

Process evaluation of digital mental health interventions for psychosis: A mixed-methods systematic review with framework synthesis.

Chloe Hampshire, Charlotte Dack, Shadi Daryan, Carolina Fialho, Rayan Taher, Ashley-Louise Teale, Jenny Yiend, Pamela Jacobsen

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Abstract

Background: Digital mental health interventions (DMHI) are a promising treatment mode for those with psychosis, though their implementation is a persistent challenge. A process evaluation, or studies conducted alongside trials, is one research method that may address this issue. However, a synthesis of process evaluation data in this literature is missing.

Objective: To review and synthesize process evaluation data from trials evaluating DMHIs for people with psychosis to explore what is known about context, implementation, and mechanisms of impact.

Methods: A mixed-method systematic review using a two-phase search strategy underpinned by the Medical Research Council (MRC) process evaluation framework was conducted. Database searches of CENTRAL and PsycInfo first identified an index sample of peer-reviewed trials evaluating a relevant DMHI that was predominantly conducted in the United Kingdom (50% United Kingdom sample in multi-country studies). Associated papers linked to this index sample were then systematically searched for and included if process evaluation data as operationalized in the MRC framework were reported. Two authors independently screened references, extracted summary data and assessed the quality of index trials. One author qualitatively analyzed process evaluation data using a framework synthesis approach using the MRC framework and synthesized findings using narrative synthesis.

Results: Searches identified 10 DMHIs and 36 papers reporting process evaluation data, though only two were labelled as such. Studies indicated most DMHIs supported users to respond to challenging situations in more helpful ways by changing their habitual responses, indicating a possible mechanism of impact. Implementation strategies aimed to enhance delivery in a trial by preparing delivery staff, providing support to users and developing interventions that were flexible and relevant to users. Implementation data also demonstrated DMHI use varied, and contextual factors affecting implementation often differed from stakeholder expectations and included users' perceptions of the DMHI, life commitments and some psychosis symptoms, and staff availability in services for blended DMHIs.

Conclusions: Our findings highlight possible considerations for future DMHI development, delivery and evaluation. Intervention personalization and user-centered design may be important DMHI design features. Further work establishing how DMHIs work is recommended. Implementation efforts should address actual, rather than perceived, determinants of DMHI implementation, including users' clinical and general context, and staff availability for blended interventions. Application of process evaluation methods in trials could strengthen this work. Clinical Trial: PROSPERO: CRD42024439117.

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Original Manuscript

Review Paper

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Conclusions: Our findings highlight possible considerations for future DMHI development, delivery and evaluation. Intervention personalization and user-centered design may be important DMHI design features. Further work establishing how DMHIs work is recommended. Implementation efforts should address actual, rather than perceived, determinants of DMHI implementation, including users' clinical and general context, and staff availability for blended interventions. Application of process evaluation methods in trials could strengthen this work.

Registration: PROSPERO: CRD42024439117.

Key words: psychosis; digital mental health interventions; process evaluation; randomized controlled trial; systematic review; framework synthesis.

Introduction

Psychosis is characterized by strongly held unusual beliefs and often distressing sensory experiences, such as hearing voices[1], and can cause difficulties in many aspects of life, including interpersonal difficulties[2], reduced quality of life[3] and increased risk of early death due to poorer health outcomes[4]. In the United Kingdom (UK), clinical practice guidelines recommend psychological interventions, such as cognitive behavioral therapy or family interventions, for individuals with psychosis[1]. However, in the UK, access to these therapies remains below recommended levels[5,6].

An early value assessment conducted by the National Institute for Health and Care Excellence in the UK highlighted Digital Mental Health Interventions (DMHI), or technology-based treatment designed to improve users' mental health[7], could be a promising treatment mode for those with psychosis[8]. However, whilst there is increasing evidence DMHIs can reduce mental health symptoms experienced by those with psychosis[9,10], implementing these interventions remains a persistent challenge[11,12].

One recommendation to overcome this DMHI evidence-practice gap made by an international commission from Lancet Psychiatry in 2024 was to adopt methods that embed implementation work throughout the research process[13]. One such research method is a process evaluation, or studies that are often embedded in randomized controlled trials (RCT) that explore how, for whom and where interventions work[14]. The most recent process evaluation guidance was published by the Medical Research Council (MRC) in the UK in 2015[14]. Process evaluation in the MRC framework explores three outcomes (Textbox 1)[14].

Textbox 1. Medical Research Council process evaluation components[14].

- Context: external factors that influence how an intervention is implemented or functions.
- Implementation: the quantity and quality of, and processes required for, intervention delivery.
- Mechanisms of impact: how an intervention produces an effect.

Importantly, some studies have used process evaluation to evaluate DMHIs used by those with psychosis[15–18]. Existing evidence highlights digital treatments may work by empowering users or facilitating self-reflection[15–18], and has identified some barriers to implementation, including user- (eg,

competing life demands)[18], service-level (eg, staff turnover)[17] factors. However, a systematic review of process evaluation in this literature is missing.

Overall, a dedicated review is warranted to understand the current state of process evaluation in this literature. In line with methodological recommendations[19,20], our review focuses on research conducted in the UK, as differences in healthcare systems and psychosis care pathways can limit comparisons between countries. Our research question was: what is currently known about the context, implementation, and mechanisms of impact from UK RCTs evaluating DMHIs used by individuals with psychosis?

Methods

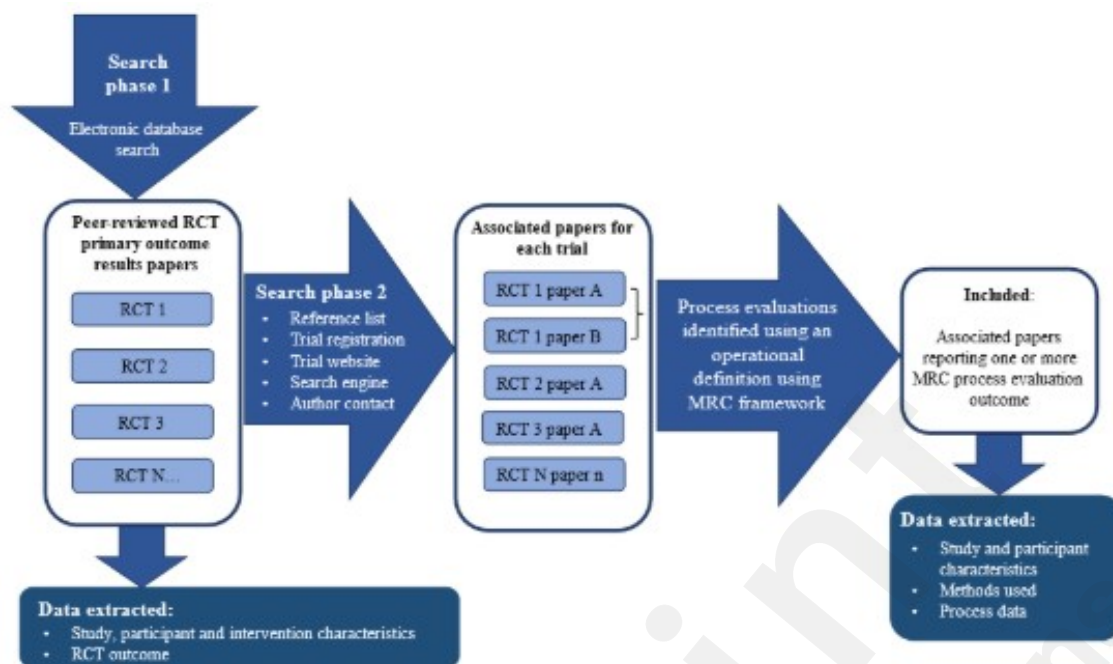
Design

This review followed Cochrane methodological guidance for synthesizing RCTs[21] and process evaluation evidence[22]. In the absence of specific reporting guidance for process evaluation syntheses[23], reporting was guided by adapted Preferred Reporting Items for Systematic reviews and Meta-Analyses[24] and Enhancing Transparency in the Reporting of Syntheses of Qualitative evidence[25] checklists (Tables S1 and S2, Multimedia Appendix 1). The protocol was preregistered and can be accessed at PROSPERO (CRD42024439117). No amendments were made to the protocol.

Search Strategy and Eligibility Criteria

A 2-phase search strategy, supported by Covidence software, modelled on prior reviews of process evaluations[26], was used to first identify relevant RCTs, then associated studies (Figure 1). This approach helped address inconsistent use of the term “process evaluation”[22,26], and is recommended for retrieving such studies[22].

Figure 1. Method overview (adapted from French and colleagues[26]).



Phase 1 identified RCTs evaluating DMHIs used by individuals with psychosis (index RCTs) using pre-planned database searches of PsycInfo and CENTRAL on 31/01/2024 (see Multimedia Appendix 2, Table S1). Studies included in phase 1 met the following requirements:

- *Population:* participants aged 14+ with psychosis established by either: (1) a diagnosis of a psychotic disorder using a validated tool; or (2) a score on a standardized psychosis measure (indicating psychotic symptoms are the primary presenting difficulty); or (3) receipt of care from a specialist psychosis service.
- *Intervention:* digitally delivered, targeting a mental health difficulty.
- *Studies:* the main outcome paper (the first peer-reviewed paper publishing the pre-specified primary outcome data) of peer-reviewed predominantly UK-based RCTs (50% UK sample in multi-country studies with comparable healthcare systems).

Phase 2 systematically identified peer-reviewed publications associated with index RCTs that reported process evaluation data. Following Cochrane guidance[23], process evaluations were identified using the 2015 MRC framework[14] and irrespective of how the studies were labelled. Definitions and coding rules are provided in Table 1. Studies in phase 2 met the following requirements:

- *Outcome:* at least one process evaluation outcome from the 2015 MRC framework (context,

implementation or mechanisms of impact)[14] using qualitative, quantitative or mixed methods.

- *Studies*: clearly linked to the main RCT (via trial registration or program grant).

Table 1. Coding framework operationalizing the Medical Research Council process evaluation components[14].

Component	Definition	Coding rules
Context	• External factors that influence intervention implementation or functioning.	• Code data about factors that are external to the intervention and its components. • For intervention implementation, code data that influences how intervention delivery or components are carried out. • For intervention functioning, code data that influences the purpose or desired effect of interventions.
Implementation	• The quality and quantity of intervention delivery • How intervention delivery is achieved (structures, processes & mechanisms).	• Code data about what is delivered in practice. • Code data about the processes required to carry out the intervention components.
Mechanisms of impact	• How interventions bring about change.	• Code data about the intermediate structures between the intervention and the outcomes that produce an effect. Data can include intended and unintended mechanisms.

In phases 1 and 2, masked reviewers (CH, SD, CF & AT) independently screened search results in Covidence using eligibility criteria on titles and abstracts, then the full text. Discrepancies in inclusion were resolved through discussion, with senior team members (PJ & CD) consulted where appropriate.

Data Extraction and Critical Appraisal

Relevant data were electronically extracted in Covidence to reduce bias. Masked reviewers (CH, SD & AT) extracted summary characteristics from index RCTs (study, participant and intervention characteristics, and RCT outcome, positive/negative) and process evaluation studies (study and participant characteristics and methods used). CH extracted process evaluation data using a pre-defined coding guide (Table 1). Missing data were not sought from authors.

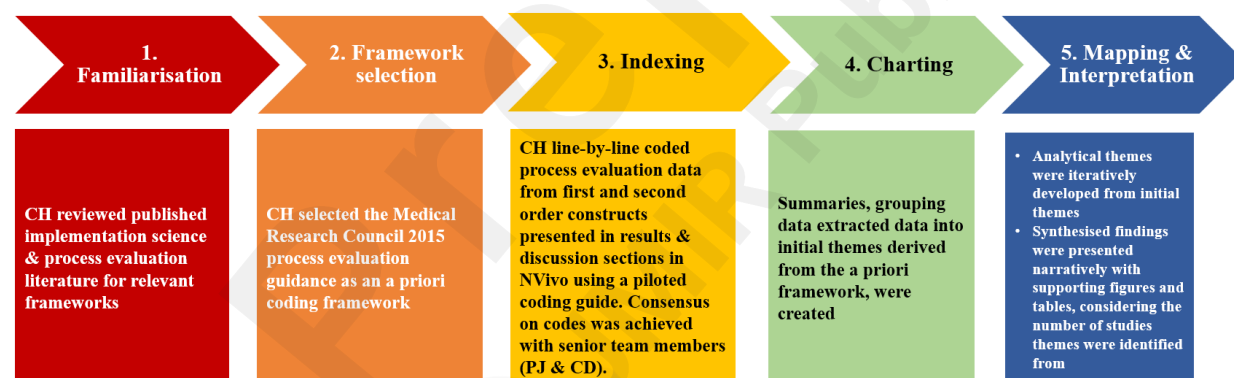
The methodological quality of associated publications was not assessed because a validated tool for process evaluations has not been developed[22] and inclusion of all studies in qualitative syntheses is

recommended[27]. Index RCTs were independently assessed by masked reviewers (CH & RT) using Cochrane risk-of-bias 2 tool, evaluating five domains: (1) randomization procedures; (2) deviations from intended interventions; (3) missing outcome data; (4) measurement of the outcome and (5) selection of the reported[28].

Data Synthesis

A convergent data-based synthesis design, supported by NVivo, was used to qualitatively analyze process evaluation data[29]. Framework synthesis, using the 2015 MRC process evaluation framework[14], guided analysis in five stages: (1) familiarization; (2) framework selection; (3) indexing; (4) charting; (5) mapping and interpretation (Figure 2)[30]. Results are presented as a narrative synthesis. To enhance synthesis clarity, we applied a frequency criterion adapted from Graham-Rowe and colleagues[31], whereby the number of studies associated with themes were considered in the narrative synthesis. The coding tree is reported in Multimedia Appendix 2.

Figure 2. Framework synthesis overview.



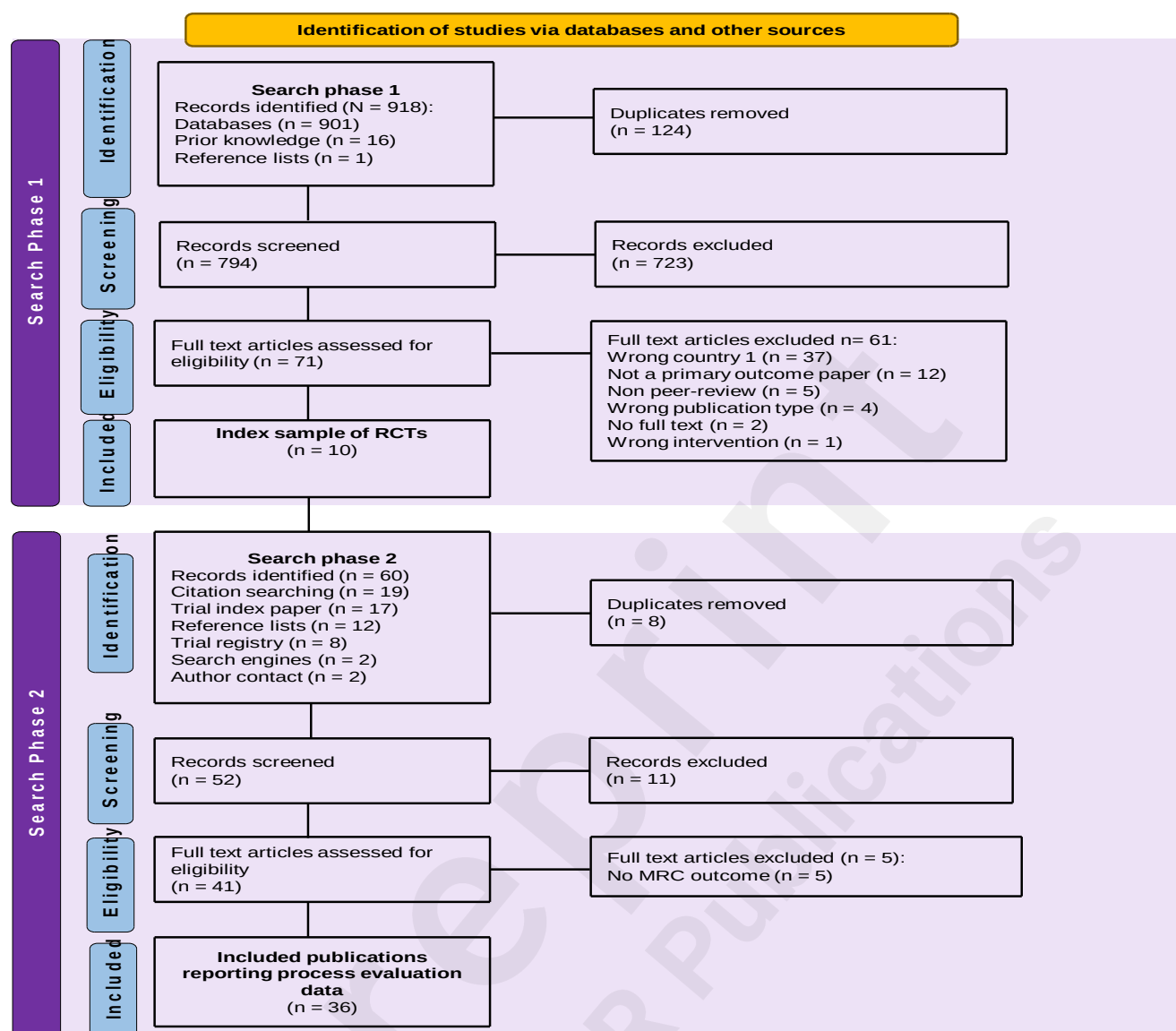
Results

The search results are summarized in Figure 3. Phase 1 initially identified 918 papers, 784 of which were excluded after deduplication, primarily because they were conducted outside of the UK or were not primary outcome papers. In phase 1, 10 index RCTs were included. Phase 2 screened 60 papers for process evaluation data (10 were index RCTs included in phase 1 and 50 papers were systematically identified in phase 2). From this, 8 duplicates and 16 papers (mostly protocols, though some did not report process evaluation) were excluded. In phase 2, 36 papers reporting process evaluation data were included (9 index

RCTs; 25 associated papers).

Figure 3. Search flow diagram.





Index RCT Methodological Quality

Quality ratings of index RCTs are included in Multimedia Appendix 2 Table S2. Most disagreements arose in domain 2 (deviations from the intended interventions) and was resolved by discussion between raters

(CH & RT). Most (6/10; 60%) RCTs showed some risk of bias, primarily due to bias arising from deviations from intended interventions or outcome measurement[32–36]. The remaining four RCTs had low risk of bias[37–40].

Index RCT Summary Characteristics

Summary characteristics of index RCTs are reported in full in Multimedia Appendix 2 Table S3, and intervention characteristics are presented in Table 3. Most DMHIs targeted psychosis specific symptoms (n=8/10; 80%) and were delivered in a participant chosen or any setting (n=5/10; 50%). Most (7/10; 70%) RCTs were conducted from a London-based University[36–40] or the University of Oxford[32–34]. One RCT was conducted outside of England in Scotland and Australia but was included because less than half of participants were Australian (29%)[41]. Based on available data, intervention users were mostly White (n=378/620; 61%), male (n=414/620; 66%), had a mean age of 41.2 years and a diagnosis of a psychotic disorder (n=514/620; 83%).

Table 3. Intervention characteristics.

Intervention	Index reference	RCT	Intervention target		Delivery setting			Delivery mode		
			Psychosis specific symptom	General mental health	Any setting/ participant choice	Clinical setting/ study site	Not stated	Virtual reality	Computer/ web	Smart-phone
Actissist	Bucci (2018)	✓			✓					✓
AVATAR	Craig (2018)	✓				✓			✓	
CBM-pa	Yiend (2023)			✓		✓			✓	
EMPOWER	Gumley (2022)	✓			✓					✓
— ^a	Freeman (2016)	✓				✓		✓		
gameChange	Freeman (2022)			✓	✓			✓		
—	Leff (2013)	✓					✓		✓	
SloMo	Garety (2021)	✓			✓				✓	✓
THRIVE	Freeman (2023)	✓			✓			✓		
V–NeST	Cella (2022)	✓					✓	✓		

^aNone given.

Studies Reporting Process Data Summary Characteristics

Summary characteristics of studies reporting process evaluation data are reported in full in Multimedia Appendix 2 Table S4 and summarized in Table 4. Most studies were published between 2021–

2023 (n=23/36; 64%), quantitative (n=14/36; 39%), used trial data (n=24/36; 67%), evaluated the study intervention (n=30/36; 83%) and did not describe the project as a process evaluation (n=34/36; 94%).

Table 4. Characteristics of studies reporting process evaluation data (N=36).

Process evaluation characteristics	N (%) ^a
Publication year	
2013–2016	2 (6)
2017–2020	11 (31)
2021–2023	23 (64)
Study design	
Quantitative	14 (39)
Qualitative	13 (36)
Mixed–methods	9 (25)
Process scope	
Study intervention	30 (83)
Intervention implementation	7 (19)
Trial procedures	6 (17)
Process evaluation data source	
Trial data	24 (67)
Additional stakeholder feedback	16 (44)
Author description	6 (17)
Labelled as process evaluation	
Yes	2 (6)
No	34 (94)

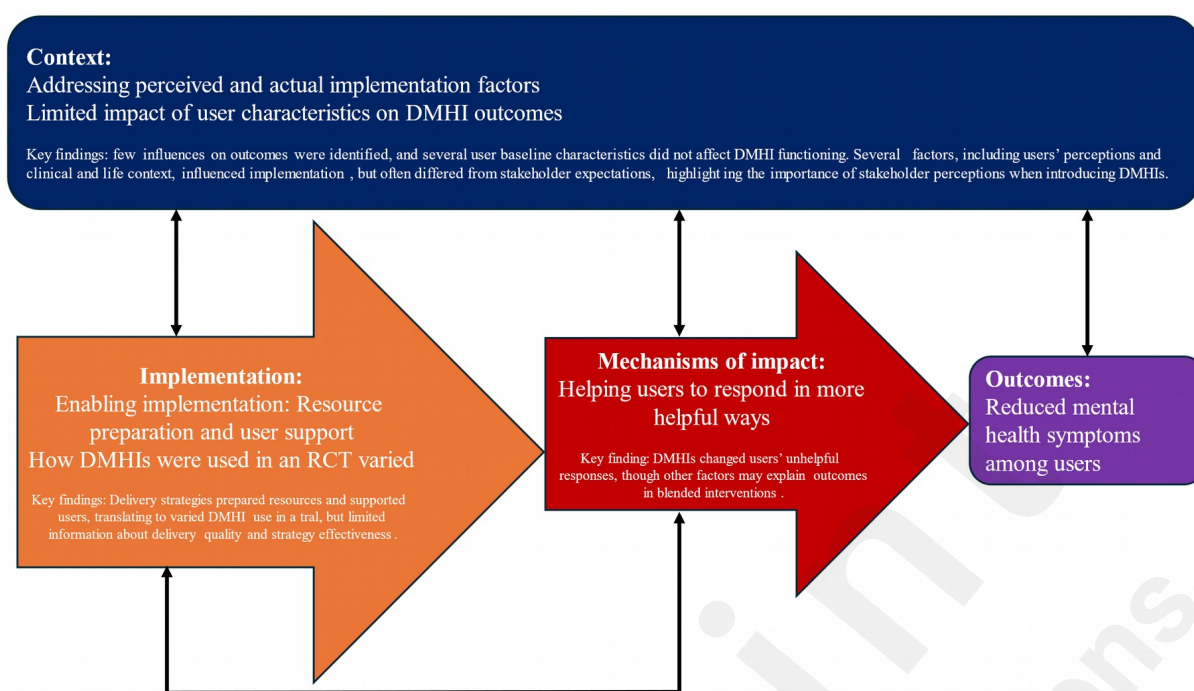
^aSome papers fall into more than one category, so categories may add to more than the overall total N.

There was a range of participants and contributors to studies reporting process evaluation data (Table S4, Multimedia Appendix 2), with trial participants comprising the majority (n=1164/1455; 80%) across 26 (72%) studies. Other contributors included healthcare professionals (n= 195/1455; 13%) and individuals with lived experience (n=173/1455; 11%). However, missing sociodemographic data in 15 (42%) studies limited the ability to accurately summarize this information.

Framework Synthesis Findings

Framework synthesis of process evaluation data generated five themes (Figure 4), all of which were coded within the components deductively derived from the MRC framework (context, implementation and mechanisms of impact)[14].

Figure 4. Framework synthesis themes summarized using the Medical Research Council process evaluation diagram[14].



Implementation

Most findings related to implementation, defined in our review as the quantity and quality of, and processes required for, delivery of DMHIs within RCTs ($n=29/36$; 81% studies; 9/9; 100% DMHIs). Two themes synthesizing implementation data, organized into the deductive categories in the MRC framework, were created: (1) how DMHIs were used in an RCT varied (implementation measures) and (2) Enabling implementation: resource preparation and user support (implementation processes)[14].

How DMHIs Were Used in an RCT Varied

Implementation measures data, or the quality and quantity of the DMHI delivered within the RCT, were identified in 13 (36%) studies in relation to 8 (89%) DMHIs. Data, drawn from quantitative trial data, indicated the amount of DMHI delivered varied across users of both blended (DMHIs are delivered in a session and guided by a member of staff, $n=6/9$; 67%) and self-administered (DMHIs are used independently, $n=3/9$; 33%) delivery models. One intervention (SloMo) used both delivery models as the app could be used in and outside of therapy sessions[40]. Session attendance for all blended DMHIs ranged from 0%-100%[33,34,37,39]. For self-administered DMHIs, intervention delivery was reported using adherence criteria[40–44], with use also varying as the percentage of users meeting app adherence criteria ranged from 65.4%[42]-91%[41]. One trial team (Actissist) reported detailed usage patterns which further indicated

variation in DMHI use as users accessed the app at various times of day, but engagement declined 67.5% over the 12-week intervention period[43].

Data about the quality of DMHI delivery in an RCT was limited. One team assessed therapist adherence and skill in delivering AVATAR therapy, reporting full adherence to the manual and high competence[37]. Another trial (CBM–pa) noted successful delivery without supporting data[38].

Enabling Implementation: Resource Preparation and User Support

Implementation processes data, or the actions taken by trial teams to support DMHI delivery in the RCT, were identified in 27 (75%) studies in relation to all 9 DMHIs. Data, identified from stakeholder feedback, trial data and author interpretation, encompasses the practical processes used by trial teams to transition DMHIs from development to delivery in an RCT. Implementation process data were synthesized into two subthemes: (1) Preparing resources for implementation and (2) Providing support to DMHI users in an RCT.

Preparing Resources for Implementation

Most (n=7/9; 78%) trial teams prepared the resources needed for delivery prior to the RCT. These seven trial teams focussed on designing the DMHI with its future implementation in mind, whilst fewer described the preparation of human resources to support implementation in an RCT (n=3/9; 33%). These teams hired appropriate workers (n=3/9; 33%)[37,42,45,46] and provided training to deliver the DMHI (n=3/9; 33%)[44–46]. To enhance implementation efforts, six of the seven teams that prepared resources for implementation designed flexible DMHIs by: (1) allowing users to personalize virtual reality– (VR), web– or app–based intervention content (n=5/9; 56% DMHIs)[33,35,43,44,47–51], (2) ensuring on–demand access to the intervention, primarily via an app (n=3/9; 33% DMHIs)[35,36,43,44,50–52], or (3) enabling multi–setting delivery for blended DMHIs (n=3/9; 33% DMHIs)[33,34,42]. Among stakeholders, DMHI flexibility was consistently seen as beneficial[35,44,49] or requested when lacking[18,52,53]. Four of the seven teams also incorporated other sources of knowledge into the design to optimize implementation efforts by increasing DMHI relevance to intended end users, primarily by consulting stakeholders using co–design or user–centered design approaches[45,51,53–56]. One trial team, SloMo, attributed engagement to their implementation–

driven intervention development prior to the RCT[40,44,44].

Providing Support to DMHI Users in an RCT

Most (n=8/9; 89%) teams supported DMHI delivery during the RCT by providing support to users, primarily via staff, though two interventions (SloMo and gameChange) also included digitized human support in the DMHI[44,45,49]. For two of these DMHIs (CBM-pa and Actissist), support was provided by researchers specifically for the RCT and not as part of the delivery model[43,53]. Across DMHIs, staff provided practical help that supported users to use the DMHI, such as technical support or practical guidance[18,39,43,45,49–52,57–59]. For blended DMHIs, an important aspect of support was staff building a positive relationship with users using existing therapeutic skills, such as talking and listening to users[18,44,49,51,52,58] and adopting an empathetic and encouraging approach[49,52,58]. User feedback was mixed about the perceived usefulness of interpersonal support. Interpersonal support was valued by some users[49,52,58], though perceived usefulness varied[39,49,51,53]. No clear patterns emerged related to intervention factors, such as the level of support provided or DMHI mode.

Context

A similar number of studies reported contextual findings, referring in our review to external factors that influence DMHI implementation or functioning in an RCT (n=27/36; 75% studies; n=9/9; 100% DMHIs). Contextual findings were explored quantitatively, such as moderation analyses (n=8/27; 30% studies) [33,33,34,40–43,60,61], and qualitatively, including consulting stakeholders (n=10/27; 37% studies) [17,18,39,49,51,53,58,62,63], and reasons for participation in or withdrawal from the trial (n=7/27; 26% studies)[35,37,39,44,46,49,64]. Two themes synthesizing context data, organized into the contextual components (intervention implementation and outcomes) from the MRC framework, were created: (1) Addressing perceived and actual implementation factors and (2) Limited impact of user characteristics on DMHI outcomes[14].

Addressing Perceived and Actual Implementation Factors

Stakeholder Misconceptions About User-Related Barriers

Across studies, healthcare professionals and some service users held misconceptions about the appropriateness of DMHIs for individuals with psychosis, often expressing generalizing concerns that

psychosis-related and technology-related factors would hinder DMHI implementation. In pre-COVID-19 studies, staff anticipated limited access to technology and limited digital skills among users would act as key implementation barriers[62,63]. However, process evaluation data contradicted these assumptions, as, despite limited digital skills, users engaged with a range of DMHI modalities, including computer-based, smartphone-based and VR-based interventions[18,39,44,51,53]. Only one DMHI, SloMo, found user engagement was higher among users who were more confident using technology prior to the RCT[42]. Concerns were also raised by staff and some potential end users that technology-related paranoia or illness severity would hinder DMHI implementation[48,62,63]. However, process evaluation data provided a more nuanced understanding: not all users had experienced technology-related paranoia[52,58], and some used DMHIs despite concerns[51,55,58].

Instead, other psychosis symptoms, including auditory hallucinations[36,50,52] and negative symptoms[39], everyday factors, such as having other time commitments such as working or studying[18,35,43,58], and feeling that the DMHI was not suited to them[18,35,37,44,46,48] were more commonly identified as actual implementation barriers.

Service Level Barriers: Perceptions and Realities

Stakeholders (service users and staff) often perceived psychosis-specialist services as lacking the resources needed to implement DMHIs, citing limitations in staff availability, physical space and technology[48,62,63]. These concerns were particularly associated with DMHIs requiring clinical involvement in delivery, EMPOWER and gameChange[62,63], the latter involving VR technology and thus had specific equipment and spatial demands[37]. Whilst research into service-level barriers is limited, data from one intervention, EMPOWER, indicated staff resource constraints linked to high workloads and turnover hindered recruitment[17] and data collection[41]. In contrast, for Actissist, staff perceptions appeared misaligned with the intervention's delivery model, as staff held generalized assumptions about NHS technological and staffing limits that were not applicable to the DMHI's actual requirements[35,62]. Delivery of Actissist did not require NHS computer systems (as the intervention was delivered on a smartphone) and did not require support from healthcare professionals in delivery[35].

Hope and Help: Positive Expectations Facilitate Implementation

An implementation facilitator in an RCT was users' and healthcare professionals' positive expectations towards DMHI use. Most users wanted to try the DMHI because they felt they would personally benefit from use[18,49,51,52,58,63,64], though other, less common, reasons included wanting to help others by participating in research[52,64] and because the DMHI offered an opportunity to try something different in the context of their treatment[39,52]. Staff reasons for wanting to deliver a DMHI were less frequently reported but aligned with users' reasons as some reported anticipating the DMHI could help their clients[48,62].

Limited Impact of User Characteristics on DMHI Outcomes

In contrast, few contextual factors influencing DMHI functioning in an RCT were identified. Only one VR DMHI (gameChange) showed enhanced effects for participants with higher baseline illness severity[60] and users who felt valued from using the intervention[61]. Across three DMHIs, most user baseline characteristics did not appear to influence DMHI outcomes[33,34,40]. Although some studies examined potential moderators, no consistent patterns emerged, though gender was not found to moderate effects[33,34,40].

Mechanisms of Impact: Helping Users to Respond in More Helpful Ways

Finally, mechanisms of impact, referring to how DMHIs produced change in an RCT, was identified in relation to most (8/9; 89%) DMHIs included in our synthesis (n=17/36; 47% studies). Most evidence was identified from qualitative sources, including DMHI user feedback (n=7/17; 42% studies[18,35,49,51–53,58]), intervention content (n=4/17; 24% studies[44,46,57,59]) and author commentary (n=1/17; 5% study[50]), while only four studies tested hypothesised mechanisms of impact quantitatively[33,34,38,40].

Across the eight DMHIs, there was an emphasis on enabling users to respond in more helpful ways to difficult thoughts or situations by changing users' habitual thinking (eg, belief inflexibility, beliefs about voices or interpretation biases[18,33,37,38,40,44,46,51–53,57]) or behaviors (eg, reducing defense behaviors or increasing assertive behaviors[33,34,37,44,49,50,57–59]). Some (n=4) interventions were theoretically informed and explicitly designed to target putative or demonstrated maintaining mechanisms[33,34,38,40]. Findings suggested that DMHIs reduced users' mental health symptoms by replacing unhelpful responses (eg,

negative interpretations of everyday situations or avoidance of everyday social situations that were perceived to be unsafe) with more helpful responses (eg, seeking alternative, less personally threatening, explanations[38,40,44,49,51–53], or entering challenging situations[33,49]). For some users, changing habitual responses was achieved by becoming aware they were responding in unhelpful ways[44,49,51,53], understanding why they responded in unhelpful ways[44,46,57], or practicing responding in new ways[44,49,51,52].

However, assumed mechanisms did not consistently explain outcomes in four DMHIs with a blended delivery model delivered via an app[40,41] or VR[33,34]. In three of these DMHIs, several targeted mechanisms (safety beliefs[33,34], defense behaviors[34], or a reasoning bias[40]) did not mediate intervention effects, though two of these interventions reported a positive RCT outcome[33,40]. In another DMHI, EMPOWER, user interviews revealed not all users experienced changes to the targeted mechanism (relapse appraisal)[18], with unclear reasons for this variability.

Discussion

Summary of Findings

We synthesized mixed-methods process evaluation data from 36 peer-reviewed papers evaluating 9 DMHIs used by those with psychosis in a predominantly UK-based RCT. We conducted this review in a context where those experiencing psychosis have limited access to psychological support from services in the UK[6], and there is growing interest in developing and introducing DMHIs for this population[8]. We aimed to understand what is currently known about context, implementation and mechanisms of impact within this literature. This review made a unique contribution by focusing on process evaluation data, which has not been included in other systematic reviews of DMHIs for psychosis[9,10,65], and by extending prior process evaluation syntheses of other conditions, such as physical health[66,67]

In line with other syntheses of process evaluations[66,67], process evaluation in this field is limited, with one trial team using this term[17,18]. Nevertheless, we identified three key findings in relation to context, implementation and mechanisms of impact. First, DMHI use varied in an RCT, with researchers

supporting engagement primarily through resource preparation, flexible DMHI design and human support, though evidence of the effectiveness of implementation strategies was lacking. Second, contextual factors that shaped implementation were often different from those assumed by stakeholders. Rather than users' technology-related paranoia or limited digital literacy, barriers were more often practical commitments, other psychosis symptoms, or service staff constraints for blended DMHIs. Finally, mechanisms of impact were often linked to helping users to respond to difficult thoughts and situations in more helpful ways, with some DMHIs targeting putative mechanisms.

Implementation

Implementation data primarily focussed on how DMHIs were delivered in an RCT, with fewer studies examining delivery quantity or quality. Aligned with previous reviews[12,68,69], all DMHIs showed varied use among users with no clear patterns emerging, suggesting DMHI use may be shaped by other factors (see 'Context'). Only one trial team evaluated delivery staff competency in a blended DMHI[37], though two others described how human resources were prepared[37,44–46]. All DMHIs included delivery support, highlighting an important knowledge gap around implementation quality.

Specifically, most implementation data (n=27/36; 75% studies) related to implementation processes, or how DMHIs were delivered in the RCT. This is notably higher than a previous review on DMHIs for psychosis, which identified 5 (2.9%) papers reporting implementation data, and is likely due to differences in search strategies and date ranges as the previous review excluded studies after October 2021[12]. The increase in studies reporting process data may indicate a growing attention to implementation processes, which is critical for identifying required delivery resources and supporting the translation of interventions into practice[14]. Specifically, many trial teams developed DMHIs with implementation in mind, incorporating features to enhance use, including DMHI flexibility, stakeholder-driven design and human support. Whilst human support is linked to higher engagement among DMHI users[12,69], we identified its perceived usefulness varied across users, likely reflecting individual preferences and the importance of tailoring this delivery component. Implementation-driven development often involved stakeholder input into DMHI designs[45,54–56], as well as flexibility through enabling personalization, accessibility using app technology and setting adaptability for blended interventions). Flexibility was consistently valued by

stakeholders[18,35,44,49,52,53] and may indicate a design priority in future DMHIs.

However, whilst trial teams reported strategies to support delivery, their effectiveness is currently unclear as our insights were largely based on author interpretation or user feedback. Although implementation strategies were not formally evaluated, incorporating flexibility and stakeholder input into DMHI designs may have enhanced intervention usability, as some interventions reported no differences in engagement[42,43], or moderation effects[33,34,40], though further research is needed.

Context

Many studies (n=27/36; 75%) reported contextual findings, primarily in relation to DMHI implementation and the intervention user. Few examined how context influenced DMHI functioning but indicated most user baseline characteristics did not affect treatment outcomes, suggesting DMHIs in this literature often work irrespective of initial user profiles. Specifically, gender did not have a moderating effect on several interventions, suggesting DMHIs may be broadly applicable across genders. However, this finding conflicts with other reviews[12,69], underscoring the need for further research to address this discrepancy.

A key finding was the prevalence of misconceptions among stakeholders about user- and service-related barriers to DMHI use. Many pre-trial concerns among healthcare professionals and some service users reflected assumptions that individuals with psychosis would struggle to access or use digital technologies due to limited digital literacy, device availability, or technology-related paranoia, though process evaluation data often challenged these assumptions. Concerns about technology-related paranoia were found to be overgeneralized[52,58]. In addition, users, including those with limited digital experience, engaged with a range of DMHI modalities including smartphone, computer, and VR-based interventions[18,39,44,51,53]. Only one intervention (SloMo) showed higher engagement among more digitally confident users[42], suggesting that technological familiarity may enhance, but is not essential for, DMHI use. However, most studies predated COVID-19[62,63], meaning attitudes towards DMHIs and user capability may have changed after the pandemic forced a move to almost entirely remote services in the UK due to two years of prolonged lockdowns[70].

Further, staff frequently cited a lack of resources as implementation barriers in services. Evidence on

service-level barriers was limited, but notable, and highlighted limited staff resources could hinder implementation in an RCT[17,41]. However, perceptions were not always aligned with actual intervention demands[62], suggesting misalignment between perceived and actual implementation needs. As negative attitudes are a known implementation barrier for DMHIs for psychosis[12], addressing this early in the implementation process may be critical for successful adoption.

A small number of barriers and facilitators were identified which are applicable beyond service settings. Identifying general, non-service-specific factors is an important contribution given DMHIs have the potential to introduce care outside of services[8], yet are often studied within service settings[11,12]. Specifically, users cited other psychosis-related symptoms (auditory hallucinations and negative symptoms) [39,52], everyday factors (eg, life commitments)[43], and perceptions that the DMHI was not personally relevant[18] as barriers to use. This finding aligns with models of DMHI engagement[71] and highlights the importance of users' clinical and life context, suggesting DMHI personalization may optimize intervention use. Positive user perceptions about the DMHI (eg, that use could benefit themselves or others) emerged as a key facilitator[52,64], further underscoring the importance of designing DMHIs that are perceived as relevant and useful to enhance implementation efforts.

Mechanisms of Impact

Review data relating to mechanisms of impact, the least reported process evaluation component, suggested DMHIs reduced user mental health symptoms by helping users to respond in more helpful ways to challenging situations by modifying unhelpful cognitive (eg, negative interpretation biases) and behavioral (eg, defense behaviors) responses. This mechanism appeared to operate across different intervention modes and targets, though a range of underlying mechanisms were modified, albeit many were not clearly delineated as such, thus indicating an important area for improvement in future reporting. An important caveat of this finding is that most mechanistic evidence came from qualitative sources (eg, user feedback and intervention content), as there was limited robust examinations of mechanisms of impact using recommended hypothesis-driven quantitative methods in reviewed studies[72].

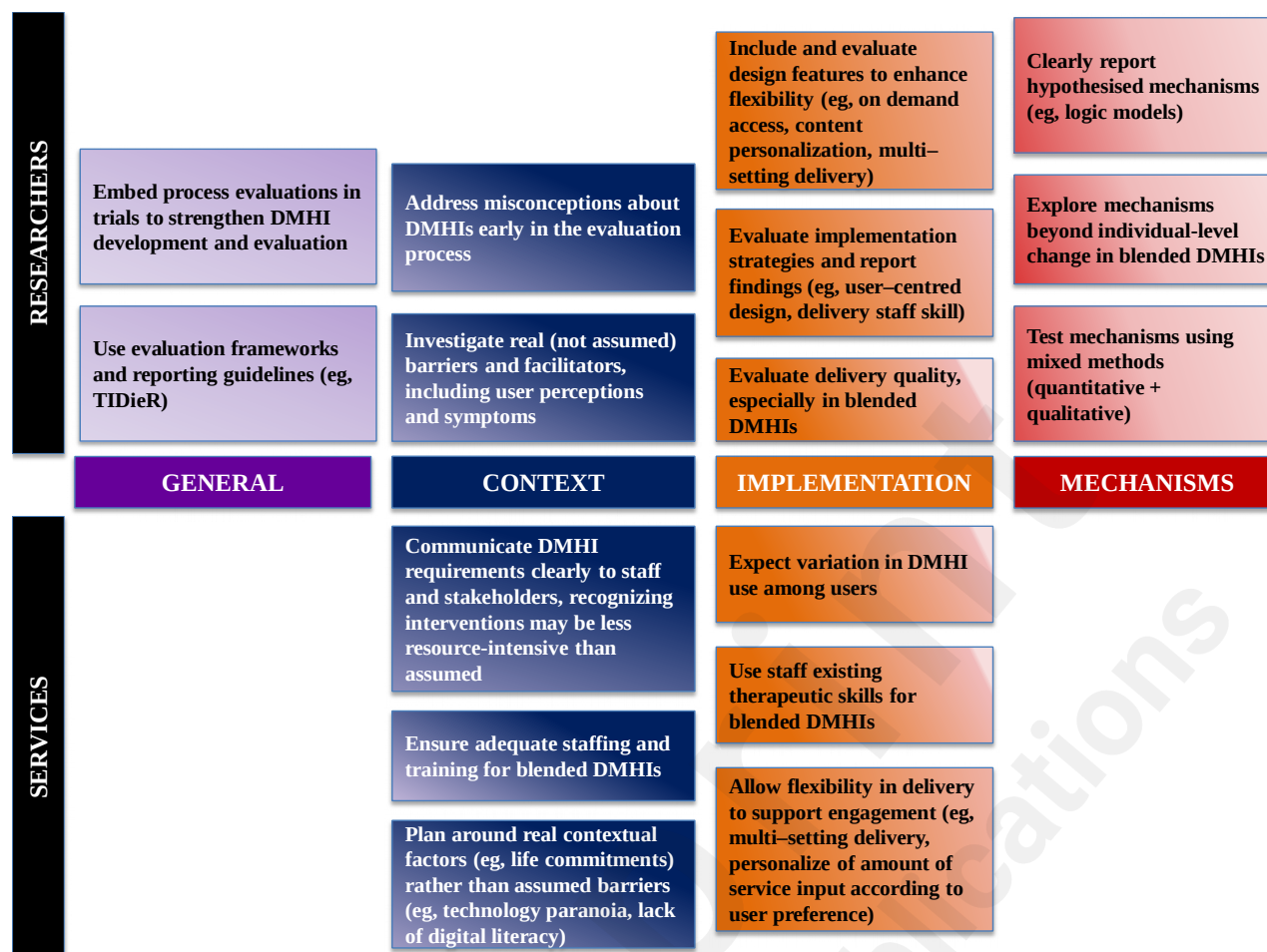
Further, hypothesised mechanisms were not consistently activated. Whilst there is some evidence

indicating DMHIs worked through assumed mechanisms[38,53], others (safety beliefs, reasoning and safety behaviors) did not mediate observed outcomes[33,34,40], though many of these trials observed a positive outcome in the RCT[33,40], suggesting DMHIs may work through other mechanisms. Given these interventions were delivered using a blended delivery model, it is possible other unexplored factors may account for intervention effects, including intrapersonal factors such as a therapeutic alliance, which have been identified as drivers of change when treating psychosis[73] and other mental health difficulties[74], and may be an important consideration for future interventions with a human support component. Additionally, in EMPOWER, not all users experienced the hypothesised cognitive change, reduced fear of relapse[18], suggesting mechanisms may work differently across users or contexts, though reasons for this variability are currently unclear.

Recommendations

Our review highlights several priorities for researchers and services to strengthen the evaluation and implementation of DMHIs (Figure 5). For researchers, key recommendations include embedding process evaluation in trials using established frameworks and reporting guidelines, further clarification of how DMHIs reduce user mental health symptoms, and more routine evaluation of blended DMHI delivery quality. Future interventions should include features that enhance DMHI flexibility and an evaluation of these implementation strategies. For services, key recommendations include clear communication of DMHI requirements to staff, addressing real, not assumed, contextual factors, and adopting flexibility in delivery.

Figure 5. Recommendations for researchers and services.



Review Strengths and Limitations

Our methodology has several strengths. To our knowledge, this is the first systematic review to synthesize process evaluation data in this field. Broad inclusion criteria, aligned with relevant guidance[22], enabled us to capture relevant studies irrespective of authors' use of the term "process evaluation". The lack of date and method restrictions further ensured comprehensive coverage. Finally, rigorous methods, including review pre-registration, double, masked screening and data extraction and use of an established process evaluation framework for synthesis, helped minimize bias.

However, several limitations should be noted. Firstly, as highlighted in another review[66], most studies did not explicitly use process evaluation terminology, and data were primarily synthesized by a single author (CH), increasing the potential for subjectivity despite use of an established framework. Further, the framework was operationalized at theme level to enhance usability, which may have limited depth of analysis. Another limitation of this review is the use of a frequency-based criterion from Graham-Rowe and colleagues[31] in the narrative synthesis. This approach may underemphasize less commonly reported

findings. Additionally, only extracting process evaluation data from results and discussion sections may have excluded relevant data reported in other sections, such as in methods sections. For example, many trial teams (n=8/9; 89%) described implementation processes (eg, training delivery staff, or providing devices to users) in the methods sections without supporting data, which were not captured in our syntheses. Finally, one included DMHI was implemented in the UK and Australia[41] which may have introduced variability in country contexts. Whilst we excluded data explicitly linked to Australian contributors to mitigate this risk, some aggregated data may reflect mixed contexts.

Conclusions

DMHIs show promise for improving mental health symptoms experienced by people with psychosis, but their uptake and impact depend on understanding delivery, mechanisms, and contextual factors. This review addresses a knowledge gap by synthesizing current knowledge on context, implementation, and mechanisms of impact for DMHIs in psychosis. We identified that DMHIs may reduce symptoms by supporting users to respond more helpfully to difficult situations by modifying their habitual behavioral and cognitive responses. Implementation efforts were supported through preparatory work, flexible design and delivery and human support, though the effectiveness of these strategies remains unclear, and resulted in varied DMHI use in RCTs. Contextual factors often differed from stakeholder expectations, and related to practical considerations or user symptoms, rather than technology-related issues assumed prior to implementation. Importantly, despite identifying a number of papers for inclusion, our findings align with other research that has identified process evaluation is an underutilized research method. Future research should embed process evaluations in trials, evaluate implementation strategies and use theory-driven approaches to clarify mechanisms of change. Process evaluation work could help to address stakeholder assumptions about DMHIs and psychosis and clarify what is required to implement DMHIs after trials.

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Authors' Contributions

CH conceptualized this study and developed its methodology with support from CD and PJ. CH conducted both search phases. CH, SD, CF & AT screened and selected studies. CH, SD & AT extracted data. CH & RT conducted the quality assessment. CH led data analysis, in collaboration with CD & PJ. CD, PJ & JY provided research supervision. CH wrote the original draft of the manuscript and CD, SD, CF, PJ, AT, RT and JY reviewed and edited the manuscript. All authors read and approved the manuscript.

Conflicts of Interest

JY is the chief investigator on one of the included interventions included in the review. However, JY was not involved in the quality rating of this index paper or analysis of intervention findings. All other authors declare no conflicts of interest.

Abbreviations

DMHI: Digital mental health intervention

MRC: Medical Research Council

RCT: Randomized controlled trial

UK: United Kingdom

VR: Virtual reality

Data Availability

All data analyzed in the study are available upon request from the corresponding author.

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Supplementary Files

Multimedia Appendixes

Reporting checklists.

URL: <http://asset.jmir.pub/assets/44461b558b31e11efbd5c1dfa1a46469.docx>

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