

Balancing purity, pragmatism and partnership in occupational therapy clinical research: trials and tribulations of recruiting for a multisite stroke trial

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Abstract

Purpose – The REFLECTS trial was a randomised controlled trial (RCT) testing effectiveness of mirror box therapy in upper limb rehabilitation among sub-acute stroke patients. REFLECTS was a large-scale, rigorously planned study; however, implementation was challenging due to low recruitment rates, 803 patients were screened and only 26 were recruited. The purpose of this study is to explore factors and challenges influencing the recruitment of participants to this multisite RCT.

Design/methodology/approach – A Communities of Practice (CoP) approach was used. Bi-monthly steering meetings were held to address recruitment issues and a focus group was conducted post-recruitment to identify influencing factors. Data from meeting minutes and the focus group were amalgamated and analysed using thematic analysis.

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Findings – The trial team ($n = 14$) comprising academics ($n = 5$) and clinicians ($n = 9$) contributed to the steering meetings. The focus group ($n = 9$) included researchers ($n = 5$) and clinicians ($n = 4$). Two major themes were identified: impact of COVID-19, including shorter in-patient stays affecting trial recruitment and clinical trials (and tribulations) highlighting therapist-led dilemmas and patient-related factors leading to patients declining to participate.

Research limitations/implications – The CoP identifies important contextual clinical service-based and therapist-led factors, which have pragmatic impacts on the design and implementation of high-quality occupational therapy clinical trials. High-quality occupational therapy evidence for stroke rehabilitation is essential, however, there is a need to critically reflect on how clinical research can best be implemented in clinical practice to ensure implementation and subsequent usability of findings. Provision of ongoing support for clinicians during trial implementation is essential to manage the therapist-led clinical dilemma.

Originality/value – Good research helps us improve therapy, however, maintaining research purity in the pragmatic “real world” of stroke rehabilitation is challenging. Clinicians encounter ethical dilemmas with randomisation in high-quality clinical trial methodologies and this study identifies the need for ongoing trial implementation support to ensure clinician and patient engagement, enhance recruitment and maintain research integrity.

Keywords Occupational therapy, Clinical intervention studies, Randomised controlled trials, Implementation of trial methodology, Future clinical trial design

Paper type Research paper

Introduction

Stroke is the second leading cause of death in middle- and higher-income countries and is the leading cause of acquired adult neurological disability worldwide (NOCA, 2023a). Early access to evidence-based stroke rehabilitation is critical for supporting post-stroke recovery and is included in the NICE (2023) guidelines for stroke management. Current access to therapy is suboptimal (NOCA, 2023b) and highlights the need for rigorous research to establish the efficacy and optimal dosage of evidence-based interventions in stroke rehabilitation to maximise patient-focused outcomes. Occupational therapy researchers have called for a continued commitment to evaluating rehabilitation, such as stroke rehabilitation interventions, ideally using randomised controlled trial (RCT) methodology to test the efficacy of interventions (Drummond and Lannin, 2020).

RCTs are considered the gold standard for testing interventions and generating evidence to guide health-care delivery (Altman *et al.*, 2002). However, implementing RCTs in clinical practice can be challenging, particularly when recruiting the required number of participants (Raftery *et al.*, 2015; Taylor-Pilliae *et al.*, 2014). Recruiting participants with chronic and disabling conditions, such as stroke, poses additional difficulties (McGill *et al.*, 2020; Schulz *et al.*, 2006). Involving clinicians in clinical trials has been shown to potentially enhance translation and implementation of research findings into practice, especially in stroke rehabilitation (Farrar *et al.*, 2022; Wottrich *et al.*, 2023); however, despite the potential benefits, research on clinician involvement in trials is limited. A systematic review by Chalmers *et al.* (2023) examined the impact of health professionals’ engagement in research on health-care performance, identifying 22 studies, only nine of which focused on RCT engagement. Contextual factors related to trial design and recruitment decisions are often underreported and greater insight from researchers and clinicians could improve future study designs and recruitment efficiencies.

This paper presents data from a qualitative occupational therapy study involving trial clinicians and researchers, exploring collective experiences of working within a multisite stroke RCT. Similar to recruitment challenges faced in other RCTs (Schulz *et al.*, 2006; Taylor-Pilliae *et al.*, 2014), the REfLECTS trial encountered unexpected difficulties in recruitment compared to the pilot study. Understanding

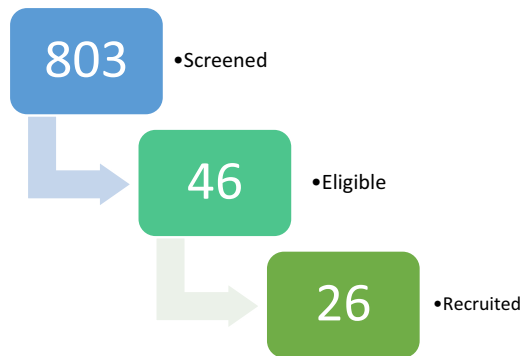
factors that influenced recruitment may provide valuable insights for enhancing future trial recruitment success and facilitating implementation.

Setting the study context

The REfLECTS trial was an occupational therapy RCT testing the effectiveness of mirror box therapy in upper limb rehabilitation among sub-acute stroke patients. Trial eligibility included, being 18 years or older; diagnosed with a first stroke in the last three months; experiencing upper limb motor loss as a result of stroke; score 35 or below on the Fatigue Severity Scale of the Fatigue Assessment Inventory; score above 19 on the Montreal Cognitive Assessment; able to follow to follow two-part spoken or written commands in the English language; and able to give consent to participate in the study.

Prior to the RCT, a pilot study ($n = 40$) was conducted to test the feasibility of trial protocol. The subsequent RCT spanned five clinical sites across two jurisdictions. Rigorous planning was undertaken to ensure adequate recruitment opportunities aligned with the trial’s power calculation. The trial team comprised 14 members including occupational therapy researchers ($n = 5$) and occupational therapy clinicians ($n = 9$). Bi-monthly trial steering meetings were embedded in the trial design and steering meetings were attended by the full trial team. Meetings provided a forum for reflexivity within the whole trial team to monitor trial progress, discuss screening and recruitment and to critically reflect all issues relating to trial delivery as recommended by Jamieson *et al.* (2023). Trial methodology applied attention to optimising recruitment strategies including regular meetings between researchers and clinicians to review screening rates and identify potential participants. Prospective participants were re-screened throughout their hospital stay and clinicians engaged in continuous trial “awareness-raising” amongst their respective multidisciplinary teams to facilitate participant identification. Figure 1 presents the screening and recruitment trajectory of the REfLECTS trial, highlighting the progression from total screenings to eligibility assessments, consented participants and final recruitment figures.

A total of 803 patients were screened for eligibility, of these, 46 patients (5.7%) met the eligibility criteria. Consent was gained from 26 patients and equates to a recruitment rate of 3.23%. This unexpectedly low recruitment rate prompted an

Figure 1. Screening to recruitment trajectory in the REfLECTS trial

Source(s): Figure created by authors

exploration into the factors contributing to this outcome within the REfLECTS trial.

Methods

A Communities of Practice (CoP) approach (Wenger, 1998) was used and included the trial steering group bi-monthly meetings minutes and a focus group to explore the factors influencing recruitment.

CoP approaches have been effectively applied in healthcare research to assess and enhance health-care performance (Holliday et al., 2023; Hennein et al., 2022), promote learning, improve clinical practices and facilitate the translation of evidence into clinical settings (Ranmuthugala et al., 2011). Within our study, CoP elements were distinctly evident during both the bi-monthly meetings and the focus group, where participants shared a common domain of interest as members of the trial team, possessing expertise in occupational therapy stroke rehabilitation and stroke research (Li et al., 2009; Wenger, 1998).

All trial team members were invited to participate in one focus group, which was facilitated by the trial's research associate (YC) using a semi-structured format with a pre-designed topic guide. The guide was collaboratively developed by YC, TS and APA and was informed by the bi-monthly trial minutes and issues identified. Guide questions explored; the expectation versus reality of screening and recruiting participants, challenges associated with recruitment and factors influencing recruitment over the duration of the trial (see Appendix for the guide). Participants received the guide in advance to help them to prepare.

Ethical approvals were obtained from Ulster University's Office of Research Ethics Committee, Trinity College Dublin, and participating hospital sites. All CoP members provided informed consent for their contributions from both bi-monthly meetings and the focus group to be included in the analysis.

To ensure accuracy, member checking was integrated into the focus group process (McKim, 2023). The facilitator paraphrased and summarised participants' responses at natural breaks and transitions, offering opportunities for clarification and corrections. The facilitator gave an overall summary at the end of the focus group and participants had further opportunity to correct or clarify

at that point. Following the focus group, participants reviewed the transcript for accuracy and provided further clarifications.

Focus group discussions were audio-recorded, transcribed and anonymised. A reflexive log (Jamieson et al., 2023) was used to summarise emerging ideas, note gaps and similarities in the data and was later used in the preliminary coding stage (Braun and Clarke, 2022). Theoretical thematic analysis was conducted using Braun and Clarke's (2022) framework, involving data familiarisation, initial coding, theme development and validation. Initial coding of the amalgamated transcript and the steering minutes was completed using the focus group guide structure to organise the data (Saldana, 2009). Hand-coding was completed by YC and TS who independently read the amalgamated transcript and extracted the codes. Both authors engaged in peer review of the identified codes throughout the extraction process and collaboratively agreed the formation of the thematic areas based on similarity of code content. Further member checking occurred when the summary of emerging themes was shared with all CoP members for validation.

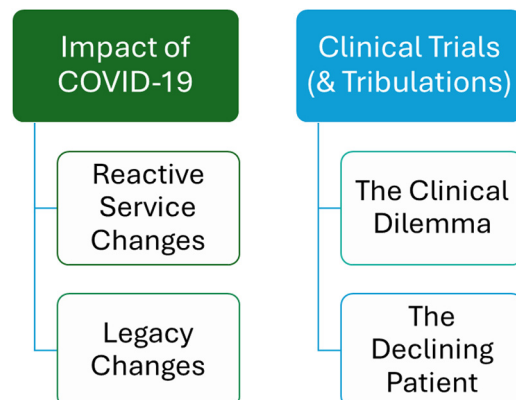
Results

The CoP comprised 14 members who all actively participated in the bi-monthly meetings throughout the trial's duration. Clinicians were senior grade (band 6) or higher and held significant expertise in stroke assessment and management, ranging from nine to 39 years of experience. Three clinicians had prior involvement in clinical research. The focus group was 75 minutes duration and included nine participants: four trial clinicians and five trial researchers. It was conducted online due to geographical spread of participants.

Two overarching themes: impact of COVID-19 and clinical trials (and tribulations) were identified, each encompassing two subthemes (Figure 2). Findings are presented using straightforward description and quotes are used to support the description of the findings.

Theme 1: impact of COVID-19

This theme incorporates two subthemes: reactive service changes and legacy changes that reflect the impact of COVID-19 on this trial.

Figure 2. Major themes and subthemes

Source(s): Figure created by authors

Subtheme 1: reactive service changes

CoP members reported that initial trial implementation aligned well with expectations and experiences from the pilot study. However, the onset of the COVID-19 global pandemic coincided with the trial's launch, severely impacting trial progress. Clinicians noted significant COVID-19-related barriers that were beyond trial team control, negatively affecting both recruitment and participant retention. Barriers included heightened pressure on clinical services and redeployment of staff at many sites, directly impacting routine clinical practices. Furthermore, restricted access to treatment spaces and limited mobility within hospitals posed challenges in delivering regular clinical interventions and hindered the practical implementation of trial protocols:

We started off not too bad and then COVID hit, and we had so many appropriate participants during that time it was so frustrating that we couldn't get them recruited because of the rules.

There was huge pressure on beds, because we were a Nightingale hospital so if our stroke patients contracted COVID, they got moved to another ward and then to try and get them back! That was hard work. [...] once they got COVID they were shipped away, and it was hard to get them back to deliver the intervention.

The pandemic necessitated a pivot in established stroke pathways, which had a negative impact on trial recruitment and retention. Service provision shifted, with less emphasis on usual rehabilitation and a heightened focus on discharge, and clinicians reported the prioritisation of early discharge from healthcare settings, whether to home or community care. However, neither home nor community care settings had established mechanisms to continue stroke rehabilitation and recovery effectively:

There was a pivot from rehabilitation to discharge.

Discharge was the ultimate focus on every single ward [...], stroke was a quicker discharge because as soon as the stroke patients were improving then the immediate push, because of COVID, was discharge.

Subtheme 2: legacy changes

Temporary changes in service delivery initiated by COVID-19 persisted beyond the acute waves of the pandemic even after the lifting of restrictions. These changes led to a permanent restructuring of healthcare services and pathways further impacting trial recruitment and retention. CoP members noted that stroke services now operate with a new approach that prioritises early discharge, a shift that was not previously the norm. This altered approach has significantly reduced the timeframe available for rehabilitation within health-care settings, posing substantial challenges for the practical implementation of clinical research:

COVID changed practice quite a bit, but it didn't just go back to exactly how it was before when the restrictions lifted because service delivery changed. Discharges are still faster than would have been before.

In addition to the reduction in the acute hospital stay reported, CoP members observed changes in the profile of patients attending rehabilitation services. They noted a higher incidence of dense stroke presentations and increased numbers of medically unwell patients in rehabilitation settings and this cohort often proved unsuitable for recruitment into the trial:

We're a rehab site and usually we'd be busy with interventions to promote stroke recovery, but since COVID the type of patients here has changed, more dense strokes, more repeat strokes, sick patients with greater full care

needs and fewer opportunities for rehab. Because they are unwell, or waiting for a nursing home they're staying much longer and that means less throughput than we'd be used to.

Recruiting participants for a trial demands sensitivity and opportunity. Balancing patient readiness and the timing of recruitment became challenging due to the altered profile of stroke patients in both acute and rehabilitation settings, exacerbated by lasting changes in service delivery such as reduced hospital stays following the initial waves of the COVID-19 pandemic. The issue of 'timing and readiness' was particularly identified in acute settings where patients were often not emotionally ready to consider rehabilitation or participate in a research study after their stroke diagnosis:

Our patients are at an acute stage, when we see them, they've just received the diagnosis. So, they're coming to terms with that as opposed to being ready to think about rehabilitation.

The window of opportunity for recruitment was significantly narrowed due to the reduced length of hospital stay and it was challenging to find the "right" moment to recruit patients, allowing enough time to initiate the intervention before their discharge:

[...] length of stay was not technically an inclusion criterion, but obviously the patient has to stay long enough to get the intervention.

Rehabilitation sites were recognised for their strength in providing adequate time for therapeutic intervention and aligning with patients' readiness to engage in rehabilitation, which was conducive to trial recruitment and retention:

We have the luxury that we can keep our patients for longer because we're subacute and so there were a few that we did rescreen, and they were happy to participate.

Theme 2: clinical trials (and tribulations)

This theme incorporates the challenges experienced in this clinical trial and two subthemes are the clinical dilemma and the declining patient.

Subtheme 1: the clinical dilemma

Robust screening criteria and processes are crucial in RCTs as they enhance the study rigor and facilitate accurate interpretation of findings. However, CoP members identified challenges with adhering to the strict requirements of rigorous trial methodology when screening in the clinical setting. Challenges included discrepancies between clinicians' gut feeling and clinical experience, and the screening test scores, the impact of timing on screening outcomes, and therapist dilemmas in deciding whether to include or exclude potential participants based on trial criteria.

CoP members highlighted a common frustration in efforts to recruit when their clinical judgements on a potential participants' eligibility to participate did not match the screening scores threshold. Clinicians discussed how they relied on their clinical experience to assess whether a participant would be suitable for the study, only to discover that their judgement conflicted with the formal screening results. This disparity between their "gut feeling" based on clinical expertise and the standardised screening criteria partly explains why there was a gap between their initial confidence in meeting recruitment targets and the actual numbers recruited by the end of the study and highlights a significant challenge in trial recruitment processes:

My gut feeling would have been that they would be able to manage [trial participation]. They weren't completely flat out [fatigued]. They would have had potential to tolerate it, but still were coming up with too high a score.

[...] we were going in with our experience of stroke and fatigue and thinking well actually this patient doesn't appear to be too fatigued. But then the score was telling us something else.

Timing of screening was widely acknowledged as influencing recruitment success, highlighting the complexities of conducting early but appropriately timed screenings, especially in settings where a springboard to discharge planning was likely. CoP members emphasised the delicate balance required: screening early enough to capture potential participants, whereas not screening too early to miss those who may later become eligible. CoP members recognised that the timing of screening carries significant risks and implications. Early screening out could inadvertently lead to participants receiving the mirror box treatment as part of routine care, thereby disqualifying them from subsequent trial inclusion. These "real world" challenges in trials conducted in clinical settings identify key factors for future trial design:

I do think the acuteness had an impact. We were eager then maybe like that screening was a bit early.

We had to be careful that because they hadn't met the criteria the first time that we didn't introduce mirror box as a treatment. That was tricky, making sure that we didn't do that and [...] we didn't know if they were going to meet the criteria the next time.

Clinician bias in recruitment was a further factor that added to the dilemmas and tribulations in this clinical trial. Clinicians' expectations were that if the participants were a good candidate for the trial, then they were a good candidate for mirror box therapy and they were conflicted with the risks associated with possible allocation to the control arm. CoP members described their own motivation for their patients to be allocated to the intervention group as they wanted them to have the best chance of best outcomes:

[...] we would be standing with the [allocation] envelope saying, "please let this be the intervention."

Clinical CoP members identified a dilemma in engaging in an RCT. On one hand, they were enthusiastic to participate in clinical research and contribute to the evidence base for stroke therapy. However, clinicians acknowledged their internal conflicts while trying to do their best for their patients and then feeling disappointed and conflicted when a patient who could benefit from mirror box therapy was allocated to the control group:

We had to keep telling ourselves that we have to do this as there are so little evidence on interventions with sub-acute stroke.

This dilemma highlights the challenges of conducting a clinical intervention study using randomised control methodologies. In this study design, it is impossible to blind either the clinicians or the participants to group allocation. Both are aware from the start whether the participant is in the intervention group (receiving mirror box therapy) or the control group (not receiving mirror box therapy). Clinicians are acutely aware that early interventions are linked to positive long-term outcomes in stroke rehabilitation. Consequently, the potential withholding of therapeutic interventions presents a quandary, particularly for patients whom the clinician believes would benefit from the intervention but are allocated to the control group.

Subtheme 2: the declining patient

In this study, 44% ($n = 20$) of eligible patients who met the inclusion criteria declined to participate. Within the focus group, several factors that may have contributed to the choice to decline were identified, including "communication for recruitment" and "fear of missing out".

Trial commencement coincided with the COVID-19 pandemic and the impact of the subsequent guidelines highlighted the importance of communication for supporting recruitment. CoP members identified how hospital pandemic restrictions, including infection control measures and limited contact times, resulted in reduced time allowed on wards for therapists. This reduction in face-to-face interactions to discuss the study with potential participants was a significant barrier to communication and greatly impacted recruitment. Mandatory use of personal protective equipment during COVID-19 created physical and social barriers, further hampering communication and the ability to build relationships with potential participants who might have considered involvement in the trial:

Influence of infection control and reduced contact times limited how long you could treat a patient for during the initial phases of COVID. Therapists' interaction was limited to 15 minutes, so that obviously had a big impact and therapists didn't have the luxury of time for the study.

CoP members highlighted how the COVID-19 guidelines and the ban on hospital visitation removed the opportunity for potential participants to discuss the trial with family members and seek their advice in the usual way. This lack of in-person family contact negatively impacted recruitment, as patients could not discuss the trial with family members, nor could family members ask questions on the patient's behalf. The reduction in family visits affected potential participants' moods, which strongly correlated with declining study involvement:

Patients would say so me 'I don't feel confident to take part in the study without discussing with my family. I don't know what they would think about me taking part' and that hesitancy really impacted participation in the study.

CoP members reported a significant impact on recruitment due to a "fear of missing out". As the trial was ongoing, some patients observed other patients on the ward receiving mirror box therapy. This visibility led to increased interest in participating in the trial, as these patients wanted to receive the mirror box intervention themselves. However, most patients consenting to participate did so with a vested interest in being allocated to the intervention group and the "risk" of being allocated to the control group and "missing out" on receiving the mirror box intervention was a significant reason why some potential participants declined to join the trial:

We had some very clever patients who thought, well, if I say no, then I'm going to get mirror box anyway. These patients or their families knew that it would be part of their therapy if they didn't sign up [to the trial].

CoP members also identified challenges in managing the control arm of the study with some participants withdrawing from the control arm to purchase their own mirror box to maximise their rehabilitation outcomes. In addition, attrition was a feature in the control group with some participants declining to engage in the three-month post-discharge assessment, feeling that their participation in follow-up assessments was pointless as they had not received the intervention:

[...] some control group participants declined the final assessment and said 'well there's no benefit in me doing this (three-month assessment) because I am in the control group anyway.

These practical challenges in trial management are important considerations for designing any clinical study. Participants in this study were eager to receive the intervention and were reluctant to risk missing out on a therapeutic treatment that could potentially enhance their chances of improvement. This eagerness identifies the need for careful planning and communication to address participants' concerns and manage their expectations effectively.

Discussion

The primary goal of clinical research is to generate high-quality, robust findings that can inform and advance evidence-based practice. Embedding quality research into practice is a priority for occupational therapy as a profession to enhance the accessibility and impact of occupational therapy interventions (Liddle *et al.*, 2024). Evidence-based practice is tripartite, requiring the integration of scientific research evidence with clinical expertise and patients' values and preferences to develop targeted interventions that improve health outcomes (Eldredge, 2024). However, maintaining research purity within the pragmatic realities of clinical stroke rehabilitation presents significant challenges. Our study explores the multifaceted barriers to screening and recruitment in clinical settings and contributes to the broader discussion on improving clinical trial design methodologies. Previous authors have highlighted that occupational therapists have a professional responsibility to support research and that occupational therapists should guide future practice using robust evidence (Drummond and Lannin, 2020). However, our findings highlight the complexity of RCTs in clinical settings and evidence that occupational therapy clinicians and patients struggled to align the demands of high-quality research methods with perceived risks to patient outcomes. Key challenges included patient recruitment, randomisation, process fidelity and retention through follow-up.

Mirror box therapy, though not widely adopted, is recommended by the *National Clinical Guideline for Stroke for the UK and Ireland (2023)* as potentially useful in stroke rehabilitation. Although some evidence supports its use (Thieme *et al.*, 2018; Yang *et al.*, 2018; Zeng *et al.*, 2018; Zhang *et al.*, 2021), robust evidence for its efficacy is lacking, highlighting the need for high-quality trials comparing it to other rehabilitation approaches used by occupational therapists. The implementation of research in clinical practice faces significant challenges (Bayley *et al.*, 2012; Grimshaw *et al.*, 2001), particularly when testing treatments, like mirror box therapy, which are used clinically in occupational therapy practice despite limited evidence.

In the "real world" of clinical practice, occupational therapists often draw on their clinical experience, using therapy treatments they believe may benefit patients, even without strong evidence. This was evident in our study where an unexpected therapist-led clinical dilemma, added to the trial's "tribulations" as clinicians hoped patients would be allocated to the intervention arm due to perceived suitability and potential to possibly benefit from mirror box therapy. Similarly, patients and families, motivated by the desire for the best recovery outcomes and a fear they might miss out on beneficial

therapy, exhibited bias in treatment preferences and retention in the study. The informed patient/family may seek out specific treatments in the hope of best outcomes, as seen when some control group participants purchased their own mirror boxes. Although the focus of the REfLECTS trial is mirror box therapy, issues identified potentially apply to all rehabilitation research involving the delivery of an intervention where the therapist and the patient cannot be blinded to the intervention or the allocation.

Bias in quantitative and qualitative health-care research has been considered in the literature (Florczak, 2021), and our study had implemented recommended strategies to mitigate it. Trial clinicians received rigorous protocol training, participated in weekly support meetings and engaged in bi-monthly trial meeting discussions to discuss dilemmas arising and optimise recruitment while adhering to study guidelines. Despite these measures, therapist-led clinical dilemma persisted. Our findings also highlight the ethical dilemmas in randomisation, where clinicians' commitment to doing the best for their patients, or "beneficence" (Varkey, 2021), conflicts with trial methodological requirements. In our study, this conflict was exacerbated by the reduction in hospital stays during COVID-19, which decreased the window for rehabilitation available, increasing ethical pressures to use all available treatments to enhance patient recovery in the knowledge that early interventions are most influential in recovery. Our study highlights some of these ethical issues occupational therapy clinicians face in clinical trials when acting as both research generators and research consumers and the possible conflict between these dual roles. This ethical dilemma underscores the need for structured education programs for trial staff recommended by Eborall *et al.* (2014) to support decision-making and manage these conflicts.

The low recruitment rates in the REfLECTS trial contrasted with the success of the feasibility study and clinicians' "gut feeling", which was informed by their stroke experience and trial training. In our study, low recruitment rates were influenced by potential participants' reluctance to risk being placed in the control group adding to the trial burden for clinicians and raising ethical dilemmas about assuring participants that involvement wouldn't disadvantage their recovery. Acknowledging bias in research, fostering critical appraisal of its various forms and promoting greater reflexivity (Florczak, 2021; Jamieson *et al.*, 2023) can significantly enhance trial design and the implementation of clinical interventions.

The influence of research methodologies on implementing trial protocols has been highlighted (Skea *et al.*, 2017; Newington and Metcalfe, 2014). RCTs are valued for their rigor in eliminating bias and testing treatment effects (Ahn and Ahn, 2010; Hariton and Locascio, 2018). However, the reality of implementing RCTs in clinical settings is difficult, particularly when the nature of the intervention renders blinding impossible. Our findings highlight the difficulties of controlling rehabilitation interventions and suggest that factors like therapist-led dilemmas, therapy decisions and patient decision-making significantly influence trial success. Challenges with recruitment in clinical intervention RCTs including those with stroke patients is acknowledged in the literature (McGill *et al.*, 2020; Schulz *et al.*, 2006; Taylor-Pilliae *et al.*, 2014). However, the disparity between trial

clinicians' "gut feeling" based on significant clinical expertise and the standardised screening criteria highlights a significant challenge in trial recruitment processes despite adherence to study protocols. These "real world" contextual factors are underreported in the literature and recognition of these trial recruitment issues can support improved transparency in the reporting of clinical intervention studies as they recognise the influence of positionality in clinical research (Jamieson *et al.*, 2023).

McGill *et al.* (2020) suggest that recruiting stroke study participants from community settings may be a more effective recruitment strategy as potential participants would be further along their recovery progress and may experience less psychological and physical stress. However, our study aimed to test an intervention in a sub-acute cohort, making early recruitment essential to the REFLECTS study and perhaps explaining some of the recruitment challenges we experienced. Although using multiple recruiters per site has been proposed as a pragmatic trial strategy (Ford and Norrie, 2016), our study found no direct correlation between the number of recruiters and improved enrolment, further emphasising the complexity of clinical trial recruitment.

Potentially alternative methodologies, like cluster randomisation, may be more effective in enhancing fidelity and reducing therapist dilemmas (Ahn and Ahn, 2010), however, this approach also has limitations, such as excluding non-eligible patients from receiving the intervention (Bayley *et al.*, 2012). Furthermore, cluster randomisation would not eliminate clinicians' (at a control group site) awareness of the treatment and their want to use it as part of supporting best patient outcomes. The idea of clinicians on a designated control site having to "withhold" an intervention that may benefit the patient aligns with the ethical principles of "non-maleficence" and "justice" (Varkey, 2021), not to deprive a patient of an intervention that may benefit them simply because they happen to be treated in a trial designated control site.

Our study underscores the importance of embedding reflexivity throughout the design and implementation of clinical intervention studies. Critical appraisal of bias, ethics and the positionality of research team members can strengthen study design, enhance data interpretation and ensure meaningful connections with the communities served (Jamieson *et al.*, 2023). Increased awareness of ethical dilemmas in RCTs can improve research literacy, helping practitioners critically evaluate findings and apply them effectively in clinical settings (Florczak, 2021). Rehabilitation therapies are complex interventions, and clinical trials differ from drug trials. Schulz *et al.* (2006) acknowledge the complexity of retaining this stroke population in research studies as potential participants may transition to another healthcare provider or care provider site, become medically unwell or die shortly before or soon after recruitment. Although our study did experience some of these challenges, attrition in the control group, where participants opted out to self-purchase mirror boxes to use it as a therapy modality themselves to enhance their opportunity for recovery, was unexpected. Retention in the REFLECTS trial was good in the intervention arm but problematic in the control group, particularly when participants saw others receiving the mirror box intervention on a clinical ward. This finding raises

questions about whether these participants, by opting out, were making informed decisions to maximise their recovery chances and underscores the need for strategies to reassure participants and clinicians about trial integrity and manage the ethical and practical challenges inherent in clinical trials.

Strengths and limitations of a Communities of Practice

Our CoP shared a common domain of interest and expertise in occupational therapy stroke rehabilitation and research. It provided a forum for learning and reflection on the experiences of conducting this clinical intervention RCT. A key strength of this approach was the inclusion of both clinicians and researchers, aligning with Farrar *et al.* (2022), who advocate for integrating clinicians into study design and delivery. In addition, Florczak (2021) suggests that CoPs can help safeguard against bias by fostering collaborative research. By pooling resources and expertise, CoPs can design studies that are more rigorous and representative, ultimately leading to more generalisable findings.

However, several limitations must be acknowledged. Our CoP was limited to the trial team and did not include trial participants or patient and public involvement (PPI). Including PPI could have provided valuable insights into patient perspectives (Florczak, 2021), potentially enhancing recruitment and retention in the study. Actively involving all interest holders in study design and implementation can improve recruitment, retention and overall engagement in RCTs. By considering how different interest holders perceive the research process, researchers can refine their methodologies to foster inclusivity and participant-centred approaches, ultimately leading to more meaningful and impactful outcomes. Furthermore, we recognise the influence of our positionality within this study. As a CoP we are not entirely objective; our experiences inevitably shape our interpretations and findings. Although we explicitly acknowledge this CoP approach throughout the paper, it is important to highlight that our intent is to share our experiences, reflections and learnings to inform and enhance future research. Adopting a reflexive approach is essential in clinical research, ensuring greater transparency and critical engagement with the complexities of trial implementation.

Conclusion

Our CoP study, based on a skilled community of occupational therapy clinicians and researchers, highlights the challenge of maintaining research purity in clinical trials and identifies the need for pragmatism and partnership with clinicians and researchers. High-quality research evidence for stroke rehabilitation and for the occupational therapy profession is essential and supporting these trials in practice requires consideration of clinical service structures, managing competing ethical factors and strategies to reduce clinicians' dilemmas and enhance participant engagement. Our findings identify key contextual factors that can improve clinical trial design and implementation, emphasising the importance of balancing purity, pragmatism and partnership.

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References

- Ahn, C. and Ahn, D. (2010), "Randomized clinical trials in stroke research", *Journal of Investigative Medicine*, Vol. 58 No. 2, pp. 277-281, doi: [10.231/JIM.0b\)13e3181c9b2d4](https://doi.org/10.231/JIM.0b)13e3181c9b2d4).
- Altman, D.G., Schulz, K.F., Moher, D., et al. (2002), "The revised CONSORT statement for reporting randomized trials: explanation and elaboration", *Annals of Internal Medicine*, Vol. 134 No. 8, pp. 663-694, doi: [10.7326/0003-4819-134-8-200104170-00012](https://doi.org/10.7326/0003-4819-134-8-200104170-00012).
- Bayley, M.T., Hurdowar, A., Richards, C.L., Korner-Bitensky, N., Wood-Dauphinee, S., Eng, J.J. and Graham, I.D. (2012), "Barriers to implementation of stroke rehabilitation evidence: findings from a multi-site pilot project", *Disability and Rehabilitation*, Vol. 34 No. 19, pp. 1633-1638, doi: [10.3109/09638288.2012.656790](https://doi.org/10.3109/09638288.2012.656790).
- Braun, V. and Clarke, V. (2022), *Thematic Analysis: A Practical Guide*, SAGE, London.
- Chalmers, S., Hill, J., Connell, L., Ackerley, S.J., Kulkarni, A.A. and Roddam, H. (2023), "The value of allied health professional research engagement on healthcare performance: a systematic review", *BMC Health Services Research*, Vol. 23, p. 766, doi: [10.1186/s12913-023-09555-9](https://doi.org/10.1186/s12913-023-09555-9).
- Drummond, A. and Lannin, N.A. (2020), "Post-COVID-19: issues and challenges for occupational therapy and the need for clinical trials", *British Journal of Occupational Therapy*, Vol. 83 No. 12, pp. 721-722, doi: [10.1177/030802620972274](https://doi.org/10.1177/030802620972274).
- Eborall, H.C., Dallosso, H.M., Daly, H., Martin-Stacey, L. and Heller, S.R. (2014), "The face of equipoise—delivering a structured education programme within a randomized controlled trial: qualitative study", *Trials*, Vol. 15 No. 1, p. 15, doi: [10.1186/1745-6215-15-15](https://doi.org/10.1186/1745-6215-15-15).
- Eldredge, J. (2024), "Evidence based practice: a decision-making guide for health information professionals", *Albuquerque (NM): University of New Mexico Health Sciences Library and Informatics Center*, available at: www.ncbi.nlm.nih.gov/books/NBK603115/
- Farrar, N., Elliott, D., Houghton, C., Jepson, M., Mills, N., Paramasivan, S., Plumb, L., Wade, J., Young, B., Donovan, J.L. and Rooshenas, L. (2022), "Understanding the perspectives of recruiters is key to improving randomised controlled trial enrolment: a qualitative evidence synthesis", *Trials*, Vol. 23 No. 1, pp. 1-17.
- Florczak, K.L. (2021), "Best available evidence or truth for the moment: bias in research", *Nursing Science Quarterly*, Vol. 35 No. 1, pp. 20-24, doi: [10.1177/08943184211051350](https://doi.org/10.1177/08943184211051350).
- Ford, I. and Norrie, J. (2016), "Pragmatic trials", *New England Journal of Medicine*, Vol. 375 No. 5, pp. 454-463, doi: [10.1056/NEJMra1510059](https://doi.org/10.1056/NEJMra1510059).
- Grimshaw, J.M., Shirran, L., Thomas, R., Mowatt, G., Fraser, C., Bero, L., Grilli, R., Harvey, E., Oxman, A. and O'Brien, M.A. (2001), "Changing provider behavior: an overview of systematic reviews of interventions", *Medical Care*, Vol. 39 No. 8, pp. II2-II45.
- Hariton, E. and Locascio, J.J. (2018), "Randomised control trials – the gold standard for effectiveness in research", *BjOG: An International Journal of Obstetrics & Gynaecology*, Vol. 125 No. 13, p. 1716, doi: [10.1111/1471-0528.15199](https://doi.org/10.1111/1471-0528.15199).
- Hennein, R., Ggita, J.M., Turimumahoro, P., Ochom, E., Gupta, A.J., Katamba, A., Armstrong-Hough, M. and Davis, J.L. (2022), "Core components of a community of practice to improve community health worker performance: a qualitative study", *Implementation Science Communications*, Vol. 3 No. 1, p. 27, doi: [10.1186/s43058-022-00279-1](https://doi.org/10.1186/s43058-022-00279-1).
- Holliday, J., Jones, N. and Cooke, J. (2023), "Organisational benefits of undertaking research in healthcare: an approach to uncover impact", *BMC Research Notes*, Vol. 16 No. 1, p. 255, doi: [10.1186/s13104-023-06526-5](https://doi.org/10.1186/s13104-023-06526-5).
- Jamieson, M.K., Govaart, G.H. and Pownall, M. (2023), "Reflexivity in quantitative research: a rationale and beginner's guide", *Social and Personality Psychology Compass*, Vol. 17 No. 4, doi: [10.1111/spc3.12735](https://doi.org/10.1111/spc3.12735).
- Li, L.C., Grimshaw, J.M., Nielsen, C., Judd, M., Coyte, P.C. and Graham, I.D. (2009), "Evolution of Wenger's concept of community of practice", *Implementation Science*, Vol. 4 No. 1.
- Liddle, J., Redman, B., Frost, D., Worthy, P., Jamieson, P. and Wallace, S.J. (2024), "Inclusive research: making more impact through accessibility and collaboration", *Australian Occupational Therapy Journal*, Vol. 71 No. 5, pp. 641-643, doi: [10.1111/1440-1630.12990](https://doi.org/10.1111/1440-1630.12990).
- McGill, K., Sackley, C.M., Godwin, J., McGarry, J. and Brady, M.C. (2020), "A systematic review of the efficiency of recruitment to stroke rehabilitation randomised controlled trials", *Trials*, Vol. 21 No. 1, p. 68, doi: [10.1186/s13063-019-3991-2](https://doi.org/10.1186/s13063-019-3991-2).
- McKim, C. (2023), "Meaningful member-checking: a structured approach to member-checking", *American Journal of Qualitative Research*, Vol. 7 No. 2, pp. 41-52.
- National Clinical Guideline for Stroke for the UK and Ireland (2023), Intercollegiate Stroke Working Party, available at: www.strokeguideline.org
- National Office of Clinical Audit (2023a), "Irish national audit of Stroke National Report 2022. Dublin: National Office of Clinical Audit", ISSN 2737-7253 (Electronic).
- National Office of Clinical Audit (2023b), "Irish National Audit of Stroke: a critical review of national stroke data for

- Ireland from 2013 to 2021”, Dublin: National Office of Clinical Audit.
- Newington, L. and Metcalfe, A. (2014), “Researchers’ and clinicians’ perceptions of recruiting participants to clinical research: a thematic meta-synthesis”, *Journal of Clinical Medicine Research*, Vol. 6, pp. 162-172.
- NICE (2023), “Stroke and transient ischaemic attack. Stroke and transient ischaemic attack”, *Topic*, NICE.
- Raftery, J., Young, A., Stanton, L., Milnes, R., Cooke, A., Turner, D. and Davidson, P. (2015), “Clinical trial metadata: defining and extracting metadata on the design, conduct, results and costs of 125 randomised clinical trials”, *Health Technology Assessment*, Vol. 1, pp. 1-138.
- Ranmuthugala, G., Plumb, J.J., Cunningham, F.C., et al. (2011), “How and why are communities of practice established in the healthcare sector? A systematic review of the literature”, *BMC Health Services Research*, Vol. 11, p. 273, doi: [10.1186/1472-6963-11-273](https://doi.org/10.1186/1472-6963-11-273).
- Saldana, J. (2009), *The Coding Manual for Qualitative Researchers*, Sage, London.
- Schulz, C.H., Wasserman, J. and Ostwald, S.K. (2006), “Recruitment and retention of stroke survivors: the CARES experience”, *Physical & Occupational Therapy in Geriatrics*, Vol. 25 No. 1, pp. 17-29, doi: [10.1080/J148v25n01_02](https://doi.org/10.1080/J148v25n01_02).
- Skea, Z.C., Treweek, S. and Gillies, K. (2017), “‘It’s trying to manage the work’: a qualitative evaluation of recruitment process within a UK multicentre trial”, *BMJ Open*, Vol. 7 No. 8, doi: [10.1136/bmjopen-2017-016475](https://doi.org/10.1136/bmjopen-2017-016475).
- Taylor-Pilliae, R.E., Boros, D. and Coull, B.M. (2014), “Strategies to improve recruitment and retention of older stroke survivors to a randomised clinical exercise trial”, *Journal of Stroke and Cerebrovascular Disease*, Vol. 23 No. 3, pp. 462-468.
- Thieme, H., Morkisch, N., Mehrholz, J., Pohl, M., Behrens, J., Borgetto, B., et al. (2018), “Mirror therapy for improving motor function after stroke”, *Cochrane Database of Systematic Reviews*, Vol. 2018 No. 7, p. CD008449.
- Varkey, B. (2021), “Principles of clinical ethics and their application to practice”, *Medical Principles and Practice*, Vol. 30 No. 1, pp. 17-28, doi: [10.1159/000509119](https://doi.org/10.1159/000509119).
- Wenger, E. (1998), *Communities of Practice: Learning, Meaning, and Identity*, Cambridge University Press, Cambridge, doi: [10.1017/CBO9780511803932](https://doi.org/10.1017/CBO9780511803932).
- Wottrich, A., Braekke, I., Johansson, L. and von Koch, L. (2023), “Therapists acting as data collectors in a post stroke research project – a door to development”, *Topics in Stroke Rehabilitation*, Vol. 30 No. 1, pp. 101-107, doi: [10.1080/10749357.2021.1956045](https://doi.org/10.1080/10749357.2021.1956045).
- Yang, Y., Zhao, Q., Zhang, Y., Wu, Q., Jiang, X. and Cheng, G. (2018), “Effect of mirror therapy on recovery of stroke survivors: a systematic review and network meta-analysis”, *Neuroscience*, Vol. 390, pp. 318-336.
- Zeng, W., Guo, Y., Wu, G., Liu, X. and Fang, Q. (2018), “Mirror therapy for motor function of the upper extremity in patients with stroke: a meta-analysis”, *Journal of Rehabilitation Medicine*, Vol. 50 No. 1, pp. 8-15.
- Zhang, Y., Xing, Y., Li, C., Hua, Y., Hu, J., Wang, Y., et al. (2021), “Mirror therapy for unilateral neglect after stroke: a

systematic review”, *European Journal of Neurology*, Vol. 24, p. 24.

Further reading

Health Service Executive (2023), “National Stroke Strategy 2022-2027. Dublin: Health Service Executive”, available at: www.hse.ie/eng/about/who/cspd/ncps/stroke/moc (accessed 2 September 2024).

Appendix. Focus group guide

Exploring experiences of screening and recruiting for a clinical trial in stroke focus group guide

The purpose of this focus group is to gather your views and experiences of screening and recruiting participants for the REfLECTS clinical trial.

This guide has been collated to help you prepare for the focus group by outlining the broad topics we are interested in hearing your views and opinions on. We would ask you to consider these topics in advance of the focus group. This guide is not exclusive and if you have other topics you feel are important to discuss, you can of course do so during the focus group.

Real-life experience of being involved in a clinical trial

- How did your expectation of screening and recruiting participants translate into the real life/actual experience of recruiting?
- What do you feel were the challenges/barriers associated with recruitment? Was this unexpected?
 - What worked well and less well in your site when screening and recruiting?
 - Recruitment targets weren’t met for this trial – what do you think were the main factors that contributed to that? Were you surprised when it came to formal screening that potential participants weren’t meeting the entry criteria?
- Were there any organisational/service delivery factors, which impacted screening and recruitment (decreased length of stay, pressure on beds, potential patients all on the one ward or dispersed around the hospital, acute v rehab beds/sites, staff pressures)?
- What are your thoughts on complexity of the screening measures and tools, and any associated impact?
- Did you find that there was a mismatch between your gut feeling and functional assessment of who would be suitable for the trial and how they scored on the screening measures? Note the high number screened out without upper limb loss – was this the typical pattern of presentation before the trial started?
- Timing of study recruitment in hyperacute/ acute phase of stroke – Do you think that the potential participants had an expectation of recovery that impacted their readiness to engage? Do you think this impacted on recruitment/ those who declined?
- What about those potential participants who declined to participate – why do you think this was? Did you notice any patterns to the “declining” patients – age, gender, time of year (i.e. Christmas). Do you think there is

anything we could have done differently to improve engagement?

- 8 What service delivery changes introduced/imposed during COVID impacted on your ability to conduct screenings at your site?

Reflections on self as a clinical therapist in a randomised control trial

- 1 As a clinician did you feel equipped, skilled and prepared to implement this research as part of your daily practice?

- 2 What was your learning as a clinician involved in a clinical trial?
- 3 Do you think that occupational therapy as a profession is ready to be involved in this type of trial in practice?

Thank you for your consideration of these questions. We look forward to discussing these at the focus group.

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