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ORIGINAL RESEARCH

Influences on recruitment and retention to mental health randomized controlled trials from the perspective of trial staff: a qualitative evidence synthesis

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Abstract

Objectives: Poor recruitment and retention are widely reported as problematic for many randomized controlled trials (RCTs). However, there is limited evidence on the context-specific challenges faced by trial staff recruiting to mental health trials. Consequently, evidence to inform effective interventions that could support trial staff in mental health trials is lacking. To address this gap, an evidence synthesis is needed to better understand the experiences and influences on trial staff recruiting to mental health RCTs to inform the development of strategies for improvement. This article aims to address this gap by synthesizing the qualitative evidence on trial staff (eg, clinicians, researchers) experiences of recruitment and retention to mental health RCTs (trials where mental health is the primary indication under investigation).

Methods: A rapid qualitative evidence synthesis (rQES) was conducted in accordance with rQES guidance and Thomas and Harden's approach to thematic synthesis. We searched MEDLINE, CINAHL, PsycINFO, Cochrane Central Register of Controlled Trials, Social Science Citation Index, and Applied Social Sciences Index and Abstracts, Web of Science, as well as key reviews and gray literature. Altogether, 4253 records were screened, resulting in 33 full-text reviews, of which 15 were eligible for inclusion. Confidence was assessed using Grading of Recommendations Assessment, Development and Evaluation-Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual). The review protocol is publicly available (PROSPERO: CRD42024601854).

Results: All studies reported on recruitment, with only one briefly reporting retention data alongside recruitment; therefore, findings of this review focus on recruitment to mental health trials. We identified 4 interrelated analytical themes capturing the influences on trial staff recruiting to mental health trials, extending beyond organizational and trial eligibility issues: (1) recruitment within existing care pathways; (2) understanding and judgments of RCTs and interventions; (3) weighing decisions to approach patients; and (4) engaging in trial conversations.

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Conclusion: Findings from this rQES highlight the complex interplay of factors shaping the context-specific challenges faced by trial staff recruiting to mental health trials. Specific concerns that trial participation could destabilize some patients, disrupt care, undermine therapeutic relationships, or trigger risk-taking behavior were identified as impacting recruitment. Findings highlight key recruitment challenges for trialists to consider in developing interventions to better support staff recruiting to mental health trials.

Keywords: Mental health; Qualitative evidence synthesis; Qualitative reserach; Participant recruitment; Randomized controlled trials; Trial recruitment

1. Background

Poor recruitment and retention are key challenges for most randomized controlled trials (RCTs) and a source of research waste, as they result in increased costs and ethical issues with unproved treatments in inconclusive trials [1]. A recent review of 388 UK publicly funded RCTs reported that only 63% (245/388) recruited to target [1]. Research to improve RCT recruitment and retention has been identified as a top priority for methodological research by a consensus priority-setting partnership group of those working in the trials field [2].

Recruitment to mental health RCTs can be particularly challenging due to stigma, patient vulnerabilities, and the added stress of trial involvement [3]. People with mental health conditions often come from the most disadvantaged populations and experience barriers in accessing services [4,5], compounded by potential community distrust linked to a history of pseudoscientific research used oppressively [6]. As such, poor recruitment and retention to mental health trials may exacerbate health inequalities.

Recruitment to mental health RCTs can also be challenging due to clinician gatekeeping, aimed at protecting perceived vulnerable participants, and prioritizing stabilization of complex symptoms [7]. Similarly, retention can pose challenges in mental health trials, as complex symptoms can impact attendance at in-person appointments and compliance with self-reporting [8].

Previous qualitative evidence syntheses (QESs) have highlighted challenges in trial recruitment, such as when to approach patients and balancing recruiter and professional roles [9]. A meta-synthesis of perspectives of staff and patients involved in depression trials identified factors influencing recruitment, including patients' health status, capacity to consent, trial burden, and welfare considerations [10]. However, no synthesis to date has focused on trial staff perspectives of recruitment and/or retention in mental health RCTs more broadly, which would help to understand the key challenges in this space. This rapid QES (rQES) addresses this gap by synthesizing these perspectives.

2. Methods

The rQES protocol was registered on the online registry PROSPERO (an international systematic review registry) (CRD42024601854) and followed Cochrane Rapid Review guidance for QES [11], employing modified, systematic, and transparent methods to accelerate a rapid synthesis, compared to a conventional review. Reporting adheres to the Enhancing Transparency in Reporting the Synthesis of Qualitative Research (ENTREQ) statement [12] for reporting the synthesis of qualitative research (Supplementary File 1).

2.1. Eligibility criteria

The SPIDER framework (Sample, Phenomenon of Interest, Design, Evaluation, Research type) [13] was used to refine the research question and guide inclusion criteria. Table 1 outlines the SPIDER domains, and the full search terms are in Supplementary File 2.

2.2. Information sources

An initial comprehensive electronic database search was conducted in 2022 of the following databases (from database inception to April 2022): Medline, Embase, PsycINFO, CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, and the Social Sciences Citation Index (SSCI) for qualitative and mixed-methods studies.

The initial electronic database search was combined with an updated search, conducted on October 1, 2024 (to ensure the search period was up to date). In line with rapid review guidance [11], the updated search was limited to three key databases most relevant to the topic: MEDLINE, CINAHL, and PsycINFO. Gray literature was searched via ProQuest Dissertations & Theses and the British Library Theses. Citation chaining [14] and manual reference checks of included studies and key reviews [9,10] were also undertaken.

2.3. Search strategy

The search strategy, based on the SPIDER framework [13], was developed by K.G. and L.B. and peer-reviewed by the team, including a health information specialist. Mental health terms drew on the strategy of the Cochrane Collaboration Depression, Anxiety and Neurosis Group, and strategies by Wilczynski et al [15]. The combined search strategy is presented in Supplementary File 2. No restrictions were applied for language, staff characteristics, country, trial type (eg, pilot), or mental health condition.

What is new?

Key findings

- Staff prioritize clinical risk management and preserving therapeutic relationships.
- Fears recruitment may disrupt care and patients, impacting therapy adherence.

What this adds to what is known?

- Concerns sensitive trial discussions may trigger risk-taking behavior.

What is the implication and what should change now?

- Developing and testing interventions for staff recruiting to mental health RCTs.
- Qualitative research needed on retention in mental health RCTs.

Studies involving recruitment via proxy decision-makers (eg, representatives for individuals lacking capacity) were included. Studies related to hypothetical RCTs were excluded. Citations were exported to EndNote for deduplication and imported into Excel for screening.

2.4. Study selection

For the initial search (up to April 2022), titles and abstracts were double screened by K.G. and 4 research student interns. For the updated search (October 2024), 2 reviewers double screened all titles and abstracts for 20% of the search results (S.M., R.N.). Selected titles and abstracts went through moderation and consensus with the review team. All remaining abstracts were screened by one reviewer (S.M.), and K.G. screened a random 10% across all titles and abstracts to identify any potential risk of overexclusion. Study numbers and exclusion reasons are shown in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram (Fig 1, Supplementary File 3).

2.5. Data extraction

Following rQES guidance [11], data were highlighted directly in electronic articles rather than extracted into a separate template. S.M. and E.M. independently piloted the process on two articles; thereafter, S.M. completed extraction, with K.G. checking 20% for accuracy. Data relevant to the review aim, including themes, verbatim excerpts, and trial staff quotations and authors' interpretations, were extracted [16]. The Characteristics of Included Studies Table is in Supplementary File 4.

2.6. Critical appraisal of included studies

Methodological limitations were appraised using the Critical Appraisal Skills Programme (CASP) tool [17]. In line with rapid review guidance [11], we utilized CASP assessments ($n = 6$) from the Farrar QES [9], and E.M. checked these assessments to ensure consistency with our appraisal, while remaining studies were assessed independently by S.M., R.N., E.M. Quality assessments were not used to exclude studies, as they could provide valuable insights [18], and informed the subsequent confidence of findings assessment [19]. CASP assessments are provided in Supplementary File 5.

2.7. Data synthesis

Guided by the RETREAT (Research question, Epistemology, Time/Timeframe, Resources, Expertise, Audience and Purpose, Type of data) framework [20], a thematic synthesis method, as outlined by Thomas and Harden [21], was used to analyze and synthesize extracted data. A line-by-line coding approach (S.M.) was used to apply descriptive codes to sections of text within each study, facilitating discussions of concepts identified among the team. Coded data were examined and checked (K.G., R.N.) and shared with the wider team during regular meetings. Codes with similar meanings and interpretations were then grouped (S.M.) through a translation process and reviewed by K.G. and L.B. Following further refinement and resolving of minor differences, coding was shared with the wider team to support analysis and ensure themes accurately reflected the data. NVivo 14 (Lumivero International) supported coding

Table 1. SPIDER framework

Sample	Trial staff (eg, clinicians, researchers, care-coordinators) involved directly or indirectly in trial recruitment/retention to mental health RCTs (defined as trials in which mental health is the primary clinical indication).
Phenomenon of **I**nterest	Factors that influence recruitment and retention to mental health trials from a trial staff perspective.
Design	Primary qualitative studies (eg, ethnography, case studies) using recognized qualitative data collection and analysis methods (eg, interviews, focus groups, content, or framework analysis). Mixed-methods studies, if data were collected and analyzed using qualitative methods, and qualitative data can be extracted.
Evaluation	The attitudes, beliefs, experiences, perceptions, and practices/behaviors of those recruiting people into mental health RCTs.
Research type	Qualitative or mixed methods.

RCTs, randomized controlled trials.

consistency and identification of patterns across studies. Finally, analytical themes were developed to move beyond description, with ongoing team discussions to ensure they represented the underlying data.

2.8. Assessment of confidence in the findings of this review

Confidence in each of the review findings was assessed using the Grading of Recommendations Assessment, Development and Evaluation-Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual) [19], comprising four components: methodological limitations, coherence, adequacy of data, and relevance [19]. S.M. and E.M. independently assessed the confidence in each finding, downgrading as appropriate. Final assessments, judged as high, low, or moderate, were discussed with L.B. and the team.

The GRADE-CERQual summary table and detailed evidence profile are presented in Supplementary Files 6 and 7.

2.9. Reflexive note

The review team comprised authors with diverse personal and professional backgrounds and experience in mental health care and clinical trials. These perspectives may have shaped the review processes and interpretations. Core review activities were undertaken by five authors (S.M., K.G., E.M., R.N., and L.B.), with all authors contributing to ongoing interpretation and synthesis through regular team meetings and shared online resources. S.M. kept notes throughout the review, documenting synthesis stages, team discussions, and rationale for analytic and methodological decisions.

3. Results

3.1. Search and study selection

All electronic database searches up to October 1, 2024, yielded 7906 records with 11 studies eligible for inclusion. Additional searching of gray literature, and manual reference checks of included studies and key reviews, identified 167 records of which 4 were eligible, providing 15 studies for inclusion. Details are shown in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram (Supplementary File 3: Figure 1).

3.2. Description of included studies

Fifteen papers were included, reporting 13 qualitative studies (three interlinked papers but treated separately in this manuscript) across 13 separate trials. All studies focused on recruitment, with one also briefly mentioning retention alongside recruitment [22]; therefore, the findings of this review focus on recruitment to mental health trials. Most studies (n = 12) were UK-based, set in primary, inpatient/outpatient, or community care, and covered various mental health conditions. The studies captured the experiences of 350 trial staff directly or indirectly involved in recruitment (doctors n = 124; nurses/other clinical staff n = 134; other roles n = 93, eg, care coordinators, trial managers, researchers) through interviews and/or focus groups. Trial staff from the three interlinked papers [23−25] were not double counted; however, any potential minor overlap due to unclear reporting is indicated in the Characteristics of Included Studies Table in Supplementary File 4.

3.3. Assessment of the methodological limitations of included studies

Methodological assessment found no concerns in three studies and minor concerns in the remaining 12 (see Supplementary File 5). Although three papers [23−25] originated from one study, each reported distinct data and was treated separately throughout this manuscript.

3.4. Confidence in the review findings

We developed 4 main themes and 10 key findings on factors influencing trial staff recruiting to mental health trials. GRADE-CERQual assessments were conducted for all findings (summary in Supplementary File 6; detailed evidence profile in Supplementary File 7). Confidence was mainly downgraded for adequacy and relevance, such as limited numbers of studies, narrow geographical coverage, or thin data, with minor methodological concerns around reflexivity, analysis, and ethics. Of the three interlinked papers [23−25], only one finding (2.2) drew on data from all three but contributed distinct data, and was further supported by eight other studies.

3.5. Synthesis and findings

Four interrelated themes were generated by the synthesis outlining the influences on trial staff recruiting to mental health trials. These themes shed light on the complexity for trial staff of integrating trial recruitment into current care pathways, balancing clinical risk management, maintaining patient stability, and preserving therapeutic relationships and treatment adherence: (1) recruitment within existing care pathways; (2) understanding and judgments of RCTs and interventions; (3) weighing decisions to approach patients; and (4) engaging in trial conversations. Themes are detailed below with supporting quotes identified as participant or author interpretations. Alongside each heading finding, we have included our GRADE-CERQual assessment, with a full evidence profile provided in Supplementary File 7. A visual summary of the factors that influence trial staff recruiting to mental health trials is provided in Supplementary File 8: Figure 2.

3.6. Theme 1: recruitment within existing care pathways

This theme encompasses the organizational, clinical, and research contexts influencing recruitment to mental health trials, including managers' expectations, staff capacity, teamwork, and communication. Variation in settings and team structures affected staff engagement with recruitment.

3.6.1. Trial delivery in care settings (moderate confidence)

Delivering trials in mental health settings alongside integration with clinical care was reported as challenging in many studies [22,23,26−34]. Recruitment could be affected by organizational issues, local research culture, and how well RCTs were integrated into sites or clinical specialties:

> *"RCTs are seldom used in connection with anorexia nervosa and so there was not widespread experience with trials…."* Campbell et al. [22] *[pg.29](author interpretation).*

> *"RAs [research assistants] reported that the organisational ethos in some sites worked against referral…" (author interpretation). "We're not managed to provide therapy; we're managed by numbers and to make sure people take their medication and stay out of hospital." (Clinician 4)(primary quote). Patterson* et al. [31] *[pg. 539].*

Delivering care in emergency or crisis settings made it difficult for some trial staff to fulfill trial requirements [31−33], particularly when assessing distressed or intoxicated patients. This highlighted tensions between recruitment demands and urgent clinical need, and for some staff a discomfort of appearing like "salespeople" [33]) [pg.9] (primary quote):

> "I just felt it was the wrong time to be, quite distressed, a lot of the time it's the middle of the night and I hate seeing people then, at 3am or 5am in the morning, it's a bit weird doing a mental health assessment when they've been up all night, distressed, so then to try and say "oh, we're doing this research thing where you might get picked but you might not", trying to sell it in a positive light…" (NHS Adult Site C). Sayal et al. [33] [pg. 9] (primary quote).

Recruiting alongside routine care in primary and secondary mental health settings also posed challenges. Some general practitioners struggled to introduce trials during long, emotionally charged consultations [30]. Organizational barriers, such as small, separate offices, were also reported as limiting opportunities to discuss the trial with colleagues or potential participants [26].

3.6.2. Expectations of managers on clinical staff (moderate confidence)

Managers' leadership styles and expectations on clinical staff to participate in trial recruitment was reported in two studies as influencing staff engagement [26,28]. Organizational priorities and hierarchical relationships indicated some staff had limited autonomy about involvement in trial recruitment:

> *"It is important to participate in the study, but I will only participate in the study if there are recommendations from our boss."* Hange et al. [28] *[pg. 145] (primary quote).*

Furthermore, other authors [31] highlighted the views of research assistants who reported a lack of enthusiasm among management for a trial, which could lead to a "reluctance to facilitate access" [31] [pg.536] (author interpretation) for a trial, even though ethics and R&D approvals had been granted.

3.6.3. Staff capacity to support recruitment (moderate confidence)

Trial staff were already managing high clinical workloads, limiting capacity to support additional trial recruitment activities. Staffing issues such as, insufficient numbers, high turnover and lack of continuity, were cited as issues which could undermine trial familiarity and communication among staff [26−28,34,35]:

> *"…the high clinical staff turnover within mental health services blocked the ability of trial staff to build relationships with clinical staff to build trust in the team and the project."* Allan et al. [26] *[pg. 6] (author interpretation).*

Staff described the challenge of remembering a trial and engaging patients amid "spinning multiple plates" and "fighting fires" [34] [pg. 5] (primary quotes). In primary care, staff reported that time pressures and often overrunning appointments made integrating research difficult [28,30].

The evidence also highlighted that staff capacity to support recruitment relied on strong working relationships and good interprofessional communication, amid competing management, research, and clinical demands [22,28].

> *"Key factors in success are having a good group of people who really can figure out what their roles are. Communicating well and fulfilling promises." Campbell et al. [22] [pg. 43] (primary quote).*

3.7. Theme 2: understanding and judgments of RCTs and interventions

This theme focuses on trial staff's knowledge of RCTs, their judgments about trial interventions and treatment

preferences; all factors that could influence whether they viewed a patient as suitable for trial.

3.7.1. RCT knowledge (moderate confidence)

Staff understanding of RCTs and perceptions of their clinical relevance, generally and specifically, influenced how they engaged with trials. Several studies reported that staff questioned the value and practical application of RCTs in routine clinical practice [23,30,31]:

> *"I suppose [research] should be an important part of what we do, …but I think a lot of us spend a lot of time reading snippets of it and then sort of getting on with." (Clinician 1). Patterson et al. [31] [pg. 537] (primary quote).*

In one study [22], staff acknowledged the limited evidence on adolescent anorexia nervosa, viewing the trial as a valuable ''empirical starting point'' (Campbell et al) [pg.32] (author interpretation) which increased their support.

Trial staff in several studies [23,31,32] reported that misunderstandings of RCT methods, limited research training, and lack of trial integration into clinical practice were problematic. Explaining control arm allocation was particularly challenging for some care coordinators.

3.7.2. Perceptions of trial and intervention acceptability (moderate confidence)

Trial staff views about treatment interventions and preferences were widely reported as influencing recruitment [23–25,28,31,32,35,36]. Our synthesis also identified that some staff were reluctant to introduce a trial, fearing they might destabilize patients or jeopardize fragile therapeutic relationships. For example, in a suicide prevention study for psychiatric inpatients [35], staff reported making treatment decisions based on their own risk judgments about who might benefit from the trial:

> *"Psychological therapy had not previously been available to inpatients in the wards where this study took place. Hence, beliefs that therapy was essentially a community treatment and was unsuitable for acutely unwell inpatients were evident."* Awenat et al. [35] [*pg. 12] (author interpretation).*

Another study reported on the anxiety among some trial staff toward patients being potentially randomized to suboptimal care [22], which could increase risks for those with anorexia nervosa:

> *"Randomisation meant that patients in far less extreme circumstances may be allocated to inpatient care, and that some in a more advanced condition be allocated to outpatient care. Some concern was expressed in interviews that if urgent inpatient care was requested, beds could be blocked by (author interpretation) "more robust" (primary quote) trial patients." Campbell et al. [22] [pg. 30].*

Specific concerns about the ''ethics'' [31] [pg. 538] (primary quote) of ''randomization and potential denial of access to an intervention'' [31] [pg. 538] (author interpretation) were highlighted in two studies [23,31] suggesting a lack of understanding about the trial and how challenging it could be for staff to explain the concept of equipoise to patients:

> *"I always want the intervention group (for them). And I feel like I hate telling them they're in the control group. I absolutely hate it….I always will want the intervention group." CC2. Howard et al. [23] [pg. 42] (primary quote).*

In instances where an individual was not randomized to the intervention arm, trial staff in one study reported how this could directly affect recruitment as ''those who received standard treatment were disappointed'' [28] [pg.145] (author interpretation), impacting trial staff motivation to recruit.

Attitudes toward treatments among other trial staff included underlying professional beliefs of intervention ''appropriateness'' [32] [pg.495] (author interpretation) for some patients or groups [28,32], insufficient information about treatment processes or patient benefits [28], as well as broader concerns about who took responsibility for a patient if referred to a trial [28,31,32,35]:

> *"The informants also expressed a sense of insecurity regarding whether the ICBT method was reliable and effective. Not knowing exactly what happened to the patient during treatment felt like handing the patient over to the unknown …. It was important for the informants to know who took responsibility for the patient after referral." Hange* et al. [28] *[pg. 146] (author interpretation).*

Clinical and emotional discomfort when considering patients for trial participation could also impact staff recruitment efforts. Staff questioned the appropriateness of treatment pathways for some patients and described how random allocation could create a ''perception of injustice,'' making it a difficult ''dynamic'' to manage [32] [pg. 496] (primary quotes). Staff in another study described allocation to usual care as a ''rejection'' [23] [pg.42] (primary quote) from the study, rather than a result of randomization, thus ''equated the intervention with the trial.'' [23] [pg. 44] (author interpretation).

Staff in two studies reported unease about the trial eligibility criteria, describing the protocol inclusion criteria as ''strict'' [28] [pg. 145] (author interpretation), and highlighting ethical dilemmas if they judged certain patients needed the trial intervention [28,36]:

> *"… definitely felt that some patients needed counselling and wasn't prepared to offer them the choice of*

being involved in a study with the chance that they would receive 'no counselling'." (GP). Fairhurst & Dorwick [36][pg. 78] (primary quote).

3.7.3. Trial as an opportunity (moderate confidence)

Across a number of studies, some trial staff perceived trial participation as an opportunity for patients to access mental health care which may otherwise have been limited or unavailable [22,23,27,35,36]. Trial opportunities identified included: filling care gaps within current provision (eg, suicide prevention therapy), accessing clinical expertise, freeing up clinical time and resources, reducing clinical responsibilities, as well as enhancing professional practice, research experience, and the profile of their clinical communities [22,23,27,30,35,36]. However, one study noted staff sometimes viewed trials less positively, as a "last resort" [36] [pg. 79] (author interpretation) having "exhausted" [36] [pg. 79] (primary quote) all other options [36] [pg. 79] (primary quote).

3.8. Theme 3 weighing up decisions to approach patients

This theme focuses on how personal and clinical factors shaped trial staff willingness to approach patients for trials and their concerns about managing any consequences of participation.

3.8.1. Personal considerations for trial staff (moderate confidence)

Decisions about approaching patients for trials centered on maintaining relationships, confidence in discussing trials, and managing potential consequences. Fear of compromising rapport and trust strongly influenced decisions to approach patients, affecting both long-standing and newly established relationships [23,30,33]:

> *"Sometimes you don't want to risk the fact you had got them to a place where they were happy and calm and I felt a reluctance to add some extra stuff on in case it kind of cheapened the interaction." (NHS Adult Site C). Sayal* et al. [33] *[pg. 9] (primary quote).*

For other staff, decisions about approaching patients for a trial centered on maintaining relationships and managing potential consequences, without the "burden of explaining a research study" [33] [pg. 9] (author interpretation). Some GPs reported that patients with depression "preferred a more directive consultation style," trusting the GP to "know what is best for them" [30] [pg. 521] (author interpretation). As such, communicating about treatment uncertainty "could be perceived as jeopardizing the patients trust in their GP" [30] [pg. 521] (author interpretation). Another study reported that when trust between patients and the treatment team was "tenuous or poor" [31] [pg. 540] (author interpretation), fewer patients were approached for a trial.

In one primary care study, it was reported that limited knowledge about a mental health condition among nurse trial staff, and a lack of local clinician engagement, could undermine recruitment [28]. Trial staff in some other studies also reported personal concerns about approaching patients, related to potential unintended consequences for themselves or patients [31,34,35].

In particular, some staff reported specific concerns about asking sensitive questions (eg, sexual functioning in people with psychosis), fearing they could "trigger traumatic memories or increase risk-taking behaviors, putting the patient in potentially harmful situations" [34], [pg. 8] (author interpretation), with implications for compliance and relapse [34]. Subsequently, staff often avoided such questions to "maintain fragile treatment relationships and promote compliance with medication" [34] [pg. 8] (author interpretation). In another study [35], negative impacts on some inpatients after therapy sessions (part of trial intervention) and the "ensuing outfall" [35] [pg. 9] (author interpretation) impacted subsequent staff referrals:

> *"One thing that you would worry about when you, when you're nominating someone for the … trial would be someone who would, talking about this could trigger maladaptive behaviour once the session had ended, and then we'd have a whole can of worms to put back in the can afterwards." (FG016). Awenat et al. [35] [pg. 9] (primary quote).*

3.8.2. Clinical considerations for trial staff (moderate confidence)

Discomfort with trial interventions and eligibility led some staff to prioritize clinical judgment over protocol adherence, to protect patients, the doctor−patient relationship, and, in part, the trial [22,23,26,28,30−35].

Some trial staff reported unease at approaching patients to preserve relationships and avoiding anything that might jeopardize this [23,26,28,30,34]. Concerns included unnecessary demands on patients [30], risk of relapse [23], symptom severity [35], poor concentration [22], difficulties coping with trial requirements and interventions [26], and protecting patients from potential "rejection" [23] [pg. 42] (primary quote) if not randomized to the intervention.

Subsequently, some trial staff adopted a risk-averse approach, avoiding trial discussions if they perceived medication changes could destabilize patients, or a patients' capacity to weigh up risks was uncertain [32]:

> *"Several clinicians raised concerns over the mental capacity of patients, 'wondering how much they were able to weigh up the pros and cons' (p21) of*

participation." [32] Phillips et al. [32] [pg 6](author interpretation/primary quote).

In a suicide prevention study, staff reported only referring inpatients they deemed "stable and less likely to engage in suicidal behavior" [35] [pg. 18] (author interpretation), partly linked to prior staff trauma from inpatient suicides. Similar issues were reported in another study, where care coordinators (responsible for initial trial contact) described prioritizing patient stability and minimizing relapse triggers, which could limit recruitment opportunities [23].

Protecting the doctor-patient relationship was also cited as influencing decisions to approach patients for trials. Some staff feared discussions might appear self-serving, "furthering their own careers." [30] [pg. 522] (primary quote). Others reported avoiding patients with "chaotic lifestyles," as judged them unlikely to fulfill trial participation requirements [23] [pg.44] (author interpretation).

3.9. Theme 4: engaging in a trial conversation with a potential participant

This theme focuses on the challenges staff face when approaching patients, including judgments about the timing of approach, explaining the trial, and responding to any patient treatment preferences.

3.9.1. Subtheme 4.1 timing of approach (low confidence)

Some trial staff reported challenges with the timing of trial discussions [22,30,33]. Perceptions of being intrusive, having limited time for in-depth conversations, or introducing the trial at the end of a consultation could undermine recruitment.

Trial staff also highlighted a "brief window of opportunity" [33] [pg. 10] (author interpretation) for initiating trial discussions, influenced by patients' desire to avoid emotionally difficult conversations. Additionally, the timing of trial approaches, day or night, could further affect recruitment [33]. For some GPs, introducing a trial was reported as being potentially disruptive to their consultation flow and risked appearing insensitive, *"adding to an already complicated encounter"* [30] [pg.522] (author interpretation) especially with distressed patients [30].

3.9.2. Subtheme 4.2 pitching the trial (moderate confidence)

Across a number of studies, trial staff reported discomfort with describing aspects of a trial to patients [22,24,28–30,32,33]. This seemed particularly related to when staff felt they had insufficient knowledge about a trial intervention and/or what would be expected of trial participants.

Some trial staff acknowledged that any treatment preferences they harbored could surface during discussions, potentially influencing recruitment [24]. Another study described that patients' reluctance to share sensitive information was linked to their awareness of clinicians' legal powers of detention, which could limit disclosure and undermine trial assessment and recruitment [35].

One study highlighted communication challenges for trial staff when some men with depression presented differently from women, complicating diagnosis and discussions about trial participation [29]. Several studies also noted that potential participants' treatment preferences further complicated trial communication [22,32,36]:

> *"A strong preference for day services was also seen by many clinicians as a deterrent for participation, with patients (author interpretation) not willing to take the risk on getting stuck in the inpatient arm" (primary quote) (P22). Phillips et al. [32] [pg. 494].*

A further challenge reported in one study related to how treatment preferences among nonrecruiting staff could potentially influence patients early in their care pathway, affecting subsequent trial recruitment discussions [28].

4. Discussion

This QES focuses exclusively on trial staff perspectives of recruitment across diverse mental health RCTs—an evidence base not previously synthesized. Our review identified factors influencing recruitment that are distinct to mental health trials, as such, the Discussion concentrates on these most salient findings.

While limited recruitment capacity in overstretched clinical settings is well-documented [9,10,37], our review indicates these challenges can be particularly acute within mental health care pathways. For example, trial staff described extremely high workloads and an overriding focus on clinical risk management, leaving little time or capacity for activities beyond routine clinical work. High staff turnover, limited research personnel, and shortages of specialist mental health nurses, particularly in primary care, further constrained recruitment.

While staff capacity constraints affect many trials, our synthesis highlights how the clinical risk context in mental health differs from that in physical health, with greater time devoted to risk management. This can undermine recruitment, particularly if considered disruptive to care or patient well-being, especially where therapeutic relationships are central to treatment adherence.

While previous reviews reported recruiters' concerns about preserving patient trust [9,10], our review provides deeper insight in the specific context for mental health trial recruitment. For example, conditions such as psychosis can affect emotional regulation and relationship-building, directly influencing recruitment and potentially extending to other mental health conditions. These findings highlight specific difficulties trial staff can face and the potential

relational impacts on both staff and patients which can make recruitment harder.

Our review identified additional, underreported challenges affecting recruitment to mental health trials. For example, some staff were reluctant to approach patients if it involved asking highly sensitive questions that might trigger traumatic memories or harmful risk-taking behavior. This was reported in a trial exploring sexual dysfunction among people with psychosis, where stabilization and medication adherence were prioritized over recruitment. Recruitment was also hindered when patients withheld information due to fears about clinicians' legal powers to have them sectioned.

These findings underscore the complexities of recruitment to mental health trials, presenting distinctive challenges less commonly reported in other clinical trial contexts. These findings have important implications for how trial staff can be better prepared and supported to manage such interactions effectively, to support recruitment efforts. Findings also link to a broader point about consideration for improved reporting of adverse events within mental health trials.

The lack of participant diversity is a problem for many trials, but the underrepresentation of marginalized groups is a particular problem for mental health trials. Although this was not explicitly reported in our included studies, stigma and distrust toward research, often rooted in historical racism and ongoing discrimination, can further deter participation among ethnic minorities [38]. Poor ethnic diversity in mental health trials is particularly concerning given that black and ethnic minorities experience unduly high levels of adverse mental health [39]. Trial staff may believe they are acting in patients' or the trial's best interests, but these findings suggest the need for further work to support staff recruiting to mental health trials, to help promote more inclusive participation, ensuring evidence better reflects those who could benefit most.

Although embedded pragmatic trials are often considered more relevant to clinical practice, trial staff did not explicitly report this as influencing recruitment to mental health trials. However, in one paper [35], the authors referred to the successful implementation of pragmatic and standard cluster trials, including in psychiatric inpatient settings, where standard RCT design was impractical. Another study [31] suggested that bridging the gap between research and practice is important for pragmatic trials to reflect the real clinical world.

4.1. Implications for practice

Trialists should give greater consideration to the added clinical risk management demands on staff recruiting to mental health trials and their impact on the therapeutic alliance and trial recruitment. Embedding trials in routine care and supporting staff to balance clinical and research responsibilities may help reduce perceived disruption to patient care and protect the therapeutic relationship. For example, adopting alternative consent pathways may be one way to improve recruitment but would require careful ethical consideration in this potentially vulnerable population. Decentralized trials—or aspects of DCTs—might also help recruitment to mental health trials; for example, using more remote data collection to reduce patient clinic visits.

The Northern Ireland Hubs for Trial Methodology Research SWAT Repository—an online database of Studies Within A Trial to improve trial design, conduct, and recruitment—currently contains a small number of SWATs focused on staff and site recruitment. Some interventions may be transferable to mental health trials, such as, centralized screening and consent (with remote options), regular scheduled contact between coordinating teams and sites, and computerized decision-support tools for eligibility decisions. Other strategies might include clinical research champions who can be a conduit between researchers and clinical services, and strengthening links between researchers and the National Institute for Health and Care Research (NIHR) Research Delivery Network.

However, it is important to recognize that any proposed ''solutions'' may present distinct consent, retention, and ethical issues. As such, these issues warrant careful exploration with people with lived experience to ensure that trial designs are methodologically robust, ethically appropriate, and ultimately more acceptable and beneficial for participants.

4.2. Implications for future research

To support future research, findings from this rQES have been used to inform a mapping exercise aimed at comparing the identified influences on trial participation from this synthesis to existing recruitment QESs [9,10] and the Cochrane reviews of interventions to improve recruitment/retention to RCTs [40,41] to establish if any intervention evidence could support identified recruitment challenges. This mapping exercise has evidenced a current lack of appropriate interventions evaluated to target trial staff recruitment challenges. As such, further research is needed to develop (using the findings of the review) and test interventions targeting staff recruiting to mental health trials. As only one study in this review briefly mentioned retention when reporting recruitment findings, highlights an important gap for future research. Further qualitative research is needed to better understand core challenges influencing staff perspectives on retention to inform more effective trial design and delivery.

4.3. Strengths and limitations

The strength of this review is that we followed key guidance on conducting a rapid QES, using modified, systematic, transparent, and reproducible methods to accelerate the synthesis of qualitative evidence [11]. The findings

considered the views of 350 trial staff involved (directly and indirectly) in recruitment to a range of mental health trials. The review includes studies from across a range of clinical mental health conditions, and although the included studies were predominately based in the United Kingdom, they included a range of primary care, inpatient/outpatient, and community settings.

Overall, our confidence in the review findings was moderate. Although there was variability in the quality of some of the included studies, this did not result in their exclusion due to the small number of studies included and their contribution to the review. As this was a rapid review, it is possible some eligible studies may have been missed, although multiple team members supported screening to mitigate this. Our confidence in most of the findings is limited to a lack of richness in data reporting; some of the studies provided thin and insufficiently rich data to fully support the findings, and 3 of the papers were interlinked, albeit reporting unique data in each paper.

5. Conclusion

This rQES has highlighted the context-specific challenges faced by trial staff recruiting to mental health trials, which can complicate and often undermine recruitment. Specific concerns were identified regarding the potential for trial participation to destabilize some patients, disrupt care, undermine therapeutic relationships, or trigger risk-taking behaviors. These nuanced findings emphasize the need for further research to support identification of strategies to support staff and enhance recruitment and retention in mental health trials.

Patient and public involvement

Three patient and public partners were involved in reviewing and providing feedback on the review.

CRediT authorship contribution statement

Sharon McCann: Writing − review & editing, Writing − original draft, Visualization, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation. **Ellen Murphy:** Writing − review & editing, Visualization, Software, Project administration, Methodology. **Rumana Newlands:** Investigation, Formal analysis. **Thomas Ward:** Writing − review & editing, Validation. **Linda Biesty:** Writing − review & editing, Supervision, Methodology, Conceptualization. **Edmund Brooks:** Validation. **Claire Carswell:** Writing − review & editing. **Firoza Davies:** Validation. **Danielle Edwards:** Writing − review & editing, Visualization, Validation. **Nicola Farrar:** Resources. **Nicola Mills:** Writing − review & editing, Visualization, Supervision. **Adwoa Parker:** Resources, Investigation. **Alba Realpe:** Writing − review & editing. **Leila Rooshenas:** Resources, Funding acquisition. **Louise Ting:** Validation. **Katrina Turner:** Writing − review & editing, Validation. **Katie Gillies:** Writing − review & editing, Supervision, Investigation, Funding acquisition, Conceptualization.

Consent for publication

No consent for publication was required, as this study involved a qualitative evidence synthesis using previously published anonymised data.

Declaration of competing interest

The authors declare that they have no competing interests.

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Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jclinepi.2026.112185.

Data availability

Data will be made available on request.

References

[1] Jacques RM, Ahmed R, Harper J, Ranjan A, Saeed I, Simpson RM, et al. Recruitment, consent and retention of participants in randomised controlled trials: a review of trials published in the National Institute for Health Research (NIHR) Journals Library (1997−2020). BMJ Open 2022;12(2):e059230. https://doi.org/10.1136/bmjopen-2021-059230.

[2] Tudur Smith C, Hickey H, Clarke M, Blazeby J, Williamson P. The trials methodological research agenda: results from a priority setting exercise. Trials 2014;15:32. https://doi.org/10.1186/1745-6215-15-32.

[3] Liu Y, Pencheon E, Hunter RM, Moncrieff J, Freemantle N. Recruitment and retention strategies in mental health trials − a systematic review. PLoS One 2018;13(8):e0203127. https://doi.org/10.1371/journal.pone.0203127.

[4] Lowther-Payne HJ, Ushakova A, Beckwith A, Liberty C, Edge R, Lobban F. Understanding inequalities in access to adult mental health services in the UK: a systematic mapping review. BMC Health Serv Res 2023;23(1):1042.

[5] Iflaifel M, Hall CL, Green HR, Willis A, Rennick-Egglestone S, Juszczak E, et al. Widening participation − recruitment methods in mental health randomised controlled trials: a qualitative study. BMC Med Res Methodol 2023;23(1):211.
[6] Shim RS. Dismantling structural racism in psychiatry: a path to mental health equity. Am J Psychiatry 2021;178:7.
[7] Borschmann R, Patterson S, Poovendran D, Wilson D, Weaver T. Influences on recruitment to randomised controlled trials in mental health settings in England: a national cross-sectional survey of researchers working for the Mental Health Research Network. BMC Med Res Methodol 2014;14:23.
[8] The Wellcome Trust. Improving recruitment and retention in mental health clinical trials: the role of digital tools [version 1; not peer reviewed]. Wellcome Open Res 2025;10:155. (document) https://doi.org/10.21955/wellcomeopenres.1115407.1.
[9] Farrar N, Elliott D, Houghton C, Jepson M, Mills N, Paramasivan S, et al. Understanding the perspectives of recruiters is key to improving randomised controlled trial enrolment: a qualitative evidence synthesis. Trials 2022;23:883. https://doi.org/10.1186/s13063-022-06818-4.
[10] Hughes-Morley A, Young B, Waheed W, Small N, Bower P. Factors affecting recruitment into depression trials: systematic review, meta-synthesis and conceptual framework. J Affective Disord 2014;172:274−90.
[11] Booth A, Sommer I, Noyes J, Houghton C, Campbell F. Rapid reviews methods series: guidance on rapid qualitative evidence synthesis. BMJ Evid Based Med 2024;29:194−200.
[12] Tong A, Flemming K, Mcinnes E, Oliver S, Craig J. Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ. BMC Med.Res Methodo 2012;12:181.
[13] Cooke A, Smith D, Booth A. Beyond PICO. The SPIDER tool for Qualitative Evidence Synthesis. Qual Health Res 2012;22(10):1435−43. https://doi.org/10.1177/1049732312452938.
[14] Nyakang'o SB, Booth A. Women's perceived barriers to giving birth in health facilities in rural Kenya: a qualitative evidence synthesis. Midwifery 2018;67:1−11. https://doi.org/10.1016/j.midw.2018.08.009.
[15] Wilczynski NL, Haynes RB. Optimal search strategies for identifying mental health content in MEDLINE: an analytic survey. Annal Gen Psychiatry 2006;5:4. https://doi.org/10.1186/1744-859X-5-4.
[16] Toye F, Seers K, Allcock N, Briggs M, Carr E, Barker K. Meta-ethnography 25 years on: challenges and insights for synthesising a large number of qualitative studies. BMC Med Res Methodol 2014;14:80.
[17] Critical Appraisal Skills Programme (CASP). CASP qualitative checklist online 2024. Available at: www.casp-uk.net/casp-tools-checklists. Accessed November 1, 2024.
[18] Barnett-Page E, Thomas J. Methods for the synthesis of qualitative research: a critical review. BMC Med Res Methodol 2009;9:59. https://doi.org/10.1186/1471-2288-9-59.
[19] Lewin S, Booth A, Glenton C, Munthe-Kaas H, Rashidian A, Wainwright M, et al. Applying GRADE-CERQual to qualitative evidence synthesis findings: introduction to the series. Implementation Sci 2018;13(Suppl 1):2.
[20] Booth A, Noyes J, Flemming K, Gerhardus A, Wahlster P, Van Der Wilt GJ, et al. Structured methodology review identified seven (RETREAT) criteria for selecting qualitative evidence synthesis approaches. J Clin Epidemiol 2018;99:41−52. https://doi.org/10.1016/j.jclinepi.2018.03.003.
[21] Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. BMC Med Res Methodol 2008;8:45.
[22] Campbell MK, Snowdon C, Francis D, Elbourne D, McDonald AM, Knight R, et al. Recruitment to randomised trials: strategies for trial enrolment and participation study.The STEPS study. Health Technol Assess 2007;11(48):iii.
[23] Howard L, De Salis I, Tomlin Z, Thornicroft G, Donovan J. Why is recruitment to trials difficult? An investigation into recruitment difficulties in an RCT of supported employment in patients with severe mental illness. Contemp Clin Trials 2009;30:40−6. https://doi.org/10.1016/j.cct.2008.07.007.
[24] Donovan JL, Paramasivan S, De Salis I, Toerien M. Clear obstacles and hidden challenges: understanding recruiter perspectives in six pragmatic randomised controlled trials. Trials 2014;15:5.
[25] Donovan JL, De Salis I, Toerien M, Paramasivan S, Hamdy FC, Blazeby JM. The intellectual challenges and emotional consequences of equipoise contributed to the fragility of recruitment in six randomized controlled trials. J Clin Epidemiol 2014;67:912−20. https://doi.org/10.1016/j.jclinepi.2014.03.010.
[26] Allan S, Mcleod H, Bradstreet S, Bell I, Whitehill H, Wilson-Kay A, et al. Perspectives of trial staff on the barriers to recruitment in a digital intervention for psychosis and how to work around them: qualitative study within a trial. JMIR Hum Factors 2021;8(1):e24055. https://doi.org/10.2196/24055.
[27] Chew-Graham CA, Lovell K, Roberts C, Baldwin B, Morley M, Burns A, et al. Achieving target recruitment in a primary care trial: lessons from PRIDE. Prim Health Care Res Dev 2007;8:264−70.
[28] Hange D, Björkelund SI, Kivi M, Eriksson MC, Petersson E. Experiences of staff members participating in primary care research activities: a qualitative study. Int J Gen Med 2015;8:143−8. https://doi.org/10.2147/IJGM.S78847.
[29] Hinton L, Zweifach M, Oishi S, Tang L, Unützer J. Gender disparities in the treatment of late-life depression: qualitative and quantitative findings from the IMPACT trial. Am J Geriatr Psychiatry 2006;14:884−92.
[30] Mason VL, Shaw A, Wiles NJ, Mulligan J, Peters TJ, Sharp D, et al. GPs' experiences of primary care mental health research: a qualitative study of the barriers to recruitment. Fam Pract 2007;24(5):518−25.
[31] Patterson S, Kramo K, Soteriou T, Crawford MJ. The great divide: a qualitative investigation of factors influencing researcher access to potential randomised controlled trial participants in mental health settings. J Ment Health 2010;19(6):532−41. https://doi.org/10.3109/09638237.2010.520367.
[32] Phillips M, Ince B, Webb H, Dalton B, Mccombie C, Irish M, et al. Autopsy of a failed trial part 1: a qualitative investigation of clinician's views on and experiences of the implementation of the DAISIES trial in UK-based intensive eating disorder services. Eur Eat Disord Rev 2023;31(4):489−504. https://doi.org/10.1002/erv.2975.
[33] Sayal K, Roe J, Ball H, Atha C, Kaylor-Hughes C, Guo B, et al. Feasibility of a randomised controlled trial of remotely delivered problem-solving cognitive behaviour therapy versus usual care for young people with depression and repeat self-harm: lessons learnt (e-DASH). BMC Psychiatry 2019;19:42. https://doi.org/10.1186/s12888-018-2005-3.
[34] Thana LJ, O'Connell L, Carne-Watson A, Shastri A, Saravanamuthu A, Budhwani N, et al. Barriers to the management of sexual dysfunction among people with psychosis: analysis of qualitative data from the REMEDY trial. BMC Psychiatry 2022;22:545. https://doi.org/10.1186/s12888-022-04193-7.
[35] Awenat YF, Peters S, Gooding PA, Pratt D, Huggett C, Harris K, et al. Qualitative analysis of ward staff experiences during research of a novel suicide-prevention psychological therapy for psychiatric inpatients: understanding the barriers and facilitators. PLoS One 2019;14(9):e0222482. https://doi.org/10.1371/journal.pone.0222482.
[36] Fairhurst K, Dowrick C. Problems with recruitment in a randomized controlled trial of counselling in general practice: causes and implications. J Health Serv Res Policy 1996;1:77−80.
[37] Hanrahan V, Gillies K, Biesty L. Recruiters' perspectives of recruiting women during pregnancy and childbirth to clinical trials: a qualitative evidence synthesis. PLoS One 2020;15(6):e0234783. https://doi.org/10.1371/journal.pone.0234783.
[38] Corbie-Smith G, Thomas SB, St. George DMM. Distrust, race, and research. Arch Intern Med 2002;162:2458−63.

[39] Woodall A, Morgan C, Sloan C, Howard L. Barriers to participation in mental health research: are there specific gender, ethnicity and age related barriers? BMC Psychiatry 2010;10:103.

[40] Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, et al. Strategies to improve recruitment to randomised trials. Cochrane Database Syst Rev 2018;2(2):MR000013. https://doi.org/10.1002/14651858.MR000013.pub6.

[41] Gillies K, Kearney A, Keenan C, Treweek S, Hudson J, Brueton VC, et al. Strategies to improve retention in randomised trials. Cochrane Database Syst Rev 2021;3(3):MR000032. https://doi.org/10.1002/14651858.MR000032.pub3.