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

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Abstract

Background: Recruitment processes for clinical trials of digital interventions for psychosis are seldom described in detail within the literature. While trial staff have expertise in describing barriers and facilitators to recruitment a specific focus on understanding recruitment from the point of view of trial staff is rare.

Methods: We applied pluralistic ethnographic methods including analysis of trial documents, observation and focus groups explored the recruitment processes of the EMPOWER feasibility trial (ISRCTN: 99559262).

Results: Recruitment barriers fell into two main themes; service characteristics (lack of time available to mental health staff to support recruitment, staff turnover, patient turnover (within Australia only), management styles of community mental health teams, physical environment) and clinician expectations (filtering effects and resistance to research participation). Trial staff negotiated these barriers through strategies such as emotional labour (trial staff managing feelings and expressions in order to successfully recruit participants) and trying to build relationships with clinical staff working within community mental health teams.

Conclusions: Researchers in clinical trials for digital psychosis interventions face numerous recruitment barriers and do their best to work flexibly negotiate these barriers and meet recruitment targets. The recruitment process appeared to be enhanced by trial staff supporting each other throughout the recruitment stage of the trial.

Trial Registration: (ISRCTN: 99559262 registered 21/12/2015)

Introduction

To better understand how interventions could be developed, evaluated, and implemented into routine care, it is important to fully understand which aspects of randomised control trials (RCT) implementation are most challenging (1). All RCTs must recruit participants for interventions to be tested (2). However, recruitment into RCTs can be very difficult and is possibly the biggest challenge within clinical research (3) with many RCTs failing to reach their recruitment targets (4). Delayed recruitment can lead to additional costs (5) and underpowered clinical trials can threaten the empirical value of intervention research (6). Systematic reviews of recruitment barriers have helped uncover specific barriers for recruiting ethnic minority populations (7), within HIV trials (8) and cancer trials (9). However, reviews are only possible if primary data are collected and shared. Digital interventions are becoming popular for increasing access to treatments, but little is known about the nature of specific recruitment barriers in these trials (10). Beyond widespread societal concern about the negative impacts of digital technology within daily life (11), there may be recruitment challenges in mental health care research such as concerns patients may struggle to use a digital device (12). However, systematic review evidence suggests that these effects are not yet understood because trial recruitment is not covered in depth in studies of implementation barriers for digital interventions for psychosis(13).

Trial staff responsible for recruiting participants must implement something novel (in this case, the recruitment process for a new intervention) within a healthcare system which comes with existing norms, knowledge and social practices. Trial recruitment involves interacting with diverse groups (14) including patients, clinical staff, clinical leaders and other members of the trial team. The healthcare system can be described as a context in which the recruitment process must fit. Process evaluations use qualitative research to develop an understanding of how trial processes such as recruitment were delivered and received by participants and trial staff (15,16). Context in process evaluation terms is defined as factors external to an intervention that influence clinical trial processes delivery (17) such as recruitment. Therefore, understanding the context of recruitment is important for understanding what factors may act as barriers and facilitators in enrolling participants within a clinical trial.

Usage of and interest in digital interventions is high in people diagnosed with schizophrenia (18) and digital

interventions for psychosis are growing in popularity (19,20). Currently, the ongoing Covid–19 pandemic has seen a surge in interest in using digital technologies to support people with mental health problems (21). However, the willingness of patients to be recruited into digital intervention clinical trials is poorly understood (22,23). People diagnosed with schizophrenia are described as a difficult to recruit population more generally within clinical trials (24). Recruitment for service users diagnosed with schizophrenia often involves approaching patients via staff; therefore, it seems particularly important to consider the role of staff within study recruitment. For example, a recent study reports that one in five mental health staff report having never recruited a service user into a research study (25).

Within trials of digital interventions, it is recommended that the recruitment of end users should be described in sufficient detail to enable readers who wish to contextualise or replicate the work (26). Feasibility studies help establish important parameters such as willingness of clinicians to recruit patients and willingness of participants to be randomised (27). Despite the importance of recruitment, CONSORT statements(28) do not require RCT reporting to describe recruitment in detail beyond documentation of participant flow (29,30). Proposed CONSORT extensions (31) recommended qualitative data be collected so context can be more fully understood so future researchers may recognise what relevant contextual elements (such as settings and stakeholder participation) which are necessary for the replication of findings observed within a particular trial. Reporting a more detailed examination of recruitment processes (particularly recruitment barriers (32)) is suggested to be useful in interpreting trial results and developing strategies for improvement (33). Moreover, failure to report recruitment experiences risks significant loss of a key source of knowledge. Additionally, it is important to note that detailed reporting of recruitment into digital intervention studies using mobile apps is noted to be scarce (34).

Trial staff are responsible for meeting recruitment targets and interact with potential participants in order to do so. This places them in a unique position to comment on the overall recruitment process and provide a narrative on 1) what happened during trial recruitment; and 2) make informed comment on why. Identifying barriers to recruitment has been identified as a strength of qualitative research within clinical trials (35,36). Furthermore, qualitative research could also describe what strategies trial staff utilise to negotiate around recruitment barriers.

Study Aims

This qualitative study within a trial (SWAT: (37)) aimed to gather and analyse data to more fully understand barriers and facilitators encountered by trial staff during the recruitment process for the EMPOWER study (described in more detail below), and to facilitate learning ahead of a full trial. Previous qualitative work conducted with carers, mental health staff and service users suggested that recruitment barriers were hypothesised within the EMPOWER trial (12) such as service users feeling paranoid in response to digital technology and a lack of staff time to support the recruitment process. Therefore, this study aimed to explore recruitment issues in some depth but was not limited to the a priori issues identified within our previous research.

EMPOWER (Early signs Monitoring to Prevent relapse in psychosis and prOmote Wellbeing, Engagement and Recovery (38), ISRCTN: 99559262) aimed to develop and evaluate a Mobile App for use with adults who experience psychosis. The EMPOWER App is a digital self-management tool (augmented with peer support) to enhance the identification of, and communication about early warning signs of relapse in people diagnosed with schizophrenia. The app enables routine self-monitoring for a variety of different experiences, including psychosis (e.g. hearing voices, suspicious thoughts), anxiety, mood, self-esteem and interpersonal support. EMPOWER participants used the App for an initial twenty-eight-day baseline period to identify their typical variation in personal wellbeing. Significant changes from baseline are then triaged by a clinician and, if necessary, mental health staff notified. EMPOWER was tested in a cluster randomised control trial (cRCT). Since EMPOWER was trying to enhance communication and shared decision making between multiple stakeholders, mental health staff, service users and carers (if relevant) were all potential participants. The feasibility of the EMPOWER intervention and study procedures were tested in a multisite trial in both Australia and the UK. The initial recruitment target was 120 service user participants (and any linked carers) and 40 mental health staff from 8 Community Mental Health Services (CMHS) before randomisation of the clusters (services). During the course of the study 8 CMHS were recruited and randomised however a revised recruitment target of n = 86 was agreed

and met.

In cluster trials, outcomes are usually measured at the level of the individual but trial procedures (such as recruitment) are applied by the research team at the level of the cluster (in this case, adult community mental health teams) (39). Therefore, developing an understanding of recruitment both within and across sites appears important in contextualising the recruitment process in a cRCT. Full details of the intervention are reported in the protocol (38). In a feasibility study such as EMPOWER, process evaluators are usually interested in facilitators and barriers to implementation so that strategies to enhance implementation of key processes such as recruitment can be put in place for a definitive trial (17).

Methods

In line with the EMPOWER process evaluation protocol (40) the theoretical framework for this study was constructivism (15) which posits that knowledge is created through social interactions. The processes that occur during intervention implementation need to be understood in ways that are responsive to the complexities and intricacies of programs, people, and places (41). Recruitment in clinical trials is a complex social action so there is unlikely to be one definitive methodology (qualitative or otherwise) that can allow us to theorise recruitment in sufficient depth (42).

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

Ethnography

Ethnography refers to both a process and outcome of research that produces rich descriptions and interpretations of a social system from the point of view of its key social actors, including their behaviours, roles and methods of interaction (43). Ethnography is useful for theorising implementation processes like recruitment because ethnographic narratives pay attention to interconnectedness while building a holistic understanding of how systems come together as a whole (44,45). Furthermore, ethnography is useful for developing internally valid theory by focusing on describing how people behave in the real-world context of doing clinical trial recruitment. Taking an ethnographic stance is advantageous in process evaluation research because it can help develop implementation theory of key trial processes with good internal validity (46). While ethnography commonly observes social processes, the examination of administrative data and study documents are important within process evaluation research (47). Therefore, the minutes of team meetings were seen as sites for ethnographic enquiry beyond what was recorded from observation.

Trial Staff Focus Groups

To triangulate findings from the ethnography, focus groups were held with members of trial staff who were involved in the recruitment process. The use of qualitative methods (48), and in particular, focus groups within an RCT facilitates understanding of the recruitment process (49). Exploring recruitment from the point of view of the research team who experienced directly is noted to be useful because it gives insight into reasons behind what can be observed (35). Ethics approval for the study was received from West of Scotland Research Ethics Service (GN16MH271 Ref: 16/WS/0225) and Melbourne Health (HREC/17/MH/97 Ref: 2017.010).

Procedure

Ethnography

SA (who was based in the UK) was present at the majority of weekly team meetings in the UK that were held during the recruitment process and had access to the minutes of the meetings from this time. All members of

the EMPOWER team who were based in Glasgow attended these meetings with the focus of discussion being on general trial business. Recruitment procedures for both the UK and Australia were discussed in these meetings. SA recorded reflective rough notes during the recruitment process and consolidated these into reflective memos once the recruitment period was over. SA revisited meeting minutes (n = 50) for the period from 03/08/2017, when recruitment started, until 05/07/2018, when the recruitment target was achieved (n = 86) to refresh their memory and wrote reflective ethnographic memos. Relevant ethnographic reflections are reported in addition to analyses from the focus groups. Observational data from meeting recordings and field notes are anonymised.

Trial Staff Focus Groups

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

All participants in this SWAT (through observation focus group participation or both) were employed in the EMPOWER trial and were involved in trial recruitment (either directly or indirectly). NVIVO (50) software was used for all analysis.

Table 1
Showing Participant Characteristics

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

Reflexivity

SA is a PhD student working on a process evaluation for the EMPOWER cRCT (38). The PhD funding SA receives is independent of any funding associated with the trial. Following observations of trial staff during the recruitment process, it seemed as though the recruitment process was a key site of enquiry to more fully understand full trial feasibility. Therefore, a decision was made to undertake a small qualitative SWAT. Supervision and finalisation of the coding process was done in conjunction with HM and AG who are academic clinical psychologists, academic supervisors to SA and investigators on the EMPOWER trial.

Analysis

All data including ethnographic observations and focus group transcripts were analysed thematically by SA using thematic analysis, a qualitative method used to identify, analyse, and report on patterns constructed within text data (51). The first stage comprised of line-by-line coding (descriptive) moving onto the second stage of coding where descriptive codes were thematically linked together into a final set of themes. Constructivist qualitative research assumes that themes do not emerge from the data but are constructed as part of a reflexive analytic processes (52) Therefore, themes will be reported as being constructed. Trial staff provided critical feedback on the rigour and validity of the thematic analysis—similar to member checking (53).

Following thematic analyses of ethnographic observations and focus groups, it seemed that there were several key recruitment barriers encountered by the research team during the process of recruitment to the trial. Beyond simply listing recruitment issues, trial staff discussed how these issues were addressed and what work was done to best negotiate these issues. In order to frame these discussions as distinct from merely reporting key issues, the concept of *trial work* (54) was utilised within a qualitative framework analysis (55). Trial work is a broad concept related to the work done to overcome barriers during the recruitment process engagement, 'buy in' to the trial across a range of stakeholders as well as work involved in managing the organisational complexity necessary to reach recruitment targets (54). Trial work appeared highly relevant to the aims of this study in terms of maximising learning and understanding from the EMPOWER recruitment process. The reporting will highlight the key *recruitment barriers* and then the *trial work* utilised to facilitate recruitment.

Key Recruitment Barriers

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

Service Characteristics

Lack of Time available to Mental Health Staff to Support Recruitment

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

Participant 1: *I don't think you can relate how busy they are. And much pressure they're under. Some of the numbers we heard about in terms of new referrals into teams were quite staggering.*

Participant 2: *Forty. Forty referrals a week, yeah. And there doesn't seem to be any sort of throughput to accommodate that additional pressure being moved around (UK)*

High Mental Health Staff Turnover

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

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

High Patient Turnover

A related sub theme (which was exclusive to Australia) was patient turnover because patients are discharged back to general practice following the end of an acute episode of psychosis, unlike in the UK where clinical

support is generally more long term for people diagnosed with schizophrenia. This was a particular barrier to recruitment because if patients were no longer in the service, they simply could not be recruited. However, this issue intersected with high clinical staff turnover to result in a complex barrier to recruitment into the study because the high clinical staff turnover within mental health services blocked the ability of trial staff to build relationships with clinical staff to build trust in the team and the project.

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

Clinician Expectations

Mental health staff may act as a filter

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

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

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

Mental Health Staff Resistance to Research Participation

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

Participant 1: *because I don't think that looking at consent figures for key workers reflects the buy into the study. …If someone asked you to sign one of these things [consent form] you'd sign it, and then you'd employ your tactics of trying to avoid having to doing anything about it.*

Participant 2: *You either cooperate or don't cooperate.*

Participant 1: …*that's a better way of putting it. [laughs]* (UK)

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

I remember one staff member talking about whether he agreed to be involved and he said "oh, do I really have a

*choice?" kind of saying "well, we've heard about it from, you know, management" and I got the sense he was communicating there was an expectation to get involved but that was just one thing I picked up about that kind of involvement. Yeah. (*Participant, Australia)

Differences in Management Styles Within Clinical Teams

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

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

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

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

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

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

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

Participant 1:. The staff were able to take that sort of leadership role.

Participant 2: So. There's quite a different style I think of leadership and management there that's permissive.

Participant 3: Yeah.

*Participant 4: Facilitating versus one that's more "we're doing this." (*UK)

Differences in Physical Environment

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

Participant 1: *The physical environment's really problematic there [named recruitment site] as well, because*

they're all in small, separate offices, so it doesn't really feel like a team. So individual and…

Participant 2: *There's nowhere to circulate and to talk to the nurses.*

Participant 1: *There's nowhere to chat amongst yourself, just to build the rapport with nurses. It was like, everyone's all huddled away in separate offices. (*UK)

Trial Work Used to Facilitate Recruitment

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

Flexibility in Approach to Barriers

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

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

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

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

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

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

Persistence

Within EMPOWER, *trial work* was characterised not only by flexibility but also by persistence. This could be seen in accounts of trial staff constantly trying to contact mental health staff. The practical work of chasing up mental health staff was readily apparent from analysis of meeting minutes and reflective accounts of the recruitment process recorded in both focus groups. Chasing up could involve telephone calls, email or visits in person to community mental health teams. This was often due to systematic issues such as a lack of staff time to support

the intervention but could also be due to local factors such as mental health staff feeling pressurised into taking part by management and then resisting against participation. However, linked to staff describing their need to be persistent there was acknowledgement that chasing up mental health staff could be a time-consuming part of trial work.

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

Emotional Labour

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

Participant 1: *Persistence. Always smiling. Always the utmost professionalism*

Participant 6*: Sometimes it's fake. [shared laughter]* (UK)

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

Building Relationships

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

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

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

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

(Researcher's Reflective Memo)

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

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

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

Utilising Pre-Existing Relationships

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

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

Relationship building—internal within the research team.

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

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

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

To summarise, relationship building internally within the team appeared to be just as important in facilitating the

recruitment process as building external relationships with mental health staff. Trial staff were there for each other throughout recruitment challenges and provided a supportive space for each other to discuss problems.

Discussion

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

While it has been recommended research exploring recruitment barriers should go beyond reporting a lack of staff time (31), it appeared a systemic problem within this trial that trial staff found difficult to negotiate. Lack of staff time has been reported as a recruitment challenge in many mental health studies (56).Therefore, our results support those of Skea (54) who suggested that researchers should take into account how essential trial recruitment processes fit in with the reality of clinical practice. The non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) framework (57) provides a framework for understanding challenges encountered in the implementation of digital technologies. NASSS frames challenges as being simple (straightforward and predictable), complicated (multiple interacting components) or complex (unpredictable and hard to reduce down into linear components). NASSS addresses challenges and complexities that occur in different domains when implementing health care technologies, including the health condition being intervened on, value proposition, technology, adopter system, organisation, wider social context and changes across time. When framing the recruitment process via healthcare organisations in the UK and Australia, it appears the macro level recruitment barriers pose particularly complex challenges because of severe resource pressures with staff struggling to find time to support research, noted by other clinical trial researchers (58). However, even more idiosyncratic challenges such as differences in leadership between cluster sites were noted by trial staff to have complex, unpredictable and sometimes large impact upon recruitment—supporting the need to understand contextual differences across clusters in cRCTs (39).

In order to negotiate complex recruitment barriers, trial staff put significant amounts of work in to engaging mental health staff during the recruitment process. Trial work is multifactorial and comprises of emotional labour, social and professional competencies. Initially, in performing trial work, staff in EMPOWER reported the importance of persistence, being flexible in trying different approaches and always being professional in their interactions with staff. Previous research on clinical trial staff has suggested emotional labour is a key part of trial work when staff are working to meet recruitment targets (59). In the face of stresses and strains created by recruitment barriers, trial staff have a duty to maintain an ethos of professionalism. Coming from the field of sociology, emotional labour is described as the silent work of evoking feelings in others and managing ones' own emotional expressions to do so (60). Emotional labour appeared a key strategy when dealing with barriers such as having to pursue contact with very busy staff while maintaining good working relationships by not letting frustrations show. Relationships between trial staff and clinicians (and the ability to quickly build and rapport) appeared essential to successful recruitment. However, barriers existed in the recruitment process which could make relationship building difficult. While a lack of clinical staff time is well reported in the literature, factors such as the layout of buildings making it impossible to have a private conversation also acted as a relationship building block.

Clinicians' exclusion of people independent of trial protocol criteria is noted to be a key challenge in mental health intervention recruitment (56,61). In the case of EMPOWER, it appeared that clinicians did regularly seek to exclude participants for reasons not stated in the protocol. Trial staff were given the impression that this was due to clinical staff having concerns about a service user's ability to cope with study participation. However, trial

staff sometimes seemed able to negotiate this challenge by invoking the trial protocol and reminding staff that determining directly from the service user their willingness (or not) to participate was an important outcome within a feasibility study. Mental health staff filtering what patients ended up being approached for recruitment was a key theme identified in previous research exploring barriers to recruitment to non-digital psychosis studies (62). Excluding participants for reasons not contained in the protocol likely has implications for the replicability and robustness of research findings because the selection criteria are obscured (61) and samples likely become biased. Therefore, there is need to learn more about why this apparent "filtering" happens (from the perspective of mental health staff)—particularly in digital interventions for psychosis where little is currently known (13) and there may be assumptions about ability of people with psychosis to use technology (12).

Mental health staff have perceptions of what is required from them professionally, and these perceptions seemed to cause tension and role conflict during the recruitment process. For example, clinical staff may not feel that they have the autonomy to decline participation because participating in research is a role expectation for clinical staff. Previous oncology research has indicated that nurses involved in conducting research describe a role conflict, where duty of care to the patient can sit uncomfortably with *feeling like a salesperson* when encouraging patient participation within trials (63). Enhancing collaborations with key stakeholders such as mental health staff is stated to be important in developing better digital interventions for psychosis (20). Therefore, it seems pertinent to understand issues such as role conflict from the perspective of trial staff and co-design recruitment procedures around the needs of mental health staff.

Persistence and flexibility of approach was important in negotiating everything from macro level barriers, such as a lack of staff time, to more micro level issues, such as community mental health centre managers having different styles. One key element of the flexible approach to recruitment that emerged during the EMPOWER trial was a peer support worker (a person with their own experiences of psychosis employed to support people in their use of the intervention) advising how to approach recruitment challenges. A review concluded that patient involvement in clinical research may be associated with increased recruitment (but not retention) to clinical trials (64). However, the mechanisms of why this effect might exist are still unclear. Within EMPOWER, actively transforming the peer support role to encompass involvement in recruitment was reported by trial staff to have been very useful for recruitment because the peer support role brought pre-existing relationships with staff and fresh insight on how best to approach recruitment challenges. While this may be very specific to EMPOWER, it nonetheless demonstrates that experiential knowledge and enhanced capacity for relationship building with clinical staff may be important mechanisms to consider when theorising mechanisms of patient and public involvement (PPI) in trial recruitment.

Future Research

The research team reported that conveying to staff that discovering rates of participant refusal helped negotiate filtering behaviour by clinical staff. Future research could explore this observed phenomenon further, perhaps using relevant behavioural change theories as a theoretical framework (65). Emotional labour in the context of clinical trials has previously been theorised in recruitment research involving direct interaction with patients (59). However, these findings suggest emotional labour may be as relevant in the everyday work of keeping clinical staff engaged in the recruitment process. The EMPOWER trial was conducted simultaneously in Australia and the United Kingdom. Therefore, it is perhaps unsurprising that a specific recruitment issue unique to one healthcare system were observed (high patient turnover within Australia) was apparent. However, there were some marked similarities across countries such as a lack of staff time. Clinical trials that are conducted across multiple countries may benefit from providing some context on differences between mental health care systems to contextualise recruitment results. Additionally, a Delphi study (66) could expand upon the barriers identified here to see if they are more widespread in trials of similar interventions.

Limitations

The findings from this study should be considered in light of several key limitations. Ethnography is an opportunistic methodology (67) so researchers are limited by what they can or are allowed to observe. Firstly,

conducting one focus group in person and another remotely may have impacted upon both the conduct of the research and analysis. Secondly, while Australian recruitment was discussed at UK based meetings and was recorded in the minutes there, SA did not attend any Australian recruitment meetings due to being based in the UK and did not directly observe Australian staff during the recruitment process. While this study has identified barriers and suggested potential ways to optimise recruitment, the potential positive impact of qualitative research in trial recruitment research needs to be further researched (35) before any comment can be made about potential utility. Furthermore, we have not focused on retention which is also an important issue in its own right (68,69). Additionally, this study focused on barriers and facilitators experienced by trial staff during the recruitment phase of the trial, which related primarily to working with mental health staff. Facilitators addressing ongoing *Service characteristics* such as staff turnover and physical environment may have emerged if the study had been widened to include service managers or other informants. Lastly, there was not much focus on the experiences of service user participants throughout the focus groups. Future research understanding barriers and facilitators to recruitment from the point of view of service users within clinical trials, building upon previous work exploring what service users think about digital interventions for psychosis in general (70,71). Another key limitation is that recruitment within EMPOWER occurred in public mental healthcare systems in both Australia and the UK, recruitment in private healthcare systems or recruitment processes conducted remotely through the internet may have unique challenges.

Conclusions

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

Declarations

Ethics approval and consent to participate

Ethics approval for the study was received from West of Scotland Research Ethics Service (GN16MH271 Ref: 16/WS/0225) and Melbourne Health (HREC/17/MH/97 Ref: 2017.010. Informed consent was obtained from all study participants.

Consent for publication

All authors read and approved the final manuscript for potential publication

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

Acknowledgements

Contributions

S. A. acquired data, formulated the research questions for this study, co-led on the qualitative analysis and contributed to the drafting and finalisation of the manuscript.

H. J. M. was involved in designing the EMPOWER study formulated the research questions for this study, supervised data analysis, and contributed to the drafting and finalisation of the manuscript.

H.W assisted in acquiring data, co-led on formulating the research questions for this sub study, supervised data analysis and contributed to the drafting and finalisation of the manuscript.

A. W.K assisted in acquiring data and contributed to the drafting and finalisation of the manuscript.

A.C assisted in acquiring data and contributed to the drafting and finalisation of the manuscript.

I.B assisted in acquiring data and contributed to the drafting and finalisation of the manuscript.

C.M assisted in acquiring data and contributed to the drafting and finalisation of the manuscript.

E.M assisted in acquiring data and contributed to the drafting and finalisation of the manuscript.

S. B. was involved in designing the EMPOWER study,was involved in acquiring data for this sub study and contributed to qualitative analysis and drafting the manuscript.

J. G. is a principal investigator of the EMPOWER trial and contributed to the drafting and finalisation of the manuscript.

J. F. is a principal investigator of the EMPOWER trial and contributed to the drafting and finalisation of the manuscript.

A. G. is chief investigator for the EMPOWER study,, co-led on formulating the research questions for this sub study, supervised data analysis and contributed to the drafting and finalisation of the manuscript.

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