Community Navigator

Community Navigator Trial

Recruiting Research Participants Blog #1

Recruiting Participants in Mental Health Research Trial: Top Tips from Study Researchers

TLDR

1 - Ask participants how they want to be contacted, respect their preferences, and communicate transparently about what the trial means for them

2 - Foster personal relationships with clinicians and reduce their activity burden to boost referrals and streamline recruitment

3 - Create systems to bolster researcher resilience and ensure everyone feels supported

Randomised controlled trials (RCTs) are crucial for evaluating the efficacy, effectiveness, and safety of new mental health interventions. However, conducting mental health research trials is far from simple – many fail to meet target sample sizes due to delays in recruitment or overestimating the number of people willing to take part. Retention presents another hurdle, with participants often becoming lost to follow-up for a variety of reasons, including changing contact details, relocating, dwindling interest in the study, or worsening health. The latter is particularly significant in mental health trials involving service users who have been unwell for an extended period of time. This blog post is based on a trial that aimed to recruit people with persistent low mood, or “treatment resistant depression” (TRD).

The Community Navigator Trial

Currently, up to a third of people with depression experience no improvement in their symptoms after two courses of antidepressants – and are therefore termed "treatment resistant". Specialist psychological interventions like Cognitive Behavioural Therapy (CBT) also don't work for everyone in this group: in a recent trial of CBT for individuals with TRD, less than 50% of people witnessed an improvement in their symptoms. These findings highlight the urgent need for new and effective support options for people with TRD.

Research suggests that people with depression frequently struggle to make and sustain social connections with others, and commonly report being extremely lonely. Supporting this, a feasibility trial by researchers from the Community Navigator Trial found that individuals with TRD were highly interested in an intervention specifically addressing loneliness.

The Community Navigator Trial has sought to investigate whether a novel social intervention targeting loneliness could help reduce depressive symptoms in people with TRD compared to standard specialist care from Community Mental Health Teams (CMHT). All participants who took part had a 50% chance of being assigned to the trial's intervention group, and a 50% chance of being in the control group (see Figure 1 below).

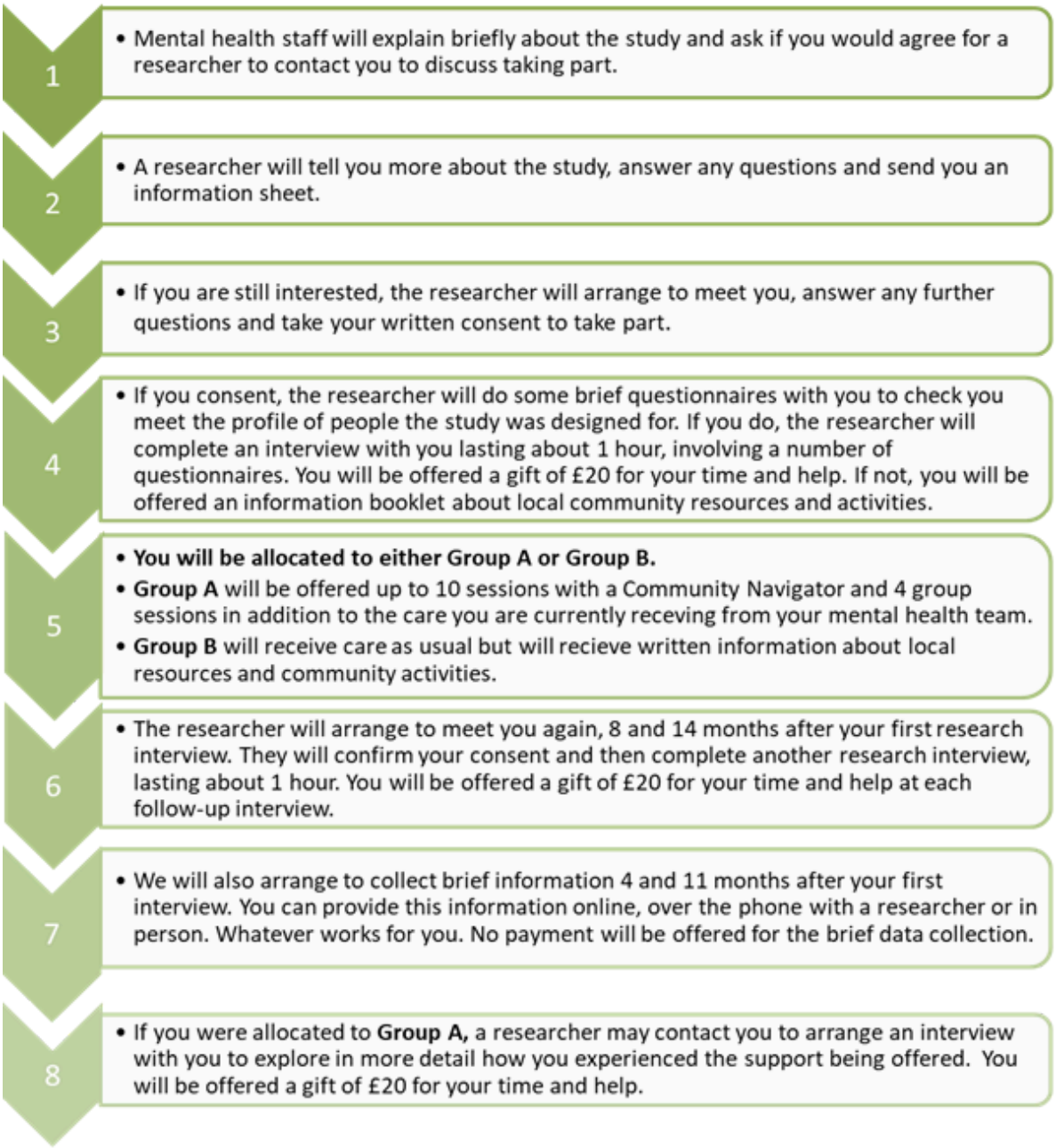

Figure 1. *Diagram to Show the Process of Recruitment of Participants to the Community Navigator Trial and Their Allocation to Treatment Groups, as Detailed in the Participant Information Sheet*

Participants in the intervention group received up to 10 one-to-one sessions over six months with a 'Community Navigator'. Community Navigators helped participants map their social world. This included identifying people, places and activities which were subjectively important to that person, and identifying new social groups or connections they might want to develop. Lapsed activities or relationships they wished to rekindle were also considered.

Community Navigators then helped participants break their goals into manageable steps, offering support as appropriate to help them enact their plans – for example, assisting participants with introductions in a social setting, or going with them to a new social group for the first time. Meanwhile, participants in the control group received routine specialist care from their community mental health team plus a printed information booklet listing social activities available in their local community.

We successfully reached (and even slightly surpassed!) our participant recruitment target for the Community Navigator trial in July 2024 – 10 months later than planned. At times, the process proved very challenging.

In August 2024, researchers involved in participant recruitment for the trial came together to reflect on challenges faced, lessons learned, and what they wished they had known from the start. This article explores those reflections and provides practical guidance for other researchers.

Based on our first-hand experiences, we'll provide key insights and top tips for:

1) The set-up phase, including building relationships with partner sites and clinicians.
2) Effective strategies for recruiting participants to the trial.
3) Tips for maintaining researcher wellbeing throughout the process.

Tips for the Setup Phase: Building Relationships with Clinicians, Sites and Services

The Community Navigator trial recruited participants from Community Mental Health Teams (CMHTs) or equivalent secondary mental healthcare services across six sites in England. During the setup phase, researchers from the trial asked clinicians in participating teams to screen their caseloads for potentially eligible participants and ask them about willingness to speak to a researcher. You can read the trial's full eligibility criteria, here. Once potential participants were identified, a study researcher contacted them to provide more information as well as a written information sheet. Finally, after potential participants had a chance to consider the information, researchers received informed consent from people who wanted to take part.

In practice, checking participants' eligibility for the trial was a huge demand for clinicians. With their already busy schedules, it wasn't easy to find the time to review inclusion criteria and screen participants against it. Therefore, we did all we could to streamline the recruitment process and make it easier for clinicians to refer potentially eligible service users.

We identified several factors that were important for maximising referrals during recruitment. Let's explore each of these, below.

- **Make it personal**: Fostering personal relationships with clinicians was key to encouraging participant referrals during the recruitment phase. While emails could easily have been copied and pasted and sent to multiple clinicians, our researchers made a point of addressing clinicians by name and expressing genuine gratitude for their time and effort. In many cases, we felt this personal touch had positive ripple effects (see Fig.1), with clinicians being more likely to refer service users into the study as a result.

- **Communication**: less is more! Keeping communication brief and to the point was crucial for keeping busy clinicians engaged in recruitment. Short emails were particularly important – clinicians simply didn't have time for lengthy correspondence. Some researchers found that when attending multidisciplinary team meetings (MDTs) (or "huddles") at participating sites, they often had just a minute or two to pitch the trial – since research matters were often low on the agenda! In these cases, having a concise, well-prepared study summary allowed for maximum impact.

- **Streamline processes and reduce clinician burden, where possible:** MDTs weren't always the most effective way to identify eligible participants, as there was rarely time to review caseloads in detail. Instead, we often found scheduling brief, 15-minute one-on-one meetings with clinicians to be a more efficient way to identify potential participants and coordinate next steps. Often, we would offer to complete referral forms on clinicians' behalf – though this was only possible when researchers had access to the Trust's service user records. Small adjustments like these helped speed up the referral process while minimising clinician workload.

- **Prevent "So what now?" moments with prompt next steps:** Once clinicians agreed to help us identify potential participants to take part, providing prompt, specific guidance was crucial to maintain momentum. Following up expressions of interest with clear, actionable instructions ensured clinicians knew exactly what to do next. For example, a simple directive like, "Please tick this box on the referral form and send it to [email address] when you identify an eligible participant" helped maintain engagement and prevent confusion or delays.

- **Don't expect clinicians to remember everything:** As a research team, it is important to remember that although the study constitutes one hundred percent of your working day, it's only a small part of what partner sites and clinicians are managing. Given their many competing demands, we can't expect them to retain every aspect of the research. Be prepared to regularly remind clinicians of the things they need to know, such as eligibility criteria and key details like the recruitment deadline.

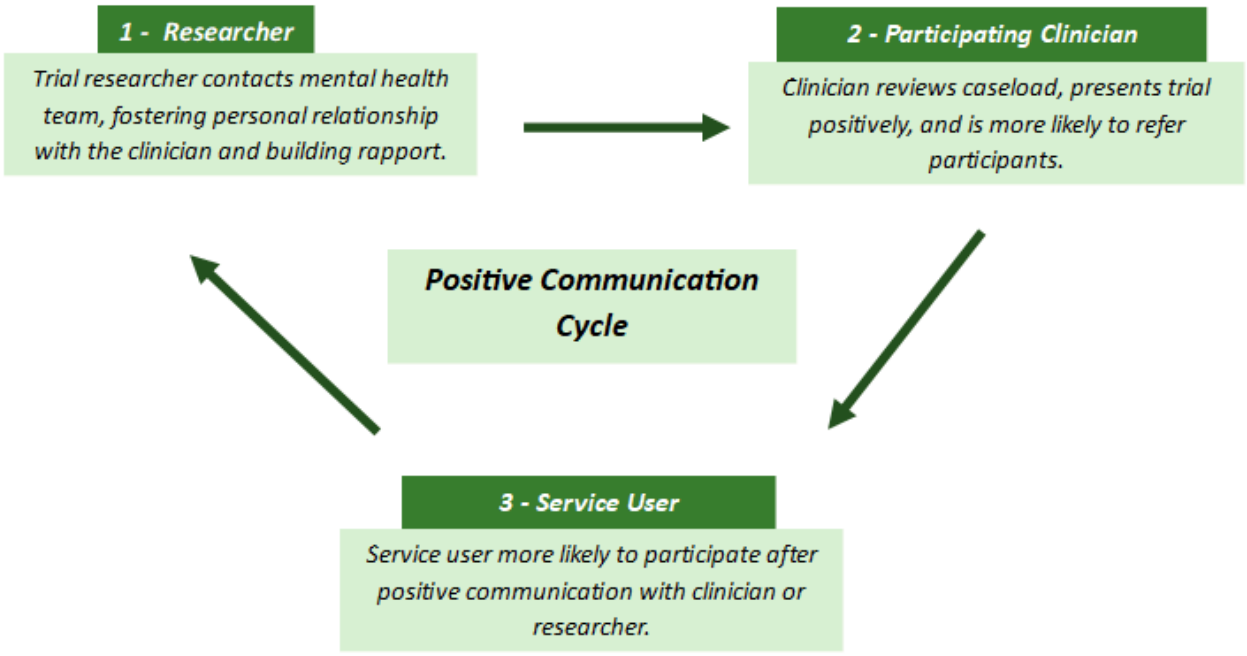

Figure 2. *Proposed Positive Communication Cycle in Recruitment to Mental Health Research Trials*

Tips for Participant Recruitment: Building Trust and Working with Respect

A recent study looking at data from NIHR HTA mental health trials found that 60% failed to reach their original recruitment target. These findings highlight an urgent need to identify effective participant recruitment strategies for mental health research trials. Based on our experiences within the Community Navigator trial, the following were important factors in ultimately successfully recruiting – and retaining – enough participants:

- **Build trust through transparent communication**: Researchers emphasised the importance of honest, frank communication with service users about exactly what the trial meant for them. This meant being clear that the Community Navigator intervention was being delivered as part of a research study – while it *might* improve people's symptoms, there was no guarantee it would. Participants needed to understand that there was a 50/50 chance of being assigned to the intervention and uncertainty as to whether being in the intervention arm would help at all. It can be tempting to accentuate the possible benefits of taking part in a research trial, but this can be counterproductive: potential participants may doubt your claims from the start or may feel disappointed and disengage if their expectations aren't met. By openly acknowledging these uncertainties, we felt we were able to build trust with participants, ultimately fostering stronger long-term engagement.
- **Prepare to be flexible**: Flexibility was essential for increasing willingness to participate. At times, this meant offering to schedule an eligibility assessment after core working hours if it meant a participant was able to attend. Offering a range of options for the location of an assessment was also valuable: we gave participants the choice of completing assessments in-person or online, but we also offered to travel directly to participants' homes if necessary, or to meet them at their local mental health service.

- **Ask participants for their preferences – and stick to them:** Research wouldn't be possible without people agreeing to be study participants – we're unable to test hypotheses and generate new knowledge without them! With this in mind, we asked participants about their communication preferences (e.g., email, text message) at the point of receiving consent, and made a point of honouring those preferences throughout the study. This attention to detail was an important way of showing appreciation, but it also helped continue to build trust in researchers.
- **Avoid assumptions about consent:** In the Community Navigator trial, researchers adopted a "respectfully perseverant" approach when following up with participants. We recognised that no response didn't necessarily mean someone didn't want to take part – it was possible someone had just missed the message or changed their contact details. Unless people explicitly opted out, the team respectfully and gently continued to follow up. At all stages, the goal was to let participants make decisions for themselves and to avoid assuming their preferences. An important aspect of this was communicating to clinicians that, even if they felt a service user wouldn't want to take part, it was better to present the option and let people state that for themselves. Not referring participants to the trial would take that choice away from them.

- **Prepare mentally for calls:** Mental preparation before speaking with participants, particularly about their mental health struggles, was important. Ensuring we were in the right headspace – both emotionally and physically (e.g., being in a quiet, private space) – was essential. If we weren't, we couldn't hold space for the participant in an effective and compassionate way. To support this, researchers took steps such as ensuring adequate rest, eating well, checking in with ourselves emotionally before a call, and taking breaks between previous calls or meetings to prevent burnout and fatigue.

- **Allocate regular, protected time for debriefs with colleagues:** We found it crucial for researchers to have protected time for reflection and debriefing with colleagues involved in the recruitment process. This allowed the team to share details of difficult conversations with participants and how they'd handled them – exchanging tips and advice to help build individual and collective confidence. Some felt it was best for the Trial Manager, Chief Investigator and Site Leads not to be present for these debriefs. These discussions also provided an important opportunity to review and distribute workloads across the research team, ensuring flexibility and dynamism.

- **Practice difficult conversations in advance:** Challenging discussions can arise when participants who have provided consent later do not meet eligibility criteria – a situation known as "screening failure". These conversations can be especially difficult as participants are often disappointed to discover they aren't able to be participants in the study after all. Similar conversations can occur when researchers inform participants that they have been allocated to the control group rather than the intervention group. To navigate these discussions effectively, we felt it was crucial to have practiced them in advance, such as through role-playing with colleagues and members of the study's lived experience advisory panel. Reminding oneself that participant frustration or anger was not personal – but a natural response to disappointment – was also important.
- **Clear protocols for passing on risk**: It was vital to establish explicit procedures for passing on risk information in a risk protocol, including contingencies in case the first contact in the protocol was unavailable. This ensured that researchers didn't feel burdened with holding on to high-risk information without a clear process for escalating it. Having well-defined steps in place helped protect researcher wellbeing as well as participants' safety.

Summary

Recruiting service users to randomised controlled trials (RCTs) is a difficult process. Participants are taking part in something unfamiliar and investing their time and hopes in something that, by definition, we can't know whether will help them at an individual level. It is understandable that people need time to carefully consider whether participation is right for them. Our role is to support people in making an informed decision – which includes encouraging practices that promote participants' autonomy over clinicians' and researchers' assumptions.

Taking time to ensure research staff feel safe, supported, and confident is crucial – especially when research is emotionally challenging. Supporting researchers requires a multifaceted approach including regular debriefs, mental preparation, being intentional with self-care, and rehearsing difficult conversations with participants in advance.

We hope what we have learned from the Community Navigator Trial can help future research teams with recruitment into mental health research trials. Our experience highlighted that systems can be set up from the start of the trial to allow positive and respectful communication between research staff, clinical staff, and participants – which, when they work, leave everyone feeling good. They may even render clinicians more likely to refer potentially eligible participants into the trial, boosting recruitment. Streamlining the referral process, reminding people of key dates and criteria, and setting out clinicians' duties clearly also make all the difference.

The results from the Community Navigator Study will be publicly available in early 2026. We will make them available here once they are published.

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Find out more about the Community Navigator Trial on our website:

https://www.ucl.ac.uk/priment/our-collaborations/community-navigator-trial

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