Clinical Rehabilitation

Recruitment challenges in stroke rehabilitation randomised controlled trials – a qualitative exploration of trialists' perspectives using Framework Analysis

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Recruitment challenges in stroke rehabilitation randomised controlled trials – a qualitative exploration of trialists' perspectives using Framework Analysis

Kris McGill[1,3], Catherine Sackley[3], Jon Godwin[2], Jodie McGarry[2], Avril Nicoll [1,4], Marian C Brady[1]

1. Nursing, Midwifery and Allied Health Professionals Research Unit, Glasgow Caledonian University, Glasgow

2. Glasgow Caledonian University, School of Health and Life Sciences, Glasgow

3. King's College London, School of Population and Environmental Sciences, Facility of Life Sciences and Medicine, London

4. Health Services Research Unit, University of Aberdeen, Aberdeen

Corresponding author: Kris.mcgill@gcu.ac.uk

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Abstract (236/250)

Objective: To explore the underlying reasons for recruitment difficulties to stroke rehabilitation randomised controlled trials from the perspective of trialists.

Design: A qualitative study using semi-structured interviews and Framework Analysis.

Participants: Twenty multidisciplinary stroke rehabilitation trialists across 13 countries with a range of clinical and research experience.

Methods: Twenty semi-structured telephone interviews were carried out. Purposeful sampling ensured a range of opinions were gathered from across the international stroke rehabilitation research community. Using Framework Analysis, the analytical framework was formed by three researchers and tested before being applied to the total dataset.

Results: Three themes described the trialists' perception of the underlying reasons for recruitment difficulties; i) decision making, ii) importance of recruiters, and iii) a broken system. Trialists described frequently disregarding evidence in favour of prior research experiences when planning randomised controlled trial recruitment. All felt that the relationship between the research and clinical teams was vital to ensure recruiters prioritised and found value in recruitment to the trial. Experienced trialists were frustrated by the lack of reporting of the reality of running trials, research governance demands, and the feeling that they had to deliberately underestimate recruitment timeframes to secure funding.

Conclusions: Stroke rehabilitation trialists described recruitment difficulties which may be related to their experiential based recruitment decision making, a lack of understanding of how best to incentivise and maintain relationships with recruiters, and unrealistic bureaucratic expectations both in terms of gaining funding and research governance.

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Introduction

Many stroke trialists experience recruitment difficulties risking inaccurate or misleading results (1-3). Recruitment to randomised controlled trials can be difficult. Trials may end with small samples sizes which, through lack of statistical power, increase the risk of results being falsely identified as positive (type I error) or negative (type II error) (4-6) and an inability to determine how well a treatment has worked (7-10). Large acute stroke trials (>300 participants) published between 1990 and 2004 recruited fewer than one participant per site per month (1) and an update of studies published in 2014 illustrated that recruitment is getting more difficult (2). Stroke rehabilitation trials are complex and may experience increased recruitment difficulties due to the involvement of multidisciplinary teams, the variance in settings, and the variety of interventions used (11). Despite notable difficulties recruiting stroke survivors, and limited improvement over the past two decades (3, 12), little research has focused on trialists' perspectives of recruitment for stroke trials. Trialist's have wealth of recruitment knowledge that they often do not get the chance to share widely.

Qualitative recruitment research has to date focused on the perspective of the recruiter, exploring: the importance of the relationship between clinical and research teams (13), the importance of value for clinicians who recruit trial participants (13), difficulties caused by the lack of allocated recruitment time, and difficulty factoring recruitment time into clinical roles (14). However, it is important for clinicians to appreciate the difficulties that trialists experience when planning recruitment (15).

One qualitative study has explored recruitment forecasting (estimating the time required for recruitment) from the perspective of trialists (15), highlighting problems caused by: the difficulty realistically determining required recruitment time, issues with trialists basing predictions on only successful recruitment experiences, and a tendency to optimistically forecast recruitment at the grant application stage (15). This forecasting study was focused on trials based in primary care settings rather than stroke rehabilitation trials. Recruitment difficulties have not been explored qualitatively from the perspective of the trialists who plan and deliver stroke rehabilitation randomised controlled trials. We aimed to explore the potential reasons for recruitment difficulties for stroke rehabilitation randomised controlled trials, from the perspective of trialists.

Method

We received ethical approval from the Glasgow Caledonian University's School of Health and Life Sciences ethical committee (HLS/NCH/16/027) in September 2017. Electronic consent was provided via email prior to interviews. Interview responses and transcripts were confidential. Trialist and trial identifiers were removed from transcripts.

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We used purposeful sampling (16), the process of actively recruiting individuals based on pre-determined criteria, to ensure that trialists represented a range of clinical backgrounds, worked in a number of different countries, and had differing degrees of trial planning experience. Participants were included if they had been involved in the planning of at least one stroke rehabilitation randomised controlled trial and were excluded if they had not planned a trial in the last ten years. The target sample was twenty stroke rehabilitation trialists, in keeping with other qualitative studies of recruitment (13-15, 17), and anticipated to be sufficient to reach data saturation due to the specificity of the questions being posed (Appendix A)(18, 19). Data saturation was confirmed when no new important information was presented in the final few interviews (18, 19). Invitation emails, including the information sheet and study protocol, were sent to 177 stroke rehabilitation trialists identified by applying the purposeful sampling criteria to authors contacted during an earlier systematic review (20). Initially 22 trialists responded, indicating an interest in participation, however, one trialist later declined without providing a reason and another was excluded as they had not conducted a stroke rehabilitation trial within the last 10 years. Interviews were conducted between November 2017 and January 2018.

Semi-structured telephone interviews were carried out at Glasgow Caledonian University and were selected because they facilitate rich data collection and supported comprehensive evaluation of the research questions (21-25). In line with qualitative methodologies (26), our interview schedule was informed by an exploration of recruitment barriers (14, 15, 27) and the findings of a recent systematic review on the topic (11). Our interview questions were piloted with two researchers with experience of stroke rehabilitation randomised controlled trials and qualitative research methodologies. After piloting, a specific question on 'gatekeepers' was added to the interview schedule. Interviews were digitally recorded, transcribed verbatim, anonymised, and transferred into NVIVO for analysis (28). Interviews were conducted during KM's PhD fellowship with the assumption that there were difficulties with recruitment of stroke survivors for clinical trials. Framework analysis was selected because it is considered one of the most transparent methods of qualitative data analysis. The process supports the involvement of researchers from different backgrounds and perspectives, and all analysis procedures are undertaken systematically (29, 30).

We applied the seven-step Framework method for analysis to support data preparation and analysis (31). This included (i) transcription (ii) familiarisation with the interview (iii) coding (iv) developing a working analytical framework (v) application of the analytical framework, (vi) charting data on to a framework matrix and (vii) data interpretation. Three researchers (KM, JM, AN) with different clinical and research backgrounds developed the working analytical framework. KM, JM, and AN independently coded three transcripts before meeting to discuss codes. A working

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framework was developed by discussing the areas that individual researchers identified as important and the most appropriate label for that code. Two researchers (KM, JM) then independently coded two further transcripts using the modified framework followed by discussion of how the working analytical framework had performed, making final changes as required and creating the final analytical framework (Appendix B). The remaining 15 transcripts were analysed using this framework (KMcG).

During the final analysis KM, supported by discussions with the rest of the team, developed final themes by going beyond individual cases, making connections between responses, and looking at the data as a whole. Themes developed by KM were challenged by other team members as were the choices of which excerpts to use. Matrixes and Memos were utilised to represent and develop the themes. All discussions were used to form the final interpretation of the data and to select excerpts that best reflected the data.

Results

Table 1 highlights the descriptive data for the included sample of stroke rehabilitation trialists.

Insert table 1 around here

Our data analysis produced three final themes: decision making, importance of recruiters, and a broken system (Figure 1). We examined what informed trialists' decision-making around recruitment, their perspective on the role of and relationship with recruiters, and their experience operating in what they described as a 'broken system'. Information on each trialist's level of experience is presented after each quote.

Insert figure 1 around here

Decision making

Trialists' described how their recruitment planning decisions were driven by a number of factors: evidence, funding, and the clinical question. While the research question influenced the choice of participants and settings, trialists reported that they did not routinely draw on an evidence base which may be found in reports of successful strategies adopted by other trials, reports and estimations provided by clinical teams at site, past performance of research networks, and methodological publications of recruitment challenges for clinical trials. Trialists described their efforts to match their recruitment plans to the funding they thought they could realistically receive.

Evidence-based decision making

Many trialists acknowledged a lack of reference to recruitment evidence:

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> *'A lot of it is you jump into it, you crush your figures, you hope for the best….'*
> *(Trialist 12 [T12]; stroke rehabilitation researcher for 25 years [25y] , contributed*
> *to 20 stroke rehabilitation trials [20 Trials]).*

Some senior trialists expressed that instead of evidence they relied upon their academic and research seniority during the grant writing stage so that funders were less likely to challenge recruitment predictions:

> *'I kind of keep it vague and pull out my, "I'm a professor. Bog off. I know what*
> *that takes".' (T19, 16Y, 12Trials).*

Many trialists adopted a recruitment rate of *one-participant-per-site-per-month*, with no clear evidence to support this expectation. Experience and shared knowledge seemed to be the primary consideration:

> *'My rule of thumb is that you will get one patient per site per month… Every study*
> *I've ever done, regardless of what it is, where it is, who it's with, that's what*
> *happens.' (T19, 16Y, 12Trials)*

Some trialists cautioned against disregarding evidence. Some sought to determine how many stroke survivors might be available and in turn increase accuracy of their recruitment predictions:

> *'I asked them [clinical team] to go through the current ward list, screen against*
> *the eligibility criteria to tell me how many people were there at the moment.*
> *Then we did that a couple of times over a period of three months' (T20, 6Y,*
> *1Trials).*

Trialists also considered the past performance of their research network: 'We have got very clear ideas about what is possible within clinical networks' (T8, 30Y, 10Trials). However, the accuracy of such retrospective-based information gathering approaches is questionable. Eligibility criteria are difficult to apply because admission and clinical networks records may not contain the necessary information for accurate comparisons.

Funding-based decision making

Some trialists said that they determine how much funding is required to achieve the recruitment target, and approach funders with clear requirements. However, some described maximising the

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use of available funding, suggesting that, from their perspective, the true trial funding requirement was unattainable:

> *'Unfortunately, it is a bit of a game of what can we do with the money that the funding agency is going to let us have...' (T13, 20Y, 4Trials).*

Some trialists did not appear to use a-priori recruitment targets, instead recruiting for as long as resources allowed:

> *'We tend to recruit until we really are running out of money and time' (T13, 20Y, 4Trials).*

Question-based decision making

Trialists were clear that the research question affects which stroke survivors are recruited and from what environment. The variability in the conditions and methods used for each stroke rehabilitation trial make the tailoring of recruitment methods vital for successful recruitment:

> *'Our research questions are mainly focused on physical activity in the community... if your research question is more about effectiveness of interventions in more acute or sub-acute stages then [you] have to go to hospitals to recruit your participants' (T11, 10Y, 2Trials).*

Importance of recruiters

Trialists highlighted the importance of the recruiters that are responsible for the onsite face-to-face recruitment of stroke survivors and the relationships between them and the core research team. To different extents, they felt it was important for the recruiter to find value in their contribution, to build relationships and trust, and to understand both the recruiter's capacity and priority. As this study was international there were many different types of recruiters described including: dedicated recruitment staff funded by organisations (e.g. clinical research network staff in the UK), employment of research assistants to work in a recruitment capacity, and the use of clinical staff who recruit alongside their clinical roles. We sought to identify common features between different recruitment staff approaches, however, trialists mostly discussed recruiters who have competing demands on their time (particularly clinical staff recruiters and research network staff).

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Value for recruiter

Recruiters finding value in trial participation was described as vital in order to maintain motivation and successfully recruit to the trial:

> *'You've got to look at how you can make your trial more attractive to people recruiting for it' (T2, 25Y, 10Trials).*

Making trial recruitment appealing to clinical staff may be a difficult task with trialists expressing differing opinions on how to achieve this. Common approaches included: 1) small incentives: 'We send them in cookies.' *(T2, 25Y, 10Trials)*, 2) training and research mentoring: 'I go and do in-service training for them and quite a bit of mentoring for people who are interested in doing research.' *(T19, 16Y, 12Trials)*, 3) newsletters: 'The newsletter became really popular between the sites *(T3, 28Y, 11Trials)*, and 4) healthy competition between sites: 'Never underestimate competition.' *(T2, 25Y, 10Trials)*.

However, incentives may not always be enough in the face of intensive workloads and clinical pressures:

> *'You cannot ask clinicians who are already very busy to do some extra work.' (T9, 12Y, 4Trials).*

Many trialists believed the only way to guarantee value for recruiters was to employ them on the trial:

> *'The reality is that I will never run a trial unless I employ an independent recruiter. That is part of the funding… people who you employ and pay…even if they're not invested in the project to begin with, I think they become invested in it.' (T14, 25Y, 20Trials).*

Relationships and trust

Trialists expressed the importance of building and maintaining positive working relationships between recruitment and research staff. They felt a mutually beneficial relationship created a positive working environment:

> *'What we try to do is really make people feel part of the big practice team. In fact, we never called it a team, we called it a family… And those things oil the wheels in terms of making people feel valued' (T15, 15Y, 14Trials).*

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There seemed to be a consensus that the communication style used to form relationships must be friendly and appreciative of the difficulties that the recruitment team experience:

> *'We just have lots and lots of dialogue. Lots of support and no blame. Never, never, any blame, only lots of understanding. Lots of understanding. Lots of congratulations.' (T15, 15Y, 14Trials).*

Trialists found that any approach perceived as hostile or accusatory could lead to a breakdown in relationships. Furthermore, relationships maintained by congratulatory contact were described as the most likely to motivate recruiters, creating a supportive rather than pressurised working environment. This seemed to hold true even if recruitment was not going well:

> *'We trained the recruiters, we followed up with them regularly, with friendly, cheerleading kind of emails, saying, ''Hey, you're doing a great job''. But, in fact, they were not doing a good job.' (T18, 12Y, 5Trials).*

Personal (rather than electronic-based) communication was described as important:

> *'Don't rely on email. You need personal contact with people. You need to pick the phone up. You need to get off your backside and go and visit people.' (T2, 25Y, 10Trials).*

However, this emphasis on providing support and encouragement was not the only strategy trialists used. One trialist described their controversial strategy saying:

> *'I use women on maternity leave. They can drag a baby with them…they become invested.' (T14, 25Y, 20Trials).*

Recruiter capacity and priority

Trialists felt that clinical staff did not always view trial recruitment as a priority. One suggested reason was the lack of financial acknowledgment of their time:

> *'It's not a priority for the clinician in most of the trials. So they may be involved even without receiving any compensation for it. So they don't prioritise of course.' (T7, 7Y, 6Trials).*

Diffusion of responsibility was thought to play an important role. Trialists believed that, where more group members were responsible for the action, an individual was less likely to perform the task:

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'Well, at least one and just preferably two but not more than two because otherwise they don't feel as involved anymore… Yes, I think then the shared responsibility factor comes' (T5, 9Y, 1Trials)

Trialists recognised the context in which clinical recruiters were operating, and that they must have the capacity within their job role to successfully recruit to the trial:

'It's just a very busy, hectic environment… pinning the nurses down, and getting them to help us with recruitment was really difficult.' (T10, 16Y, 3Trials); 'I mean at the moment the NHS is in meltdown and asking people to do extra things (recruitment), it doesn't happen and I think that's perfectly reasonable.' (T19, 16Y, 12Trials).

To address lack of staff capacity, they tried to make trial recruitment as easy as possible:

'Try to make it minimal work as possible for whoever is doing the recruitment…' (T8, 30Y, 10Trials).

A broken system

Trialists described operating within systems that they perceive as 'broken'. Trialists identified these systems as the processes for securing research funding and the research governance associated with trial conduct. They described playing the system in order to receive funding for trials. This issue is reinforced as knowledge of the underlying system-based problem may be kept hidden rather than being made transparent. Trialists were pessimistic about the prospect for improvement because demands of research governance are perceived as hampering rather than facilitating recruitment. Most trialists in this study described their respective country's funding and governance systems as flawed. Therefore, the 'broken system' theme is not reflective of any single country or trialist's perspective.

'Playing the system'

Some trialists were overly optimistic when planning recruitment duration (and other aspects of trial development) in order to secure funding:

'To be blunt, if you were honest about how long it was going to take no funding body is really going to think it's that attractive…. and I'm sure this is the reality for most people, you probably aren't that honest about what you're going to say is the recruitment time' (T2, 25Y, 10Trials).

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Some exaggerated recruitment timeframes so that it looked achievable within the funder's expectations:

> *'… we actually overemphasise the recruitment rate, because otherwise we're never going to make it look like we're going to get a sample. Some funding bodies only have a 12-month time span to spend their money…' (T17, 14Y, 5Trials).*

One trialist described the process of exaggerating recruitment timeframes as: 'the secret that dare not speak its name.' *(T19, 16Y, 12Trials).* If this is the case, there are potential knock-on effects for the research community as trialists worried that anyone who realistically outlines recruitment timeframes would be perceived as slow and inefficient and would not receive funding:

It is important to note that only the most experienced researchers (more than 20 years' experience) talked openly about 'playing the system'. Less experienced researchers described striving to generate as accurate a prediction as possible. More senior researchers indicated they were more likely to admit that they were exaggerating recruitment rates, as they had built their career and reputation already:

> *'Yes, so when you're as old as me, and you've been there and done it, and actually you just think, to hell with it, tell the truth.' (T2, 25Y, 10Trials).*

There were indications that some trialists were aware of this practice, but they stressed the need for accuracy and transparency when making recruitment predictions:

> *'I would always really, really, warn people against deliberately overestimating to make it look better to a funder, because you need the money, and you need the contingency money to do it properly.' (T15, 15Y, 14Trials).*

Non-transparent trial knowledge

A lack of transparency relating to recruitment experiences in published research made it difficult for trialists to benefit from previous recruitment planning experiences. They believed that, while reporting can be restricted by word counts, omission of recruitment details contributes to research waste:

> *'When you're publishing a trial, you don't have many words and … everybody's looking for flaws in the study. So, you never actually report … all the stuff you went through to actually do the recruitment, because you have to report it going, oh look, we had this good idea, we did this and it all worked, it was terrific. You're*

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not…I mean I think there's a big thing about not sharing the realities of running
these particularly of complex interventions. It's a bloody nightmare, to be honest.'
(T19, 16Y, 12Trials)'

One participant recognised the wider value of their recruitment experience and highlighted the potential of publication options such as supplementary materials to overcome limited word counts:

'Very often you go and you read a trial and you really want to know certain things
about how they've done something and it's just not presented. We very often
publish the methodology separate from the trial so that we can give more details
about, well, how did we recruit' (T16, 15Y, 6Trials).

Research governance

Trialists expressed frustration with research governance which they perceived as inhibiting recruitment:

'I think the biggest barrier is the way that the data protection laws are
interpreted and implemented. There's kind of no sense of proportionality about it.
*It's just bonkers... it's like so much of the Ethics. You think, "Oh for f***s sake."'*
(T19, 16Y, 12Trials).

Research governance was described as impossible to navigate without having a contact within the system:

'It's quite extraordinary. I don't know how you'd do it if you didn't have a contact
there… It would just be impossible'. (T14, 25Y, 20Trials).

Senior trialists witnessing the vast changes in research governance over the past three decades described it as 'overkill' *(T2, 25Y, 10Trials)* and detrimental to recruitment. Attempts to streamline the process were perceived to have failed, only making things more convoluted:

'In my career there have been vast changes in research governance but it's like
an onion, there is layer upon layer of research governance and ethics. I don't
actually think it improves the quality of the trials or the studies that we do. I think
that people talk about streamlining which makes me laugh. I mean, I have no
idea what their idea of streamlining is but none of this is streamlined.' (T2, 25Y,
10Trials).

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The area that elicited the most frustration from senior trialists was the increasingly complex consent processes that are now required:

> *'I feel like a double-glazing sales (person) sometimes when I consent people, when I say "...and initial here, here and here and this is a copy of the form to keep"... I think we have gone completely mad.' (T2, 25Y, 10Trials).*

Trialists felt that the procedures required were disproportionate for a rehabilitation study, compared to the requirements for drug or surgery trial:

> *'I understand it's a human rights issue, but it should be graded, 'cause there is a big difference between what we do with people, and pumping them full of new drugs.' (T10, 16Y, 3Trials).*

Trialists expressed a very clear desire for review and reform of research governance procedures because it may be a key contributor to the recruitment difficulties experienced by trials:

> *'So I think it's a radical think about our research governance and really whether it's fit for purpose and I would throw most of it out the window and we would optimise our recruitment overnight.' (2, 25Y, 10Trials).*

Discussion

Our study highlighted some of the underlying contributors to recruitment difficulties described by international stroke rehabilitations trialists. The themes identified were consistent across trialist responses despite our sample being reflective of a wide range of countries, stroke rehabilitation interventions, and differing research governance systems. Although our results are specific to stroke rehabilitation randomised controlled trials, the results are likely reflective and informative for other aspects of rehabilitation and recruitment to other research study designs. Three themes were identified: i) decision making, ii) the importance of recruiters, and iii) a broken system.

Our participating trialists perceived that many recruitment difficulties experienced stemmed from the trial planning, grant application, and development stages. Trialists described some disregard for the necessity of planning trial recruitment based on available evidence which may be a consequence of the current lack of stroke rehabilitation randomised controlled trials recruitment research. Most trialists reported basing recruitment decisions almost exclusively on their past experiences, a process which has been described as difficult and prone to selection biases (15, 32,

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33). Furthermore, much of the knowledge required for successful recruitment planning was described as hidden during trial reporting. While publication word count limits may contribute, this may reflect an environment where trialists fell that reporting the realities of recruiting to a trial could reflect poorly on their trial design and conduct.

Previous research, looking at how to incentivise clinicians to recruit, stressed the importance of value in participation but gave no clear indication of how trialists might create this (34). The participants in this study reported that value for the recruiter can come from the social aspects of trial recruitment, which creates an environment where the recruiter is helping the trialist who they trust and have a good working relationship with (13). They believed that the number of recruiters at each site plays a key role in the clinician's ability to make recruitment a priority. With larger numbers of recruiters at a single site there is greater diffusion of responsibility: the more people responsible for a task, the less likely any one person is to do it (35-38).

Political-economic factors were described as clearly influencing recruitment planning processes. Many trialists described presenting an overly ambitious recruitment rate or duration to funders. Trialists did not feel that an honest illustration of recruitment rate or duration would receive funding. However, presenting idealised recruitment rates sets trial recruitment up to fail. Pressure is placed on sites to recruit faster when this might not be possible. Recruiters in turn are aware that this occurs and have expressed concern over the allocation of short recruitment time windows (14). At trial level, this can create the need for recruitment intervention, extension, or early trial termination. The longer-term effect may be that this leads funding bodies to expect shorter recruitment time windows and increased site recruitment rates. Overly optimistic recruitment rates may contribute to a reluctance to fund trials which describe realistic recruitment predictions, because they are seen as requiring an excessive amount of time to recruit. Clinicians should understand that trialists are not deliberately underestimating recruitment timeframes, rather it may be that political-economic factors are forcing trialists into reducing timeframes.

Our qualitative exploration of recruitment difficulties is as far as were are aware, the first to have explored recruitment from the perspective of stroke rehabilitation trialists. Our topic guide was based on the findings of a systematic review, and three researchers with different academic and clinical backgrounds developed and implemented the analytical framework. Our international study's purposeful recruitment strategy ensured that we included participants with varying clinical and trial experiences from three continents and thirteen countries. Our Framework Analysis methods were transparent and systematic (29-31). Despite the purposeful sampling technique adopted, we were unable to recruit a trialist with experience of recruitment in an Asian country

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where trial recruitment has been reported to be more successful (11). Although our sample reflected diverse clinical backgrounds of stroke rehabilitation trialists we included more physiotherapists compared to other professions. Our study was informed by an international perspective and telephone interviews were an adequate alternative as the costs of face-to-face interviews could not be supported (39). Phone interviews may have affected trialists' responses and led to the lack of ability to observe body language (39, 40).

Our findings will enhance future trial recruitment through better understanding of the underlying issues contributing to recruitment difficulties. Recruitment to stroke rehabilitation trials can be improved by 1) trialists reviewing their own practices when planning and seeking trial funding support. Specifically, trialists should take a more evidence based approach to recruitment planning utilising reports of successful strategies adopted by other trials, reports and estimations provided by clinical teams at site, past performance of research networks, and methodological publications of recruitment challenges for clinical trials. Where recruitment evidence is not available this should be prioritised, and methodoglical research conducted to fill this gap. 2) A review of the bureaucracy surrounding clinical trial research is warranted, both in terms of the unrealistic research governance for stroke rehabilitation trials and the current system of trial funding. Funders should find a way to discourage trialists from competitive undercutting of recruitment timeframes which is likely directly leading to recruitment waste. 3) Clinical science involves humans, and for this reason the social aspect of relationships and trust between recruitment staff and research teams cannot be ignored. As recruiters often have other priorities, trialists need to be proactive in building and maintaining these relationships and providing incentives where possible. Tackling these issues using the steps outlined above could inform better rehabilitation for stroke survivors through a more robust interventions evidence base.

In addition to the steps that can be taken by trialists, funders, and governing bodies to improve recruitment, clinicians can assist recruitment by: 1) being as realistic as possible with how much time they have to conduct trial recruitment, 2) avoiding diffusion of responsibility and taking ownership of their vital role as a recruiter for the trial, 3) taking part in methods-based research exploring recruitment difficulties for trials, and 4) getting involved with the planning stages of trials in order to provide their perspective on successful recruitment.

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Clinical message:

Trialists described the recruitment difficulties that weaken the intervention evidence base as a consequence of:

- Relying on experience when making recruitment decisions
- A lack of understanding of how best to support recruiters
- Unrealistic bureaucratic expectations from research governance and problems with the system of how research is currently funded

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Recruitment challenges in stroke rehabilitation randomised controlled trials – a qualitative exploration of trialists' perspectives using Framework Analysis

Abstract (246/250)

Objective: To explore the underlying reasons for recruitment issues for stroke rehabilitation randomised controlled trials from the perspective of trialists.

Design: A qualitative study using semi-structured interviews and Framework Analysis to support thematic analysis.

Participants: Twenty multidisciplinary stroke rehabilitation trialists across 13 countries with a range of clinical and research experience.

Methods: Twenty semi-structured telephone interviews were carried out. Purposeful sampling ensured a range of opinions were gathered from across the international stroke rehabilitation research community. Using Framework Analysis, the analytical framework was formed by three researchers and tested before being applied to the total dataset.

Results: Three themes described the trialists' perception of the underlying reasons for recruitment difficulties; i) decision making, ii) recruiters, and iii) a broken system. Trialists described frequently disregarding evidence in favour of personal/past experience when planning randomised controlled trial recruitment. All felt that the relationship between the research and clinical teams was vital to ensure recruiters prioritised and found value in recruitment. Experienced trialists were frustrated by the lack of reporting of the reality of running trials, research governance demands, and the feeling that they had to deliberately underestimate recruitment timeframes to secure funding.

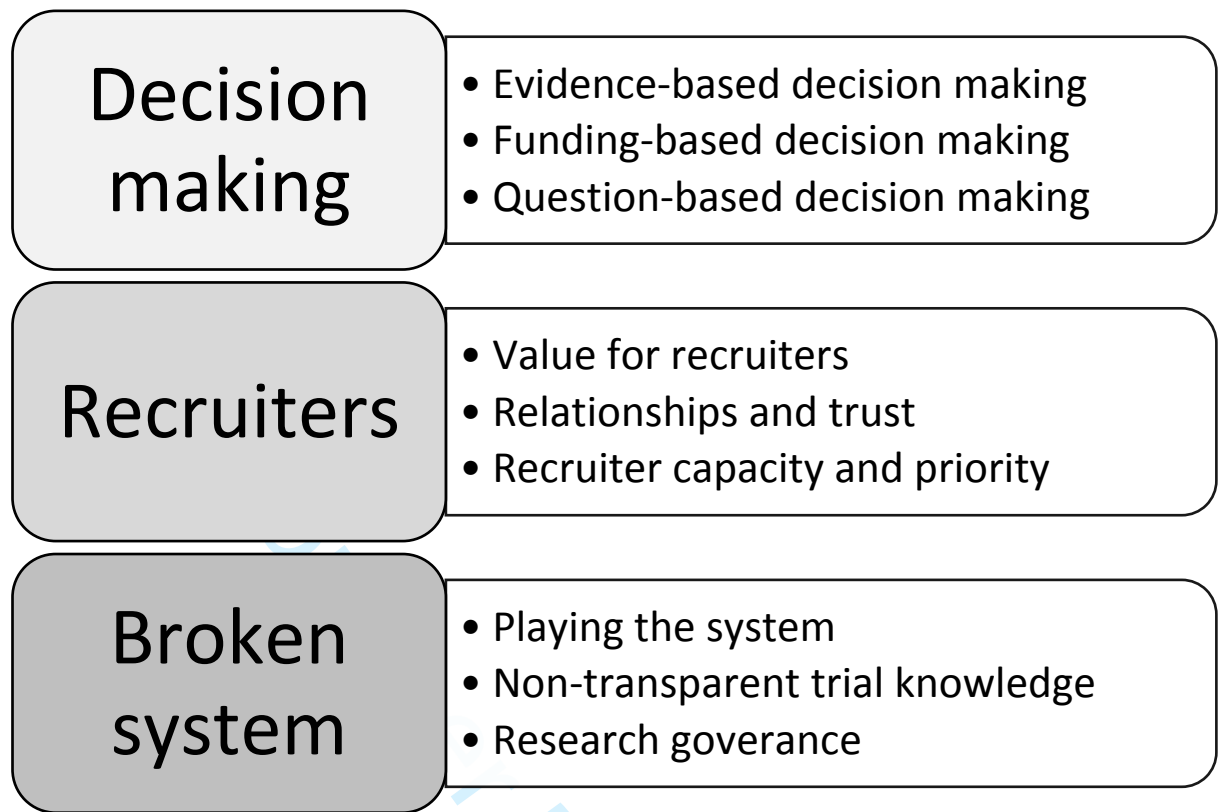**Conclusions:** Participating trialists perceived that many of the difficulties experienced in recruitment to stroke rehabilitation trials originate during trial development and grant writing. Trial recruitment tends to be based on experience rather than evidence, be influenced by political economic pressures to secure funding, and struggles to form and maintain meaningful relationships between clinical and research teams.

Table 1 – Descriptive data representing interview duration, stroke rehabilitation experience (clinical and research), number of trials conducted, professional background, and recruitment country

	Mean	Standard deviation	Min-Max
Years working as a stroke rehabilitation clinician	12.5	9.35	0 – 31
Number of stroke trials conducted	7	6	1 - 20
Years working as stroke rehabilitation trialist	15.85	7.26	6 - 30
Interview duration (mins)	30.65	8.09	18 - 45
	Categorical descriptor (frequency)		
Professional background	Occupational therapist (1), Physiotherapist (11), Speech and language therapist (1), Medic (3), Academic (1), Bioengineer (1), Neuro-psychologist (2)		
Country trialists had recruited from	UK (7), Australia (3), Canada (1), Netherlands (2), Norway (3), Brazil (1), New Zealand (1), Germany (3), USA (3), Belgium (1), Denmark (1), Spain (1), South Africa (1)		

Figure 1: The final themes and subthemes developed through the framework analysis

Decision making
- Evidence-based decision making
- Funding-based decision making
- Question-based decision making

Recruiters
- Value for recruiters
- Relationships and trust
- Recruiter capacity and priority

Broken system
- Playing the system
- Non-transparent trial knowledge
- Research goverance

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Appendix A

Topic	Questions
Basic information	**I'd like to start by asking you a few questions about your experience of stroke rehabilitation.** Could you tell me about any experience you have had working in a stroke rehabilitation setting? *(As a clinician, therapist, nurse, SLT etc.)* *For how many years did you work in this setting?* Could you tell me about any other experience working in a healthcare setting? *For how many years did you work in this setting?* How many years have you been working as a stroke rehabilitation researcher? How many stroke rehabilitation randomised controlled trials have you conducted? What was your role in designing or implementing these trials? In which country or countries were these trials conducted?
Recruitment planning	**Let's move on to a few questions about recruitment planning. The following questions do not refer to any one trial you have conducted. You are welcome to discuss your experience of recruitment from multiple trials or from a single trial. I would however ask you to only consider stroke rehabilitation trials.** For the trials that you have been involved in designing how much influence did sample sizes calculations have in the planning of your recruitment methods? *Could you tell me about the process?* Did you meet your sample size requirements for these trials? *If no: What in your opinion were the key reasons behind not meeting the targets?* *If yes: Did you meet these targets in the originally planned time? Or was an extension involved?* *Did you find it difficult to meet these targets?*

	Previous research has suggested that when trialists are planning RCTs they can be over-optimistic in their recruitment planning – Do you have any experiences of this?

Could you tell me about any experience you have had using gatekeepers to access stroke survivors for your trial?
Give them some examples of potential gatekeepers
Did this help or hinder recruitment

When preparing a grant application or your trial protocol, how do you estimate how much time to allow for recruitment?
Who is involved in this planning?
Where do you get the evidence for this decision from?
Is there somewhere else you would prefer to get this evidence form?

How do you decide upon the number of sites/wards/services to approach for participation?

How do you decide how many recruiters per site to have?

How do you decide where to recruit your stroke survivors from?
(hospital, rehab centre, home, support groups, etc.)

How do you decide what stage of rehabilitation to target?
Acute 0-1 month, sub-acute 1-6 months, chronic >6 months

Thinking about the questions above (referring to the number of sites, number of recruiters, location of recruitment, and stage of recovery) where do you get your evidence for making these decisions?
Is there somewhere else you would prefer to get this evidence from? |
| Recruitment implementation | **I would now like to ask you a few questions about the implementation of recruitment methods.**

When recruitment for the trial is underway how do you identify if there are any issues with recruitment?

At which point during the trial do you identify a problem with recruitment if there is one?

Could you tell me about any strategies you have used to boost recruitment when an issue has been identified?

Did any of these strategies work?
Why do you think they worked? |

	Did any of these strategies not work? *Why do you think they didn't work?*
Improving recruitment	**Finally, I will ask you a few questions about potential ways to improve recruitment.** Have you learned any lessons during recruitment that have affected or will affect the way you recruited in a future trial? *Could you tell me about these lessons?* Do you have ideas for optimising recruitment that you think might work but haven't been tested yet? Is there anything else you would like to add?

Appendix B

Final analytical framework

Lessons learned/ facilitators of recruitment success	

Theme	*Brief theme description*
Recruitment strategy efficiency	An explanation of the effectiveness or description of a specific recruitment strategy utilised by the trialist
'Playing the system'	A description of any process that implies steps that are taken in order to successful attract funding
Non-transparent trial knowledge	Any description of knowledge that is gained through experience that is not transparent and potentially not evidence based
Value for recruiters	Value in any capacity that is created or occurs for the recruiters within the trial
Recruiter capacity and priority	The capacity the recruiter has to recruit and/or mention of the priorities of the recruiter
Communication style	Any mention of communication styles
Relationship building	Any mention of the building of relationships between trial staff and recruiters/site staff
Research governance	Any description or criticism of the involvement of research governance
Stroke survivor characteristics	Description of the stroke survivor characteristics
Difficulties with recruitment predictions	Expression of the difficulties associated with making recruitment predictions
'Actually knowing what is going on'	Accurate knowledge of the recruitment process and within site recruitment
Recruitment blockages and barriers	Any exploration of recruitment blocks or barriers

Gatekeeper	Any description of the role of gatekeepers in either facilitation or the blocking of recruitment
'Cherry picking'	Any mention of the creation of a bias sample via the recruitment process
Recruitment intervention	A description of an intervention aimed at improving recruitment while the trial is underway
Rank in academia and potential entitlement	Mention of position within research hierarchy and/or language that suggests an entitled position
Culture	Any mention of the consideration of culture during trial recruitment
Approaching the patient	Description that includes reference to the approach of potential participants
Novel recruitment ideas	Any mention of novel/new ideas for future recruitment
Resource limitation	Issues with recruitment caused by limitations in resources
Incomprehension	An expression of Incomprehension regarding the reasons behind recruitment difficulties

Reasoning behind recruitment planning and decision making

Theme	*Brief theme description*
Question based decision making	Decision making processes governed by the question being asked
Honesty	Any suggestion of honesty or dishonest within the planning process
Experience lead decision making	Decision making that is led by the trialists previous experience of recruitment
Dropout consideration when planning	Taking dropout into consideration when planning trial recruitment

Funding based decision making	Decision making processes that are based on the funding that has or is to be awarded
Maintaining control	Decision making that is based on maintaining control of the trial, or the illusion of control
Contingency	Evidence of a contingency plan be part of the decision making/planning process

Identification and reaction to recruitment issues

Theme	*Brief theme description*
Honest dialogue	Honest dialogue between recruitment staff and trialists
Creating value for recruiters	An intervention used to create value for the recruiter while the trial is underway
Effective monitoring	Mention of the effective monitoring of the recruitment process
Tailored site predictions	Creating tailored predictions for each of the sites within the trial
Individual site monitoring	Individual monitoring for each site within the trial
'Find the modifiable'	Discussion of finding modifiable features within the trial
Stroke survivor characteristics	Assessment or adjustment based on the stroke survivors being approached for enrolment
Ethics	Any mention of barriers created by ethical processes during reaction to recruitment issues