddlestone *et al.*, 2020). The affordances framework proposed appears to encompass several NPT constructs including coherence, cognitive participation and reflexive monitoring but employing Occam’s razor suggests affordances is a good theoretical explanation for coherence, cognitive participation, and reflexive monitoring. As implementation science has traditionally focused on staff, there has been a lack of focus on implementation processes that occur when patients implement interventions, which this thesis highlights. For example, coherence within NPT describes the sense making work that potential implementers do when introduced to a new intervention (May *et al.*, 2018). From the identified themes, it appeared that patients were the primary implementers because they found ways the intervention made sense to them, leading to initial engagement. Mental health staff could then use the fact that a patient was using EMPOWER to open up conversations about wellbeing, but this was only possible because of the primary implementation work conducted by patients. As covered in Chapter 3, mental health staff foreground their knowledge about an individual patient when making clinical decisions, so it makes sense that their implementation behaviours focus around using EMPOWER as an adjunct for what they already do. Overall, these findings contribute to knowledge and open up the “black box” about what processes underpin implementation of user-led digital interventions from the perspectives of patients, staff, and a single carer. Additionally, by collecting improvement suggestions this thesis suggests ways in which implementation may be enhanced in future research by creating a more positive user experience which is a key driver of sustained engagement with digital interventions (Alqahtani and Orji, 2020).

11.3 Refining the EMPOWER intervention itself (in the form of a SWOT)

The final aim of this thesis was to suggest adaptations for EMPOWER based on findings from the empirical studies. A strengths, weaknesses, opportunities and threats (SWOT) analysis was chosen because this approach helps present a general picture of a specific area (Fernández-Alvarez *et al.*, 2019). The SWOT analysis consolidates EMPOWER (internal) and environmental (external) research in a SWOT matrix, acknowledging that an intervention cannot operate in isolation but is constantly interacting with a changing environment. The SWOT matrix is the basis for prioritising fields of action and deriving strategies for improving EMPOWER in a full-scale trial. With EMPOWER being a feasibility study and feasibility studies being critical for suggesting intervention and evaluation refinement, a SWOT analysis using empirical data across all process evaluation studies is now presented.

11.4 Strengths

11.4.1 EMPOWER was Flexible and Afforded Multiple Opportunities for Patient Participants

EMPOWER was a flexible intervention, and the process of patient-user engagement was best understood through a process of affordances. This was a strength of the intervention, as it meant that participants could engage with and be helped by the intervention for various reasons. For example, socially isolated participants were afforded access to human connection. Furthermore, intervention affordances appeared to be emergent and hard to predict in advance. For instance, while there was an assumption by the intervention developers that participants would use the charts generated by the app to understand their own personal ebb and flow – there were cases where participants used a combination of their own memory for previous responses and whether the app asked them “branch questions” which indicated a more extreme score than usual, to show there had been a change. There were also cases where a patient participant opted to only engage with peer support, not the app, and only use the app and not engage in peer support. Future intervention development should focus on ensuring the intervention remains flexible.

11.5 Weaknesses

11.5.1 Intervention is Not Currently Tailored Enough for Patients’ Symptoms and Experiences

One weakness is that EMPOWER was not tailored to divergent participant needs. For example, participants who did not hear voices were asked to self-report voice-hearing experiences daily via the daily self-monitoring questions. Additionally, patient participants who did not listen to voices were sent wellbeing messages about coping with voices that were not relevant to them. Estimates suggest voice-hearing rates are around 40-80% in people diagnosed with schizophrenia (Larøi *et al.*, 2012) which, while common, are not universal. Therefore, before patients are set up, it seems worthwhile assessing what early warning signs they are likely to exhibit in advance because participants reported it was demotivating to constantly get material not relevant to them. This is in line with wider recommendations for researchers and clinicians measure and assess a wider variety of psychosis experiences and not to assume everyone will experience similar phenomena (Pagdon and Jones, 2022). Beyond initial assessment, this recommendation also asks that the app be adapted to provide more tailored content.

11.6 Opportunities

11.6.1 EMPOWER does not challenge standard EWS monitoring.

Study 3 suggested that current early warning signs-based relapse prevention management is complex and is driven by weighted decision-making. This weighted decision-making makes clear there are intensive social-cultural underpinnings to relapse management, particularly for staff with role-related expectations. While the process can be flexible and incorporate various information, it can become very rigid in the face of perceived risk. From staff interviews in Study 6, EMPOWER appeared to be accepted by mental health staff because it was seen as an optional extra for patients, where staff could intervene if there were an actual risk. This suggests EMPOWER may be implementable and functions almost like the lower levels of stepped care pathway for relapse prevention.

11.7 Threats

11.7.1 Patients are likely to be an unrepresentative sample due to systemic issues with trial recruitment

Study 5 suggested that the patient participants who took part are likely to be filtered by artefacts from the recruitment process and are unlikely to be genuinely representative of the people specific in EMPOWER's patient inclusion criteria. A definitive RCT would be enhanced by incorporating an individual RCT design, reducing the pressure to recruit and randomise a cluster around the same time, which is what happened in the cRCT. This is a key threat because it is hard to predict what recruitment might be like for a definitive trial. Nonetheless, Study 5 suggested ways to mitigate the threats, such as by focusing on supporting research assistants as they do trial work. Implementation research may help researchers understand interventions work for particular subgroups (Michie and Johnston, 2017) but this will only be possible if trial samples are representative and reach the true diversity of the population of interest. The findings here reflect wider concerns about sample representativeness in schizophrenia research where it appears around 80% of patients would unlikely be eligible for relapse prevention trials and those who are ineligible are at higher risk of hospitalisation (Taipale *et al.*, 2022). More generally, there are concerns that clinical trials are not inclusive of ethnic minorities (Morris *et al.*, 2022) which limits the generalisability of clinical findings in addition to being unethical. In the Glasgow site, 23% of people randomised to receive EMPOWER were of a non-white ethnic background compared to 21.4% of people who live in Glasgow overall (UK Population Data, 2022). Going forward, future research should aim for a broad intersectional approach to trial recruitment which ensures participants are representative in terms of ethnicity, gender and characteristics relevant to schizophrenia research such as experiences of the forensic system (Pedersen *et al.*, 2021) or digital exclusion which common in the lives of people living with schizophrenia (Greer *et al.*, 2019). Furthermore, digital exclusion can be complex. For example, someone who only access digital services on a mobile phone may have a poorer experience than someone who accesses digital services on a computer (Robinson, Schulz, Dunn, *et al.*, 2020) and people may lack confidence in how to use technology. Digital inequality might be mitigated by providing digital devices and training like what already happened in the feasibility study.

11.8 Overall Interpretation of Findings from Section 11.

As highlighted in section 1.3.8, conducting implementation research is challenging, and researchers are faced with a large variety of possible frameworks upon which to base their research. To make working with this complexity more manageable, the MRC process evaluation guidelines (Moore *et al.*, 2015) recommend implementation researchers should not try to reinvent the wheel and check whether previous interventions with similar theoretical underpinnings have implementation research which could be built upon. However, the systematic review conducted in Chapter 3 suggested that no other interventions were based upon the cognitive interpersonal model of relapse prevention, which justified the development of a novel implementation framework. From the synthesis above, creating an *a priori* logic model to identify key knowledge gaps prior to conducting a process evaluation and then later refining the logic model with empirical data from studies designed to address those gaps resulted in an understanding of the implementation that is relevant for patients, mental health staff, carers as well as researchers. Taken together, this suggests people evaluate intervention evidence in terms of what it affords them. Developing a process evaluation framework (presented as a logic model) grounded in stakeholder expertise in advance of feasibility testing and then refining this following actual implementation with a particular focus on gathering end-user perspectives from qualitative interviews was key in mapping out the affordances framework, which was not anticipated within advance but appeared theoretically relevant.

Affordances appear a useful framework for understanding successful implementation process within the EMPOWER study because they focus on the outcome of the relationship between EMPOWER and its end users. Affordances can also help explain barriers to implementation because this framework forces us to go deeper and think about perceived potentials for action. For example, during the qualitative interviews, a participant who did not use the diary function said they did not do so because recording their daily experiences in a diary did not make sense to them because they realised, they would not get a response from mental health services regardless of the content of what they recorded. Their personal goal was to have mental health staff be aware of their mental state, and because of this, they engaged strongly with the self-monitoring function, which did afford them this. Affordances also appear relevant to understanding the implementation of other interventions like EMPOWER, which will now be discussed.

From the taxonomy developed in Chapter 3, it was possible to then look at qualitative work designed to understand interventions which were like EMPOWER in terms of aims (self-management) but also which had similar intervention interactions, particularly open-ended interactions with facilitators and also the opportunity to access new information such as the FOCUS (Jonathan *et al.*, 2019) and HORYZONS (Valentine *et al.*, 2020) interventions. Both qualitative papers appeared to describe emergent affordances. The FOCUS qualitative study (Jonathan *et al.*, 2019), in particular, reported that patient participants FOCUS afforded them extra support that was not typically available in standard psychosis care, which was similar to the perspectives of EMPOWER patient participants. The findings from Chapter 8 are novel because they suggest affording additional support not typically available within mental health care was also important for mental health staff. For example, by making it possible for participants to self-monitor in a supported way, EMPOWER invited mental health staff to “back off” and afford patients increased autonomy. Additionally, EMPOWER offered patients a chance to engage with a wider range of recovery opportunities (from messages and interactions with peer support workers) which seemed to be an implementation facilitator because staff generally supported this because it was linked with their supportive role as clinicians and did not take up staff time.

EMPOWER was well implemented, as evidenced by the main paper findings showing that 71% of randomised participants met the *a priori* adherence criterion (Gumley *et al.*, 2022), and this seems explained by it is likely seen as an acceptable intervention by staff because it did not challenge their own clinical practice. This is a key finding because previously, crisis planning interventions which have attempted to change how staff respond have failed to be implemented (Thornicroft *et al.*, 2013) because, during crises, staff resorted to “custom and practice” (Farrelly *et al.*, 2016) in the face of increased clinical risk. While EMPOWER was designed to influence staff behaviour, this did not happen because the staff took a more hands-off approach and left patients to just get on with using it themselves, as described in the proposed change mechanism: “Increased Staff Self-Confidence that Patients could Self-manage at least some of the time”. A large review of why digital interventions fail to be implemented highlighted that staff resisting the *policy* reflected within the intervention (such as changing key aspects of the staff role) is a common reason for staff rejection and implementation failure (Greenhalgh *et al.*, 2017). EMPOWER seems to have succeeded in being well implemented at the patient level because it failed to influence staff behaviour and did not recreate a common implementation barrier. However, the findings from Chapter 5 suggested trial staff may have filtered outpatients who they considered too “at risk” to even take part in the first place, which suggested staff resisted the intervention implementation to a degree because they had concerns about patient safety.

The findings from the main trial suggest the intervention is likely to be safe, with no significant differences between the control and treatment groups in terms of adverse events (Gumley *et al.*, 2022). However, as interventions like EMPOWER are used by patients in their homes it may be the case that adverse events might be missed. As covered in the Chapter 1, the perspectives of people diagnosed with schizophrenia are considered to be low quality evidence and at high risk of bias. It is likely the case they are victims of epistemic injustice which describes discrimination against marginalized people as “knowers” and comprises two facets which are relevant to the consideration of adverse events: testimonial injustice, where patients’ descriptions of an intervention causing distress is dismissed, and hermeneutical injustice where patients are not able to contribute to deciding how best to define an adverse event in this space (Fricker, 2007). Going forward, a future RCT evaluation of EMPOWER would be enhanced by focusing more on adverse events from the patient perspective and trial staff should be aware of both the potential for interventions to cause harm and the importance of not dismissing patient perspectives.

11.9 Strengths and Limitations

This thesis presents a comprehensive process evaluation of the EMPOWER intervention, which was appropriately designed to address key uncertainties of a feasibility study which included a validity check of underlying theoretical assumptions about the underlying intervention theory using relevant time series methods. The process evaluation studies were based on a pre-published protocol which is in line with good practice in the field (Greenwell *et al.*, 2016). In addition to describing and explaining intervention-specific processes for how end users implemented EMPOWER, the findings also contribute to generalisable knowledge about how patients with schizophrenia engage with digital interventions available to them for up to a year. Most importantly, the thesis has foregrounded end-user experiences and positioned them as essential for understanding implementation in ways the main RCT could not. The affordances within the revised process evaluation align with key credibility criteria for determining affordances (Evans *et al.*, 2017) and fits in line with a range of concepts from commonly used implementation theories while being parsimonious. Additionally, this thesis adhered to “open science” principles (Bell, 2017) by sharing the R code used to analyse the data for Chapter 9 on the Open Science Framework and the interview schedules for Chapter 8 in a pre-published protocol. The typology developed in

Chapter 3 was also based on a pre-published protocol and enabled meaningful comparisons to be made with interventions like EMPOWER which suggested affordances may be helpful for understanding implementation of user-led interventions more broadly.

However, there were substantial limitations. The individual study limitations are described within their respective papers, but there are further limitations to discuss here. The typology developed in the systematic review was based on systematic searches conducted in 2021. While the typology was developed to classify future research, it may be the case that it requires updating. The recruitment study was inclusive of the control group, but by not focusing on the experiences of people randomised to treatment as usual beyond Study 5, this has minimised knowledge of experiences of trial participants overall and has prioritised discovery about what using the intervention was like more than trial procedures. The patient participants interviewed were comparable in age, gender, duration of contact with mental health services and trial site (Scotland or Australia). However, while patients did not differ in positive symptoms, those interviewed had significantly fewer negative symptoms. This raises a concern that the individual qualitative interview may not have been a suitable method for data collection and may even have been ableist as it was potentially not inclusive of different communication styles (Denham and Onwuegbuzie, 2013). One further major limitation is that this thesis represents a small instrumental approach to understanding the implementation of user-led interventions for psychosis by focusing on a single feasibility trial as a case study and all studies were exploratory. Future research would be enhanced by building upon the findings of this thesis and being more targeted and hypothesis driven. Additionally, affordances may have their limitations as an implementation construct. Drawing on the work of Maar and colleagues (Maar *et al.*, 2017), in future studies, it would be important to differentiate implementation innovation (new ways people use an intervention that is goal orientated towards the intervention) from drift (new ways people used an intervention that demonstrates low fidelity).

One final overarching limitation of this PhD is the speed of digital health innovation that occurred during its conduct which means the range of interventions described as user-led might be considered somewhat dated. For example, virtual reality interventions which were traditionally not considered to be user-led interventions (under the definition used in this thesis) are now increasingly being designed as user-led interventions (Geraets *et al.*, 2021). A recent economic analysis of the gameChange (Freeman *et al.*, 2022) RCT found that because virtual reality equipment is becoming cheaper and easier to use, it would be feasible to provide patients with a device to use at home to access interventions without the need for in-person staff support during its use (Altunkaya *et al.*, 2022). Future research would be enhanced by interrogating user-led virtual reality via process evaluation which considers patients to be key implementation agents in addition to mental health staff.

11.10 Implications of Thesis

11.10.1 Future Research

Future research would be enhanced by addressing the limitations stated above. Additionally, the results and limitations of this thesis suggest the following avenues for research:

The perspectives of people who did not engage or dropped out early would be informative and valuable. The data in this thesis suffers from likely “inverse aware law” as we know more about the experiences of people who were able to engage and less from people who did not. Of particular concern is that the group of participants I spoke to seemed to be a separate population with lower negative symptoms – with a large effect size as measured with PANSS negative subscale (Leucht *et al.*, 2005). This warrants comment because the group of participants whose engagement with the app was high enough to contribute to the network analysis did not significantly differ in terms of negative symptoms, which suggests negative symptoms were relevant for giving feedback via qualitative interview but not necessarily for intervention engagement. It may be the case that qualitative interviews may even be considered ableist because it prioritises people who can take part in qualitative interviews. Future research would be greatly enhanced by using observational methods early on during app usage and allowing user feedback to be gathered in the app nonverbally. People diagnosed with schizophrenia are likely to have difficulties with reading and writing (Vanova *et al.*, 2021). Therefore, assessment options such as emoji-based rating scales may be useful here to supplement the assessment of user experience beyond what is measured in the User Version of the Mobile Application Rating Scale (uMARS) (Stoyanov *et al.*, 2016) and it would be most beneficial to include a patient public involvement (PPI) group to ensure measurement is appropriate for the target population.

The main trial outcome suggests people randomised to receive EMPOWER showed reduced relapse rates. If this finding is replicated in a fully powered RCT, it would be important for future process evaluations to explore whether there are moderators or mediators of this effect – in line with MRC process evaluation recommendations (Moore *et al.*, 2015). From the qualitative assessment, the intervention appeared to create an impact by increasing a sense of self-efficacy. This may be measured through the use of The Self-Efficacy for Personal Recovery Scale (Villagonzalo *et al.*, 2018) and including score changes within the model. PPI work would enhance research to develop the assessment schedule to ensure it is not burdensome to participants, ensuring the psychometric scale is delivered accessibly and pre-registering hypothesis. Additionally, this would be especially enhanced if the next trial included an active control because this can help exclude the symptom-reducing effect of self-monitoring psychosis symptoms noted in other psychosis studies (Hanssen *et al.*, 2020).

Developing a quantitative assessment of affordances would be useful to understand what underpins implementation behaviours of user-led interventions. For example, a Cognitive Affordances of Technologies Scale (CATS) (Dabbagh and Susan, 2013) has been developed to identify what teaching and learning attributes a digital technology might afford. It may provide a basis for a similar tool to assess what affordances might be present for user-led interventions. Currently, people with schizophrenia are characterised as having deficits in the ability to perceive affordances (Kim and Kim, 2017), which is not in line with the impression from the qualitative interviews where affordances seemed prominent. Additionally, affordances were also experienced by staff and carers who said EMPOWER afforded them a chance to be a bit more ‘hands-off and to use the fact a patient was using the intervention as a conversation starter.

11.10.2 Implications for Practice

This thesis addressed a gap in the literature by creating a process evaluation which foregrounded end user perspectives in psychosis. This thesis generated internally valid process evaluation data which will be useful for future iterations of intervention development. However, the results from this thesis also have external implications for the development of psychological therapies, general intervention development and process evaluation methodology which are discussed in the next section.

11.10.3 Psychological Therapies

While user-led interventions offer an important alternative to traditional face-to-face interventions led by clinical psychologists, these interventions may offer an important adjunct to traditional high-intensity psychological therapies such as CBT for psychosis (CBTp). CBTp has not demonstrated good efficacy for relapse prevention (Morrison, 2009). However, Liu and colleagues (Liu *et al.*, 2019) noted that this might be because CBTp was not developed with relapse prevention in mind and devised a specific relapse prevention protocol with three stages: engagement and assessment, coaching patients on how to manage and identify positive symptoms and emotional problems and finally with specific relapse prevention sessions. In the relapse prevention sessions, patients learned about 1) stages of relapse; 2) EWS of relapse; 3) how to make their own list of signs of relapse; 4) how to monitor symptoms in daily life; 5) how to make emergency plans for early warning signs including grading signs, prevention strategies and plans for seeing help and coping. The intervention group demonstrated significantly lower rates of relapse (defined as worsened psychosis symptoms) compared to treatment as usual at twelve months and suggested the benefits of developing a specific relapse prevention protocol. This was possibly enhanced by increasing patient confidence that they could cope with distressing experiences – noted as a key mediator of symptom change in other CBTp studies (Schlier *et al.*, 2020). However, the approach may still be improved by incorporating patient preferences.

A patient-led Delphi study identified that patients want to make equal decisions with clinicians in what help would be best for them and also for approaches suitable for people with concentration problems and cognitive difficulties (Byrne and Morrison, 2014) when undertaking CBTp. Radical collaboration empowers clients to identify their own goals within a supportive, collaborative relationship freed from therapist demands about how a patient's therapy should progress (Chadwick, 2006). Radical collaboration is underpinned by an assumption that it is unrealistic to demand that people change and behave in predetermined ways. EMPOWER being so open-ended can enable patients to identify their own relapse prevention goals by appraising the intervention components and what they can offer them. They can also reject certain parts of the intervention if it does not afford them the means to reach their relapse prevention goals.

Additionally, the EMPOWER intervention can provide information on self-management, which may be new to patients, which democratises knowledge and may position the psychologist as less of the assumed expert. Mental health staff and the one carer interviewed appeared to use EMPOWER participation as a conversation starter to discover what the person was doing with the intervention and what they had learned from it. Blending EMPOWER and relapse prevention-focused CBTp suggests a route for working together in an empowering way for recovery-focused CBTp for clinical psychologists and may further boost the potential offered by a relapse-specific protocol. Additionally, EMPOWER may be useful for cognitive problems because it prompts patients to interact with it – further addressing patient preference for CBTp.

11.10.4 Intervention Development

The findings from this thesis strongly suggest that people diagnosed with schizophrenia can engage with digital interventions and can experience self-efficacy when doing so. Additionally, the custom and practices of typical relapse prevention management by mental health nurses suggested that contrary to expectations, mental health nurses were comfortable taking a hands-off approach when participants were relatively stable and did not expect to be routinely involved in intervention implementation. The findings from this thesis suggest that user-led interventions that have a degree of human support are likely to be optimal and will not necessarily need routine clinical support from a patient's clinical team. Interventions that require a lot of input from mental health staff tend to be poorly implemented (Aref-Adib *et al.*, 2018) so this is a key finding – especially because it emerged unexpectedly and highlights the value of process evaluations for explaining unexpected consequences within clinical trials.

A further recommendation from this thesis is that user-led interventions for psychosis should be designed with affordances in mind to maximise likely implementation. Recommending an affordance-based approach to intervention development and evaluation is in line with recommendations that complex interventions should be standardised by form rather than content (Hawe, Shiell and Riley, 2004). For instance, in the case of EMPOWER, when standardised by form, increased access to information may look like "informational content delivered from messages", but when standardised by function, this could look like "if a participant expresses a need-to-know information, the information can be provided by messages or peer support workers during conversation". Taking this focus invites evaluation at the level of the affordance and the interactional process between a person and the digital intervention.

Specifically for future iterations of EMPOWER, patients suggested intervention improvements such as being able to save wellbeing messages in a personal database that they could access at any time and enhanced tailoring content such as only offering wellbeing messages relevant to symptoms they experience. The reach of EMPOWER was likely constrained by recruitment barriers and sample composition within both the UK and Australia. EMPOWER was designed with the assumption that a patient would share data with their clinical team to prevent relapse at the level of CMHT clinical management, which is why the feasibility trial was designed with a cluster randomisation design. However, data sharing did not occur in this manner, and wellbeing data was not frequently shared and when it was mostly shared with staff on an *ad hoc* basis. While mental health staff did not regularly view patient self-monitoring data but instead used the fact the person was taking part in EMPOWER to open conversations about mental health, Therefore, to estimate an effect size on relapse, conducting a standard RCT with individual randomisation seems sensible. A full-scale trial would be further enhanced by including the recommendations for improvements suggested by patients.

11.10.5 Process Evaluation Methodology

The MRC process evaluation framework suggests that process evaluators should look to previous process evaluations of interventions that are based on similar theories to understand what earlier findings they can build on (Moore *et al.*, 2015). This is an important recommendation because process evaluations can be significant undertakings, so it is in the best interests of researchers to know when it is possible to replicate and expand upon each other’s work. However, developing this information requires that researchers take a curatorial approach to available research evidence – something which is rarely done and is argued to have minimised the impact of research conducted to understand the impact of the Covid-19 pandemic (Horton, 2022). Curating the available research evidence means developing effective means to organise and present information in a way which optimises the understanding and application of that information for other scientists. This PhD thesis contributes to new knowledge by providing a database of theories underpinning various user-led interventions for psychosis. However, as shown in Chapter 3 only 54 % of interventions identified could be based on an identifiable intervention theory or model which means it would be difficult for process evaluators to know what previous work they can build upon. Future research of user-led interventions of psychosis would be gratefully enhanced by reporting a clear description of the theoretical framework that underpins the intervention. This would enable process evaluators to have access to information to conduct relevant research.

11.11 Conclusions

This mixed-method process evaluation was a comprehensive assessment of the feasibility of the EMPOWER intervention, which used the MRC process evaluation guidelines as an investigation framework. The findings from this process evaluation suggest that EMPOWER is likely to be a feasible digital relapse prevention intervention that can be evaluated in a full-scale clinical trial. Regarding programme theory, experiencing fear of relapse was associated with increased anxiety, depression, sleep changes and fear of deterioration on the next day, but the observed effect sizes were small. Patients suggested intervention improvements such as saving wellbeing messages in a personal database that they could access at any time and enhanced tailoring content such as only offering wellbeing messages relevant to symptoms they experience. The reach of EMPOWER was likely constrained by recruitment barriers within both the UK and Australia. EMPOWER was designed to assume that a patient would share data with their clinical team to prevent relapse at the level of CMHT clinical management, which is why the feasibility trial was designed with a cluster randomisation design. However, data sharing did not occur in this manner, and wellbeing data were not frequently shared. When sharing with staff occurred, this was usually on an ad hoc basis. While mental health staff did not regularly view patient self-monitoring data but instead used the fact the person was taking part in EMPOWER to open conversations about mental health, Therefore, to estimate an effect size on relapse, conducting a standard RCT with individual randomisation seems sensible. A full-scale trial would be further enhanced by including the recommendations for improvements suggested by patients.

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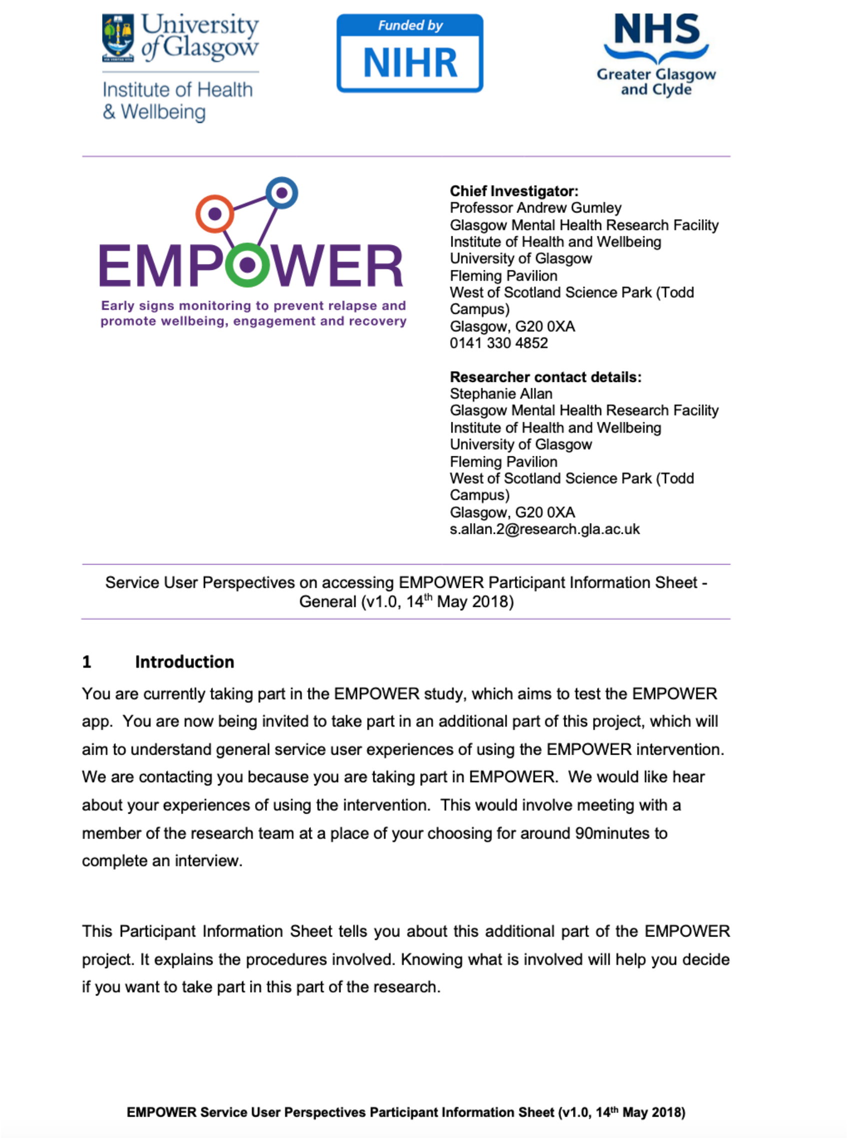
Appendices

A. Chapter 3 Supplementary Materials

Supplementary materials for the systematic review including modal reporting of the theory coding scheme, ratings for risk of bias and application of typology coding can all be seen on the Open Science Framework: https://osf.io/gse7r/

B. Patient Participant Information Sheet for Chapter 8 Study



University of Glasgow
Institute of Health & Wellbeing

Funded by NIHR

NHS Greater Glasgow and Clyde

EMPOWER
Early signs monitoring to prevent relapse and promote wellbeing, engagement and recovery

Chief Investigator:
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Service User Perspectives on accessing EMPOWER Participant Information Sheet - General (v1.0, 14th May 2018)

1 Introduction

You are currently taking part in the EMPOWER study, which aims to test the EMPOWER app. You are now being invited to take part in an additional part of this project, which will aim to understand general service user experiences of using the EMPOWER intervention. We are contacting you because you are taking part in EMPOWER. We would like hear about your experiences of using the intervention. This would involve meeting with a member of the research team at a place of your choosing for around 90minutes to complete an interview.

This Participant Information Sheet tells you about this additional part of the EMPOWER project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in this part of the research.

Please read this information carefully. It is important for you to understand why the research is being done and what it will involve. Ask questions about anything that you do not understand or want to know more about.

Participation in the EMPOWER study is voluntary. If you do not wish to take part in this additional part of the project, you do not have to. It will not affect your participation in the wider study. If you decide that you want to take part, you will be asked to sign an additional consent form for this part of the research.

You will be given a copy of this Participant Information Sheet and a copy of the Consent Form that you sign to keep.

2 What is the purpose of this research?

The aim of EMPOWER is to evaluate the mobile telephone App (EMPOWER), which is designed to help people with experiences of psychosis to stay well. We also now hope to explore service user experiences of engaging with services during episodes of relapse (or early warning signs for relapse). Support and intervention around relapse can help to improve outcomes and promote recovery. EMPOWER involves using an App, in addition to engaging with peer support workers and a research nurse. We would like to know your thoughts and feelings about these different parts of the EMPOWER intervention.

3 Who is eligible to take part in this study?

All service users participating in EMPOWER will be eligible to take part in this additional interview. People are invited to use EMPOWER up to a year. We will periodically invite some service users currently using EMPOWER to complete an additional interview.

4 What does participation in this research involve?

You will be asked to meet with a researcher somewhere you feel comfortable for around 90 minutes. The researcher will talk with you about your experiences of using EMPOWER. This will usually be completed in a single appointment.

We will ask your permission to re-contact you if a further interview would be helpful. This may happen for example if information is gathered from other participants later in the study that we would like to hear your views on. This is usual practice with the research methods we have chosen and helps to gain a deeper understanding of the issues we are exploring.

5 Do I have to take part in this research?

No, participation in any research is voluntary. If you do not wish to take part you do not have to. Whether you choose to complete this interview **will not** affect your participation in the wider EMPOWER trial.

If you decide to take part in the study and later change your mind about participating that is also OK. For further information see section 9: 'What if I withdraw from this research project?'

6 What are the possible benefits of taking part?

We cannot guarantee that you will receive any benefits from this research. However, it will be an opportunity to contribute your views and experiences to research that may help improve digital interventions for people with psychosis. Some participants in previous studies have also reported finding the opportunity to discuss their experiences helpful.

7 What are the possible risks and disadvantages of taking part?

It is possible that reflecting on personal experiences using EMPOWER may be potentially upsetting. We are aware experiences of EMPOWER may be highly personal and we hope the interview will feel supportive and non-judgemental.
The researcher has experience in interviewing people. You will be free to stop taking part at any time without giving a reason.

8 What if I withdraw from this research project?

You can withdraw from the study at any time. You do not have to provide a reason and if you withdraw it will not affect your receipt of mental health services from NHS Greater Glasgow & Clyde or accessing EMPOWER.

If you do withdraw from the study, any personally identifiable information about you will be destroyed. However, anonymised data already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time that you withdraw will form part of the research project results. If you do not wish this to happen you should choose not to participate in this study.

9 Could this research project be stopped unexpectedly?

We do not expect this research project to stop unexpectedly. If this did happen, a member of the research team would contact you.

10 What happens when the research project ends?

This project is being conducted as part of the EMPOWER trial. Information about the end of the EMPOWER trial is provided in your original Participant Information Sheet.

11 Will my taking part be kept confidential?

The information you provide will be treated confidentially and not shared with others. Information that identifies you (e.g., your name, address, or date of birth) will be stored separately from other information you provide, such as interview transcripts. All data will be stored on a password-protected computer.

Study data may be examined by representatives of the study sponsor, NHS Greater Glasgow & Clyde, to ensure our research has been conducted to the proper standards

12 What will happen to information about me?

You have already consented to share information about you for the EMPOWER trial. Additional information collected by the current project will include an interview with a researcher. This will be recorded and transcribed by the research team.

Data collected by this part of the project will be treated in the same way as information collected for the rest of the EMPOWER trial. Specifically, any information obtained for the purpose of this research project that could be used to identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. Any paper files will be stored securely at the University of Glasgow. All researchers involved in the study will have access to anonymised data at the end of the study. Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of EMPOWER will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Anything published from this study will only include summary information that describes the whole group of participants in this study and not any individuals involved.

13 Who is organising and funding the research?

The EMPOWER trial is being conducted by an international research team and is sponsored by NHS Greater Glasgow and Clyde. The Chief Investigator for the study is Professor Andrew Gumley at the University of Glasgow.

The EMPOWER project is funded by the National Institute for Health Research Health Technology Assessment (NIHR-HTA) and the National Health and Medical Research Council (NHMRC) – through a Collaborative Research Grant.

14 Who has reviewed the research project?

The research has been reviewed by West of Scotland Research Ethics Committee and NHS Greater Glasgow and Clyde Research and Development Service.

15 Can I speak to someone who is not involved in the study?

Yes you can. Professor Tom McMillan, who is not involved in the study, can answer questions or give advice about participating in this study. Professor Tom McMillan is a Professor of Clinical Neuropsychology at the University of Glasgow and an experienced Clinical Psychologist. His telephone number is 0141 211 3927.

16 Will you want to know my experiences of participating in this research?

Yes, we very much value listening to and understanding your experiences of participating in our research project. This means that we can improve how we do our research and incorporate viewpoints we have not considered. You will already have indicated your preferences for this on the original EMPOWER consent form.

17 What will happen if there is a problem or if I want to make a complaint?

If you have any concerns about the study or the way it is conducted or if you want to complain about any aspect of this study, please contact Prof. Andrew Gumley, Mental Health Research Facility, Institute of Health and Wellbeing, University of Glasgow, Fleming Pavilion, West of Scotland Science Park (Todd Campus), Glasgow, G20 0XA, 0141 330 4852, or the Research & Development Department, NHS Greater Glasgow & Clyde on 0141-232 1818.

The normal NHS complaint mechanisms will also be available to you.

Thank you for reading this Participant Information Sheet

C. Carer Information Sheet for Chapter 8 Study

Funded by NIHR

EMPOWER

Early signs monitoring to prevent relapse and promote wellbeing, engagement and recovery

Chief Investigator:
Professor Andrew Gumley
Glasgow Mental Health Research Facility
Institute of Health and Wellbeing
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s.allan.2@research.gla.ac.uk

EMPOWER Carer Participant Information Sheet - v1.0, 14th May 2018)

1 Introduction

You are currently taking part in the EMPOWER study, which aims to test the EMPOWER app. You are now being invited to take part in an additional part of this project, which will aim to understand carer experiences of relapse. We are contacting you because a participant who has identified you as a carer has recently experienced an increase in symptoms of psychosis. We would like hear about your experiences during this time. This would involve meeting with a member of the research team at a place where you feel comfortable for 90 minutes to complete an interview.

This Participant Information Sheet tells you about this additional part of the EMPOWER project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in this part of the research.

Please read this information carefully. It is important for you to understand why the research is being done and what it will involve. Ask questions about anything that you do not understand or want to know more about.

Participation in the EMPOWER study is voluntary. If you do not wish to take part in this additional part of the project, you do not have to. It will not affect your participation in the wider study. If you decide that you want to take part, you will be asked to sign an additional consent form for this part of the research.

You will be given a copy of this Participant Information Sheet and a copy of the Consent Form that you sign to keep.

2 What is the purpose of this research?

The aim of EMPOWER is to evaluate the mobile telephone App (EMPOWER), which is designed to help people with experiences of psychosis to stay well. Support and intervention around relapse can help to improve outcomes and promote recovery. However, not much is known about how carers understand and respond to relapse when the person that they care for is using a relapse prevention tool such as EMPOWER. Creating a model to illustrate how carers respond to these episodes will help inform future service and training development to support mental health staff, service users and carers during relapse.

3 Who is eligible to take part in this study?

All carers participating in EMPOWER will be eligible to take part in this additional interview. We are tracking the occurrence of relapse, or increase in early warnings signs, as part of the EMPOWER study. Where an episode is identified, we may contact carers of a service user who has experienced a relapse to invite them to complete an additional interview.

4 What does participation in this research involve?

You will be asked to meet with a researcher somewhere you feel comfortable for around 90 minutes. The researcher will talk with you about your experiences during the episode in question. This will usually be completed in a single appointment. We will ask your permission to re-contact you if a further interview would be helpful. This may happen for example if information is gathered from other participants later in the study that we would like to hear your views on. This is usual practice with the research methods we have chosen and helps to gain a deeper understanding of the issues we are exploring.

5 Do I have to take part in this research?

No, participation in any research is voluntary. If you do not wish to take part you do not have to. Whether you choose to complete this interview **will not** affect your participation in the wider EMPOWER trial.

If you decide to take part in the study and later change your mind about participating that is also OK. For further information see section 9: ‘What if I withdraw from this research project?’

6 What are the possible benefits of taking part?

We cannot guarantee that you will receive any benefits from this research. However, it will be an opportunity to contribute your views and experiences to research that may later inform development of training or support for other carers as well as service users and staff. Some participants in previous studies have also reported finding the opportunity to discuss their experiences helpful.

7 What are the possible risks and disadvantages of taking part?

It is possible that reflecting on personal experiences of caring for someone experiencing relapse and early warning signs may feel upsetting. We are aware these topics are potentially upsetting and hope that the interview will feel supportive and non-judgemental. The researcher is experiencing in conducting interviews. You will be free to stop taking part at any time without giving a reason.

8 What if I withdraw from this research project?

You can withdraw from the study at any time. You do not have to provide a reason and if you withdraw it will not affect the person you care for being in receipt of mental health services from NHS Greater Glasgow & Clyde.

If you do withdraw from the study, any personally identifiable information about you will be destroyed. However, anonymised data already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time that you withdraw will form part of the research project results. If you do not wish this to happen you should choose not to participate in this study.

9 Could this research project be stopped unexpectedly?

We do not expect this research project to stop unexpectedly. If this did happen, a member of the research team would contact you.

10 What happens when the research project ends?

This project is being conducted as part of the EMPOWER trial. Information about the end of the EMPOWER trial is provided in your original Participant Information Sheet.

11 Will my taking part be kept confidential?

The information you provide will be treated confidentially and not shared with others. Information that identifies you (e.g., your name, address, or date of birth) will be stored separately from other information you provide, such as interview transcripts. All data will be stored on a password-protected computer.

Study data may be examined by representatives of the study sponsor, NHS Greater Glasgow & Clyde, to ensure our research has been conducted to the proper standards

12 What will happen to information about me?

You have already consented to share information about you for the EMPOWER trial. Additional information collected by the current project will include an interview with a researcher. This will be recorded and transcribed by the research team.

Data collected by this part of the project will be treated in the same way as information collected for the rest of the EMPOWER trial. Specifically, any information obtained for the purpose of this research project that could be used to identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. Any paper files will be stored securely at the University of Glasgow. All researchers involved in the study will have access to anonymised data at the end of the study. Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of EMPOWER will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Anything published from this study will only include summary information that describes the whole group of participants in this study and not any individuals involved.

13 Who is organising and funding the research?

The EMPOWER trial is being conducted by an international research team and is sponsored by NHS Greater Glasgow and Clyde. The Chief Investigator for the study is Professor Andrew Gumley at the University of Glasgow.

The EMPOWER project is funded by the National Institute for Health Research Health Technology Assessment (NIHR-HTA) and the National Health and Medical Research Council (NHMRC) – through a Collaborative Research Grant.

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The research has been reviewed by West of Scotland Research Ethics Committee and NHS Greater Glasgow and Clyde Research and Development Service.

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Yes you can. Professor Tom McMillan, who is not involved in the study, can answer questions or give advice about participating in this study. Professor Tom McMillan is a Professor of Clinical Neuropsychology at the University of Glasgow and an experienced Clinical Psychologist. His telephone number is 0141 211 3927.

16 Will you want to know my experiences of participating in this research?

Yes, we very much value listening to and understanding your experiences of participating in our research project. This means that we can improve how we do our research and incorporate viewpoints we have not considered. You will already have indicated your preferences for this on the original EMPOWER consent form.

17 What will happen if there is a problem or if I want to make a complaint?

If you have any concerns about the study or the way it is conducted or if you want to complain about any aspect of this study, please contact Prof. Andrew Gumley, Mental Health Research Facility, Institute of Health and Wellbeing, University of Glasgow, Fleming Pavilion, West of Scotland Science Park (Todd Campus), Glasgow, G20 0XA, 0141 330 4852, or the Research & Development Department, NHS Greater Glasgow & Clyde on 0141-232 1818.

The normal NHS complaint mechanisms will also be available to you.

Thank you for reading this Participant Information Sheet

D. Process Evaluation Ethical Approval for Conducting Interviews

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Professor Andrew I Gumley
Professor of Psychological Therapy
University of Glasgow
Institute of Health and Wellbeing
Mental Health and Wellbeing Research Group
Gartnavel Royal Hospital
Glasgow
G12 0XH

West of Scotland REC 4
Research Ethics
Clinical Research and Development
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
G3 8SJ
(Formerly Yorkhill Childrens Hospital)

Date 19 July 2018
Direct line 0141 232 1808
E-mail WoSREC4@ggc.scot.nhs.uk

Dear Professor Gumley

Study title:	**EMPOWER: Early signs Monitoring to Prevent relapse in psychosis and prOmote Wellbeing, Engagement and Recovery - a pilot Cluster Randomised Controlled Trial**
REC reference:	**16/WS/0225**
Protocol number:	**GN16MH271**
Amendment number:	**3.0 04/06/18 (REC Ref AM04)**
Amendment date:	**26 June 2018**
IRAS project ID:	**212143**

Summary of Amendment

A) Process Evaluation - development of a Logic Model to provide a clear description of the intended intervention, how it will be implemented, and how it is expected to work. It will provide the basis for organising observations of processes and outcomes throughout the study. Section 5.7 of the protocol (Process Evaluation) has been amended to reflect this which can be seen in the tracked document. The following new documents have been created for process evaluation:-

- *Carer Process Evaluation Interview v1.0*
- *Carer Process Evaluation PIS v1.0*
- *Carer Process Evaluation Consent Form v1.0*
- *Service User Process Evaluation Interview v1.0*
- *Service User Process Evaluation PIS v1.0*
- *Service User Process Evaluation Consent Form v1.0*
- *Care Co-ordinator Process Evaluation Interview v1.0*
- *Care Co-ordinator Process Evaluation PIS v1.0*
- *Care Co-ordinator Process Evaluation Consent Form v1.0*

B) Protocol Harmonisation - this is to ensure that the protocol is fully harmonised for both UK and Australia. The following protocol sections have been changed to reflect this:-

- *Section 5.54 (page 23)*
- *Table 1 (pages 31-33)*
- *Section 5.10 (page 36)*

- *Section 7.6 (page 41)*

C) Recruitment - It was found that the time period to recruit from local CMHS meant that some people may become eligible to participate during the recruitment period. In order to account for this a sentence was added at Section 5.4.1 of the protocol (page 18).

D) EMPOWER arm leaflet - this has been devised for those randomised to the EMPOWER app.

E) Participants discontinuing services from participating CMHS (Section 5.4.7, page 19 of protocol) - a paragraph has been added about the facilitation of the continued use of the App if participants' care is transferred to a different CMHS. The EMPOWER Service User PIS WP4 has also been amended to include this.

F) Previous non-substantial amendments approved by the Sponsor:-

- *NSA NOV17 - Addition of a new investigator to the Research Team to support the analysis of the Relapse Assessment methodology.*
- *NSA DEC17 - Two fields added to the care coordinator baseline v.10*
- *NSA JAN18 - The following docs were created to improve the way which participants information is batched: -*

  # Carer Baseline identifiable v1.0
  # Carer all time points v1.0
  # Researcher baseline identifiable v1.0
  # Researcher baseline non-identifiable v1.0
  # Researcher follow up v1.0

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Sub-Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Summary of Discussion

On 5 July 2018, the sub-committee requested clarification on the following points:-

1. In the interview schedules for participants in the "*Setting up*" section, it is mentioned in more than one interview schedule that: "*At end of interview, participant to be thanked for their time and be made aware of how their data will be utilized. Participant will ask if they need to ask any more questions*". The sub-committee asked if the participant should be made aware of how their data will be utilized at the beginning of the interview as well as at the end. To rectify this, the PIS could be available at the start of the interview, and the researcher should initially run through the salient points (purpose of study; use of information; right to withdraw) before the interview commences.

2. If the Service User did not give consent to taking part in the evaluation, would the researcher still interview the Carer and Care Coordinators? The sub-committee wanted to know if the Service User should be made aware that both their Carer and Care Coordinator would be asked to discuss them in similar interviews. The sub-committee was of the opinion that the Service User, who is the main focus of this research and the vulnerable party, should give consent to have confidential information about them shared with the researcher for this additional piece of evaluation.

a) They also noted that the PIS for the Service User did not explicitly state that Service Users' carers would also be interviewed. This should be made clear, and that the gathered data will be anonymous so as not to identify the carer or the service user. Furthermore, the Service User should have to consent that they are happy for their Carer to participate and offer their views which are based on the interaction with the Service User.

On 13 July 2018, the applicant provided a response to these queries and submitted updated documents. Upon review of these, the sub-committee noted that all of their concerns had been addressed and was content to give a favourable opinion of the amendment.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [EMPOWER arm leaflet]	1.0	17 May 2018
Interview schedules or topic guides for participants [Care coordinator Process Evaluation Interview schedule]	1.0	06 June 2018
Interview schedules or topic guides for participants [Carer Process Evaluation Interview schedule]	1.1	12 July 2018
Interview schedules or topic guides for participants [Service User Process Evaluation Interview schedule]	1.1	12 July 2018
Notice of Substantial Amendment (non-CTIMP)	3.0 04/06/18 (REC Ref AM04)	26 June 2018
Other [Carer Baseline Identifiable]	1.0	09 January 2018
Other [Carer all time points]	1.0	09 January 2018
Other [Researcher baseline identifiable]	1.0	09 January 2018
Other [Researcher baseline non-identifiable]	1.0	09 January 2018
Other [Researcher follow-up]	1.0	09 January 2018
Other [Care coordinator baseline]	1.0	07 September 2017
Other [Sub-cttee queries for applicant]	N/A	05 July 2018
Other [Applicant response to subcttee queries]	N/A	13 July 2018
Participant consent form [Carer Process Evaluation consent form]	1.0	06 June 2018
Participant consent form [Care coordinator Process Evaluation consent form]	1.0	06 June 2018
Participant consent form [Service User Process Evaluation consent form]	1.1	12 July 2018
Participant information sheet (PIS) [Care coordinator Process Evaluation PIS]	1.0	06 June 2018
Participant information sheet (PIS) [Carer Process Evaluation PIS]	1.0	06 June 2018
Participant information sheet (PIS) [Service Users PIS WP4]	1.3	25 June 2018
Participant information sheet (PIS) [Service User Process Evaluation PIS]	1.1	12 July 2018
Research protocol or project proposal [Phase II Protocol - tracked]	1.3	04 June 2018

Membership of the Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/WS/0225:	**Please quote this number on all correspondence**

Yours sincerely

On behalf of
Dr Ken James
Chair

Enclosures:	*List of names and professions of members who took part in the review*
Copy to:	*Joanne McGarry, NHS Greater Glasgow & Clyde*

West of Scotland REC 4

Attendance at Sub-Committee of the REC meeting in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Michael Fail	Consultant Geriatrician	Yes	Chair of Sub-Committee
Dr Kay Greenshields	Senior Scientific Officer	Yes	
Mrs Laura Kenicer	Prescribing Support Pharmacist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Rozanne Suarez	REC Manager

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APPROVAL OF AMENDMENT

6 May 2019

Dear Prof John F Gleeson,

HREC Reference Number: HREC/17/MH/97
SSA Reference Number: SSA/17/MH/328
Local Project Number: 2017.010

Research Title: Early signs Monitoring to Prevent relapse and PrOmote Wellbeing, Engagement, and Recovery (EMPOWER): A pilot cluster randomised controlled trial

Type of review: HREC and Governance Review

I am pleased to advise that the amendment to the above project has been reviewed and approved by the Melbourne Health HREC (ethical approval). This approval applies to all sites for which the Melbourne Health HREC has issued ethical approval. The amendment has also been approved to be conducted at Melbourne Health (governance approval). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

Amendment Approval Date: 6 May 2019

Approved Documents: Ethics Approval

- Key Clinician Process Evaluation Patient Information Consent Form version 1.0, dated: 21 January 2019
- Carer Process Evaluation Patient Information Consent Form version 1.0, dated: 21 January 2019
- Service User Process Evaluation Patient Information Consent Form version 1.0, dated: 21 January 2019
- EMPOWER Phase II Protocol version 1.3, dated: 21 January 2019
- EMPOWER Carer Process Evaluation Interview version 1.0, dated: 21 January 2019
- EMPOWER Service User Process Evaluation Interview version 1.0, dated: 21 January 2019
- EMPOWER Key Clinician Process Evaluation Interview version 1.0, dated: 21 January 2019
- Peer Support Worker Process Evaluation Patient Information Consent Form version 1.0, dated: 21 January 2019
- EMPOWER PSW key informant Process Evaluation topic guide version 1.0, dated: 21 January 2019
- EMPOWER PSW Process Evaluation topic guide version 1.0, dated: 21 January 2019
- Additional Personnel for Ms Stephanie Allan and Ms Bethany Moir
- SOP for Adverse Events version 1.2, dated: 17 January 2019
- CHIP process evaluation Patient Information Consent Form version 1.0, dated: 21 January 2019
- EMPOWER CHIP process evaluation interview version 1.0, dated: 21 January 2019
- Service User Patient Information Consent Form version 1.3, dated: 25th March 2018

Please refer to the Melbourne Health Office for Research website to access guidelines and other information and news concerning research at: https://www.thermh.org.au/research/researchers

Please Note: Template forms for reporting Amendments, Adverse Events, Annual Report/Final Reports, etc. can be accessed from: https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting

For any queries about this matter, please contact the HREC Manager on 03 9342 8530 or via email on: research@mh.org.au

Yours sincerely,

Professor Peter Colman
Chair – Melbourne Health Human Research Ethics Committee (HREC)

Dr Angela Watt
Director Research Governance and Ethics

E. Improvement Suggestions from Chapter 8

The EMPOWER trial tested whether the intervention was feasible, this means qualitative interviews had merit in gathering end user suggestions for intervention refinement. These are not ‘themes’ so are expressed as a list with evidence from the qualitative interviews for transparency.

A phone with better battery life

People who were given a smartphone to use stated that the phone did not have good battery life.

“The battery life’s not that great. The battery life isn’t that great at all. I’m charging it every night for an hour or two” (Michaela, UK)

Being provided with a phone cover

Participants were given a phone without a phone cover. Due to the fragility of the smartphone some participants were concerned about breaking the phone if they took it outside or dropped it. Offering a smartphone case might make using the app more feasible.

SA: “I know you mentioned that you were worried about dropping the phone would the team providing you with a phone case to make it sturdy would that be helpful?”
Participant: “Yeah that would be helpful yeah uh-huh.” (Emily, UK)

Being able to choose questionnaire timing

The pseudorandomised prompt timing was a key frustration along with the limited time available to answer it. Participants suggested it would be good to change the timing and bring this under participant control.

“To be honest with you, I prefer to pick a time of my own. And I know that at that time that I sit down and devote attention that I want to.” (Matilda, UK).

Not asking questions (or sending wellbeing messages to) participants about experiences participants do not have

This suggestion was particularly marked from people who did not hear voices. Participants would appreciate an intervention which is more tailored towards their own mental health rather than assumptions about what they are likely to experience by virtue of having a particular psychiatric label.

Participant: “I’ve found a few of them [wellbeing messages] helpful but mostly they’re all about voices, and I don’t really get voices, so they’re not applicable to me, most of them. So, I think they could be more tailored to the answers you’ve put.” (Keith, UK)

Being able to save message content in a personal bank

The EMPOWER messages that gave participant information on managing psychosis, quotes and links to videos were refreshed daily which meant participants could not save ones that were meaningful to them. Several participants remarked that this would be improved by enabling them to save messages.

“[the messages] disappear the next day so they’re not there. And I’ll think “oh, maybe I could listen to that one again”, and it’s not there anymore. So, if it was somewhere where you could click on it the next day or however long you wanted to keep track of it, that would be good.” (Agatha, UK)

F. Chapter 9 Supplementary Materials

Supplementary materials including analysis code and further sensitivity tests are available on the Open Science Framework at the following link:
https://osf.io/prcs4