Digital Health Interventions for Fear of Recurrence

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Chapter One: Systematic Review

Digital health interventions for fear of cancer recurrence: a systematic review

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Abstract

Background: Fear of Cancer Recurrence (FCR) is a significant concern for many cancer patients and survivors, yet barriers exist for accessing traditional face-to-face psychological interventions. Given the increasing use of digital technology in healthcare, digital health interventions offer promise in addressing FCR in adults.

Objectives: The primary objective of this systematic review was to identify the digital health interventions that have been developed and evaluated in adults with FCR. Secondary objectives related to participant characteristics, intervention components and application, and intervention outcomes.

Methods: A systematic search of Medline, EMBASE, PsychINFO, and CINAHL was performed to identify relevant studies. Data were extracted and analysed to summarise the digital health interventions, the clinical and demographic characteristics of the sample, the intervention components, application methods, and intervention outcomes. Methodological quality and transparency of reporting were assessed using established tools. Results were summarised using a narrative synthesis.

Results: Eighteen studies were included in the review. Eleven distinct interventions were reported, with CBT being the most common approach. Self-guided web-based interventions were the predominant modality. Digital health interventions were found to be associated with reduced FCR in 12 out of 18 studies. Transparency of reporting appeared high across studies.

Conclusions: This systematic review was the first to provide a comprehensive summary of digital health interventions developed and evaluated in adults with FCR. The findings from this review provide valuable insights for healthcare providers and researchers seeking to develop and implement interventions for FCR in clinical practice.

Keywords: *cancer; digital health interventions; fear of recurrence; systematic review.*

Introduction

Cancer is a broad term used to describe a large group of diseases where cells in a specific part of the body become abnormal and divide uncontrollably to make more abnormal cells. The four most common cancers occurring worldwide are female breast, lung, bowel and prostate cancers (Cancer Research UK, 2023). In the UK and US, cancer claims an estimated 166,000 and over 600,000 lives annually, respectively (Cancer Research UK, 2019), and is the leading cause of death worldwide, accounting for nearly 10 million deaths in 2020 (World Health Organization, 2023).

Over recent decades, survival rates of cancer have significantly improved due to advances in diagnostic techniques, treatment methods, early detection, and screening (Hanna et al., 2020; Loud & Murphy, 2017; Siegel et al., 2021). However, these benefits are not observed equally in all communities (Benjamins et al., 2021). Data from the US reveals that non-Hispanic Black Americans exhibit higher mortality rates from nearly all cancer types than other Americans (National Cancer Institute, 2021). Similarly in the UK, disparities persist, with evidence pointing to poorer survival rates among Asian and Black women with breast cancer and Black men with prostate cancer compared to other ethnic groups (National Cancer Intelligence Network, 2009).

Despite advances in cancer treatment and prognosis, many cancer survivors still face the possibility of their cancer returning. The fear, worry or concern relating to the possibility of cancer returning or progressing, is referred to as a “Fear of Cancer Recurrence” (FCR) (Lebel et al., 2016).

When experienced at a low level, FCR can be adaptive as it alerts individuals to potential signs of a new or recurrent cancer, promoting positive health behaviours such as attending medical follow-ups or adopting healthy lifestyle changes (Simonelli et al., 2016). Higher FCR can have a debilitating impact on an individual (Lebel et al., 2016), leading to depression (Koch et al., 2013), decreased quality of life (Tauber et al., 2019), impaired functioning (Thewes et al., 2014) and excessive use of healthcare services (Lebel et al., 2012).

Qualitative analysis of interviews with cancer survivors revealed key features of clinical FCR: fear of not surviving if cancer returns, feelings of isolation despite support, and intolerance of uncertainty regarding recurrence (Mutsaers et al., 2016). Participants also reported recurrent daily cancer-related thoughts and imagery that were difficult to control and increased over time, causing distress, and impacting daily life. In a Delphi study, clinical FCR was further conceptualised as a multidimensional construct, characterised by high levels of preoccupation, persistent elevated levels of worry, and a hypervigilance towards bodily symptoms (Mutsaers et al., 2019).

In a recent review of 9,311 cancer patients and survivors, 59% reported moderate FCR and an additional 19% reported severe FCR, as assessed using the Fear of Cancer Inventory (Luigjes-Huizer et al., 2022). Notably, FCR is regarded as the most common unmet supportive care need among all cancer survivors (Harrison et al., 2011), highlighting the critical need for effective, evidenced-based interventions (Vandraas et al., 2020).

Psychological interventions have been developed and evaluated to address FCR, with cognitive-behavioural therapies (CBT) being the most commonly used approach (Tauber et al., 2019). In their systematic review and meta-analysis of 23 psychological intervention

trials, Tauber et al. (2019) found evidence that psychological interventions are effective in reducing FCR. Specifically, their review suggests that contemporary CBT, such as mindfulness and acceptance and commitment therapies (ACT), which focus on mental processes such as worry, rumination, and attentional bias, are more effective than traditional CBT that aims to modify negative thoughts or biases (Tauber et al., 2019). Most interventions evaluated in the review were delivered face-to-face by skilled psycho-oncology staff, either in individual or group format. However, this resource-intensive, time-consuming approach may not be scalable. Additionally, factors such as distance needed to travel and the burden of the disease itself can also be barriers to these traditional in-person interventions (Clover et al., 2014; Savioni et al., 2021).

Given the recent effects of the COVID-19 pandemic which limited individuals' access to healthcare and forced cancer patients into obliged isolation, there has been an additional need highlighted for the remote delivery of health interventions more than ever before (Jnr, 2020). As digital health interventions have shown promise in addressing the psychosocial needs of cancer patients (Skrabal Ross et al., 2020), developing and evaluating more accessible FCR interventions has become a top research priority (Shaw et al., 2021). The increased focus on remote and accessible FCR interventions can potentially benefit minority groups by overcoming some of the barriers they may face in accessing traditional healthcare. However, it is important for these interventions to be culturally sensitive, available in multiple languages, and designed with the specific needs of minority communities in mind to ensure equitable access and outcomes.

A recent scoping review by Cincidda et al. (2022) investigated the availability and effectiveness of different modalities of CBT psychological interventions (including face-to-

face, remote, and blended interventions) for reducing FCR in adult cancer patients. They found effective outcomes with remotely delivered CBT-based psychological interventions. However, their review only included traditional and contemporary CBT interventions and potentially overlooked other available psychological therapies. Moreover, as this was a scoping review, it did not assess the quality of all available studies, which impact the reliability and validity of their findings. Therefore, a more comprehensive systematic review that captures a wider range of digitally delivered psychological approaches and evaluates the quality of available evidence is merited.

Objectives

The purpose of this systematic review was to synthesise current evidence on digital health interventions for adults with FCR. The primary research question was as follows: In adults with Fear of Cancer Recurrence, what digital health interventions have been developed and evaluated? The following secondary outcome questions were also addressed:

1. What were the demographic and clinical characteristics of the population sample who received the digital health interventions?
2. What were the components involved in the digital health interventions and how were they applied?
3. What were the outcomes of the identified digital health interventions?

Method

Protocol and Registration

This systematic review was registered with the International Prospective Register of Systematic Reviews (PROSPERO) in adherence to guidelines outlined in the Preferred

Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Page et al., 2021). Modifications of the protocol are documented on www.crd.york.ac.uk/prospero/ (registration number: CRD42023422740).

Search Strategy

An initial scoping exercise was conducted to identify relevant articles in the area to assess feasibility of the review. Systematic searches of the literature were carried out on the 29th of April 2023 using the search terms described below, and relevant studies were located within electronic databases including Medline, EMBASE, PsychINFO and CINAHL.

Search Terms

The search terms used in this review were developed based on the keywords of relevant articles identified in the initial scoping phase. To refine the search terms, advice was sought from a medical librarian at the University of Glasgow. Search terms were adapted for different databases and reviewed by the librarian for sensitivity and specificity. Included terms related to population (fear, cancer, and recurrence) and intervention (digital health) (see Appendix 1.1). All searches were limited to human studies, English language, and from inception of the databases until date of search. The full search strategy is available in Appendix 1.2.

Eligibility Criteria

Inclusion

To be included in this systematic review, articles were required to meet the following criteria using the PICOS (population, intervention, comparison, outcome, study) framework (Sackett et al., 1996) outlined in Table 1.1.

Table 1.1: PICOS Framework Inclusion Criteria

PICOS	Inclusion Criteria
Population	Adults aged 18 years or above who have been diagnosed with cancer, (either currently or in the past), and report experiencing FCR.
Intervention	Any digital health intervention that uses psychological methods to reduce FCR. The Interventions may be delivered purely remotely or through a blended approach.
Comparison	Any control group.
Outcomes	Studies must have used one or more validated quantitative measures of FCR to report their outcome. Studies were eligible if they employed pre- and post-intervention data, or pre-post change score data relating to FCR.
Study design	Randomised Controlled Trial's (RCT's), non-RCT's, quasi-experimental studies and pilot studies.

Studies must have been published in peer-reviewed journals and written in English. If explicit age criteria were not specified in the studies, we included studies where most participants were adults. Our inclusion criteria for "digital health interventions" included self-guided technologies (such as smartphone apps, websites, virtual reality) as well as remotely delivered clinician-led interventions (such as telephone or video-based interventions), as long as the interventions had a psychological component (i.e., used therapeutic techniques grounded in psychological theory).

Exclusion

Studies that used qualitative assessments, quantitative measures at one time point only, or those that only assessed broader psychological constructs such as general anxiety or worry were excluded. Additionally, grey literature, editorials, conference proceedings, study protocols, review articles, and single case studies were excluded from this review.

Study Selection

Articles were exported into Endnote and duplicates were removed. A preliminary screening based on the titles and abstracts was conducted by the main author (NK), using a checklist (Appendix 1.3), and studies that appeared irrelevant were excluded. In cases where there was uncertainty about the inclusion of an article following the title and abstract screening, a second (SB) and third (AG) reviewer was consulted to reach a final decision.

For all abstracts that met the inclusion criteria, full-text articles were obtained for further evaluation. Two authors (NK + SB) independently screened each article's full-text copy, in accordance with the inclusion and exclusion criteria, and any disagreements were resolved through discussion with the third reviewer (AG). The agreement rate between the two reviewers was 84% (see Appendix 1.4 for summary of resolved discrepancies).

Reference lists of studies that met the eligibility criteria were also screened to identify additional relevant studies. Citation searching was also conducted on the included studies and a manual search using relevant keywords was conducted on Google scholar.

Data Extraction and Synthesis

Due to the heterogenous nature of the included studies, a narrative synthesis was used to analyse and present the data focusing on both the primary outcomes (the digital health interventions developed and evaluated) and the secondary outcomes (participant clinical

and demographic characteristics, intervention component and application, and intervention outcomes).

The following details from each study was systematically extracted: first author; year of publication; study design; sample size; outcome measure tool; age; gender; ethnicity; type and stage of cancer; intervention type; application of digital intervention including mode of delivery, clinician involvement, treatment duration, type of platform; the overall main findings and whether FCR was significantly reduced or not. Data extraction of participant characteristics focused on those who received a digital health intervention.

Methodological Quality

The quality of the included studies was assessed using the Joanna Briggs Institute (JBI) Critical Appraisal Tools for RCT's and Quasi-Experimental Studies (Tufanara et al., 2017) (Appendix 1.5). These tools were used to assess the extent to which the studies addressed potential bias in their design, conduct, and analysis. The JBI checklist for RCT's consists of thirteen assessment items, covering aspects such as randomisation, blinding, intervention and follow-up procedures, statistical analysis of results, and study design. Each item is evaluated using the response options "yes", "no", "unclear", and/or "not applicable". Similarly, the JBI checklist for quasi-experimental studies comprises nine assessment items with the same response options. No overall risk of bias score is produced using this tool.

The main author rated all papers, and to ensure inter-rater reliability in quality ratings, a second rater (SB) and a third rater (AG) independently reviewed a subset (33%) of the studies. There was a 77% agreement rate between NK and SB and a 78% agreement rate between NK and AG. Discrepancies were discussed and final ratings were agreed. No studies

were excluded due to their quality; instead, the potential impact of study quality was considered as part of the overall synthesis.

Transparency of Reporting

The descriptions of the interventions in the included studies were assessed using the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014) (see Appendix 1.6). The TIDieR checklist is an extension of item 5 from the Consolidated Standards of Reporting Trials (CONSORT) 2010, which requests the need for comprehensive intervention descriptions. It consists of 12 items that facilitate a detailed account of the intervention. These items include the intervention's name, the rationale for its development and theoretical framework, the content of the intervention, the delivery method, the intervention provider, the time period and location of delivery, the number of sessions, whether the intervention was personalised, if any modifications were made, if adherence was assessed, and the extent to which the intervention was delivered as planned. The checklist was completed by the main author for all the included studies.

Results

An overview of the search results and article selection processes are outlined in Figure 1.1. The search identified a total of 9599 articles across four databases. Following de-duplication, 3036 articles were removed. The remaining 6563 articles underwent title and abstract screening, resulting in 38 articles for full-text review. From this, a total of 18 studies met the full eligibility criteria and were included in the review for the quality appraisal and full data extraction process. Hand searches of reference lists from included articles and manual searches of relevant keywords on Google scholar identified no further studies.

Relevant details of the study characteristics can be found in Table 1.2 and a summary of the interventions are presented in Table 1.3.

Figure 1.1: PRISMA 2020 Flow Diagram (Page et al., 2021)

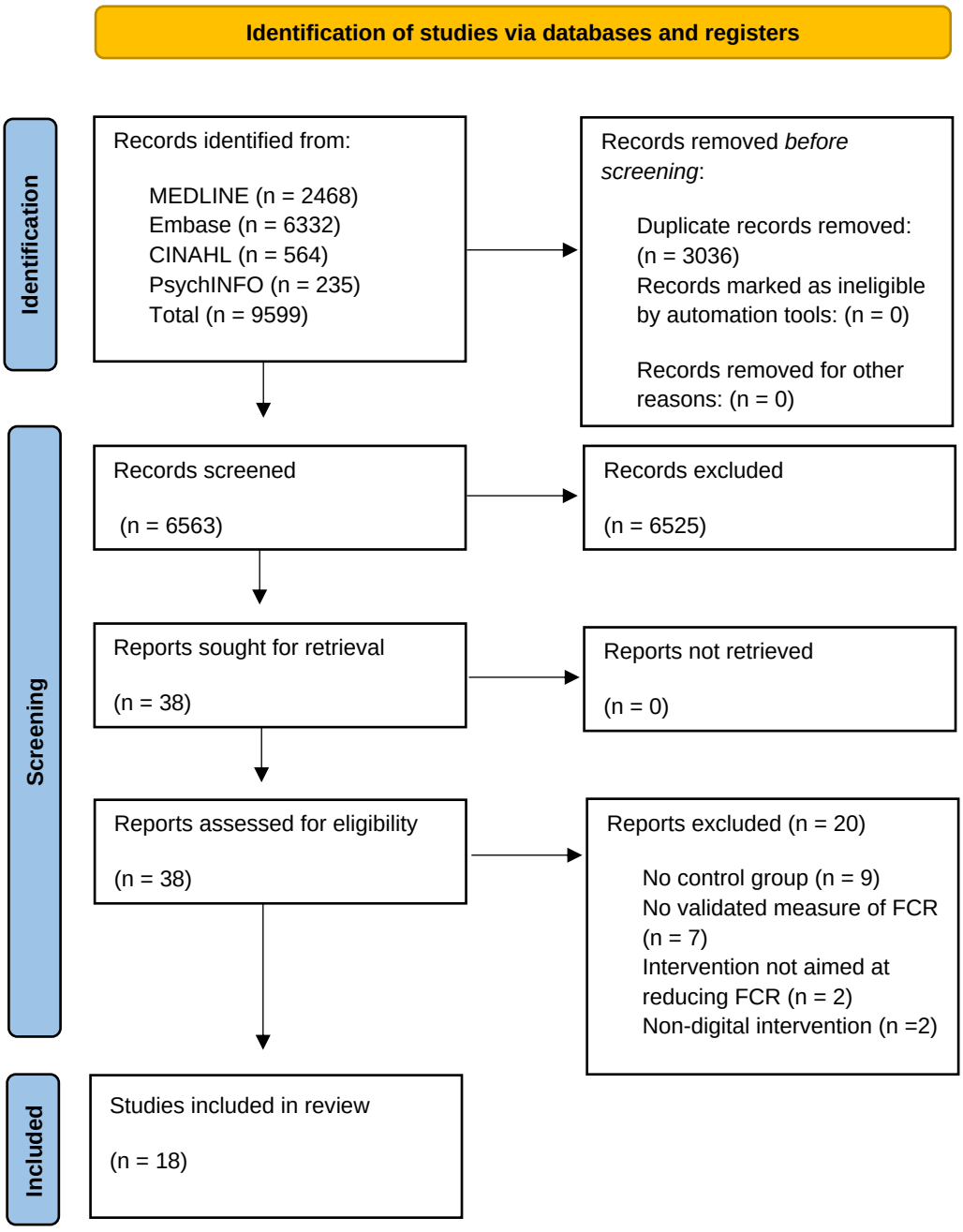

Table 1.2: Study Characteristics

	Study					Demographic Characteristics		Clinical Characteristics	
	Author (Year); Country	**Study Design**	**Sample Size**	**FCR Measure**	**Mean Age (SD)**	**Gender**	**Ethnicity**	**Cancer Type**	**Cancer Stage[a]**
1.	Akechi et al. (2023); Japan	RCT	Total:447 Intervention:223 Control: 224	CARS and FCRI-SF	43.9 (4.57)	Female: 223 Male: 0	Not reported	Breast	0 – 22 I – 89 II – 89 III – 15 Unknown: 8
2.	Akkol-Solakoglu et al. (2023); Ireland	Pilot RCT	Total: 72 Intervention: 49 Control: 23	CWS	47.12 (7.92)	Female: 49 Male: 0	Not reported	Breast	I – 12 II – 18 III – 16 IV – 0 Unknown: 3
3.	Compen et al. (2018); Netherlands	RCT	Total: 245 Intervention: 90 Non-DHI: 77 Control: 78	FCRI	52.4 (10.7)	Female: 77 Male: 13	Not reported	Breast, Gynaecological, Prostate, Colon, Non-Hodgkin's Lymphoma, Skin, Thyroid, Bladder, Neuroendocrine Tumour	Not reported
4.	Dieng et al. (2016); Australia	RCT	Total: 151 Intervention: 70 Control: 81	FCRI	60.2 (10.9)	Female: 20 Male: 50	Not reported	Melanoma	0 – 1 I – 43 II – 23 Missing: 3

5.	Dirkse et al. (2019);[b] Canada	Non-Inferiority Trial	Total: 83 Intervention: 42 Control: 41	FCRI-SF	50.62 (13.11)	Female: 34 Male: 7	Not reported	Breast, Gynaecological Gastro-intestinal, Genitourinary, Haematologic	Not reported
6.	Fang et al. (2020); Taiwan	Quasi-Experimental	Total: 165 Intervention:83 Control: 82	ASC (CW subscale)	50.99 (9.68)	Female: 83 Male: 0	Not reported	Breast	I – 42 II – 28 III – 13
7.	Lange et al. (2017); Germany	Quasi-Experimental	Total: 44 Intervention: 18 Control: 26	MAX-PC	60.53 (5.70)	Female: 0 Male: 18	Not reported	Prostate	Not reported
8.	Lichtenthal et al. (2017); USA	Pilot RCT	Total: 97 Intervention: 64 Control: 33	CARS	55.8 (7.4)	Female: 64 Male: 0	White: 46 Black: 7 Hispanic: 3 Asian: 7 Missing: 1	Breast	0 – 6 I – 29 II – 27 III – 2
9.	Murphy et al. (2020); Australia	RCT	Total: 114 Intervention: 53 Control: 61	FCRI	53.28 (9.22)	Female: 46 Male: 7	Not reported	Breast, Prostate, Gynaecological, Lymphoma, Bowel, Melanoma	Not reported

10.	Neubert et al. (2023); Germany	RCT	Total: 157 Intervention: 78 Control: 79	FoPQ-SF	55.2 (12.2)	Female: 56 Male: 22	Not reported	Breast, Head/Neck, CNS, Lung, Skin, Gynaecological, Gastrointestinal, Gallbladder, Pancreatic, Hemato-Oncological Malignancies	Not reported
11.	Peng et al. (2022); China	RCT	Total: 57 Intervention: 28 Control: 29	FCRI-SF	Mean not reported	Female: 28 Male: 0	Not reported	Breast	I – 6 II – 15 III – 6 IV – 1
12.	Russell et al. (2019); Australia	Pilot RCT	Total: 69 Intervention: 46 Control: 23	FCRI	53.5 (12.1)	Female: 25 Male: 21	Not reported	Melanoma	Not reported
13.	Thompson et al. (2021); USA	RCT	Total: 228 Intervention: 108 Control: 120	CARS	55.8 (9.7)	Female: 108 Male: 0	Not reported	Breast	"Early": 80 "Locally Advanced": 28
14.	van den Berg et al. (2015); Netherlands	RCT	Total: 150 Intervention: 70 Control: 80	CWS and CAS	51.44 (8.30)	Female: 70 Male: 0	Not reported	Breast	Not reported
15.	van de Wal et al. (2017); Netherlands	RCT	Total: 88 Intervention: 45 Control: 43	CWS and FCRI	Age split by cancer diagnosis	Female: 24 Male: 21	Not reported	Breast, Prostate, Colorectal	Not reported

16.	van Helmondt et al. (2020); Netherlands	RCT	Total: 262 Intervention: 130 Control: 132	FCRI	55.3 (10.1)	Female: 130 Male: 0	Not reported	Breast	Not reported
17.	Wagner et al. (2021); USA	Factorial RCT	Total: 196 Intervention: 172 (23*2=16 unique groups) [c]	FCRI and CARS	Age split by factor	Female: 172 Male: 0	Reported separately by factor	Breast	Reported separately by factor
18.	Zhang et al. (2022); China	RCT	Total: 77 Intervention: 38 Control: 39	CARS	52.29 (7.686)	Female: 38 Male: 0	Not reported	Breast	I – 6 II – 16 III – 11 IV – 5

Note. Abbreviations: ASC= Assessment of Survivors Concerns, CARS= Concerns About Recurrence Scale, CAS= Cancer Acceptance Scale, CW= Cancer-Worry, CWS= Cancer Worry Scale, FCR= Fear of Cancer Recurrence, FCRI= Fear of Cancer Recurrence Inventory, FCRI-SF= Fear of Cancer Recurrence Inventory-Short Form, FoPQ-SF= Fear of Progression Questionnaire Short Form, MAX-PC= Memorial Anxiety Scale for Prostate Cancer

[a] "Unknown" refers to participants who said they did not know their stage of cancer, whereas "missing" refers to missing data.

[b] Non-inferiority trial comparing a self-guided vs technician-guided intervention. The self-guided intervention was considered the experimental condition for data extraction purposes.

[c] Study involved a factorial design comprising of 3 CBT components (relaxation, cognitive restructuring, and worry practice) alone or in their combination.

Table 1.3: Summary of Interventions and Main Findings

	Study	Digital Health Intervention					Outcomes
	Author; Year;	**Delivery Mode; Platform**	**Intervention Type**	**Treatment Duration**	**Clinician Involvement**	**FCR Reduced**	**Main Findings**
1.	Akechi et al. (2023)	Mobile Application (iPhone/iPad)	PST, BA	PST: 9 sessions BA: 6 sessions 8-week duration.	Self-guided + Automated e-mail reminders	✓	The intervention group had statistically greater improvements than controls at week 8 on the CARS (difference –1.39; 95% CI, –1.93 to –0.85; *P* < .001) and the FCRI-SF (difference –1.65; 95% CI, –2.41 to –0.89; *P* < .001
2.	Akkol-Solakoglu et al. (2023)	Website (SilverCloud)	CBT	7 modules 8-week duration.	Self-guided + Post-session feedback provided to each participant by a "supporter" (graduate psychologist)	×	No significant group-by-time interaction effects were found for FCR.
3.	Compen et al. (2018)	Website	MBCT	8 modules 9-week duration	Self-guided + Participants asked to write about own experiences in an essay and received feedback from therapist via email.	✓	Compared with TAU, eMBCT intervention significantly reduced FCR (Cohen's d, .53).

4.	Dieng et al. (2016)	Blended Non-digital Booklet + Telephone	Psycho-education (booklet) + Psycho-dynamically oriented therapy (telephone)	76-page booklet: 8 modules + Three telephone sessions 4-week duration	Self-Guided (non-digital booklet) + Clinician-guided (telephone sessions with a psychologist).	✓	Intervention group reported lower FCR severity, trigger, and distress scores than the control group at 6months. Mean difference was −1.9 for FCR severity (95% CI, −3.1 to −0.7; *P* =.002), −2.0 for FCR triggers (95% CI, −3.3 to −0.7; *P* =.003), and −0.7 for FCR distress (95% CI, −1.3 to −0.1; *P* =.03). Decrease in FCR severity (but not triggers or distress) remained statistically significant after adjustment for other covariates (*P* =.04).
5.	Dirkse et al. (2019)	Website	CBT	5 modules 8-week duration	Self-guided + Automated e-mails reminders	✓	Medium effect sizes were found for reductions on FCR (Cohen's *d*, 0.65) which increased to large effects by 1-month follow-up (Cohen's d, 0.93). Significant percentage change in symptoms was also observed from pre- to post-treatment on the FCRI-SF (16%).

6.	Fang et al. (2020)	Website (Smartphone/ Tablet)	Survivorship Care Plan	7 modules 5-week duration	Self-guided + Automated push notifications	✓	FCR declined significantly over time. The interaction of time and group also reached significance, indicating a significant decrease in FCR from the baseline in the intervention group compared to the control group after the 12th month follow-up (ß=-1.56, SE = .49, P_{ftd} = *.021*)
7.	Lange et al. (2017)	Website (Online Chat Rooms)	Guided chatroom	5 group sessions 8-week duration	Clinician-guided: Online chat program with a psychological therapist.	×	No significant difference between control and intervention group was found in relation to FCR.
8.	Lichtenthal et al. (2017)	Computer	CBM	8 sessions 4-week duration	Self-guided	✓	The intervention led to statistically significant reductions in health worries on the CARS, compared to the control group at a 3-month follow up.
9.	Murphy et al. (2020)	Website	CBT	8 modules 16-week duration	Self-guided + Automated emails + Personalised emails from clinician were sent to participants post module 1 & 2, to address any personal matters.	✓	Compared to the control group, there was a significant reduction for total scores on the FCRI, with a small effect size (FCRI-Total, g= 0.39).

10.	Neubert et al. (2023)	Website (Desktop, laptop, or tablet)	Video Sequence	8 videos 4-week duration	Self-guided	×	There were no significant differences in FoP between the intervention and control group.
11.	Peng et al. (2022)	Website + Smartphone App	MBI	6 group sessions 6-week duration	Clinician-guided: Online weekly group intervention + Self-guided: Daily home practice with the 5P Medical App	✓	Compared to the control group, FCR in the intervention group was significantly alleviated (F= 9.63, P= 0.00). The interaction effect between the two groups were also significant in FCR (F= 5.32, p= 0.01).
12.	Russell et al. (2019)	Website Laptop, tablet, smartphone	MBI	6 modules 6-week duration	Self-guided + Automated e-mail reminders.	✓	Intervention significantly reduced the severity of FCR compared to control group (mean difference = − 2.55; 95% CI − 4.43, − 0.67; *p* = 0.008). There was no difference between the intervention and control groups on any of the other FCRI subscales.

13.	Thompson et al. (2021)	Website (Tablet, Computer)	Survivor Stories	Three x 2-week "exposures" to 12 topics 6-week total duration of exposure (over a 12-month period)	Self-guided	×	No significant differences in FCR between the intervention and control. Exploratory analysis revealed that more time using the intervention was associated with an increase in concerns about recurrence.
14.	van den Berg et al. (2015)	Website	BREATH[a]	16 modules 16-week duration	Self-guided	✓	The intervention led to significant improvements on two FCR measures with small to medium effect sizes (d= 0.41 to 0.55). A significant time x group interaction effect was found for FCR (CWS; F[3, 120] = 4.563; *P* = .005), with the intervention group reporting less fear than the control group at a 6-month follow-up (−1.459; 95% CI, −2.743 to −0.175)

15.	Van De Wal et al. (2017)	Blended approach Website + face-to-face therapy sessions + e-consultations	CBT	Five face-to-face sessions combined with three e-consultations 12-week duration	Self-guided website + clinician-delivered therapy	✓	Intervention group reported significantly less FCR than those in the control group (mean difference, –3.48; 95% CI, –4.69 to –2.28; *P* < .001) with a moderate-to-large effect size (*d* = 0.76). Clinically significant improvement in FCR was significantly higher in the intervention group than in the control group (13 [29%] of 45 compared with 0 [0%] of 43; *P* < .001); self-rated improvement was also higher in the intervention group (30 [71%] of 42 compared with 12 [32%] of 38 in the control group; *P* < .001).

16.	van Helmondt et al. (2020)	Website	CBT	6 modules 12-week duration	Self-guided	×	LGCM showed no differences between the average latent slope in both groups (χ^2_1 = .23, *P* = .63), suggesting that the treatments did not differ in their change in FCR over time. Moreover, no differences were found in the effects of the predictors on the latent slope in both groups (χ^2_1 = .12, *P* = .73), suggesting that no significant predictors were found for the effect of the intervention on FCR.
17.	Wagner et al. (2021)	Website	CBT	4-week duration	Self-guided + Automated text reminders	✓	FCRI scores decreased statistically significantly from baseline to postintervention (T0 = 53.1 [17.4], T2 = 41.9 [16.2], P < .001). The magnitude of reduction in FCRI scores was comparable across CBT and control conditions and was predicted by increased self-efficacy.

18.	Zhang et al. (2022)	Virtual Reality	VR-CALM psycho-therapy	6 sessions 12-week duration	Clinician-guided	×	No significant differences between the intervention and control arms in FCR.

Note. Abbreviations: ACT= Acceptance Commitment Therapy, BA= Behavioural Activation, CARS= Concerns About Recurrence Scale, CBM= Cognitive Bias Modification, CBT= Cognitive Behaviour Therapy, CI= Confidence Interval, CWS= Cancer Worry Scale, eMBCT= Internet-Based Mindfulness-Based Cognitive Therapy, FCR= Fear of Cancer Recurrence, FCRI= Fear of Cancer Recurrence Inventory, FCRI-SF= Fear of Cancer Recurrence Inventory-Short Form, FoP= Fear of Progression, LGCM= Latent Growth Curve Modelling, MBCT= Mindfulness-Based Cognitive Therapy, MBI= Mindfulness Based Intervention, PST= Problem-Solving Therapy, TAU= Treatment As Usual, VR-CALM= Virtual Reality Managing Cancer and Living Meaningfully.

[a] BREAst cancer e-healTH [BREATH] self-management intervention

Study Characteristics

Sample Size

A total of 18 studies comprising of 2702 participants were included in this review. Among them, 1407 received a digital health intervention.

Study Design

Fifteen studies were RCT's (including three pilot RCT's and one factorial RCT), two were quasi-experimental studies, and one was a non-inferiority trial.

Transparency of Reporting

A summary of the TIDieR checklist for the 18 included studies is available in Appendix 1.7. Overall, the studies demonstrated transparent reporting in terms of describing the intervention name, rationale, materials, procedures, providers, and delivery details (items 1-8). Item 5, regarding the intervention provider was non-applicable in ten studies given the fully automated nature of the interventions. The area where reporting was relatively weaker was item 11, which pertains to intervention adherence or fidelity and strategies used to maintain or improve fidelity; only four out of the 18 studies provided information on this aspect. Nevertheless, the extent to which the interventions were delivered as planned (item 12) was reported in the majority of studies (11 out of 18).

Primary Outcome

Digital Health Interventions for FCR

Among the 18 studies included in this review, 11 distinct interventions were reported. CBT was the most common, with six studies using this approach. Mindfulness-based interventions were reported in three studies, while the remaining study interventions

included: Problem Solving Therapy and Behavioural Activation, Psychodynamic Therapy, Survivorship Care Plan, Video Sequence, Survivor Stories, BREATH (BREAst cancer ehealTH), VR-CALM psychotherapy (Managing Cancer and Living Meaningfully), Cognitive Bias Modification, and a Guided Chatroom Intervention.

Secondary Outcomes

Demographic and Clinical Characteristics

The majority of participants who received a digital health intervention were female (89%), and their mean age ranged from 43 to 60 years. One study (Peng et al., 2022) did not report the mean age. Additionally, one study (Van De Wal et al., 2017) presented age data across different cancer diagnoses, and another (Wagner et al., 2021) split age by factor, preventing the extraction of an overall mean age. Breast cancer was the most commonly represented cancer type in the intervention group, accounting for 83% of the studies (15 out of 18). Seven studies did not report participants' stage of cancer. Among those that did, cancer stage for those in the intervention group varied from stage 0 (5%), stage I (41%), stage II (39%), stage III (11%), and stage IV (1%). Only two studies reported participants' ethnicity.

Components of the Digital Health Interventions

The components of the 11 distinct interventions are described below:

1. CBT interventions:

The components within the CBT-based interventions in the six studies incorporated various tools and techniques to reduce FCR. These included: cognitive restructuring, which involved identifying and modifying negative or maladaptive thoughts (Akkol-Solakoglu et al., 2023; Dirkse et al., 2019; Murphy et al., 2020; Van De Wal et al., 2017; Wagner et al., 2021); behavioural modification, which focused on behaviour monitoring, goal setting, activity

scheduling, behavioural activation, and promoting adaptive behaviours (Akkol-Solakoglu et al., 2023; Murphy et al., 2020; Van De Wal et al., 2017); and coping skills training, which included relaxation techniques, worry management, and strategies to stop rumination (Akkol-Solakoglu et al., 2023; Murphy et al., 2020; Van De Wal et al., 2017; van Helmondt et al., 2020; Wagner et al., 2021). Additional skills training included problem solving (Akkol-Solakoglu et al., 2023; Murphy et al., 2020), assertiveness and communication skills (Dirkse et al., 2019; Murphy et al., 2020). Psychoeducation was another important component within the CBT interventions and was used to improve participants' knowledge about their experience and symptoms.

2. Mindfulness-Based Interventions (MBI):

The components within the mindfulness-based interventions in the three studies involved: psychoeducation to help participants understand the potential benefits of using mindfulness in their day-to-day life; meditation exercises, such as mindful daily activity and gratitude exercises; and the use of practice diaries to keep track of and help encourage and establish daily practice (Compen et al., 2018; Peng et al., 2022; Russel et al., 2019).

3. Problem Solving Therapy (PST) + Behavioural Activation (BA) intervention:

Akechi et al. (2023) used PST in conjunction with BA to help alleviate psychological distress and reduce FCR by a) providing strategies to resolve daily life problems, and b) increasing meaningful and pleasurable activities. The component involved in their PST intervention included a structured, five-step strategy for problem solving (Step 1: Organising and clarifying the problem, Step 2: Being specific about the goal, Step 3: Thinking of a solution, Step 4: Choosing a better solution, Step 5: Implementing the solution and evaluating the results) and the component involved in their BA intervention included two strategies (1.

recognising and re-trying behaviours that are no longer performed and 2. trying new behaviours).

4. Psychodynamic Psychotherapy (digital) + [*Psychoeducation (non-digital) intervention*]:

Dieng et al. (2016) used a blended intervention involving a psychoeducational booklet, in conjunction with psycho-dynamically-oriented psychotherapy, to help facilitate effective emotional and behavioural coping strategies in adults with FCR. The components of their psychodynamic therapy involved: 1. Focusing on affect and expression of emotions, 2. Avoidance behaviours, 3. Identifying patterns in actions, thoughts, feelings, experiences, and relationships, 4. Exploring both past experiences and future possibilities, 5. Focusing on interpersonal experiences, 6. Emphasising the therapeutic relationship, and 7. Exploring patients' needs, goals, and wishes.

5. Survivorship Care Plan (SCP) intervention:

Fang et al. (2020) used a SCP intervention to provide tailored information based on participants' unmet needs. One component of the intervention involved psychoeducation of recurrence, treatment, symptom management and health promotion, (e.g., physical activity, healthy eating, and smoking cessation). Another component involved management of long-term physical and psychosocial effects of cancer treatments, e.g., strategies to help body image concerns. A third component involved integrating care, e.g., providing skills for participants to discuss cancer-related concerns with their family and friends for support.

6. Video Sequence intervention:

Neubert et al. (2023) used a video sequence intervention to reduce fear of progression. Components of their intervention included psychoeducation on distress and psychological

symptoms, and two core ACT processes (contact with the present moment and diffusion). Psychoeducation also included an introduction to psychological approaches, such as CBT techniques and the relationship between thoughts and emotions.

7. Survivor Stories intervention:

Thompson et al. (2021) used breast cancer Survivor's Stories as an intervention to improve quality of life and reduce FCR. The component of this intervention involved sharing health information about cancer treatment and survivorship through stories. The stories aimed to engage participants and immerse them into the narratives, so that they would be more receptive to the content of the stories, identify with the survivors, potentially vicariously learn from their experiences, and make appropriate decisions regarding their diagnosis and treatment recommendations.

8. BREATH (BREAst cancer ehealTH) intervention:

The BREATH intervention in van den Berg. (2015) study used CBT techniques to guide participants chronologically through the transition from 'breast cancer patient' to 'survivor', covering four phases of adjustment: looking back, emotional processing, strengthening, and looking ahead. The components of the intervention included psychoeducation, cognitive reframing, goal planning, and process evaluation.

9. VR-CALM Psychotherapy intervention (Managing Cancer and Living Meaningfully):

The VR-CALM intervention in Zhang et al. (2022) study addressed specific issues of advanced cancer and comprised of four major components: (1) symptom management and communication with healthcare providers; (2) changes in self and relationships with others;

(3) spiritual wellbeing and the meaning of life, (4) communication about future concerns, hopes, and mortality.

10. Cognitive Bias Modification (CBM) intervention:

CBM was used as an intervention in Lichtenthal et al. (2017) study to reduce FCR. The component of this intervention involved targeting cognitive biases associated with FCR, by using rapid stimuli of cognitive tasks designed to encourage shifts in attention and interpretation of threatening cancer-related content.

11. Guided chatroom intervention:

Lange et a. (2017) used a guided chatroom intervention to allow participants to exchange concerns through text interaction. Although the intervention was described as a 'behaviour therapy-oriented group approach without defined goals', no specific behavioural interventions were described. As the original manual is in German, it was not possible to ascertain further details. Participants joined virtual chatrooms that covered the following topic areas: incontinence, fear of progression, partnership and sexuality after prostatectomy, doctor-patient communication, occupational reintegration, resource-orientation, and coping.

Application of Digital Health Intervention

The digital health interventions in the 18 included studies were applied in various ways using a range of devises including smartphones, mobiles, iPhones, iPads, desktops, laptops and tablets. The majority of studies used online websites as the primary delivery method (n=13). Other digital platforms included telephone, virtual reality, and smartphone apps.

Most of the interventions were fully self-guided (n=10), allowing the participants to engage with the materials independently. Three studies incorporated online feedback from a therapist alongside access to self-guided material. Online group interventions were delivered in two studies. Moreover, two studies used a blended approach: one combined face-to-face sessions with website access and e-consultations (chat application), while the other combined telephone sessions with a non-digital booklet. A one-to-one remote intervention was also delivered in one study.

The number of modules/sessions and the duration of the intervention period varied, ranging from 5 to 16 modules and 4 to 16 weeks, respectively. The most common intervention length was 6 modules, which was observed in 5 studies.

Outcomes of Digital Health Interventions

Compared to control groups, digital health interventions were associated with a significant reduction of FCR in 12 out of the 18 studies included in this review. Six studies found no significant difference between groups. There were no specific patterns favouring particular intervention types in studies with significant results compared to those without.

Quality Appraisal

A summary of each study's quality rating across the JBI items is included in Appendix 1.8. Only one study reported blinding participants themselves to the intervention they received (Lichtenthal et al., 2017). The nature of the digital health interventions makes it evident to participants whether they are receiving the intervention or not, therefore making participant blinding unfeasible. Similarly, blinding of intervention providers was not possible in studies that used clinician-led remotely delivered interventions, again due to the inherent

nature of the intervention. As a result, blinding of participants (item 4) and intervention providers (item 5) was not possible in the context of this review.

Furthermore, the majority of studies relied on self-report measures completed by participants through digital means. Consequently, blinding of outcome assessors (item 6) was not applicable for most studies, as the responsibility for completing outcome measures lay with the participants themselves. Similarly, reliability of outcome measures (item 11) was also not applicable for these studies, as this item focused on the reliability of the raters, e.g., their training, and the inter-rater reliability within the study. Moreover, allocation concealment (item 2) was also poorly reported, with many of the included studies providing limited information on this aspect.

Discussion

This review synthesised the existing evidence on digital health interventions for adults with FCR. Eighteen studies, published between 2015 and 2023 were included. Three secondary questions were explored which related to participant characteristics, intervention components and application, and intervention outcomes.

Our review found 11 distinct digital health interventions, with CBT being the most commonly used approach, supported by the findings of Tauber et al. (2019), which identified CBT as the most effective psychological intervention in reducing FCR. However, some studies in this review used a combination of different psychological approaches, making it difficult to determine the active ingredients of the component which had the most effect in reducing the symptom burden for each participant. Similarly, in terms of

intervention application, some studies used various delivery methods in conjunction with one another, making it difficult to pinpoint the most effective approach.

Self-guided interventions constituted the majority of the studies, which offered flexibility and convenience as participants were able to access and utilise the interventions at their own pace. As self-guided interventions are less resource intensive, these findings indicate that such interventions hold promise for scalability within the NHS. However, the variations across studies in the number of modules, sessions, and the length of the intervention period demonstrate the diversity in intervention structures and highlight the need to investigate the optimal duration and frequency of interventions. Therefore, further exploration is needed to determine the most effective 'dosage' and duration of interventions for achieving sustainable outcomes in adults with FCR.

Web-based interventions were identified as the predominant digital health platform in the reviewed studies. One reason for its popularity could be the wide accessibility and versatility it offers, as it can be accessed through a number of devices including laptops, desktops, tablets, and smartphones. This flexibility allows users to engage with the intervention using their preferred device, offering choice, and accommodating for their technological capabilities.

It was surprising however, that smartphone apps were only used in two out of the 18 included studies, despite their numerous advantages. Like web-based interventions, Smartphone apps offer a potentially engaging and interactive experience through multimedia elements and interactive modules, however, they provide the added benefit of portability, enabling access to the intervention anytime and anywhere. Smartphone apps

can also enable push notifications to remind users to engage with the intervention and encourage them to practice self-management techniques related to their FCR. Real-time symptom tracking on Smartphone apps can also motivate users to use FCR related strategies more promptly. Offline access is also possible with apps, enabling continuous engagement even in areas with limited network connectivity, such as hospital settings.

The aim of the interventions in these studies was to reduce FCR, however many studies did not explicitly include FCR as an eligibility criterion for participation. Although this raises concerns regarding the internal validity of the studies, we made the decision not to modify the inclusion criteria for this review, as doing so could have potentially excluded relevant studies and resulted in a much smaller pool of included studies, thus limiting our understanding of the topic. It is worth noting that despite FCR not being explicitly listed as an inclusion criterion, high levels of FCR were consistently reported by participants at baseline, indicating that the target population of individuals with FCR was still represented in the interventions included in this review.

Most studies reported statistically significant improvements in FCR following digital interventions, however, the use of different statistical analyses contributed to heterogeneity in results and made direct comparisons challenging. While no specific patterns were observed between interventions with significant and non-significant results, it is worth considering that success of digital interventions may depend on various factors beyond the specific intervention type, for example, the quality of implementation, level of support, intervention duration, timing of assessments, and participant engagement.

In terms of participant characteristics, the majority of studies focused on breast cancer, reflecting its prevalence as the most common type of cancer in the UK (Cancer Research UK, 2020). Notably, many studies did not report the participants' stage of cancer, limiting our understanding of how disease stage may influence the effectiveness of the interventions. Among the studies that did report cancer stage, most participants had stage 1 or stage 2 cancer.

The underrepresentation of participants with more advanced stages of cancer may be due to a variety of reasons that require further study. For instance, the five-year net survival rate for women in England with stage 4 breast cancer is 27.9%, as compared to 98.8% for those with stage 1 (Broggio & John, 2019). The extreme disparity between the expected prognosis of women in the early versus later stages of breast cancer raises important considerations regarding the psychological factors that may influence their willingness and motivation to engage in interventions targeting FCR. Moreover, this underrepresentation may be due to the complexities of conducting trials in this population, as individuals with advanced cancer may encounter unique emotional and practical challenges that could affect their ability to adhere to interventions.

It is also important to consider the applicability of FCR versus fear of cancer progression (FoP) in understanding the underrepresentation of participants with more advanced stages of cancer. FCR is most relevant to individuals who have entered remission but fear their cancer returning. Conversely, those with metastatic cancer and ongoing active disease are more logically concerned about the cancer progressing rather than returning. Additionally, individuals whose cancer has already recurred cannot fear recurrence, but many still fear progression. However, the literature lacks a clear distinction between those with and

without current active disease or their specific fears, leading to the consensus definition of FCR as the fear that 'cancer will come back or progress'. This definition conflates FCR with FoP and assumes they represent the same latent construct.

Nevertheless, a recent study conducted a factor analysis on items from the FCR-I severity subscale and FoP-Q-SF, revealing that while FCR and FoP are highly correlated and predicted by some of the same constructs, fear of the cancer returning and progressing should not be treated synonymously (Coutts-Bain et al., 2022). This conflation may lead to suboptimal recommendations for clinical practice. Drawing conclusions about one construct may not apply to the other, thus potentially inadequately addressing the fears of individuals with advanced cancer. As a result, the underrepresentation of people with advanced cancer stages in this systematic review may be influenced by the conflation of FCR and FoP in the literature.

Furthermore, only two studies reported participants' ethnicity. A specific concern with this is that digital poverty is considered to impact ethnic minorities and marginalised groups disproportionately (Zhai, 2021). Moreover, research has shown repeatedly that racial and ethnic minority groups often have disproportionally worse healthcare outcomes and experience greater difficulty in receiving cancer care and support services (Zavala et al., 2020). Therefore, understanding the barriers in engaging with digital health interventions in these populations would be important to ensure equitable clinical practices.

Strengths and Limitations of Review

This is the first systematic review to synthesis the existing evidence on digitally delivered psychological interventions in adults with FCR, signifying its originality and importance.

Unlike a previous scoping review that focused solely on CBT (Cincidda et al., 2022), this review included all types of psychological interventions, as well as all formats of digital delivery. Due to this broad and inclusive approach in methodology, a more diverse and comprehensive understanding of digital interventions in FCR was captured in this review. Moreover, given that RCT's are recognised as the gold standard for evaluating intervention effectiveness (Hariton & Locascio, 2018), the prevalence of RCT's within this review enhanced the overall validity and reliability of the included studies and boosted the credibility and robustness of the review's outcomes.

There were, however, limitations in our methodology which should be considered when interpreting this review. Although we adhered to the TIDieR checklist as a measure of transparency of reporting, we encountered several limitations in its application. Most studies generally appeared to demonstrate transparency in their reporting, however, this did not always mean that the specific psychological interventions employed were always clear. For example, in the study by Lange et al. (2017), their psychologist-facilitated guided chatroom intervention was described as a 'behaviour-therapy oriented' approach, and while there appeared to be clear detail regarding the topic of discussions, how the discussions took place, and the modality of the chat, there was no detailed information on the behaviour therapy techniques and strategies, or the mechanisms targeted. The absence of such information hindered our ability to discern the specific mechanisms targeted, the methods by which they were addressed, and the extent to which the intervention was delivered as intended. Therefore, item 11 of the TIDieR checklist proved somewhat inadequate in capturing the essential criticisms that are highly relevant to psychological interventions.

Item 11 on the TIDieR checklist could be expanded further to include greater clarity and detail about (a) the specific mechanisms targeted, (b) the techniques applied to address those mechanisms, and (c) the extent to which techniques are appropriately delivered. Enhancing this aspect of the TIDieR checklist could improve the evaluation of psychological interventions and facilitate a more comprehensive understanding of their impact.

Furthermore, the JBI tool which was selected to appraise the quality of the included papers required two authors to independently rate each paper, however, due to the large number of included studies, it was not feasible to achieve this and only a third of the included studies underwent independent rating. The JBI tool also does not provide summary scores to generate an overall quality rating, however, the use of summary scores in critical appraisal tools has faced criticism as they may overlook significant weaknesses in specific areas while assigning higher scores in other areas (Crow & Sheppard, 2011).

It may also be worth noting that most of the recruited participants in this review were female, reflecting the gender disparity in breast cancer incidence. However, a more balanced representation of gender and the inclusion of more diverse cancer types would have broadened the scope of this review and enhanced the generalisability and applicability of the findings to a wider population of adults with FCR. Moreover, the exclusion of non-English and non-peered-reviewed studies may have also limited the generalisability of the review's findings and introduced publication bias.

Although we did not set out to investigate outcome signals in relation to digital health interventions as a primary outcome, we recognise that meta-analyses could be used to

detect significant effects on measures of FCR. Meta-analyses may be indicated for future studies, and we therefore recognise this as a limitation of this review.

Clinical and Research Implications

Healthcare providers can consider the findings of this study when planning tailored interventions for patients with FCR. They may explore the use of self-guided web-based interventions, consider incorporating elements of CBT, and be aware of the potential benefits of digital health tools in their practice. This study also highlights the importance of refining research methodology and enhancing reporting standards within the field. These clinical and research implications not only inform future efforts to address FCR but also provide a foundation upon which policymakers can base the formulation of best practice guidelines.

Conclusions

The available evidence of digital health interventions for adults with FCR have been synthesised in this review. The findings provide valuable insights for healthcare providers and researchers seeking to develop and implement interventions for FCR in clinical practice and contributes to the growing body of knowledge in the field. Future studies should also consider conducting meta-analyses to strengthen the evidence base for digital health interventions in managing FCR.

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Chapter Two: Major Research Project

A qualitative study aimed at developing a digital health intervention for people with psychosis who are fearful of relapse

Prepared in accordance with submission requirements for Journal of Medical Internet Research JMIR Author Guidelines

Plain English Summary

Title: Developing a digital health intervention for people with psychosis who are fearful of relapse

Background: Psychosis involves having unusual sensory experiences (e.g., hearing things/seeing things that others do not) and having distressing beliefs (e.g., paranoia, where people become suspicious or fearful of others). Although many will recover, some will relapse which means their distressing experiences return. Those who have a fear of relapse (FoR) are more likely to relapse. Despite this, there are not many treatment options targeting FoR. Smartphone apps can be effective in increasing access to support; however, it is important to involve people with lived experience in their design. This way, the intervention is more engaging, more acceptable, and more likely to be successfully used.

Aims: The aim of this study was to engage people who have experienced psychosis to investigate their preferences in the development of a Smartphone app that focuses on FoR and supports them with strategies to stay well.

Research Questions: Do service users look after their health using Smartphone apps? What would their preferences be with regards to the design and content of an app that targets FoR and what would they hope to gain from using it?

Methods: 12 adults with lived experience of psychosis took part in the study. Participants were invited to a focus group, or if they felt more comfortable, a one-to-one interview with the researcher instead. The interviews and focus group sessions were audio-recorded and typed word-for-word. These transcriptions were analysed using a research method known

as Thematic Analysis, which involves looking for patterns and similarities across experiences and opinions.

Findings: The analysis resulted in six themes and twenty-three subthemes. (1) 'Contextual Factors': Participants used physical activity, a healthy lifestyle, engaging the mind, and social connections to stay well. They owned and used smartphones, had positive experiences with digital health apps, had varying degrees of FoR, and most felt comfortable seeking help. (2) 'Preferences in the design of the app': Participants wanted a personalised app with customised reminders and notifications, visual symptom tracking, and a user-friendly interface. (3) 'Preferences for the content of the app': Participants wanted reliable and accurate psychosis-specific resources, self-assessment quizzes for symptoms, and direct access to support. (4) 'Information sharing and privacy concerns': Confidentiality and having control over data were emphasised. Some participants appreciated the option to share data for peer support via a social platform element. (5) 'Factors influencing user engagement and deterrence': Regular updates with informative and engaging content, along with flexible data input, were important for user engagement. App costs, advertisements, and excessive notifications were viewed as deterrents. (6) 'Outcomes and effectiveness': Participants believed the app could be worthwhile if it prevented hospitalisation, reduced anxiety, helped them recognise when they need help, and facilitated a return to their normal routines.

Conclusions: This study provides valuable information about what people with lived experience of psychosis want in digital health interventions to help them overcome their fear of relapse. This knowledge can be used to create a digital app that meets their specific needs.

Abstract

Background: Fear of recurrence (FoR) is a risk factor for future relapse in people experiencing psychosis. Despite this, there is a distinct lack of interventions which target FoR. Digital health technology has shown promise as an effective intervention for people with psychosis, with the potential to reduce hospital admissions, improve medication adherence, and alleviate positive symptoms. Despite its potential benefits, the real-world usage rates of these interventions remain relatively low. Evidence suggests that involving people with lived experience in the design of digital interventions can improve acceptability, and subsequently lead to more successful implementation and uptake of the intervention.

Objective: The aim of the study was to explore the perspectives of individuals with lived experience of psychosis regarding their preferences for a hypothetical digital health intervention which addresses FoR and supports them with strategies to stay well.

Method: This study used a qualitative research design. Twelve participants were recruited to attend a focus group, or a supplementary individual interview to facilitate inclusivity. A topic guide was used to facilitate the discussion, which centered on the content, format, style and delivery of the hypothetical FoR intervention. Thematic analysis was used to analyse the data collected from the interviews and focus groups.

Results: Six themes and twenty-three subthemes were identified. (1) 'Contextual Factors': Participants used physical activity, a healthy lifestyle, engaging the mind, and social connections to stay well. They owned and used smartphones, had positive experiences with digital health apps, had varying degrees of FoR, and most felt comfortable seeking help. (2) 'Preferences in the design of the app': Participants wanted a personalised app with

customised reminders and notifications, visual symptom tracking, and a user-friendly interface. (3) ‘Preferences for the content of the app’: Participants wanted reliable and accurate psychosis-specific resources, self-assessment quizzes for symptoms, and direct access to support. (4) ‘Information sharing and privacy concerns’: Confidentiality and having control over data were emphasised. Some participants appreciated the option to share data for peer support via a social platform element. (5) ‘Factors influencing user engagement and deterrence’: Regular updates with informative and engaging content, along with flexible data input, were important for user engagement. App costs, advertisements, and excessive notifications were viewed as deterrents. (6) ‘Outcomes and effectiveness’: Participants believed the app could be worthwhile if it prevented hospitalisation, reduced anxiety, helped them recognise when they need help, and facilitated a return to their normal routines.

Conclusions:

Our findings contribute to the existing literature by providing insights into the interests, preferences and outcomes valued by individuals with lived experience of psychosis regarding digital health interventions aimed at reducing fear of relapse. These findings have the potential to inform the design and content of a digital health app that is aligned with their needs and expectations.

Keywords: *digital health intervention; fear of recurrence; psychosis; relapse*

Introduction

Psychosis is an umbrella term referring to a group of conditions that describe a person's altered perceptions, thoughts, moods, and behaviours causing them to perceive or interpret reality in a different way from those around them (Arciniegas, 2015). Symptoms of psychosis can be divided into two groups: (1) 'positive', which reflect the presence of sensory experiences such as hallucinations (e.g., voices), delusional beliefs (e.g., paranoia) and disorganised speech or behaviour, and (2) 'negative', which reflect an absence or loss of experiences characterised by social withdrawal, emotional apathy, and lack of drive (American Psychiatric Association, 2013).

Psychotic disorders are associated with premature mortality (Hjorthøj et al., 2017) largely resulting from physical health comorbidities, but suicide risk is also higher in this population (Taylor et al., 2014). Approximately 1-2% of the population will experience psychosis in their lifetime; however, prevalence rates vary according to age, sex, ethnicity, population density and socioeconomic status (Department of Health, 2016). People from minoritized groups are at a higher risk of experiencing psychosis (Selten et al., 2019) likely, due to traumatic pre-migration experiences of violence and war (Hollander et al., 2016), and discrimination, marginalisation, isolation, socioeconomic deprivation and inequalities in welfare, employment, housing and health (Morgan et al., 2019). Higher incidence of psychosis has also been reported among men (van der Werf et al., 2012), with an onset occurring in late adolescence into early adulthood (DOH, 2016).

'Relapse' in the context of psychosis has been conceptualised as the exacerbation of positive symptoms which impact on functioning and behaviour (Burns et al., 2000), associated with emotional distress (Gumley & Schwannauer, 2006), resulting in increased residual

symptoms (Takeuchi et al., 2018). Relapse is often preceded by 'early warning signs' (EWS) which are subtle changes in affect, thought and behaviour occurring prior to frank psychosis (Birchwood et al, 2000) and may materialise as anxiety, low mood, sleep changes, withdrawal, and low-level paranoia (Eisner et al., 2013). Approximately 82% of people diagnosed with a first episode of psychosis will experience a relapse within 5 years (Brown et al., 2010), carrying with it a significant need for health services including unplanned hospitalisations (Ascher-Svanum et al., 2010).

Fear of Recurrence (FoR), defined as an individual's distress and worry of having a relapse, is more likely to occur among individuals who have had traumatic and distressing experiences of psychosis (White & Gumley, 2009) e.g., feeling coerced into care or the experience of involuntary hospitalisation (Berry et al., 2013). People with FoR commonly hold catastrophic beliefs about relapse, for example, beliefs relating to their perceived loss of control, which are often grounded in the reality of their past experience of psychosis (Gumley et al., 2015). These threats are closely linked to post-traumatic reactions including post-psychotic post-traumatic stress disorder (PPTSD) (Rodrigues & Anderson, 2017) as well as relapse itself (Gumley et al., 2015). Gumley et al. (2020) in their cognitive interpersonal model of relapse, state that FoR is also associated with emotional, cognitive and behavioural avoidance and delayed help-seeking, often due to fear of hospitalisation (Gumley et al., 2003).

Although monitoring for EWS is commonplace in the care of psychosis, research indicates this to be a modest predictor of relapse (Eisner et al., 2013). FoR on the other hand, was found to be a better predictor of time to relapse as compared with EWS (Gumley et al., 2015) potentially due to its ability to capture the emotional and cognitive dimensions of relapse vulnerability. It has been proposed that FoR considers the catastrophic appraisals of

relapse, fear, vigilance, and interpersonal threat sensitivity, which EWS may not fully account for, therefore making it a more sensitive predictor, as it explores the nuanced meanings and emotional distress associated with the early stages of relapse, beyond symptoms alone (Gumley et al., 1999). However, it is still important to note that these models may impact minority voices differently, as individuals from marginalised communities may face unique challenges related to both the experience of psychosis and the expression of FoR. Cultural, social, and systemic factors can influence how individuals from minority backgrounds perceive, express, and seek help for these experiences, highlighting the need for culturally sensitive and inclusive approaches in mental health care and research.

Interventions for FoR are well developed in areas of physical health such as cancer (Grozdziej, 2015). These interventions often involve self-management techniques, (consisting of, for example, coping strategies, encouragement of medication adherence, and psychoeducation of illness and treatment), which can be an effective way to aid people with long-term health conditions to take an active role in their recovery. Interventions targeting FoR in psychosis are, on the other hand, less well established. A meta-analysis, however, found that self-management interventions could also improve outcomes for adults with severe mental illness (Lean et al., 2019) and reduce the likelihood of relapse in people with psychosis (Zou et al., 2012).

In recent years, research has shown that the use of digital technology can be an effective intervention for people with psychosis, reducing hospital admissions, increasing medication adherence, and improving positive symptoms (Álvarez-Jiménez et al., 2012). Smartphone usage among people with psychosis appears to be growing, with rates of ownership

reported to be around 81.4% and rising (Firth et al., 2015). Furthermore, people with psychosis are interested in and are willing to engage in mental health interventions delivered via smartphones (Aref-Adib et al., 2016). However, it is important to recognise the role of digital poverty. Limited access to digital devices and the internet can exacerbate health disparities, hindering equitable access to these interventions, especially among marginalised populations. Bridging the digital divide is therefore crucial to ensure the widespread scalability of digital health interventions for FoR.

Smartphones can collect data in real-time at various time points, thereby enhancing the assessment of psychological processes with the potential of helping to identify an individual's on-going symptomology. Given that adherence to daily monitoring via smartphone apps have been reported to be over 85% (Ben-Zeev et al., 2014), smartphone apps which have been used to deliver self-management interventions have been found to be feasible, acceptable, and potentially beneficial in supporting recovery in people with psychosis (Bucci et al., 2018a). Findings from a recent feasibility trial conducted by Gumley et al. (2022), demonstrated that a blended intervention involving a smartphone app reduced relapse rates and FoR in participants with schizophrenia.

Despite the potential benefits, many digital health interventions are unsuccessful and have low real-world usage rates, possibly due to the lack of involvement from people with lived experience in the design of the intervention (Bucci et al., 2019b). A more collaborative approach can help predict subsequent user engagement with digital health interventions (Killikelly et al., 2017), illuminate different perspectives, bring forth new ideas, and help in the anticipation of problems that may not have been considered by the research team alone.

Present Study

FoR has been described as an important clinical construct in psychosis, as well as a potentially modifiable mechanism in an area where interventions are lacking. By engaging people with a lived experience of psychosis, this study aimed to explore the possible utility and desirable features of a digital health intervention that addresses FoR and supports people with strategies to stay well. We asked the following questions:

- What experiences do service users have in using digital health apps to support their mental health and wellbeing?
- What preferences do service users have with regards to the design and content of a digital health app that aims to alleviate fear of psychosis recurrence?
- What outcomes do service users value from the use of a digital health app?

Method

Ethical Considerations

Ethical approval was obtained from the West Midlands Black Country Research Ethics Committee (22/WM/0270; Appendix 2.1) and managerial approval was granted by the NHS GG&C Research and Innovation (R&I) Department (GN22MH312; Appendix 2.2). Written informed consent was obtained from all participants, and data handling adhered to NHS data protection policies. Participant identifiable information was removed, and pseudonyms were used to ensure anonymity.

Design

This study used a qualitative research design to gather interview data from participants through focus groups and individual one-to-one interviews. A flexible topic guide, influenced

by the Medical Research Council (MRC)'s framework for complex interventions (Skivington et al., 2021), was developed in consultation with the researcher's supervisor (see Appendix 2.3). The topic guide facilitated discussions about the potential features of a hypothetical digital intervention for FoR. Participants were encouraged to provide suggestions regarding the content, format, style and delivery of the intervention.

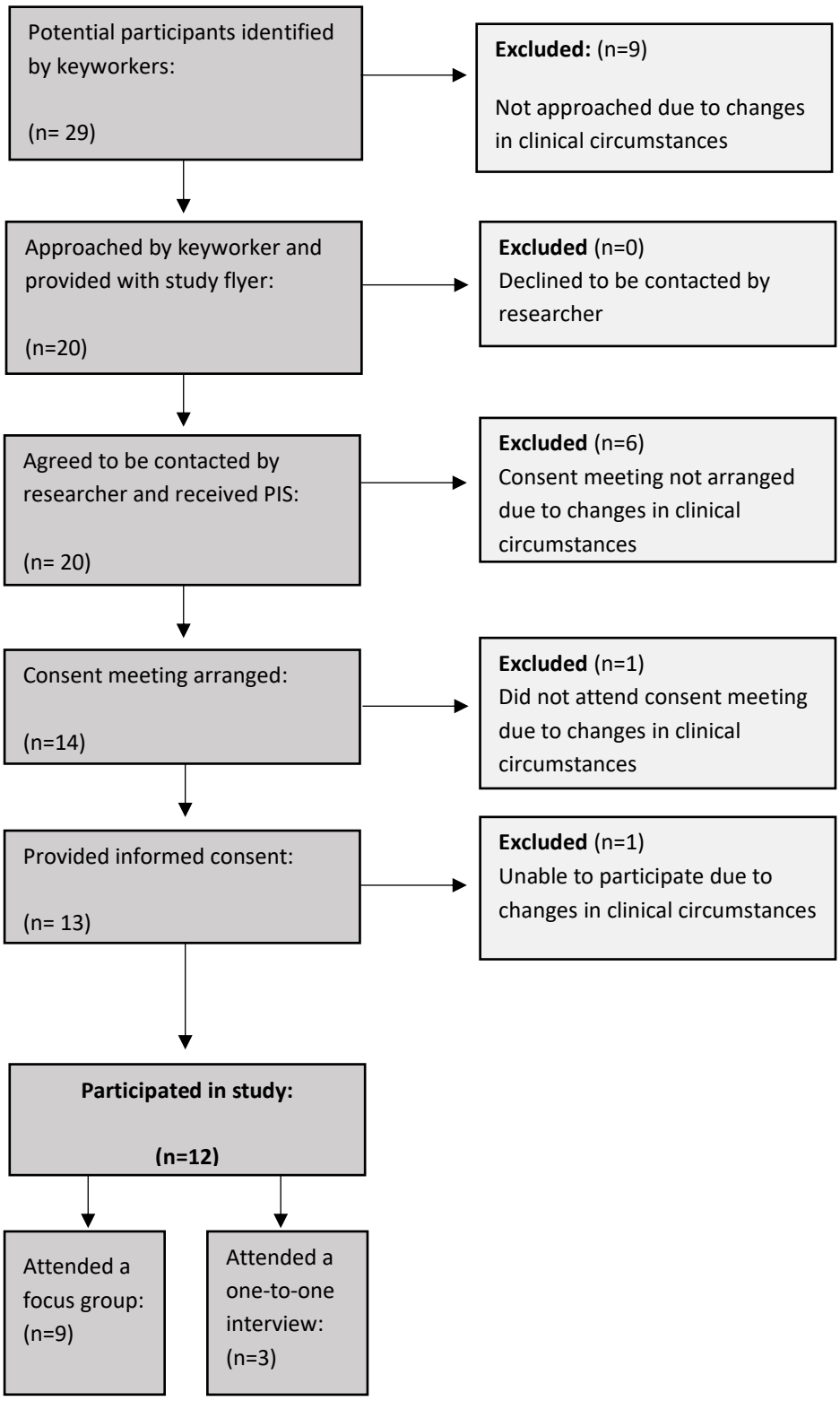
Recruitment and Eligibility

The recruitment phase took place between February and April 2023 within an early intervention in psychosis (EIP) service in NHS Greater Glasgow & Clyde (NHS GG&C). To identify potential eligible participants, the study was presented at the EIP multi-disciplinary team (MDT) meetings, and key workers were provided with a Staff Information Leaflet (Appendix 2.4). Participants were eligible if: they were 16 years or older, had a definite or probable diagnosis of a psychotic disorder, could communicate in English, and had the capacity to provide informed consent. Those experiencing acute psychosis were excluded, and approach to consent was suspended for at least four weeks post-discharge from an acute psychiatric inpatient unit.

Keyworkers approached potential participants and provided a Study Flyer (Appendix 2.5) outlining the study aims. Interested participants gave verbal consent to be contacted, which was documented in their case notes. Keyworkers completed a Proforma Email (Appendix 2.6) to inform the researcher. The researcher then sent a Participant Information Sheet (PIS) (Appendix 2.7) to the patient. Potential participants could also contact the researcher directly.

After receiving the PIS, potential participants were given a minimum of 24-hours to consider participation. The researcher then contacted them to arrange a meeting either through MS Teams or face-to-face, to discuss the PIS in more detail. If the potential participant expressed a wish to participate, written informed consent was obtained using a Consent Form (Appendix 2.8). For face-to-face meetings, the form was signed at the time. For online meetings, a copy was sent via post, and participants were asked to return the signed form in an addressed envelope or via scanned email. Online meetings were recorded through MS Teams. Consent meetings were conducted individually with each participant before the focus groups/individual interviews. Figure 2.1 illustrates the recruitment flow.

Figure 2.1: Flow Diagram of Recruitment



Participants

Twelve participants (7 males and 5 females), aged between 17 and 33, (M= 22, SD= 4.97) were recruited from an NHS GG&C EIP service. Three participants attended an individual interview with the principal researcher, while the remaining nine participated in one of three focus groups. No demographic data beyond participant age and preferred pronoun were collected. Participant characteristics can be found in Table 2.1.

Table 2.1: Participant Characteristics

Name*	**Gender**	**Age**	**Attended**
Colin	Male	24	Focus Group 1
Bria	Female	33	Focus Group 1
Harris	Male	23	Focus Group 2
Alec	Male	25	Focus Group 2
Maya	Female	32	Focus Group 2
Elin	Female	27	Focus Group 2
Ava	Female	20	Focus Group 3
Leigh	Female	21	Focus Group 3
Darra	Male	17	Focus Group 3
Sid	Male	21	Individual
Jonty	Male	26	Individual
Noam	Male	21	Individual

**Pseudonyms*

Research Procedures

Participants who provided consent were invited to a 90-minute online focus group facilitated by the Chief Investigator (AG) and the Principal Investigator (NK). Individual interviews were offered to those who faced difficulties in group settings, and face-to-face meetings were arranged for participants unable to join online. The same topic guide was used for consistency.

Participants were briefed on confidentiality, including its limits, and were reminded they could take breaks, decline questions, or withdraw from the research for any reason. In the focus groups, emphasis was placed on maintaining respectful communication to prevent any potential distress caused by inappropriate interactions. After participation, a debriefing session outlining the sources of support listed in the PIS was provided to all participants via telephone, along with a Debrief Document (Appendix 2.9) sent by email or post. All participants received a £20 Love2Shop voucher to thank them for their participation.

Topic Guide

To help encourage open communication and establish rapport, initial questions were broad, neutral, and non-specific to mental health difficulties, and focused on general mobile phone usage, experience with digital health apps and current health and wellbeing practices. Discussions then shifted towards understanding participants' perception of FoR, with an aim to establish a shared understanding. The interviews also explored whether participants had received help for FoR, and if so, what their experience of this was. Finally, conversations were facilitated to gauge participants' perspectives on the types of information and supports they would find helpful in relation to FoR.

Individual interviews lasted between 38 and 65 minutes, while focus groups ranged from 65 to 71 minutes. Five out of six interviews were conducted online, with one conducted in-person.

Data Analysis

The interviews were audio recorded, transcribed verbatim by the principal researcher, and then pseudo-anonymised before progressing to analysis. The analysis followed Braun and Clarke's (2006) six-phase methodology (detailed in Appendix 2.10). The process involved iteratively coding the data, organising codes into themes, and reviewing themes to create a cohesive analysis. Initially, each transcript was carefully examined, capturing reflections and preliminary codes. Transcripts were read numerous times to uncover patterns and differences across transcripts, identifying any new codes. Codes which related to one another where then organised into clusters, forming themes and sub-themes that captured the essence of each category. Analysis of focus groups and individual interviews were conducted separately, then synthesised to look for evidence of thematic convergence and areas of thematic divergence.

Epistemological Perspective

The aim of the interviews was to generate ideas for an intervention based on the participants' experiences, while also considering how the intervention would be implemented within the NHS. As such, the data collected was interpreted within the context of the NHS, using a critical realist epistemological perspective. Critical realism combines a realist ontology, which acknowledges the existence of an objective reality that is independent of our perceptions and social systems, with an interpretivist epistemology that recognises that our understanding of this reality is shaped by our personal perspectives and

experiences (Olsen, 2007). By using this perspective, the study aimed to develop a contextualised understanding of the data, accounting for both the objective reality of the situation and the participants' subjective experiences.

Reflexivity

As an NHS trainee clinical psychologist on placement within the EIP service which this research project was based in, it was important to remain mindful of how my familiarity of the service could influence my data interpretation. Throughout the research process, a reflective diary (see Appendix 2.11 for excerpts) was kept so that any preconceived notions I had about patients' needs and expectations were recorded, and that any themes that aligned with the priorities of the service could be reviewed and acknowledged. Pre-existing therapeutic relationships with two participants who were on my caseload during the time of the interviews may also have introduced a power dynamic, or social desirability bias, potentially influencing their responses. This bias may have led them to overstate the potential benefits of a hypothetical app, despite the researchers' efforts to encourage critical feedback. This diary therefore served as a tool for recognising and examining any interaction between my prior assumptions and views, with the information that was being collected and the themes that were developed.

Working in another EIP service in a previous role, further shaped my understanding of participants' concerns, preferences, and needs related to FoR. Working on a RCT of a digital health intervention for individuals with psychosis provided me with additional knowledge and exposure to this domain and influenced my views towards the potential benefits and feasibility of digital health interventions. It was therefore important to recognise this and remain open to exploring opposing viewpoints that were not limited by any pre-existing

perspectives I held. Supervision provided an opportunity for further reflection, ensuring that the participants' views were not given more weight solely because they aligned with my own prior views.

Finally, it is important to acknowledge that the MRC complex interventions framework which guided our work and was reflected in my research supervisor's guidance, played a significant role in shaping our understanding and interpretation of the data. This framework emphasises intervention fidelity, feasibility, and acceptability within the NHS context. Therefore, it was important to recognise that its influence may have resulted in an emphasis on these specific aspects during the analysis process. However, efforts were made to critically engage with the data to ensure a balanced interpretation.

Results

A thematic map (Figure 2.2) was generated to explore how provisional themes related to one another. Once refined, the thematic analysis resulted in six themes, with twenty-three sub-themes (see Table 2.2). As an example, full details of quotes, codes, and sub-themes of theme one is provided in Appendix 2.12.

Figure 2.2: Thematic Map

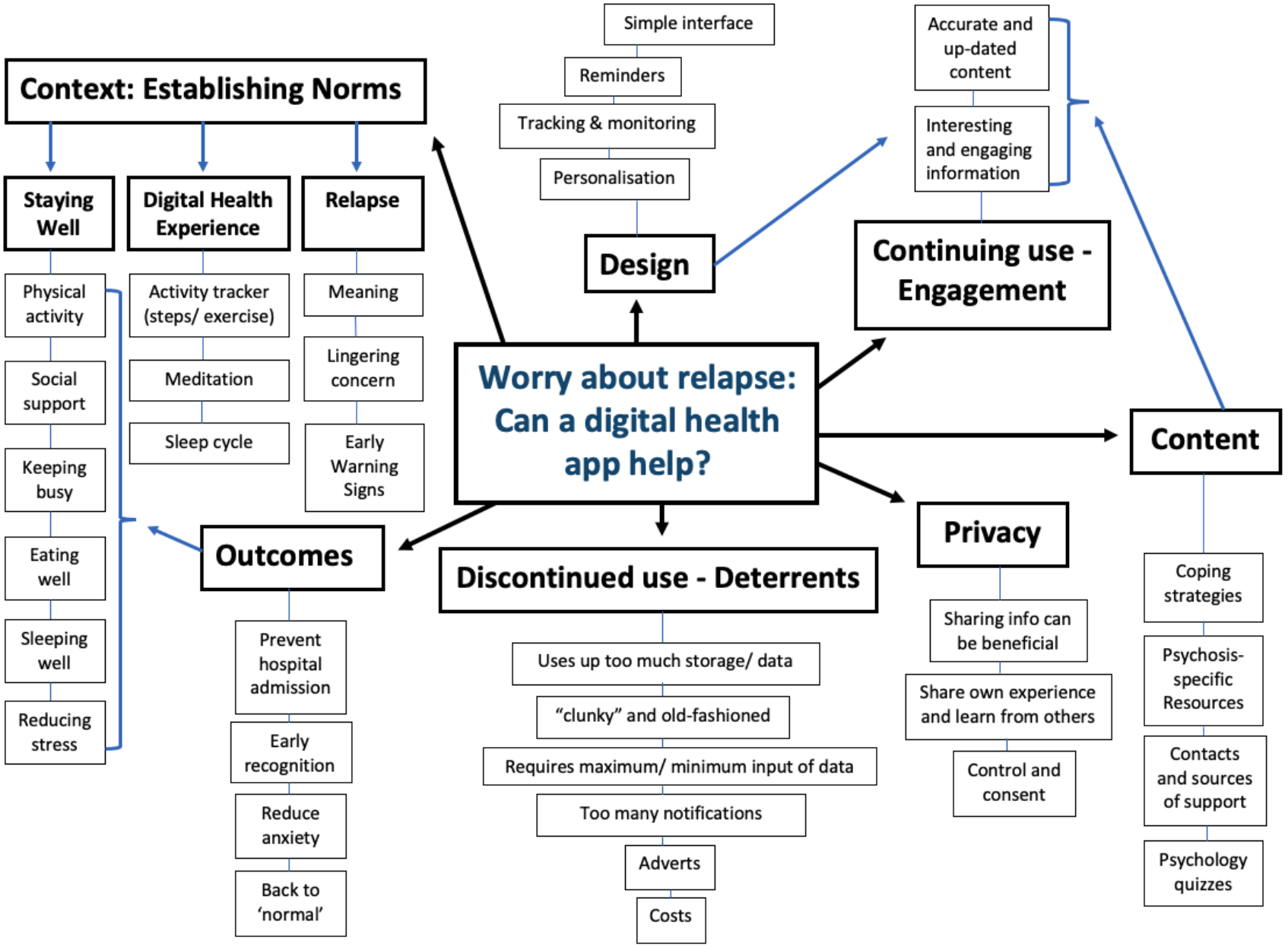


Table 2.2: Themes and Sub-Themes

Theme	Sub-Theme
1) Contextual Factors	Staying well
	Current phone usage and digital health app experience
	Conceptualisation of relapse and seeking help in psychosis
2) Preferences in the design of the app	Personalisation, tracking and making entries
	Visual progress monitoring
	Visual appeal and user-friendly interface
	Reminders and notifications
3) Preferences for the content of the app	Reliable and accurate psychosis-specific resources and centralised information
	Psychological self-assessment
	Access to support
4) Information sharing and privacy concerns	Importance of confidentiality and control
	Benefits of sharing
	Social platform element
5) Factors influencing user engagement and deterrence	Continuous refinement and maintenance
	Informative and engaging content
	App functionality
	App costs and advertisements

	Flexibility in data input
6) Outcomes and effectiveness	Preventing hospitalisation
	Reducing anxiety
	Early recognition and prompt help
	Return to normality
	Reliance on other support systems

1. Contextual Factors

This theme highlighted important contextual factors, for example, what people do to look after their health generally, what they do to monitor their health and wellbeing, the extent to which they use digital technology to do that and the extent to which they would engage with FoR as an intervention target. Three sub-themes were identified within this theme: 1) staying well, 2) current phone usage and digital health app experience, and 3) conceptualisation of relapse and seeking help in psychosis.

Staying Well

Physical activity and exercise were essential components of staying well, with activities such as going to the gym, walking, swimming, cycling and yoga being mentioned. Ava stated how exercise makes *"you feel good afterwards about yourself, like you get all those feel-good hormones like dopamine".* Maintaining a healthy lifestyle was also emphasised, for example, eating well, sleeping well, avoiding drugs and excessive alcohol, and managing stress levels. Participants highlighted the importance of keeping their minds engaged through activities such as work, reading, meditation, baking, gardening, and enjoyable activities. Social support also played an important role in maintaining wellbeing. Participants

highlighted the importance of *"staying in contact with people"* (Sid), for example, *"instead of watching tv by yourself, watch it with someone"* (Alec). Noam reflected on the value of seeking support from the right people during difficult times, such as his psychologist and CPN.

Current phone usage and digital health app experience

Jonty opted to use an older phone without internet access due to social media related fears when unwell. The remaining participants had smartphones, with the majority extensively using them for communication (e.g., texting, calling, WhatsApp), information retrieval (e.g., reading news, browsing the web, Google, Google Maps), entertainment (e.g., TikTok, watching videos on YouTube) and social apps (e.g., Instagram, Facebook). However, some participants found that the abundance of apps were *"sometimes overwhelming"* (Elin).

The Apple Health™ app, particularly the step counter feature was used extensively among participants. They valued the app for its accuracy and its ability to *"help you focus on your fitness level and set goals for yourself"* (Colin). They found it easy to compare activity levels across different weeks. Accessibility and ease of use were highlighted; *"I like it comes with the phones. There's a kind of degree of like, the interface sort of matching up, so you don't have to manually input a lot of data into the app"* (Leigh), *"the apps like easy to use basically"* (Darra). Leigh and Darra also mentioned other features of the Health App, such as inputting health information and emergency contacts, though they had not opted to use these features.

Sid used Strava™ to track his exercise and record his routes while walking or cycling, and appreciated the social networking aspect of the app. However, he disliked the app's push

for paid features. Jonty used the Under Armor Running app and enjoyed recording his routes and sharing with friends. Some participants mentioned using MyFitnessPal™ to track their calorie intake, finding it helpful to monitor eating habits. However, Leigh acknowledged the potential risks of developing disordered eating behaviours and becoming overly focused on calorie-counting. Noam was the only participant who mentioned using a smartwatch.

Conceptualisation of relapse and seeking help in psychosis

Relapse was commonly described as *"the familiarity of old symptoms coming back"* (Alec), and *"re-living the symptoms you had before"* (Harris). For Sid, *"it would mean a return to, you know, probably hospitalization. Umm, just losing my independence, and, you know it's, I'd say it would probably, it'd be quite damaging again to my relationships"*. Participants experienced cognitive changes like paranoid thoughts, delusional beliefs, and suicidal thoughts, as well as changes in behaviour including withdrawal or risk-taking. Ava identified her triggers for relapse, *"like when I'm not sleeping well, not eating well. I'm kind of secluding myself, isolating myself from my, my friends, not really talking to them about how I feel, and isolating myself from my family as well […], believing things that are just not true. Um. You know, like having like, really like, wacky ideas"*. These were also experienced by Leigh and Darra.

Some participants worried about the uncertainty of how relapse could manifest, and not knowing when it might occur. Colin compared the unpredictable nature of relapse to the onset of a cold, emphasising the presence of warning signs and patterns that would alert him to the possibility of becoming unwell again: "*I'm worried that like I don't know how it will strike again. Like what if I'm just walking and then I eventually notice myself becoming*

unwell. […] it's just like a cold […] You never know when you're gonna get the cold. It can just come. But. But it's alright, you know, even with a cold, I guess if it's freezing outside, you know, like, OK, I need to wrap up and stay warm and eat, you know. Uh, put a big jacket on, so there will be signs and stuff".

Participants expressed various concerns about relapse, including potential embarrassing public episodes and their effects on personal and professional lives, the impact on family, experiencing more severe symptoms than the first episode, uncertainty about recognising when help is needed, fear of post-partum psychosis, and worries about medication-induced psychosis.

Most participants acknowledged that the fear of relapse was present in their thoughts, albeit it did not dominate their daily thinking. According to Ava, *"it's kind of like in the back of my mind, but it's not something that like, I constantly think about"*. They expressed confidence in managing potential relapses due to their experience with psychosis and knowledge of effective treatments. Leigh stated, *"it's a little bit scary thinking about relapse. But now that I've had this experience and I've kind of been treated and we know what treatment works and what doesn't, there wouldn't be such a long period of like, trial and error with like different medication and different treatments. Because now there's that kind of, treatment plan, like in place. So it's almost less scary thinking about relapse".*
Nevertheless, the thought of relapse served as a reminder for them to take precautions and maintain their well-being, as mentioned by Darra: *"it is kind of thought in the back of your mind […] in some ways it's a good way, cause it, kinda, leads me to not go down that path of like, sleeping badly, and like, stuff like that, and high stress levels and all that"*.

Participants expressed their growing confidence in recognising early signs that could indicate the possibility of relapse. They emphasised their prior knowledge gained from previous experiences, stating that "*things don't just happen overnight. You know, like there will be signs. There will be patterns that, red, red warning signs that will alert you to like if you're not becoming, if you're becoming unwell. So, I'm more confident over that"* (Colin).

Participants highlighted the importance of seeking help and building a support network to manage concerns related to relapse. Bria expressed, *"I really um know the benefits of having social connections, having someone to trust is really important to uh, to my recovery"*. They recognised the role of family and friends in creating a supportive environment that fosters recovery and emphasised the value of open communication with mental health professionals. However, Darra faced difficulties in seeking help, particularly due to societal expectations on men to show strength.

2. Preferences in the design of the app

This theme explored the preferences expressed by participants regarding the design of the app. For example, what the app should look like; how it should present information; whether it should monitor and track participant wellbeing, and if so, how it should do this. Four sub-themes were identified: 1) personalisation, tracking and making entries, 2) visual progress monitoring, 3) visual appeal and user-friendly interface and 4), reminders and notifications.

Personalisation, tracking and making entries

Participants stressed the importance of personalisation in the app's design, allowing it to adapt to their specific needs and preferences. They wanted the app to offer suggestions

based on their reported feelings and for it to remember previous responses for subsequent check-ins, *"[…] So if it just sort of builds up on what you've said that would be really, really good"* (Colin). Colin wanted a friend-like or conversational interaction with the app, where it considers his past experiences and suggests relevant actions based on his current state.

Additionally, participants expressed the need for a feature that would enable them to write and reflect on daily thoughts, akin to a *"mini journal"* (Alec), with the option to revisit entries as evidence of well-being or periods of being unwell.

Participants wanted their 'staying well plan' to be included within the app. However, they expressed concerns about the time required to enter information into the app manually. They proposed selecting common items from a list to create the plan and suggested having a section for custom entries to personalise it further. They wanted easy access to the plan whenever they felt anxious or low in mood and suggested a dedicated page with a bullet-pointed to-do list that allows them to tick off completed wellbeing tasks.

Visual progress monitoring

Participants valued the ability to visually track their progress over time, through graphs. According to Alec, *"it'd be nice to see your progress visually. Cause you can see how far you've come in your head, but to just have like a graph or something with the scores gradually going up or down or up. Uh, to, to have that would be quite nice to see, it would make you feel better about yourself I think".* Tracking progress was also valuable for self-reflection and sharing with support networks, providing a tangible representation of their recovery journey. Leigh mentioned, *"it would be good to kind of compare like if you are having a bad day, it would give you confidence to look at the kind of bigger picture and say*

well, like this is just one day and there's like a sea of other days, it doesn't mean that this day is going to be the one that is like them all, it's just going to be a bad day and it will end tomorrow".

Visual appeal and user-friendly interface

Participants emphasised the importance of an intuitive interface with clear and logical options, providing a user-friendly experience. They also valued written text that was clear, concise, and easily understandable, and a visually engaging design with colourful elements. Some participants suggested integrating the app with other tools, like calendars or phone notifications and recommended including a built-in tutorial to aid initial navigation of the app.

Some participants expressed a preference for video content as opposed to lengthy texts, as they felt it would cater to a younger audience with shorter attention spans and would be more appealing for those who may not enjoy reading. Leigh disagreed and expressed a preference for written content as she felt it was harder to concentrate on videos. Additionally, participants wanted the app to automatically suggest content, "*Cause then that will save me having to go look for the resources when you're already in a low mood, you don't really want to go and do that. You just want to sulk, so it's better if, like, they give you the resources"* (Ava).

Reminders and notifications

Participants highlighted the importance of daily reminders for engaging in self-care activities and suggested receiving daily notifications for completing progress-tracking symptom

quizzes. Customisability was also emphasised, allowing participants to choose the timing and frequency of reminders based on their individual needs.

3. Preferences for the content of the app

This theme highlighted content-related factors such as the types of psychoeducational information participants felt would be valuable to learn about, and the relapse-specific sources of support they would find beneficial. Three sub-themes were identified: 1) Reliable and accurate psychosis-specific resources and centralised information, 2) psychological self-assessment, and 3) access to support.

Reliable and accurate psychosis-specific resources and centralised information

Participants expressed wanting comprehensive information on psychosis recovery within a single app, covering medication, coping mechanisms, and support services. They highlighted the challenges they faced in accessing reliable information when unwell, and suggested a preference for having all the relevant information in one place, *"I think having all the information on one app would be very useful cause, during my first episode, scattering through loads of different Internet searches to try and lock down what the best, um, but having all the information under one portal, um, so you could just click, scroll through, find what you need, just read about it or learn different coping mechanisms. Um, I think that'd be really beneficial"* (Alec).

Psychological self-assessment

Participants discussed the usefulness of a quiz or assessment tool that could help them better understand their experiences and potentially lead them to seek appropriate help. They preferred short, simple questionnaires or scale-based systems for quick assessments.

Participants felt that such tools could provide initial insights into their symptoms, offer suggestions based on the results, and guide them in deciding whether to contact crisis support, *"[…] if you're feeling very low, you can have like another quiz inside the app, um, that will link you more to the crisis teams or something. So I think there's, or even a chart to follow and how you're feeling, it splits off into what your next step should be"* (Alec). They viewed this as a potential first step toward understanding their experience, even if it did not replace a formal diagnosis. A mood tracker within the app was also considered to be important, allowing participants to record their daily moods, identify patterns over time, and connect their mood with their activities to understand the relationship between them.

Access to support

Participants highlighted the need for the app to provide pathways for contacting health services in case of emergencies or suicidal thoughts. They emphasized the importance of having contact details readily available within the app and suggested integrating crisis contact, emergency contacts, keyworker, helplines, and charities. They suggested having the option to connect with their designated 'support contact' which could include friends or family members who could then seek help on their behalf when needed. The ability to engage in text communication with these contacts was seen as beneficial, particularly during times when they might not feel confident or comfortable with other forms of communication, *"like if I was in a bad state, I wouldn't wanna do a video call. […] if at some point you don't feel confident in like your ability to communicate with people, it might be quite tough to even call. Umm. And text might just be, you know, like kind of bare minimum that you can use"* (Sid).

4. Information sharing and privacy concerns

This theme explored participants' perspectives on the sharing of personal information and the importance of privacy within the context of a digital health app. Three sub-themes were identified: 1) importance of confidentiality and control, 2) benefits of sharing, and 3) social platform element.

Importance of confidentiality and control

Participants emphasised the need for transparency and consent, *"I'll trust the app, as long as it like it reminds me when it when it you know it's gonna use my information, it says are you OK with this? Like just tick yes or no something like that"* (Colin). They want to be informed about how their data would be used, having the ability to opt in or out of sharing specific information, ***"****it's important to have a level of kind of like self-involvement with that. Like know when your data is being shared and know what data would be included […] you wouldn't want the entirety of your data of being kind of like put into your, put into the hands of your CPN and your GP if you didn't feel like this, is representative"* (Leigh). They stressed the importance of having control over what the app can access and suggested that users should be able to define the boundaries of information sharing, *"it shouldn't access everything, it should just, be what you want the app to know"* (Ava). Some participants preferred keeping their information private and separate from healthcare professionals, expressing concerns about confidentiality, *"especially if. Like. Like. You're on the verge of relapse or something, and you're really paranoid as well. You might be really concerned about that"* (Sid).

Participants valued having the flexibility to choose what information they felt comfortable sharing and with whom and suggested having two distinct sections within the app: one for

keeping information private and another for sharing with experts, healthcare professionals, or family members. They also highlighted the need for additional security measures to protect their information within the app, *"maybe an option to have an extra pin on the app […] an extra kind of layer of protection that kind of says to me, you know, even if someone was to able, was to be able to get into my phone, then the information that's on the app is protected"* (Jonty). Harris suggested installation via a secure link for restricted access to the app. Participants also valued the option to delete their account or request deletion of their data.

Benefits of sharing

Participants were willing to share their data if they believed it would enhance the app's functionality and provide personalised suggestions to improve their wellbeing. They saw benefits in sharing their mood/symptom entries with their keyworker for a comprehensive understanding of their mental health beyond clinical appointments. They suggested the app should identify patterns and notify healthcare professionals when certain thresholds on the self-assessment quizzes are reached, in order to facilitate timely interventions, *"if your mood was constantly low, and your anxiety levels are constantly high, like maybe it could flag it up for your CPN or something like that so that they can talk to you about it"* (Ava).

When asked whether they would like prompts before alerting a contact about becoming unwell, participants preferred not to receive prompts, as they felt they might say no and prevent themselves from accessing the support they need, *"I think that's a difficult one because when you're in that moment, sometimes you'll just say no if a prompt comes up when you do actually need the help […] it's so easy just to say no and, and you don't realise if you're unwell"* (Alec).

Social platform element

Participants suggested a feature for users to share their experiences and read about others in similar situations. They wanted both experts and users to provide comments, suggestions, and insights. Participants recognised the value of expert feedback but also saw benefits in peer support within the app.

Some participants mentioned the idea of creating groups or forums within the app where they could selectively share experiences and insights with a trusted community of service users. They emphasised the need for moderation to ensure a safe and supportive environment for sharing and suggested automated systems to identify concerning content and alert appropriate healthcare professionals, *"some sort of system that picks up on certain words that if someone's going to post something with some keywords in them, then it picks up on that and contacts umm the crisis team on behalf or a key worker or something like that would be useful"* (Alec).

5. Factors influencing user engagement and deterrence

This theme explored the factors that influence participants' engagement with a digital health app and potential deterrents that may hinder their usage. Five sub-themes were identified: 1) continuous refinement and maintenance, 2) informative and engaging content, 3) app functionality, 4) app costs and advertisements, and 5) flexibility in data input.

Continuous refinement and maintenance

Participants mentioned that if they felt bored or if the app seemed outdated or lacking in regular updates, they would be deterred from using it. They emphasised the need for continuous refinement and maintenance to keep the app effective and relevant.

Participants also discussed the value of the app having a clinical background and being maintained by professionals. They believed that knowing the app was supported by experts would instil trust and confidence in its effectiveness.

Informative and engaging content

Participants expressed interest in learning about mental health issues, their causes, and preventive measures. They wanted access to interesting facts, figures, and the latest research findings to maintain engagement with the app, *"it will become boring if it just keeps on asking me the same things […] give me general information about mental health […] interesting facts and figures like, this is how many people get affected by this, and this is how much happened in this, this is because of this, and give me statistical latest research and update about stuff […] So my interest keeps on going in with the app"* (Noam).

App functionality

Participants preferred receiving a limited number of notifications from the app to avoid becoming overwhelmed or ignoring them. They also mentioned being put off by the app being *"too heavy to install*" (Harris) and taking up significant storage space on their mobile devices. Participants also felt put off by an app that was clunky to use or felt old-fashioned. They preferred the app to focus primarily on mental health rather than tracking physical activity or sleep patterns, as they recognised the limitations and inaccuracies of using a phone for such tracking.

App costs and advertisements

Participants expressed that a cost associated with the app would be off-putting and reduce

the likelihood of downloading it. They also indicated that the presence of numerous advertisements within the app would be off-putting and may discourage them from using it.

Flexibility in data input

Participants expressed concerns about the app mandating a specific minimum or maximum amount of data input each day, as they may have days when they do not wish to provide any information.

6. Outcomes and effectiveness

This theme focused on the specific factors that would make the app worthwhile for participants. Five sub-themes were identified: 1) preventing hospitalisation, 2) reducing anxiety, 3) early recognition and prompt help, 4) return to normality, and 5) reliance on other support systems.

Preventing hospitalisation

Participants indicated that a desirable outcome of the app would be its ability to help prevent hospitalisations. If the app effectively kept them out of hospital, they considered it a successful outcome, benefitting both their wellbeing and saving healthcare resources.

Reducing anxiety

Participants expressed that the app's effectiveness would be measured by its ability to reduce anxiety and provide support, helping them manage their symptoms. They would assess its impact based on their interaction with it, such as regular use of the mood tracker and reviewing progress charts. They felt that tracking their progress through the app would help decrease their worry about their mental health and reduce thoughts about relapse. If

such thoughts arose, they would rely on their support network to remind themselves of their progress.

Early recognition and prompt help

Participants emphasised the importance of early recognition of their deteriorating mental health. They desired timely alerts or messages from the app to indicate when they needed to seek help. This feature would prevent their condition from worsening and enable them to take prompt action, as expressed by Jonty, *"I would want the app to essentially tell me early on if I'm unwell, and that way it would stop me from kind of, for lack of a better word, well, for lack of a better term, from ruining my life"*.

Return to normality

Participants mentioned that the effectiveness of the app would be reflected in their ability to get back to their daily routines and activities, regaining a sense of normalcy.

Reliance on other support systems

Some participants acknowledged that while an app could offer certain benefits, it could not replace the support provided by individuals, such as family or healthcare professionals, *"there's only so much an app can do"* (Noam). They highlighted the value of their support network rather than a reliance on the app, *"[…] My parents in particular, they remind me in the morning to take my medication. Um, And I feel like that's an example which kind of highlights the fact that there are like, an app might not necessarily be the best place to go for well-being, whereas other like people, like your parents and stuff like that, they can be a better source of support when it comes to things like medication adherence or coping strategies"* (Jonty).

Discussion

This study aimed to engage people with a lived experience of psychosis to explore their preferences and establish a framework for the development of a digital health app which aims to alleviate fear of psychosis recurrence. Three research questions that focused on the experiences, preferences, and outcomes of a hypothetical digital health app were addressed and six themes were generated.

The theme of "contextual factors" played an important role in helping us understand the contextual background that is crucial for integrating a digital health intervention into current practices (Aref-Adib et al., 2019). This theme captured participants' overall health practices, their use of digital technology, and their conceptualisation of relapse and help-seeking in the context of psychosis. Our findings align with previous research indicating that people with psychosis, similar to the general population, commonly own and use smartphones (Aref-Adib et al., 2019). Participants in our study also expressed positive experiences with using digital health apps to support their health, reflecting their willingness to engage with such interventions (Bonet et al., 2017). Their perspectives on the desirable features of existing health apps, aligned with a systematic review which found that perceived ease of use significantly influences the extent to which users engage with and benefit from mobile health apps (Wang & Qi, 2021).

It was interesting to observe that all participants, when asked about their current strategies for maintaining their mental health, placed a strong emphasis on 'physical activity' as the foremost aspect mentioned at the start of their responses. This finding was unexpected but significant, as it highlighted the critical role of physical activity in promoting wellbeing and preventing relapse, and therefore signalled the importance of its inclusion in the design of a

digital health app. For example, a valuable feature of the app could involve daily reminders to prompt and motivate participants to engage in some form of physical activity.

Building on from this, participants in our study also expressed a strong desire for a personalised app experience that would send them tailored notifications and reminders to engage in self-care activities, that aligned with their specific methods of maintaining wellbeing. They cautioned against excessive notifications and suggested that users should have the ability to customise the frequency of notifications according to their individual needs and preferences. These preferences are consistent with previous research that recognises the role of notifications in increasing engagement with mental health apps (Druce et al., 2019). Studies have shown that relevant and personalised notifications, as well as factors such as the content, design and frequency of message prompts, significantly impact their effectiveness in increasing engagement (Alkhaldi et al., 2016).

Moreover, a recent scoping review conducted by Simões de Almeida and Marques (2023) explored factors influencing user engagement in mobile apps designed for people with schizophrenia. Their review highlighted app personalisation and customisation as pivotal factors for engagement, while noting that text-heavy content and a lack of aesthetic appeal in design were unappealing to users. These findings align closely with our own observations in one of our sub-themes, where participants emphasised their preferences for personalisation, visual appeal, and a user-friendly interface when discussing the design of the hypothetical digital intervention. Our study participants also expressed a desire for an app feature that would allow them to track and monitor their symptoms, which has been shown in previous studies to be beneficial in people with psychosis (Bucci et al., 2018b; Lewis et al., 2020), supporting shared decision-making processes (Bucci et al., 2019a).

Participants expressed their preferences for app content, feeling it was important to have access to support, for instance, having the ability to contact keyworker, crisis team, or a designated 'support contact' directly through the app. These preferences align with previous research findings that highlight the crucial role of human support in digital interventions, emphasising the significance of therapeutic alliance even in digital settings (Szinay et al., 2021; Tremain et al., 2020).

Participants also expressed a strong interest in having a 'profile' or forum within the app where they could share their own experiences and learn from the experiences of others. This desire for peer interaction and social support aligns with established strategies for 'illness management' in psychosis (Mueser et al., 2006). Connecting with peers who have lived experience is recognised as an important facilitator of recovery (Biagianti et al., 2018), and peer support is recommended in National Institute for Health and Care Excellence (NICE) guidelines (2014). Therefore, integrating a peer-to-peer communication feature within the app could prove highly beneficial.

While the notion of a "social platform element" garnered significant appeal, a number of participants expressed concerns regarding data protection, privacy and confidentiality. Qualitative research suggests that these concerns are prevalent among individuals with psychosis (Berry et al., 2019). Hence, it is important to address these issues appropriately and ensure the secure handling of information when incorporating such features into the app, so that users can connect and share experiences while maintaining their privacy and confidentiality.

Within the theme of “factors influencing user engagement and deterrence”, an important sub-theme revolved around the app’s credibility, specifically in terms of its development and maintenance by experts in the field. The credibility of an app can significantly impact user engagement, especially when it incorporates expert clinical knowledge (Ouzzani et al., 2016).

Another important aspect explored in our study was the desired outcomes of the hypothetical digital health app. Research has shown that users’ perception of the app’s value and usefulness plays a crucial role in determining their level of engagement (Greenhalgh et al., 2017). Therefore, it is essential for users to perceive the app’s outcomes as relevant to their needs in order for it to be an effective intervention. An important sub-theme developed where some participants expressed scepticism about the app’s ability to achieve their desired outcomes, such as preventing hospitalisation. Instead, they emphasised the importance of human support from friends, family, and healthcare professionals. This finding further reinforces the points highlighted in the theme, where participants stressed the importance of wanting direct access to support through the app. It suggests that while the app can play a valuable role, it should be seen as a complement to, rather than a replacement for, human support networks in achieving desired outcomes.

Strengths and Limitations

The strengths of this study lie in its focus on engaging individuals with lived experience of psychosis, allowing their voices to shape the development of a digital health intervention. The thematic analysis of the qualitative data provided rich and detailed insights into the participants’ interests, experiences, and preferences. Moreover, the study employed flexible recruitment strategies to ensure maximum engagement and diversity of views. For example,

participants had the option to meet one-to-one with the researcher if they felt uncomfortable participating in a group setting. Additionally, in-person meetings were offered to individuals who were unable to participate online due to digital exclusion, poverty, or personal preference. This was to facilitate inclusivity in the design, offer people choice, and to include voices of people who might otherwise be unable to participate.

However, there are some limitations to consider. Consultations with service-users regarding the development of the topic guide had to be cancelled due to dropouts from covid-related illness, resulting in the topic guide not being collaboratively developed with service-users. To address this issue, participants were asked for critical feedback at the end of each interview regarding the relevance of the discussions and whether they felt any important aspects were missed or should not have been included.

While there is no universally 'optimal' number of participants in a focus group, and the number can vary based on research goals, the term 'focus group' typically implies a group dynamic and interaction among participants, which is traditionally associated with more than two participants. Therefore, it is important to acknowledge that the sample sizes in some of the focus groups in this study, such as the two participants in Focus Group 1, were notably low. Referring to a session with only two participants as a 'focus group' may be perceived as a limitation as it departs from the conventional expectations and potential benefits of such group discussions in qualitative research. For future research in this area, alternative terminologies and approaches when working with smaller participant groups could help avoid potential misrepresentation or misinterpretation of the research method.

Although the inclusion criteria did not specifically target individuals with a fear of relapse, it became evident from the interviews that all participants, to varying degrees, experienced a fear of relapse. It is important to note that in the context of cancer care, some concerns about recurrence are considered adaptive and beneficial. Thus, fear of relapse can be seen as a spectrum, ranging from adaptive fears to severe concerns that significantly impact quality of life. With this in mind, the diverse range of participants in our sample offers an advantage as it offers a spectrum of severity in fear of relapse.

The study may have benefited from collecting participants' clinical characteristics, such as information about stage of recovery. This factor may have influenced their perspectives and preferences and enabled a more nuanced analysis and interpretation of the findings. Research indicates that tailoring digital health interventions to individuals' stage of recovery enhances user engagement by ensuring the content remains relevant (Jonathan et al., 2019).

Finally, the absence of participant ethnicity data is a notable limitation in our study that warrants further consideration, particularly in the context of individuals impacted by psychosis. Existing research has highlighted disparities in access to digital health interventions based on various socio-demographic factors, including ethnicity (Zhai, 2021). Understanding the nuanced challenges faced by marginalised groups in engaging with digital health interventions is essential for promoting equity in clinical practices. Different cultural backgrounds may influence how individuals perceive and interact with mental health support, including digital interventions. Without ethnicity data, we may miss crucial insights into culturally sensitive design and content preferences, potentially overlooking opportunities to tailor interventions to better meet the needs of specific communities.

Therefore, future studies should ensure the collection of clinical characteristics and participant ethnicity to enhance the depth and inclusivity of the research findings.

Clinical Implications

The findings of this study hold clinical implications for the development of digital health interventions targeting FoR in individuals with psychosis. For example, participants emphasised the role of physical activity in maintaining well-being and preventing relapse, suggesting that incorporating prompts for physical activity into such interventions could be beneficial. Moreover, their interest in receiving direct support through a digital app, coupled with their preference for peer-support, highlights the synergistic potential of digital interventions in complementing human support networks for achieving desired outcomes.

Research Implications and Future Studies

The perspectives and collaboration of people with lived experience plays a vital role in this study, as they are the key stakeholders who can shape the development of a digital health app and predict subsequent engagement with the intervention. By providing insights into the specific features and content valued by individuals in a hypothetical digital health app targeting FoR, this research paves the way for future studies in this area. The inclusion of individuals from diverse backgrounds and stages of recovery in future research can enhance our understanding of nuanced preferences and needs. It will be important to collect data on participant ethnicity to address potential disparities in access to digital health interventions and to tailor these interventions to specific communities, particularly given the impact of digital poverty on marginalised groups.

Future studies should also consider incorporating the views of clinicians and mental healthcare professionals. Including these additional perspectives could provide valuable

insights into the implementation and delivery aspects of digital interventions from a practitioner's standpoint. This, in turn, can lead to the development of more effective, evidenced-based interventions that better align with the practical realities of clinical settings. Moreover, understanding their viewpoints can help identify potential barriers, facilitators, and best practices, ultimately facilitating the integration of these interventions into clinical practice and improving the overall quality of care for people with lived experience.

Conclusions

To ensure the development of an engaging and effective digital intervention, it is important to collaboratively create and validate features with the people who intend to use them. Our findings contribute to the existing literature by providing insights into the interests, preferences and outcomes valued by individuals with lived experience of psychosis regarding digital health interventions aimed at reducing fear of relapse. These findings have the potential to inform the design and content of a digital health app that is aligned with their needs and expectations. By incorporating the perspectives of participants in this study, the developed app can better address the specific concerns and challenges that are faced by people with experiences of psychosis.

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Appendices

Appendix 1: Systematic Review

Appendix 1.1 Search terms

https://www.crd.york.ac.uk/PROSPEROFILES/422740_STRATEGY_20230502.pdf

Appendix 1.2: Search Strategies

Medline (OVID)

1. exp Fear/ (39426)
2. Anxiety/ (105315)
3. exp Psychological Distress/ (6635)
4. (fear* or afraid or worr* or anxi* or concern* or distress*).tw. (1236035)
5. 1 or 2 or 3 or 4 (1265546)
6. exp Neoplasms/ (3822223)
7. exp Carcinoma/ (721532)
8. (Cancer* or tumo?r* or neoplas* or malign* or carcinoma*).tw. (3877591)
9. 6 or 7 or 8 (5001510)
10. exp Recurrence/ (200036)
11. exp Neoplasm Recurrence, Local/ (142689)
12. (Recur* or relaps* or reoccur* or progress* or coming back or return*).tw. (2445831)
13. 10 or 11 or 12 (2537922)
14. 5 and 9 and 13 (28645)
15. exp Telemedicine/ (44112)
16. exp Mobile Applications/ (11245)
17. exp Internet-Based Intervention/ (1108)
18. exp User-Computer Interface/ (39391)
19. (digital* or mobile* or cellphone or cell phone or electronic* or internet* or virtual or web* or online or telehealth or E-health or smart phone or smartphone* or app or apps or application* or computer* or technolog* or remote or mHealth).tw. (3343663)
20. 15 or 16 or 17 or 18 or 19 (3367049)
21. 14 and 20 (3355)
22. limit 21 to humans (2712)
23. limit 22 to english language (2468)

Embase (OVID)

1. exp fear/ (365969)
2. exp anxiety/ (297374)
3. exp distress syndrome/ (64196)
4. exp patient worry/ (5350)
5. (fear* or afraid or worr* or anxi* or concern* or distress*).tw. (1754494)
6. 1 or 2 or 3 or 4 or 5 (1838274)
7. exp neoplasm/ (5947054)
8. exp carcinoma/ (1509795)
9. (Cancer* or tumo?r* or neoplas* or malign* or carcinoma*).tw. (5579046)
10. 7 or 8 or 9 (7190749)
11. exp relapse/ (185975)
12. exp cancer recurrence/ (270394)
13. (Recur* or relaps* or reoccur* or progress* or coming back or return*).tw. (3711395)

14. 11 or 12 or 13 (3764227)
15. 6 and 10 and 14 (58249)
16. exp telemedicine/ (70321)
17. exp mobile application/ (24498)
18. exp web-based intervention/ (2602)
19. exp telehealth/ (85828)
20. exp computer interface/ (36026)
21. (digital* or mobile* or cellphone or cell phone or electronic* or internet* or virtual or web* or online or telehealth or E-health or smart phone or smartphone* or app or apps or application* or computer* or technolog* or remote or mHealth).tw. (4222732)
22. 16 or 17 or 18 or 19 or 20 or 21 (4268686)
23. 15 and 22 (7310)
24. limit 23 to human (6637)
25. limit 24 to english language (6332)

PsychINFO (Ebsco)

1. DE "Fear" (30,634)
2. DE "Anxiety" (96,402)
3. DE "Distress" (28,712)
4. TI (anxi* or afraid or worr* or anxi* or concern* or distress) OR AB (anxi* or afraid or worr* or anxi* or concern* or distress) (631,029)
5. S1 OR S2 OR S3 OR S4 (660,169)
6. DE "Neoplasms" OR DE "Benign Neoplasms" OR DE "Breast Neoplasms" OR DE "Endocrine Neoplasms" OR DE "Leukemias" OR DE "Melanoma" OR DE "Metastasis" OR DE "Nervous System Neoplasms" OR DE "Terminal Cancer" (60,113)
7. TI (Cancer* or tumo#r* or neoplas* or malign* or carcinoma) OR AB (Cancer* or tumo#r* or neoplas* or malign* or carcinoma) (91,034)
8. S6 OR S7 (95,718)
9. DE "Relapse (Disorders)" (8,475)
10. TI (Recur* or relaps* or reoccur* or progress* or coming back or return*) OR AB (Recur* or relaps* or reoccur* or progress* or coming back or return*) (294,122)
11. S9 OR S10 (294,757)
12. S5 AND S8 AND S11(2,317)
13. DE "Digital Interventions" (1,287)
14. DE "Video-Based Interventions" (215)
15. DE "Telemedicine" OR DE "Online Therapy" OR DE "Teleconferencing" OR DE "Teleconsultation" OR DE "Telepsychiatry" OR DE "Telepsychology" OR DE "Telerehabilitation" (13,900)
16. DE "Mobile Applications" (3,053)
17. DE "Online Therapy" (4,068)
18. TI (digital* or mobile* or cellphone or cell phone or electronic* or internet* or virtual or web* or online or telehealth or E-health or smart phone or smartphone* or app or apps or application* or computer* or technolog* or remote or mHealth) OR AB (digital* or mobile* or cellphone or cell phone or electronic* or internet* or virtual or web* or online or

telehealth or E-health or smart phone or smartphone* or app or apps or application* or computer* or technolog* or remote or mHealth) (613,957)
19. S13 OR S14 OR S15 OR S16 OR S17 OR S18 (616,557)
20. S12 AND S19 (259)
21. S12 AND S19 with English and Human limiter (235)

CINAHL (Ebsco)

1. (MH "Fear+") (18,351)
2. (MH "Worry") (560)
3. (MH "Anxiety+") (59,764)
4. (MH "Psychological Distress") (4,858)
5. TI (fear* or afraid or worr* or anxi* or concern* or distress) OR AB (fear* or afraid or worr* or anxi* or concern* or distress) (416,092)
6. S1 OR S2 OR S3 OR S4 OR S5 (434,575)
7. (MH "Neoplasms+") (645,079)
8. (MH "Carcinoma+") (103,341)
9. TI (Cancer* or tumo#r* or neoplas* or malign* or carcinoma) OR AB (Cancer* or tumo#r* or neoplas* or malign* or carcinoma) (689,630)
10. S7 OR S8 OR S9 (874,930)
11. (MH "Recurrence+") (54,295)
12. (MH "Neoplasm Recurrence, Local") (25,627)
13. TI (Recur* or relaps* or reoccur* or progress* or coming back or return*) OR AB (Recur* or relaps* or reoccur* or progress* or coming back or return*) (454,778)
14. S11 OR S12 OR S13 (481,296)
15. S6 AND S10 AND S14 (8,301)
16. (MH "Digital Health+") (23,695)
17. (MH "Mobile Applications") (11,923)
18. (MH "Telemedicine+") (19,363)
19. (MH "Telehealth+") (34,397)
20. (MH "Internet-Based Intervention") (754)
21. TI (digital* or mobile* or cellphone or cell phone or electronic* or internet* or virtual or web* or online or telehealth or E-health or smart phone or smartphone* or app or apps or application* or computer* or technolog* or remote or mHealth) OR AB (digital* or mobile* or cellphone or cell phone or electronic* or internet* or virtual or web* or online or telehealth or E-health or smart phone or smartphone* or app or apps or application* or computer* or technolog* or remote or mHealth) (716,318)
22. S16 OR S17 OR S18 OR S19 OR S20 OR S21 (738,628)
23. S15 AND S22 (1,058)
24. S15 AND S22 with English and Human limiters (564)

Appendix 1.3: Screening Checklist

Title/Abstract Screening Checklist Items:

Responses:
No = 0
Yes = 1
Unclear = ?

- ☐ Adults (18+) with cancer (current or past) with FCR
- ☐ Any digital health intervention
- ☐ Any control group
- ☐ Use of validated quantitative measure of FCR to report outcome
- ☐ RCTs/ non-RCTs/ quasi-experimental / pilot study
- ☐ Peer-reviewed article

Score (out of 6):

Outcome (Include or Exclude):

Comments:

Appendix 1.4: Summary of Resolved Discrepancies

Discrepancies in Screening Abstracts

Author (Year)	Title	NK Screen	SB Screen PICOS	Outcome after AG Discussion	Resolved
Lange et al. (2017)	Effectiveness, acceptance and satisfaction of guided chat groups in psychosocial aftercare for outpatients with prostate cancer after prostatectomy	INCLUDE	**EXCLUDE:** Not specifically focussed on FoR. Includes fear of progression within larger measure but not reported in isolation. Population: Y Intervention: Y Comparison: Y Outcomes: N Study Design: Y	**INCLUDE:** The construct of FCR has evolved and become more elaborated recently to include fears of progression as well. Therefore, it is reasonable to include as it has the FCR data within it.	✓
Compen et al. (2018)	Face-to-face and internet-based mindfulness-based cognitive therapy compared with treatment as usual in reducing psychological distress in patients with cancer: A multicenter randomized controlled trial	INCLUDE	**EXCLUDE:** Appears to be adult sample but does not specify over 18 Population: N Intervention: Y Comparison: Y Outcomes: Y Study Design: Y	**INCLUDE:** The participant characteristics table states mean age as 50 years. Although they don't specify over 18, we can assume vast majority of sample are over 18.	✓

Fang et al. (2020)	Long-term effectiveness of an E-based survivorship care plan for breast cancer survivors: A quasi-experimental study	**INCLUDE**	**EXCLUDE:** This look predominantly to be health information of psychological methods. See suppl table 1 Population: Y Intervention: N Comparison: Y Outcomes: Y Study Design: Y	**INCLUDE:** Study uses an educational intervention which includes psychoeducation. Psychoeducation in itself can be deemed as a psychological intervention according to my protocol.	✓
Dirkse et al. (2019)	Making Internet-delivered cognitive behaviour therapy scalable for cancer survivors: a randomized non-inferiority trial of self-guided and technician-guided therapy	**INCLUDE**	**EXCLUDE:** Non-inferiority trial - compares technician guided with self-guided use of the same intervention. Population: Y Intervention: N Comparison: Y Outcomes: Y Study Design: Y	**INCLUDE:** It was not in my inclusion/exclusion criteria to exclude non-inferiority trials	✓
Chambers et al. (2017)	Mindfulness-Based Cognitive Therapy in Advanced Prostate Cancer: A Randomized Controlled Trial	**INCLUDE**	**EXCLUDE:** No specific FoR measure, not clear that intervention is targetting FCR. Population: Y Intervention: N Comparison: Y Outcomes: N Study Design: Y	**EXCLUDE:** For same reasons. Study looked at cancer distress rather than FCR.	✓

Zhang et al. (2022)	The Impact of VR-CALM Intervention Based on VR on Psychological Distress and Symptom Management in Breast Cancer Survivors	**INCLUDE**	**EXCLUDE:** Appears to be adult population but does not specify lower age limit Population: N Intervention: Y Comparison: Y Outcomes: Y Study Design: Y	**INCLUDE:** Mean age is 52 years. Therefore, majority of participants will be over 18	✓

Appendix 1.5: The JBI Critical Appraisal Checklist for RCT's and Quasi-Experimental Studies

JBI Critical Appraisal Checklist for Randomized Controlled Trials

Reviewer_____Date_____

Author _____Year_____Record Number_____

		Yes	No	Unclear	NA
1.	Was true randomization used for assignment of participants to treatment groups?	☐	☐	☐	☐
2.	Was allocation to treatment groups concealed?	☐	☐	☐	☐
3.	Were treatment groups similar at the baseline?	☐	☐	☐	☐
4.	Were participants blind to treatment assignment?	☐	☐	☐	☐
5.	Were those delivering treatment blind to treatment assignment?	☐	☐	☐	☐
6.	Were outcomes assessors blind to treatment assignment?	☐	☐	☐	☐
7.	Were treatment groups treated identically other than the intervention of interest?	☐	☐	☐	☐
8.	Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	☐	☐	☐	☐
9.	Were participants analyzed in the groups to which they were randomized?	☐	☐	☐	☐
10.	Were outcomes measured in the same way for treatment groups?	☐	☐	☐	☐
11.	Were outcomes measured in a reliable way?	☐	☐	☐	☐
12.	Was appropriate statistical analysis used?	☐	☐	☐	☐
13.	Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

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JBI Critical Appraisal Checklist for Quasi-Experimental Studies (non-randomized experimental studies)

Reviewer_____Date_____

Author _____Year_____Record Number_____

		Yes	No	Unclear	Not applicable
1.	Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?	☐	☐	☐	☐
2.	Were the participants included in any comparisons similar?	☐	☐	☐	☐
3.	Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	☐	☐	☐	☐
4.	Was there a control group?	☐	☐	☐	☐
5.	Were there multiple measurements of the outcome both pre and post the intervention/exposure?	☐	☐	☐	☐
6.	Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	☐	☐	☐	☐
7.	Were the outcomes of participants included in any comparisons measured in the same way?	☐	☐	☐	☐
8.	Were outcomes measured in a reliable way?	☐	☐	☐	☐
9.	Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Appendix 1.6: The TIDieR Checklist

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	_____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	_____	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_____	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	_____	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	_____	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	_____	_____
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	_____	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	_____	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_____	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	_____	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	_____	_____

Appendix 1.7: The TIDieR Checklist – Completed for all Studies

Measure of transparency of reporting: The TIDieR Checklist

Author (Year)	**TIDieR Checklist Item Number**											
	1 Name	**2 Why**	**3 What**	**4 Procedure**	**5 Who Provided**	**6 How**	**7 Where**	**8 When and How Much**	**9 Tailor**	**10 Mod**	**11 How Well**	**12 Actual**
Akechi et al. (2023)	p1	p2	p3 + SM p10	p3	n/a	p3	p2	p3	n/a	n/a	absent	p4
Akkol-Solakoglu et al. (2023)	p1	p2	p2 + SM p1	p2	p2	p2	p2	p2	n/a	n/a	absent	p4 p7
Compen et al. (2018)	p1	p2	p2	p2	p2	p2	p2	p2	n/a	n/a	absent	absent
Dieng et al. (2016)	p1	p2	p3 + study protocol	p2-3	p3	p3	p3	p3	Appendix p12	n/a	absent	p5
Dirkse et al. (2019)	p1	p2	p3-4 + SM p2-3	p3	n/a	p3-4	p3-4	p3-4	p3	n/a	absent	absent

Fang et al. (2020)	p1	p2	p2+ SM data p1	p3	n/a	p2	p2	p2	p2	n/a	absent	p3
Lange et al. (2017)	p1	p2	p2-3	p2-3	p2-3	p2-3	p2-3	p2-3	n/a	n/a	absent	p4
Lichtenthal et al. (2017)	p1	p2	p2-4	p2-4	n/a	p3-4	p3-4	p3-4	p4	n/a	p4	p6
Murphy et al. (2020)	p1	p2	p2 + SM data 1, p1	p2 + SM data 1, p1	p2 + SM data 1, p4	p2 + SM data 1, p1	p2	p2 + SM data 1, p1	SM data 1, p4	n/a	absent	absent
Neubert et al. (2023)	p1	p2	p3-4	p2-4	n/a	p2-4	p2-4	p2-4	n/a	n/a	absent	p5-6
Peng et al. (2022)	p1	p2	p3	p3	absent	p3	p3	p3	n/a	n/a	absent	absent
Russell et al. (2019)	p1	p2	p3	p2-3	n/a	p3	p3	p3	n/a	n/a	p3	p4-5
Thompson et al. (2021)	p1	p3	p4	p4	n/a	p4	p4	p4	n/a	n/a	p5	SM data 2, p1-2
van den Berg et al. (2015)	p1	p2 + SM p3	p3 + SM p6-7	p2-4 + SM p3	n/a	p3	p3	p3	n/a	n/a	absent	absent

van de Wal et al. (2017)	p1	p2	p2 + Study protocol	p2	p2	p2	p2	p2	n/a	p2	absent	p8
Van Helmondt et al. (2020)	p1	p2	p2 + SM2 p1	p2	n/a	p2	p2	p2	n/a	n/a	absent	absent
Wagner et al. (2021)	p1	p2	p2 + SM p1-3	p2	n/a	p2	p2	p2 + SM p1-2	n/a	n/a	p2 + SM p3-4	p7
Zhang et al. (2022)	p1	p2	p2-3	p2	p3	p3	p3	p3	n/a	n/a	absent	absent

Note. Abbreviations: SM= Supplementary Material

Appendix 1.8: JBI Quality Rating Scores – Completed for all Studies

Randomised Controlled Trials: JBI Critical Appraisal Checklist for Randomised Controlled Trials

Author (Year)	**JBI Item Number**												
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**
Akechi et al. (2023)	Y	Y	Y	N	N/A	N/A	U	Y	Y	Y	N/A	Y	Y
Akkol-Solakoglu et al. (2023)	Y	U	N	N	N	U	Y	Y	Y	Y	U	Y	Y
Compen et al. (2018)	Y	U	Y	N	N	Y	Y	Y	Y	Y	U	Y	Y
Dieng et al. (2016)	Y	Y	N	N	N	N/A	Y	U	Y	Y	N/A	Y	Y
Lichtenthal et al. (2017)	Y	U	N	Y	U	U	Y	Y	Y	Y	Y	Y	Y
Murphy et al. (2020)	Y	Y	N	N	N	N/A	Y	N	Y	Y	N/A	Y	Y
Neubert et al. (2023)	Y	Y	U	N	N/A	N/A	Y	Y	U	Y	N/A	Y	Y
Peng et al. (2022)	U	U	Y	N	N	U	Y	N	N	Y	U	Y	Y

Russell et al. (2019)	Y	Y	U	N	N/A	N/A	Y	Y	Y	Y	Y	Y	Y
Thompson et al. (2021)	Y	U	Y	N	N/A	N	Y	Y	Y	Y	U	Y	Y
van den Berg et al. (2015)	Y	Y	Y	N	N/A	N/A	Y	Y	Y	Y	N/A	Y	Y
Van De Wal et al. (2017)	Y	Y	Y	N	N	U	Y	Y	Y	Y	U	Y	Y
Van Helmondt et al. (2020)	Y	Y	N	N	N/A	N/A	Y	Y	Y	Y	N/A	Y	Y
Wagner et al. (2021)	Y	Y	Y	N	Y	N/A	U	Y	Y	Y	N/A	Y	Y
Zhang et al. (2022)	Y	Y	Y	N	N	U	Y	U	U	Y	U	Y	Y

Note. Abbreviations: Y= Yes, N=No, U=Unclear, N/A= Not Applicable.

Quasi-Experimental Studies: JBI Critical Appraisal Checklist for Quasi-Experimental Studies (Non-Randomised Experimental Studies)

Author (Year)	JBI Item Number								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Fang et al. (2020)	Y	N	N	Y	Y	Y	Y	U	Y
Lange et al. (2017)	Y	N	N	Y	Y	N	Y	U	U
Dirkse et al. (2019)[a]	Y	N	Y	N	Y	U	Y	N/A	Y

Note. Abbreviations: Y= Yes, N=No, U=Unclear, N/A= Not Applicable.

[a] Technically no control group as this was a non-inferiority trial, however for the purpose of this review, "technician-guided" was counted as the control, whereas "self-guided" was counted as the experimental.

Appendix 2: Major Research Project

Appendix 2.1: Ethical approval from the West Midlands Black Country Research Ethics Committee

NHS
Health Research Authority

West Midlands - Black Country Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0207 104 8019

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

22 December 2022

Professor Andrew Gumley
Institute of Health and Wellbeing, University of Glasgow
Mental Health and Wellbeing Research Group
Gartnavel Royal Hospital
G12 0XH

Dear Professor Gumley

Study title:	**A qualitative study aimed at developing a digital health intervention for people with psychosis who are fearful of relapse**
REC reference:	**22/WM/0270**
IRAS project ID:	**316110**

Thank you for responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Recommendation with the favourable opinion

The REC favourable opinion is given alongside the following recommendations:

The Committee recommended that the patient information sheet version 1.3 should be implicit that it is a Staff information sheet.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device

- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:
https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at:
https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study

- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Tracked - Study Flyer]	1.3	15 December 2022
Copies of materials calling attention of potential participants to the research [Clean - Study Flyer]	1.3	15 December 2022
Copies of materials calling attention of potential participants to the research [Tracked - Information Leaflet]	1.3	15 December 2022
Copies of materials calling attention of potential participants to the research [Clean - Information Leaflet]	1.3	15 December 2022
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UofG insurance]	1	20 July 2022
GP/consultant information sheets or letters [GP Letter]	1.2	31 October 2022
Interview schedules or topic guides for participants [Topic Guide]	1.2	31 October 2022
IRAS Application Form [IRAS_Form_03112022]		03 November 2022
Other [Return Address for envelope]	1.1	31 October 2022
Other [Eligibility Document]	1.1	31 October 2022
Other [Email Template Proforma]	1.1	31 October 2022
Other [Ground Rules for focus group]	1.1	31 October 2022
Other [Data Management Plan]	1.2	31 October 2022
Other [Debrief Document]	1.0	15 December 2022
Other [Amendment responses]	1.0	15 December 2022
Participant consent form [Participant Consent Form]	1.3	31 October 2022
Participant information sheet (PIS) [Tracked - PIS]	1.4	15 December 2022
Participant information sheet (PIS) [Clean - PIS]	1.4	15 December 2022

Research protocol or project proposal [Study Protocol]	1.5	15 December 2022
Summary CV for Chief Investigator (CI) [Chief Investigator CV]	1.0	18 March 2022
Summary CV for student [Principle Investigator Research CV]	1	31 October 2022
Summary CV for supervisor (student research) [Field Supervisor research CV]	1.0	31 October 2022

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.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 316110 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

PP:Miss Nicola Brooks
Chair

Email:blackcountry.rec@hra.nhs.uk

Appendix 2.2: NHS GG&C Research and Innovation (R&I) Department Ethical approval from the West Midlands Black Country Research Ethics Committee

Senior Research Administrator: Kirsty Theron
Telephone Number:
E-Mail: Kirsty.theron@ggc.scot.nhs.uk
Website: https://www.nhsggc.org.uk/about-us/professional-support-sites/research-innovation

Research & Innovation
Dykebar Hospital, Ward 11
Grahamston Road
Paisley, PA2 7DE
Scotland, UK

25/01/2023

Negar Khozoee
Administration Building,
Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow
G12 0XHD

NHS GG&C Board Approval

Dear N Khozoee

Study Title:	A qualitative study aimed at developing a digital health intervention for people with psychosis who are fearful of relapse
Principal Investigator:	Negar Khozoee
GG&C HB site	Esteem Community Mental Health Teams
Sponsor	NHS Greater Glasgow and Clyde
R&I reference:	GN22MH312
REC reference:	22/WM/0270
Protocol no: (including version and date)	Version 1.5 (15.12.2022)

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file. Researchers must follow NHS GG&C local policies, including incident reporting.

2. **For all studies** the following information is required during their lifespan.
   a. First study participant should be recruited within 30 days of approval date.
   b. Recruitment Numbers on a monthly basis
   c. Any change to local research team staff should be notified to R&I team
   d. Any amendments – Substantial or Non Substantial

e. Notification of Trial/study end including final recruitment figures

f. Final Report & Copies of Publications/Abstracts

g. You must work in accordance with the current NHS GG&C COVID19 guidelines and principles.

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Kirsty Theron
Senior Research Administrator

CC: C Montgomery Sardar, Prof A Gumley

Appendix 2.3: Topic guide

https://osf.io/a9ve3

Appendix 2.4: Staff Information Leaflet

https://osf.io/kcun3

Appendix 2.5: Study Flyer

https://osf.io/htgb2

Appendix 2.6: Proforma Email

https://osf.io/ke4wm

Appendix 2.7: Participant Information Sheet

https://osf.io/r2g5f

Appendix 2.8: Participant Consent Form

https://osf.io/p8hvj

Appendix 2.9: Participant Debrief Document

https://osf.io/b2kdc

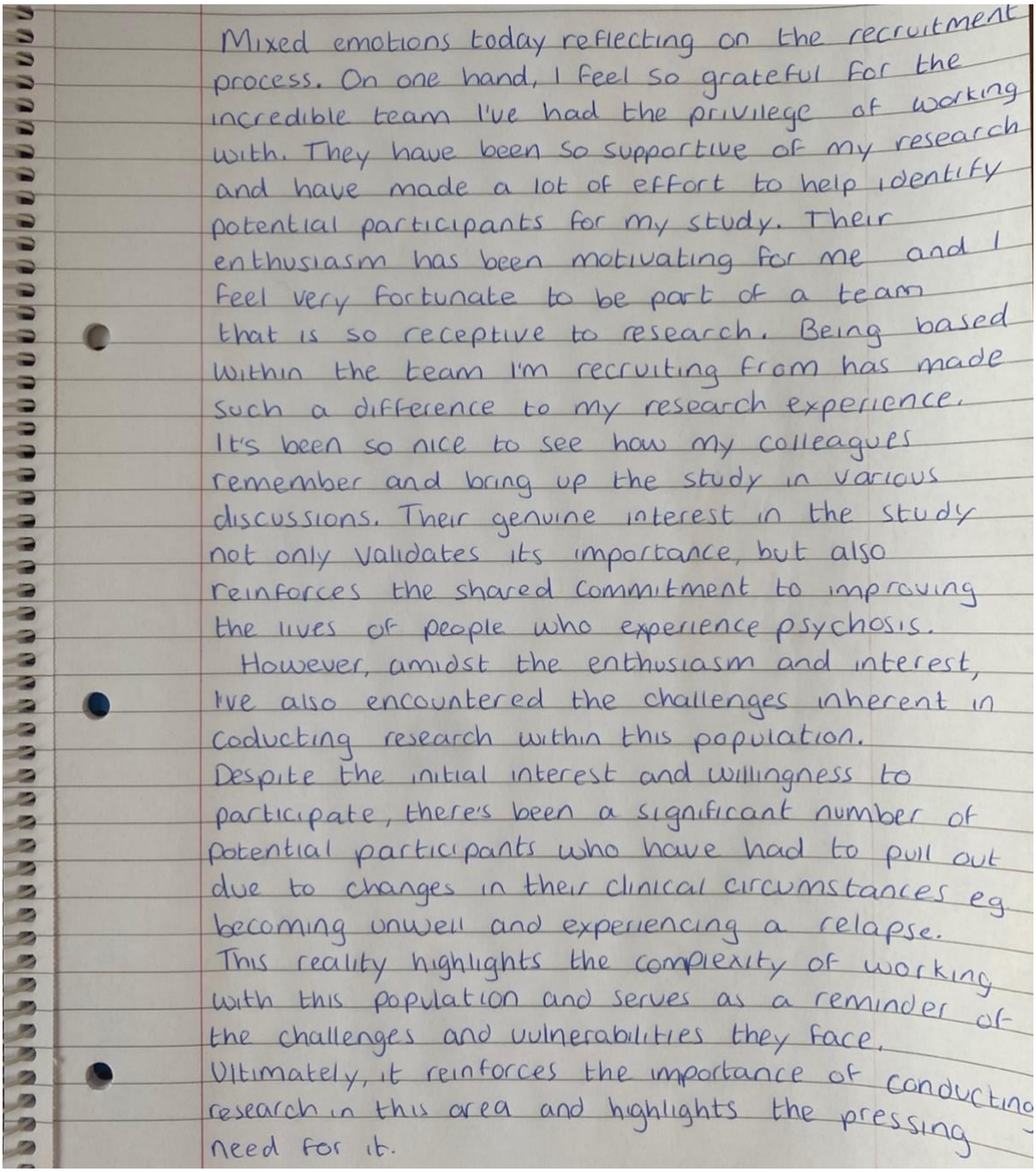
Appendix 2.10: Braun & Clarke's Six Phases of Thematic Analysis (2006)

Braun & Clarke's Phases of Thematic Analysis

Phase	**Description of the process**
1. Familiarising yourself with your data:	Transcribing data, reading and rereading the data, noting down initial ideas
2. Generating initial codes:	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes:	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes:	Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic map of the analysis.
5. Defining and naming themes:	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells; generating clear definitions and names for each theme.
6. Producing the report:	Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back the analysis to the research question and literature, producing a scholarly report of the analysis.

Appendix 2.11: Excerpts from Reflective Diary

Recruitment:

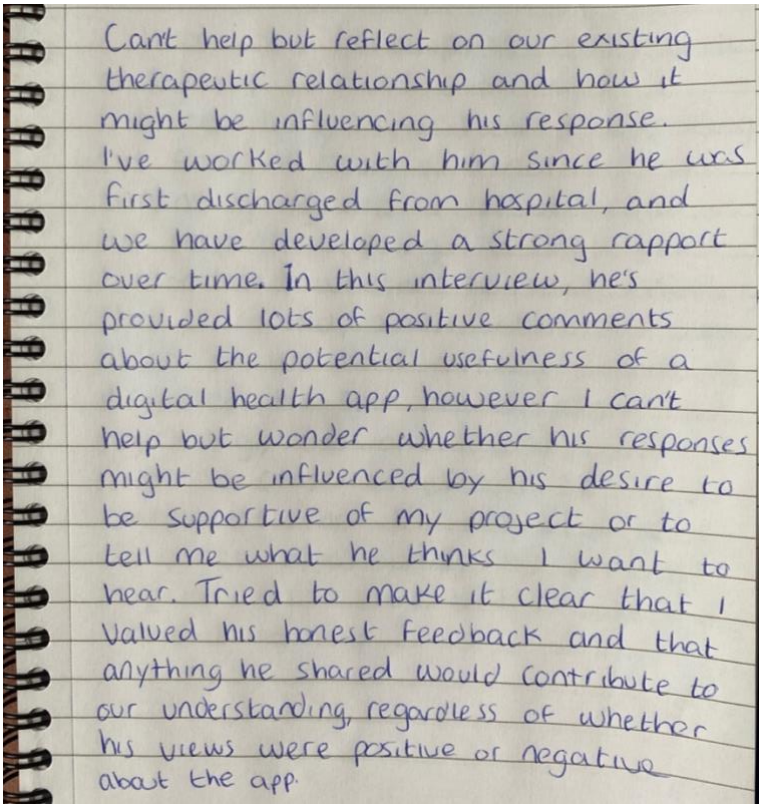


Mixed emotions today reflecting on the recruitment process. On one hand, I feel so grateful for the incredible team I've had the privilege of working with. They have been so supportive of my research and have made a lot of effort to help identify potential participants for my study. Their enthusiasm has been motivating for me and I feel very fortunate to be part of a team that is so receptive to research. Being based within the team I'm recruiting from has made such a difference to my research experience. It's been so nice to see how my colleagues remember and bring up the study in various discussions. Their genuine interest in the study not only validates its importance, but also reinforces the shared commitment to improving the lives of people who experience psychosis.

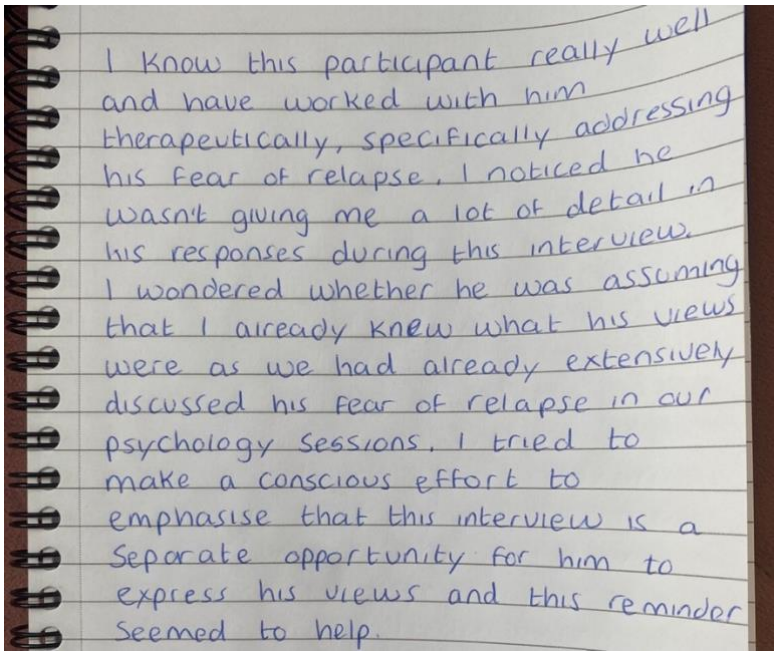
However, amidst the enthusiasm and interest, I've also encountered the challenges inherent in coducting research within this population. Despite the initial interest and willingness to participate, there's been a significant number of potential participants who have had to pull out due to changes in their clinical circumstances eg becoming unwell and experiencing a relapse. This reality highlights the complexity of working with this population and serves as a reminder of the challenges and vulnerabilities they face. Ultimately, it reinforces the importance of conducting research in this area and highlights the pressing need for it.

Data Collection:

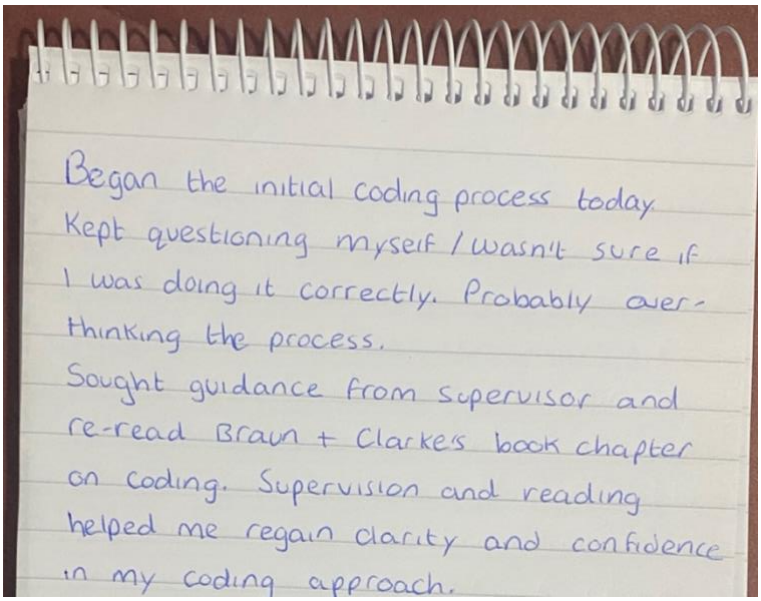
Participant reflection 1-


Can't help but reflect on our existing therapeutic relationship and how it might be influencing his response. I've worked with him since he was first discharged from hospital, and we have developed a strong rapport over time. In this interview, he's provided lots of positive comments about the potential usefulness of a digital health app, however I can't help but wonder whether his responses might be influenced by his desire to be supportive of my project or to tell me what he thinks I want to hear. Tried to make it clear that I valued his honest feedback and that anything he shared would contribute to our understanding, regardless of whether his views were positive or negative about the app.

Participant reflection 2-


I know this participant really well and have worked with him therapeutically, specifically addressing his fear of relapse. I noticed he wasn't giving me a lot of detail in his responses during this interview. I wondered whether he was assuming that I already knew what his views were as we had already extensively discussed his fear of relapse in our psychology sessions. I tried to make a conscious effort to emphasise that this interview is a separate opportunity for him to express his views and this reminder seemed to help.

Coding Process:



Appendix 2.12: Example of Quotes, Codes, and Sub-Themes of Theme One

Theme	Sub-Theme	Code	Quotes from transcripts
Contextual Factors	**Staying Well**	Physical activity	**Colin** […] having a regular gym routine. You know like it helps me, just, keep my mind, you know, occupied on, on something healthy. **Bria** Doing exercise every day. For example, walking. **Sid** I try and stay active. Going outside. Um. Walking or cycling, say. Um, going to the gym. **Jonty** […] I mean, I, I walk, you know, I walk to the bus stop and kind of you know, I don't drive everywhere or anything like that. **Noam** Well, first of all, I go on walks **Harris** […] riding bike is nice as well. **Maya** I've been swimming quite a lot recently and finding that quite helpful **Ava** I like to go on walks a lot.

			Leigh I like walking as well, I find that, if I spend more time, kind of, in the house, I get kind of, like my mental health kind of worsens, I feel kind of, more like, cabin feverey. Like I do make the effort to kind of try and get, fresh air, for good kind of, chunk of time each day. **Darra** A walk definitely makes you feel a bit more, awake, and like, just feel a bit better.
		Maintaining a healthy lifestyle	**Colin** […] eating well. **Sid** […] Uh, abstaining from drugs. Um, and limiting my intake of alcohol. **Jonty** […] And I also like to, you know, sleep for as long as I can. And. Eat meals, eat three meals a day **Noam** […] Make sure I sleep well. **Ava** […] I also like to take a lot of like vitamins uh, for my health. I'm eating healthy as well. **Leigh** I try to eat well. Like um, in terms of, kind of getting enough, like fruits, vegetables, protein. […] Yeah, uh, part of it is just avoiding, like, drug use, which I did a bit beforehand. And alcohol over use, like just kind of keeping an eye on, like I don't consume any substances other than alcohol really, but just like, keeping an eye on, like not over drinking and not like drinking at home.

			Darra […] trying to eat healthy and not have too many takeaways and stuff like that. […] staying away from drugs and stuff like that.
		Stress Management	**Leigh** I try not to like, over timetable myself like. […] Yeah, that's a big one for me. Keeping my stress levels down. Like not over committing to things. **Ava** […] keeping my stress levels down, is a way that I stay well. **Darra** Just, trying to keep the stress levels down **Jonty** […] And, and just make sure that I don't stress myself out too much because I feel like stress can be kind of triggering when you've got, when you have previous mental health issues.
		Engaging the mind	**Colin** [**…**] And also meditating as well. I love that as well and it really helps me just keep a clear mind. Reading. Reading, as well. Reading non-fiction, fiction, I love that as well. **Jonty** […] one of the things that helps me is a program called Restart. […] And it helps me. It's essentially an occupational, occupational health kind of program […] You know, it just kind of gets you out of the house, gets you interacting with people. There's a number of classes […] they're interesting. […] certainly for me it's nice to have something to focus on and concentrate on.

			Harris […] work and activities like, like Elin said, that helps you keep your mind busy, you know, you're not thinking about the time. Me here, personally, I bake cakes with my family. So that keeps us, my mind focused on something nice. **Alec** I think distractions quite a good thing. So as Harris said, keeping your mind off certain things helps. **Maya** […] being back at work. **Elin** I found quite helpful to garden **Darra** […] just, doing things that I enjoy.
		Social connections and support network	**Harris** […] having someone to share their experiences **Alec** […] also just speaking to people and doing activities, like not even too big activities. So you just go on a walk with someone or just, instead of watching TV by yourself, watch it with someone so the company's nice as well. **Sid** […] staying in contact with people.

			Jonty […] Other ways that I look after myself, so at weekends. Umm, there's a Costa nearby and usually I go there with family at the weekend and we have a coffee and we chat about our week and kind of what's been happening and stuff like that. **Noam** […] I talk to my friends, socialize with them. Because the biggest mistake I did was, back then even when I tried to socialize with my friends with the problems I faced with, I didn't socialize with the right people. […] because I'm going to the psychologist now, just now. […] we are putting down all the symptoms I had before my psychotic episode. And looking back at them and seeing how things could have turned out differently if I dealt with them in different way, like looking at it from different angles kind of thing.
	Current phone usage and digital health app experience	Attitude towards phone use	**Jonty** I do have a mobile phone, but it's not a smartphone. I used to have a mobile phone that was a smartphone, but unfortunately I had some issues with social media when I was unwell, so I've switched to one of the older phones that don't have Internet, just to give me that piece of mind. **Colin** Yeah, I'm actually using it right now, so yes, so I, I always use my phone all the time. You know, I have a laptop, but I prefer using the phone like it's just easier to like, carry around and stuff like that.
		Use of phone for various purposes	**Bria** […] most of them is about social apps because I'm outside my country, so that's my family. And Google. Google map, Google. Yeah. Google Chrome. **Colin** […] socializing, checking information on Google, even maps and stuff like that. […] So

			yeah. Mainly socializing, though, like, you know, WhatsApp, Facebook, Instagram and so on. **Ava** Social media […] WhatsApp, e-mail, TikTok as well like. Like, that's like the app I spend the most time on. **Leigh** Social media, e-mail, watching things like, um, Youtube and student services. **Darra** Things like, social media and all that and like. Mainly TikTok. **Sid** Um, watch a lot of Youtube. Um, I text my friends. Um, look at the news. Um, look up like research stuff on the web browser or Wikipedia say. […] I'm absolutely addicted to the Guardian for the news. Um, I mean, I use it every day and read, you know, a few articles at least so. **Jonty** I just use it for calling and texting **Noam** Music, like for YouTube
		Overwhelming nature of apps	**Elin** Sometimes they are overwhelming **Alec** […] especially social media can be quite overwhelming.

		Tracking health using digital health technology	**Bria** I was using um, a meditation app. **Colin** Like there's a step counter app, that, you know, like and you can do it to track your fitness. […] I like the app, you know, because it was, it was accurate. You know, your steps, it counts your steps accurately. It helps you like focus on your fitness level and you know like, you know, set goals for yourself. So I really like the goal setting exercise. Maybe you know you can get quite neurotic about reaching 10,000 steps, so maybe that was the downside of it. Sometimes the goals, I set them too high and then if I don't meet them, I'll be quite sad. So yeah, that was what I didn't really like about that. But it was really good though. Overall I really enjoyed it. **Maya** Track my sleeping on an app that's quite helpful. It's good to see, like when it shows you different stages of sleep. And yeah, I find it helpful. **Alec** I have that general health app. It tracks your like your steps and stuff you do which like I use quite a lot during lockdown, cause otherwise I wouldn't go out the house. **Leigh** Um, I use like the Apple Health app to track my steps and my menstrual cycle. **Darra** Ohh I use the step counter on that as well. Like sometimes I'll just have a look at it every couple of weeks and see like, cause it lets you compare like the averages and stuff like that. See if you've been more active during the week and all that.

			Ava The health app is what I use. **Leigh** I like the kind of, it comes with the phones. There's a kind of degree of like, the interface sort of matching up, so you don't have to manually input a lot of data into the app. **Ava** I like how accessible it as. Cause it's easy just to check on your phone, how, how many steps you're doing and it's easy to compare um, how you're doing compared to the other weeks. **Darra** […] just the fact that it's, um mainly like the apps like easy to use basically. Well it's not really complicated or anything like that. Just, you go on, look at the step count or whatever, and activity levels and that's it. **Darra** I'm just curious about how many steps I've done. **Leigh** Um, you can put in like, more health information and like emergency contacts […] but I haven't been in an emergency so I don’t know. **Darra** I've seen like, you can put in your medical ID in or whatever like that, but I've never really done it.

			Ava Sometimes I use um, MyFitnessPal like to track my calories, to see how much calories I'm consuming. **Leigh** I've had friends when I was younger that would use MyFitnessPal. And I think it's quite, easy to fall into, with a kind of, borderline kind of disordered mindset. Not saying that that happens for everyone, but it can be used as a tool, to kind of, dissect what you're eating and to get like, it can kind of build calorie counting into something that is part of like your every meal every day as opposed to a tool that can help kind of work out an average. **Ava** I honestly find it helpful like. I don't really think there's like. I get how you can use it for bad, like some people can develop eating disorders when they're just checking their calories all the time to try and, I don't know, lose like a bad amount of weight like. But for me, I, I find it helpful. **Leigh** No, not really got into the kind of smart watch thing, cause like, I have a smartphone already, and I just don't really want to spend the money on getting like a watch that has less functionality. **Sid** I use Strava. Um like as an exercise tracker. Um. Mainly just to kind of record routes um where I've been walking or cycling so. And then there's a social networking aspect to it as well. […] I like how you can sort of, share, what you been up to and, you know share pictures and stuff and you can make commentary. Umm. But I suppose that's just a social aspect of it as well. […] I think it could be a bit annoying how it pushes a paid feature. Uh,

			I, I rarely spend a lot of money on my phone, so I wouldn't exactly use that. Um. What else. **Jonty** I've used Under Armour […] what I liked about the, the running app is that you could share, or you could kind of like see what your mates are running. […] There was um, another app, again I can't remember the name. I think it's like my fitness plan or something like that. […] I found that quite helpful as well because all you have to do, it's very user friendly. All, all you have to do is just scan the bar code and you get however, however many calories are in there so you can keep track of your diet. Um and the other ones. Umm, I haven't used smartwatches or Fitbits and stuff like that. I never really bought into the idea of using them, but those two apps I would say are the main ones that I used. […] sometimes just track my steps, like how many steps I'm doing in a day. Like with Samsung Health **Noam** I used to have a smartwatch, like a Galaxy watch pro, but I, forgot the charger in Pakistan.
	Conceptualisation of relapse and seeking help in psychosis	Understanding of relapse	**Bria** I can explain it like a, I have the anxiety of getting, for example, some of my past disorders, or going to hospital. **Harris** I think it would be like, um, re-living the symptoms that you had before, seeing them coming back. You know, one by one kind of thing. It might not even be the same. But, just the psychosis knocking the door saying, hi there. I'm still here, kind of thing. **Maya** For me it would be having my old symptoms come back.

			Alec Yeah I think you've nailed it on the head there. Yeah, it's the familiarity of old symptoms coming back. **Maya** I think, mine would probably start back with like, um, having more paranoid thoughts again, cause that was a big one for me. **Elin** […] I was dressing up to run away from home and leave all behind because I had suicidal thoughts, um. Everything was kind of mixed and I thought there were cameras, um, watching us. Um. They were hiding in the flat somewhere. **Ava** Like when I'm not sleeping well, not eating well. I'm kind of secluding myself, isolating myself from my, my friends, not really talking to them about how I feel, and isolating myself from my family as well. That was like something I'd done and, just like, believing things that are just not true. Um. You know, like having like, really like, wacky ideas and stuff like that, that's one thing. **Leigh** […] I try to make an effort to like sleep well, um, socialise well, if I, like if I don't sleep well, I do notice the difference, and if I don't eat well, I kind of notice a difference as well, so it's just like, if I notice that kind of pattern happening, I just need to nip it in the bud. **Darra** If I notice that I'm not really sleeping as well or like, I just feel more stressed than like, kind of, on the edge, I'm more likely to be a bit like, I don't know how to describe it, like, get a bit more annoyed at things that I shouldn't really get annoyed about um. […] if I've

			had any thoughts of like, like, that are a bit out there, like paranoid thoughts and all that, um, I suppose it's just, whether you know if you'd recognise them. **Sid** I think for me um, it would, it would mean a return to, you know, probably hospitalization. Umm, just losing my independence, and, you know it's, I'd say it would probably, it'd be quite damaging again to my relationships. […] I end up more paranoid, more delusional. Umm. You know, making conclusions that just don't make sense in my head. […] Cognitively there's a lot that changes. […] In terms of behaviour, um. I might be more outgoing, put myself at more risk. Um, or even just like kind of hole, hole up and hideaway if it's, you know, if I'm getting a lot of paranoia. **Noam** […] There was a lot of stress that accumulated which led to my psychotic episode. […] I would associate that with becoming unwell, not able to manage my stress properly and not taking my medication most importantly, because the medication is the main reason why, is, it makes a big, big, big part of me being well. So hopefully taking my medication and it won't happen like that, things like relapse. […] I would feel differently as well, but more importantly, I would think differently. Like my thinking will change. Like, you become delusional and stuff like. Thinking that people are out to harm me and stuff, like that kind of things.
		Concerns and worries about relapse	**Colin** […] I'm worried that like I don't know how it will strike again. Like what if I'm just walking and then I eventually notice myself becoming unwell and so on. […] You know, like there will be signs. There will be patterns that, red, red warning signs that will alert you to like if you're not becoming, if you're becoming unwell. So, I'm more confident over that. But there is that still the bit of anxiety, you're not knowing, you know, uh, when it will strike.

			It’s like, it’s just like a cold or something. You never know when you're gonna get the cold. It can just come. But. But it's alright, you know, I can, but I get, even with a cold, I guess if it's freezing outside, you know, like, OK, I need to wrap up and stay warm and eat, you know. Uh, put a big jacket on, so there will be signs and stuff, so **Maya** […] and having to go back into hospital. […] I worry about relapse and because, well, partly because, um, with a, when I first had psychosis, I feel like I was very lucky in that it was caught and I didn't do anything publicly that was embarrassing. Like everything was quite contained. Um, and I guess I worry that if I relapsed, then people at work, could see me relapse then or, or I would say something online or something like that. Um, yeah. Ohh just one last thing is that I want to have a child at some point and a big fear for me is having postpartum psychosis, that is like a big, a big worry for me. **Harris** […] my mom just said the other day that she's a bit scared of relapse not because I'm showing any signs, but because she doesn't want to experience that again. **Sid** Yeah I do worry about relapse a bit. […] but yeah, not, not usually often. […] I'd say if I’m, if I’m, up really high mood wise or not. You know, I feel as if, um. I feel really good. Then, you know, you might not kind of notice, like the symptoms of, of psychosis and that, in that moment. Um, so yeah, I, I've been concerned about that. But, initially when I got admitted to hospital first time, I did go in voluntary voluntarily. Um, so looking back at that, as a past decision, I've been more confident in seeking help because of that. **Jonty** […] The thing that worries me, is not knowing when you need help. That's one of the things that kind of worry me because before I went into hospital, I didn't think that I had

			anything wrong with me, you know? So I didn't have any insight into the fact that I was unwell. **Noam** I don't worry about it. Um. It's the last thing I would ever want, a relapse. But um. Because I've never had any symptoms, never had any thoughts, never like, […] it took, a time to take a toll on my mind, so I know there's tell-tale signals, if this is happening then I need to watch it out and kind of stuff. Because I've been through that, I know, like, the things which um, might, which might cause psychosis, but knowing those things is a blessing. […] Relapse to me is, I don't, I don't think, God willing, I would never have it, because I've never had any symptoms or anything like that ever since I'm out of hospital. But I hope it never happens, like never ever again. Like a relapse.
		Relapse as a lingering thought	**Alec** Yeah, I think because we now know, how bad it can get, and it can also get even worse than how I was before, I think that's something that's always kind of in my head. **Leigh** Not much day-to-day, […] And it is, it's a little bit scary thinking about relapse. But now that I've had this experience and I've kind of been treated and we know what treatment works and what doesn't, there wouldn't be such a long period of like, trial and error with like different medication and different treatments. Because now there's that kind of, treatment plan, like in place. So it's almost less scary thinking about relapse and now, kind of like, know what would happen. So there's more like, fear of the unknown, that kind of once it's happened, it's almost less scary. **Ava** Ok. Um, it's kind of like in the back of my mind, but it's not something that like, I

			constantly think about. […] as long as I take my medication and keep my stress levels down, I think I'll be OK. **Darra** Yeah, I'd say like, it's not something I worry about, like on the, a daily basis, but like something, it is kind of thought in the back of your mind. Like. Ohh God, if that happened again, like, it wouldn't be good and all that. Like, I wouldn't, wouldn't be having a good time. Uh, yeah. Like, I suppose it's just something that's always kind of there in the back of my head, which is a bit annoying, but in some ways it's a good way, cause it, kinda, leads me to not go down that path of like, sleeping badly, and like, stuff like that, and high stress levels and all that. But at the same time like, in a way, I'd kind of rather forget that it happened. But at the same time. I think, as you said earlier, like there's a kind of healthy level. But, yeah, it's not something I worry about like every day, just occasionally and sometimes you're like, ohh thinking about it, and what if that happened again sort of thing.
		Seeking help and having a support network	**Colin** […] over the weeks and months I've been getting more confident about not relapsing because, we see that things don't just happen overnight. You know, like there will be signs. There will be patterns that, red, red warning signs that will alert you to like if you're not becoming, if you're becoming unwell. So, I'm more confident over that. **Bria** Umm, every time that I worry about relapse, I, I share my thoughts and my emotions to my therapist or someone that for example, my husband, and someone that knows about my situation.

			Bria […] I really um know the benefits of having social connections, having someone to trust is really important to uh, to my recovery. **Colin** […] building a support network, you know, and having more that you know that sense of self-confidence, knowing that there are people around me that, that I can always ask for help for, so you know. […] feeling of safe and secure and yeah, happy that there's a support network. **Harris** I believe because I'm always in contact with the psychologist and my key worker, we, we, can chat about lots of things and I never noticed that it was coming back. […] they, could see that I was improving **Leigh** Yeah, I talk to the disability support in my college and stuff, and I've got, like, an extended learning support plan in place with them. So that's kind of something that I've considered like letting my CPN help me with, […] I think it's important to kind of access everything that I am entitled to, though it can sometimes feel like kind of a big, like more of a big deal than it is really, but I think it's just important to take advantage of the resources that are designed to help you. **Ava** I personally haven't asked for help about relapse yet, cause I haven't really like thought about it that much, but if I was to ask for help I would ask my CPN cause I see her like, every two weeks so it'd be easy for me to talk to her. **Darra** I'm not too sure what, I feel like, I don't know. Asking for help is like a bit difficult for me

			sometimes, like I don't know, just not something that I'm that good at, but um. Like. Yeah, I'm, I'm just not really sure on that one. […] Even though it's becoming kind of a wee bit less of a thing, like that sort of mindset. **Sid** You know, family and friends there to be able to, weigh in and um, an opinion and say. Umm. You know, you're just not acting yourself. […] It was the people that, um, is the crisis team in my local area who sort of, who suggested I go in. Um. And they were just, like, really patient, understanding. Um, and just listened to me, and they could tell like, um, I was probably a good a good way to um, move things on. **Jonty** Yeah. So I, I spoke to my CPN about this, about the early warning signs of my psychosis um, and he gave me a, a table. I think there's about 30 early warning signs in there […] I know what the early warning signs are, and I feel like knowing what the early warning signs are is a bit reassuring for me because it kind of lets me know that I can do something about kind of relapsing and I can do something about being able to detect it early. Umm. And so if I notice certain changes, I can say, OK, this is an early warning sign. I need to speak to my CPN or I need to speak to my psychiatrist and make sure that whatever is going on isn't allowed to kind of ruin my life any further. […] I personally come from a medical family and we're always very open and honest about our health struggles and stuff like that. And if we need help, we always kind of get it out in the open. but in terms of asking for help, um, so I don't, I don't worry about asking for help. **Jonty** I think a good relationship with your CPN, that's something that I, I think would be important and I am fortunate to have a CPN who I get along with very well. And, so you know, I can just, if I'm worried about anything, I can just pick up the phone and speak to them and you know, ask them a question and stuff like that. So I think having good

			relationship with your CPN and your psychiatrist is very important when it comes to asking for help. **Noam** This time I would go straight up to the doctor and be like, give me some medication because this medication isn't working or something like that. […] I would share, go to people and start talking it out rather than making assumptions of what they're thinking, what they're doing and stuff. And most probably go to the doctor first, my psychiatrist. I'll ask my, the psychiatric nurse, contact her and stuff.

Appendix 2.13: MRP Study Protocol
https://osf.io/rce7w

Appendix 2.14: Standards for Reporting Qualitative Research (SRQR) Checklist

Standards for Reporting Qualitative Research (SRQR)*

http://www.equator-network.org/reporting-guidelines/srqr/

	Page/line no(s).
Title and abstract	
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	Page 58
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	Page 61
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	Pages 63-66
Purpose or research question - Purpose of the study and specific objectives or questions	Page 67
Methods	
Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	Page 67 Pages 73-74
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	Pages 74-75
Context - Setting/site and salient contextual factors; rationale**	Pages 68 and 72
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	Study Protocol, page 14
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	Page 67 Appendix 2.1, 2.2
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	Pages 67-75
Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Pages 67-68 Pages 72-73
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Pages 70-71
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	Pages 67-68
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	Page 73
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	Pages 74-75

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Pages 75-92
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Appendix 2.12

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Pages 93-100
Limitations - Trustworthiness and limitations of findings	Pages 97-99

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Page 58
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	N/A