**Project title: Understanding influences on recruitment and retention in mental health trials: a rapid qualitative evidence synthesis and evidence mapping to identify solutions.**

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**Introduction**

Recruitment and retention are key challenges for almost all RCTs. Mental health RCTs can face particular issues impacting participation, such as concerns from healthcare professionals about patient vulnerabilities, and potential added burdens of trial involvement for people with mental health conditions. Poor trial recruitment and retention can increase costs, contribute to research waste, delay treatments, reduces participant representativeness, widen health inequalities and raise ethical issues with unproven treatments in inconclusive trials.

**Aims & Objectives**

We aimed to understand the reported influences that impact on recruitment and retention to mental health RCTs, compared to other clinical conditions. Our objectives were to:

1) Conduct a rapid qualitative evidence synthesis to identify key influences that impact on recruitment and retention to mental health RCTs, from the perspective of trial staff;

2) Compare the identified influences on trial participation identified from this rapid synthesis to existing recruitment Qualitative Evidence Syntheses (QES)1,2 and the Cochrane reviews of interventions to improve recruitment/retention to RCTs3,4 , to explore similarities and differences between recruitment/retention issues for mental health RCTs and trials more generally; and

3) Analyse findings from objective 2 to propose if/how existing recruitment/retention interventions/strategies might (or might not) increase trial recruitment and retention in mental health RCTs and make recommendations for designing new interventions/ strategies for mental health RCTs.

To guide the rapid QES we followed guidance on Cochrane Rapid Reviews5. The rapid QES used modified, systematic, transparent and reproducible methods to accelerate the synthesis of qualitative evidence so that completion of the review output could occur earlier than with a typical QES.

**Progress**

**Searching the literature**

We searched MEDLINE, PsycINFO and CINAHL, and supplemented searching with a targeted search of the grey literature and citation chaining based on key papers. We did not apply date or language limits, and searching was from database inception up to 30th September 2024.

**Eligibility criteria**

We included qualitative studies including mixed methods studies with a qualitative component where the qualitative data could be separated for inclusion in our synthesis. We included the experiences of staff involved directly or indirectly, in trial recruitment and/or retention processes.

**Study selection**

Two reviewers screened titles and abstracts for the first 20% of search results, we moderated to reach consensus, and all remaining abstracts were then screened by one reviewer. A third reviewer screened a random 10% of all abstracts to validate the process, and this was repeated for full texts.

**Data extraction**

We extracted the following study characteristics:- author, country, date, host trial, intervention/ comparator, recruiter role in intervention delivery; review article (aims/methods/who & where conducted); review article participants (number, age/gender/disease); trial behaviour (e.g. screening, approaching potential participants, discussing trial treatment options, data collection follow up with participants), time points for qualitative data collection; findings.

**Quality Appraisal**

The methodological quality for all studies was appraised using the CASP tool 6 (Critical Appraisal Skills Programme).

**Data analysis and synthesis**

A descriptive thematic synthesis was undertaken, using Thomas & Harden’s framework7 .

**Assessing confidence in findings**

To assess confidence in each of the review findings, Confidence in the Evidence from Review of Qualitative Research (GRADE-CERQual)8 approach was used.

**Patient and public involvement**

We had three patient and public partners (PPI partners) involved in the research process, including dissemination activities. All PPI partners were UK-based and self-identified as having one or more mental health conditions. During regular meetings, we presented broad themes with illustrative quotes from our included studies and asked attendees for their input, based on their life experience, cultural norms, and beliefs. This presented an ongoing opportunity for PPI partners, and other project members (e.g. clinical staff) to sense-check findings and consider if/how findings from studies conducted in various contexts resonated with their own experiences. As part of the research team, our PPI partners will continue to be involved in ongoing dissemination activities.

**Main Findings**

Fifteen studies (reporting trial staff experiences across 13 trials) met our inclusion criteria, and all focussed on trial recruitment. Most studies were set in the UK (n=12 ); other countries included USA (n=1), Australia (n=1) and Sweden (n=1). Studies were based in a range of settings:- primary care (n=5); inpatient/outpatient (n=3); community (n=4); inpatient /community (n= 3). The clinical contexts of the 13 trials were: Depression (n=5); Schizophrenia (n=3) ; Anorexia nervosa (n=2); Psychotic or chronic affective disorder (n=2); Generic mental health (n=1). The types of interventions evaluated in the trials were: behavioural (n=8); drug (n=1); mixed (n=4).

Altogether our included data reports on the experiences and perspectives of 350 trial recruiters reported as being involved directly/ indirectly in trial recruitment: doctors ( n=124) nurses/other clinical staff (n=134); all other (n=93) e.g. care-coordinators, TMs, RAs.

Data were collected by individual interviews and/or focus group discussions and focussed on recruitment issues. Only one study mentioned retention briefly. Those involved in trial recruitment, directly or indirectly, are herein referred to as ‘trial staff’.

From these studies, we developed four key themes. Findings are presented within the themes below.

**Theme 1: Recruitment within existing care pathways**

* 1. *Trial delivery in care settings*

**Finding 1**: Integrating an RCT into mental health care pathways was identified as challenging and could negatively impact trial staff views about supporting a trial.

**Finding 2**: Trial staff operated in various team frameworks and experienced a range of organisational issues and research cultures which influenced their levels of engagement in trial recruitment activites. 

* 1. *Expectations of mangers on clinical staff*

**Finding 3***:* The expectation of mangers could support clinical staff to recruit, or be perceived as undermining their professional autonomy, making recruitment more problematic.

*1.3 Staff capacity to support recruitment*

**Finding 4:** Clinicians were already managing high clinical workloads, limiting capacity to support trial recruitment activities.

**Finding 5**: Limited staff resources linked to high staff turnover/shift patterns could make communication and engagement with staff more difficult, undermining recruitment opportunities.

**Finding 6**: Insufficient consultation time for trial staff to include an in-depth discussion with patients about a trial, was not conducive to supporting trial recruitment.

**Finding 7**: A lack of dedicated research staff or primary care nurses with limited mental health care knowledge could limit in-depth trial recruitment discussions.

**Theme 2: RCT understanding and judgements about interventions**

*2.1 RCT knowledge*

**Finding 8**: Trial staff (mis)understanding of RCTs generally or specific trials they were involved with, could curb enthusiasm and willingness to engage in trial recruitment activities.

*2.2 Perceptions of trial and intervention acceptability*

**Finding 9**: Trial staff judgements about the research question and clinical importance of the trial influenced their enthusiasm and willingness to support recruitment.

**Finding 10**: Acceptability of trial interventions amongst trial staff enhanced recruitment. Trial staff preferences for treatments could negatively impact whether a patient was approached for a trial.

**Finding 11**: Trial staff discomfort about the eligibility criteria and issues of ethicality relating to patients potentially not being randomised to the intervention, could result in trial staff not approaching some patients for a trial.

*2.3 Trial participation as an opportunity*

**Finding 12**: Trial staff perceptions of trial participation as an opportunity to offer something that might not have been available or limited within current care provision, encouraged recruitment efforts.

**Finding 13**: Some trial staff were inclined to support the trial with a reluctant acceptance they had nothing else to offer patients.

**Theme 3: Weighing up decision to approach patients**

*3.1 Personal considerations for trial staff*

**Finding 14:** Trial staff valued the importance of relational aspects between them and patients, with a disinclination to introduce something which could potentially undermine a fragile patient-clinician dynamic.

**Finding 15:** Trial staff discomfort about potential harms to some patients by participating in a trial, and being left to deal with any fallout, could undermine their willingness to recruit.

**Finding 16**: Trial staff who described themselves as primarily caregivers and being a patient advocate, were less comfortable with supporting trial recruitment.

**Finding 17**: Confidence amongst trial staff to approach patients was enhanced if they judged themselves to have the appropriate skills, trial knowledge and familiarity with trial processes.

*3.2 Clinical influences on trial staff*

**Finding 18**: Trial staff were more likely to prioritise their clinical judgements for certain patients over their researcher role.

**Finding 19**: Trial staff had strong views about being clinically responsible and protective of patients. As such, trial staff were less likely to invite patients to a trial if they believed it could trigger a destabilisation in their health.

**Finding 20**: Some trial staff feared discussions during trial recruitment that required asking sensitive questions, could potentially ‘trigger traumatic memories’ or increase harmful risk-taking behaviours amongst patients. As such, trial staff were less likely to engage in a trial recruitment discussion.

**Finding 21**: Trial staff assessments about patient vulnerabilities and capacity to consent, along with fears about who would be responsible for patients referred into a trial, undermined recruitment opportunities.

**Finding 22**:Trial staff concerns about patients' lifestyle and ability to meet trial requirements (beyond the relevant trial inclusion criteria) discouraged them from approaching certain patients. 

**Theme 4: Engaging in a trial conversation**

*4.1 Timing of approach*

**Finding 23:** Judgements about the appropriateness of initiating a trial conversation could be problematic for trial staff, especially in a crisis care context and if the patient in a distressed state.

*4.2 Pitching the trial*

**Finding 24**:Difficulties in explaining a trial, trial staff preferences and responding to any patient treatment preferences could undermine recruitment efforts.

**Finding 25**:Reluctance amongst certain patients to accept a mental health diagnosis, making it problematic for recruiters to engage in a trial discussion.

**Finding 26**: Undertaking trial eligibility assessment could be undermined by a patient’s reluctance to disclose sensitive information related to knowledge of their legal powers of detention. As such, trial recruitment opportunities could be negatively impacted as trial staff were unable to make a trial assessment.

**Mapping, outputs and future plans**

The findings from this rapid QES have been used to inform a mapping exercise aimed at: comparing the identified influences on trial participation identified from this synthesis to existing recruitment Qualitative Evidence Syntheses1,2 and the Cochrane reviews of interventions to improve recruitment/retention to RCTs3,4, to establish if any intervention evidence could support identified recruitment challenges. In summary, some of the themes have considerably more overlap than others, indicating which of the mental health QES findings, or aspects of them, are specific to this study. This mapping exercise has also helped evidence a lack of appropriate interventions evaluated to target these recruitment challenges.

From the mapping exercise, we are currently working towards informing the development of suggested tailored solutions that could support trial recruitment to mental health trials, and this will be supported by further discussion and input from the wider team. We will also continue to work closely with our PPI partners to support dissemination activities and to produce summary findings that are communicated in an accessible way via infographics, video and social media posts.

**Publication**

We are currently drafting a manuscript of the qualitative evidence synthesis for publication in the Journal of Clinical Epidemiology and anticipate submission Summer 2025.

**Feedback from our PPI partners about involvement in the project**

“*The review was a very interesting piece of work and also an important one in my opinion. I felt respected, valued, and a part of the team. Sharon was kind and a good chair/ lead, who explained things well and sought to include the patient partners. I also enjoy learning new things and this was a nice challenge for me… I didn’t feel anyone was “unequal” e.g. dominated conversation. Points I made were always valued and taken onboard. There was also talk of particular areas where public partners had extra relevant expertise, which helped me feel like the PPI perspective was being considered and drawn upon.*” Louise T

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“It was really interesting reading the data extracts and noting the common themes and issues that emerged…It was definitely supportive. I felt the availability of the Protocol really helped me understand the context and substance of the meetings. I thought my reference to the multi faceted aspects of the burden shared by recruiters and referrers was taken onboard and shared by the group.” Edmund B

**References**

1. Farrar N, Elliott D, Houghton C, Jepson M, Mills N, Paramasivan S, Plumb L, Wade J, Young B, Donovan JL, Rooshenas L. Understanding the perspectives of recruiters is key to improving randomised controlled trial enrolment: a qualitative evidence synthesis. Trials. 2022 Oct 20;23(1):883. doi: 10.1186/s13063-022-06818-4. PMID: 36266700; PMCID: PMC9585862
2. 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 Affect Disord. 2015 Feb 1;172:274-90. doi: 10.1016/j.jad.2014.10.005. Epub 2014 Oct 16. PMID: 25451427.
3. Treweek, S., Pitkethly, M., Cook, J., Fraser, C., Mitchell, E., Sullivan, F., Jackson, C., Taskila, T. K., Gardner, H., 2018. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews, Issue 2. Art. No.: MR000013 28.
4. Gillies K, Kearney A, Keenan C, Treweek S, Hudson J, Brueton VC, Conway T, Hunter A, Murphy L, Carr PJ, Rait G, Manson P, Aceves-Martins M. Strategies to improve retention in randomised trials. Cochrane Database Syst Rev. 2021 Mar 6;3(3):MR000032
5. Booth A, Sommer I, Noyes J, Houghton C, Campbell F; Cochrane Rapid Reviews Methods

Group and Cochrane Qualitative and Implementation Methods Group (CQIMG). Rapid reviews methods series: guidance on rapid qualitative evidence synthesis. BMJ Evid Based Med. 2024 May 22;29(3):194-200.

1. Critical Skills Appraisal Programme. <https://casp-uk.net/casp-tools-checklists>
2. Thomas, J., Harden, A. Methods for the thematic synthesis of qualitative research in systematic reviews. BMC Med Res Methodol 8, 45 (2008). https://doi.org/10.1186/1471-2288-8-45
3. Lewin, S., Booth, A., Glenton, C., Munthe-Kaas, H., Rashidian, A., Wainwright, M., Bohren, M. A., Tancalp, O., Colvin, C. J., Garside, R., Carlsen, B., Langlois, E. V., Noyes, J., 2018. Applying GRADE-CERQual to qualitative evidence synthesis findings: introduction to the series. BMC Implementation Science, 13: 2.