Title:

The circular paradox of including people with severe brain injuries and reduced decisional capacity in research: a feasibility study exploring randomised research, consent-based recruitment biases, and the resultant health inequities.

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Abstract

Background: People with severe brain injuries (PSBI) and reduced capacity to consent (CTC) frequently develop muscle contractures. Standard care includes prolonged stretch (PS) but there is limited condition specific evidence from randomised controlled trials (RCTs).

Purpose: Identify factors affecting the inclusion of PSBI and reduced CTC in a PS RCT and methodologies more capable of generating condition specific outcomes.

Methods: Mixed-methods feasibility study, including a pilot RCT (PSBI, adults with reduced CTC) comparing PS treatments (serial casting and splinting) and focus groups/interviews with physiotherapists involved in PS treatment. Reflexive thematic analysis developed themes.

Results: Two PSBI were included in the pilot RCT with no significant safety concerns or adverse effects. Twelve physiotherapists participated in 2 focus groups and 2 interviews. Four themes were identified: 1. the complexity of contracture management; 2. the burden of decision making; 3. lack of evidence and uncertainty; 4. challenges to RCT acceptability and feasibility.

Conclusions: Reduced CTC contributes to the exclusion of PSBI from experimental research, and a circular paradox where poor research inclusion contributes to generalised healthcare and 'evidence-biased medicine'. Due to the complexity of their condition, simply including PSBI in randomised research is unlikely to create meaningful health outcomes. Improving their care requires a paradigm shift towards pluralistic methods of knowledge generation.

Key words: research inclusion, capacity to consent, evidence-based medicine, severe brain injury, muscle contracture.

Introduction

Reduced capacity to consent (CTC) effects approximately two million people in England and Wales (Shepherd, Hood, and Wood, 2022). An estimated 350,000 people in the United Kingdom (UK) have a neurological condition and physical disabilities necessitating specialist life-long care (Turner-Stokes et al, 2016, 2019). Under the Mental Capacity Act (MCA), decisions about their participation in research require a triadic collaboration between researcher, healthcare workers, and proxy (a nominated consultee able to contribute to recruitment decisions) (Mental Capacity Act, 2005). Despite the complexity, unpredictability, and vulnerability of their condition, lifelong dependency and high resource use, research about their physical healthcare needs remains sparse. Their reduced CTC provokes protective exclusion from research and limits knowledge about their healthcare needs (Trivedi and Humphreys, 2015). Their exclusion makes research samples misrepresentative of their complexities, with misleading and poorly generalizable conclusions producing an 'evidence-biased medicine' incapable of improving their care (Shepherd, Hood, and Wood, 2022; Subbiah, 2023; Witham et al, 2020). Evidence-based medicine (EBM) struggles to incorporate complexity and leaves this group of patients underserved by research (McGlinchey, Faulkner-Gurstein, Sackley, and McKevitt, 2023; Shepherd, Hood, and Wood, 2022). Our failure to include them in research means we cannot know how their responses to interventions/treatments differ from other populations and leaves them in a 'knowledge shadow' with inequitable treatment (National Institute for Health, 2020; Shepherd, 2020).

Providing equitable evidence-based healthcare requires a methodological rethink and a transition from 'protection by exclusion' to 'protection by inclusion' (Shepherd, 2016). Fears about research inclusion must be considered against the risks of continued exclusion; a condemnation to the narrow horizons of under researched 'standard care',

nihilistic biases about treatment responses, and the perpetuation of healthcare inequities through research avoidance (Shepherd, 2020). But fundamentally, we are unsure of how to include this population in research. Shepherd, Hood, and Wood (2022) describe a circular paradox, where the protective exclusion of complex populations from research has led to a failure to develop inclusive methodologies. Exclusion perpetuates exclusion, methodologies remain undeveloped, inclusive trials remain rare, and those most in need of research about their condition remain underserved by evidence (Shepherd, 2020; Shepherd, Hood, and Wood, 2022).

The management of muscle spasticity and contracture presents one such challenge. Spasticity and contracture are common and disabling (Farag, Reebye, Ganzert, and Mills, 2020; Milinis and Young, 2016) with little evidence to guide their treatment (Association of Chartered Physiotherapists in Neurology and College of Occupational Therapists, 2015; Kilbride et al, 2013). Adults with severe neurological disability have specific characteristics which make them more vulnerable to muscle contracture and negative contracture outcomes than the broader neurological population (Tariq et al, 2022). Standard care commonly includes botulinum toxin (BoNT) and prolonged stretch (PS) interventions such as splints (SPL) and serial casts (SC) (Kilbride et al, 2013; Royal College of Physicians et al, 2018). Both risk pain and soft tissue injury (STI) (Salierno et al, 2014), with increased adverse event (AE) frequency and severity in those with severe disability (Pohl, Mehrholz, and Rückriem, 2003). Experimental research suggests some effectiveness differences between SPL and SC but has limited inclusion of adults with reduced CTC and severe physical disability (Carda, Invernizzi, Baricich, and Cisari, 2011; Leung, King, and Fereday, 2019; Moseley, 1997; Verplancke et al, 2005). The specific responses (long-term benefits and harms) to PS treatments for PSBI remains unknown.

Improving contracture treatment for people with severe brain injury (PSBI) needs research capable of reducing decision-making uncertainty. EBM advocates theory verification and causality assessment via a powered blinded randomised controlled trial (RCT) (Creswell and Creswell, 2018) but evidence suggests several feasibility uncertainties which threaten RCT success. To be representative the sample must include people with reduced CTC, but their involvement in RCTs remains rare due to under-recruitment fears (Caldwell, Hamilton, Tan, and Craig, 2010; Ross et al, 1999) and inadequate methodological knowledge to guide their inclusion (Hamilton et al, 2017). People with reduced CTC are possibly the most challenging to include in experimental research, partly due to the clash between the homogeneous EBM paradigm and individualistic and flexible patient centred care (Shepherd, 2020; Shepherd, Hood, and Wood, 2022). Research methodologies must bridge the dichotomy of theory and practice which contributes to persistent research gaps in clinical complexity and the poor translation of evidence to practice (Yardley, 2023).

Although the potential efficacy knowledge from a PS RCT is desirable, specific characteristics of this population and their treatment contexts (complex and adaptive healthcare settings) suggest multiple key uncertainties to its implementation. Mixed methods feasibility research methods are recommended to progress the knowledge base in such complex questions (Skivington et al, 2021).

Study Aims

To identify and understand the key feasibility factors affecting the inclusion of PSBI and reduced CTC within randomised controlled trials.

Contribute to the development of inclusive research methods which enable their research participation and the subsequent development of an evidence base to meet their specific healthcare needs.

Materials and Methods

Design

A mixed-methods feasibility study incorporating quantitative and qualitative methods to explore the acceptability and feasibility of including PSBI and reduced CTC within experimental research. We used a comparative effectiveness question (which PS treatment is more effective at reducing muscle contracture after hamstring botulinum toxin treatment) and a pilot RCT to assess feasibility (estimating recruitment, refusal, and withdrawal rates), acceptability (recruitment, adverse events, treatment end points, and withdrawal) and fidelity (protocol variations, reliability of outcome measure completion). A single blinded pragmatic parallel groups pilot RCT (1:1 allocation ratio) was developed to compare two PS interventions (SPL and SC) (figure 1) and to meet 'real world' testing standards for complex interventions (Craig et al, 2008; Minary et al, 2019). As part of the mixed-methods feasibility study, the pilot RCT did not aim to test a hypothesis, assess efficacy, or contribute to power calculations. Sample size was an outcome of interest and not pre-determined. Quantitative outcomes were analysed alongside qualitative analysis of RCT acceptability (from focus groups and interviews) to better understand research inclusion barriers. The PI kept a research journal of reflections and experiences throughout the research project.

Methods were expansively combined for a deeper understanding, with data integration in the reporting phase (Halcomb and Hickman, 2015).

Ethical approval was granted by the Queens Square Health Research Authority Research Ethics Committee (REC) on the 02.12.2020 (REC reference: 20/LO/1148).

Participants and Recruitment

Sampling was purposively conducted at a single inpatient brain injury rehabilitation facility. This supported the recruitment of participants with specific characteristics (PSBI and their family members and physiotherapists), was able to work across mixed methods, and allowed exploration of local knowledge within the study's critical realist ontology (Krauss and Putra, 2005; Palinkas et al, 2015). Quantitative and qualitative recruitment occurred concurrently.

Quantitative Phase: Pilot Randomised Controlled Trial

Potential participants were screened by the primary investigator (PI) through the research sites spasticity clinic. Inclusion/exclusion criteria (table 1 and supplementary materials) were used to identify a sample with high physical dependence receiving hamstring botulinum toxin (BoNT) treatment for muscle contracture for whom PS interventions would be safe and clinically indicated. Inclusion criteria limited participants to those receiving hamstring BoNT treatment. Evidence suggests joints respond differently to PS treatments and advocates a joint specific approach to PS research (Farag, Reebye, Ganzert, and Mills, 2020). Exclusion criteria included established PS precautions (Association of Chartered Physiotherapists in Neurology and College of Occupational Therapists, 2015).

[Table 1]

Initial contact with potential consultees was made by a member of the persons therapy team who sought verbal consent to be contacted by the PI. Assessment of CTC to research participation was conducted by an appropriately skilled healthcare professional separate to the study, in line with the MCA (2005), and Department of Health & Welsh

Assembly Government guidance (2008). Following discussions and the provision of participant information sheets, participants were enrolled through a consultee process with a family representative. All recruitment was conducted by the PI.

Qualitative Phase: Focus Groups and Interviews

As the population of interest were unlikely to be able to share their experiences, inclusion/exclusion criteria purposefully defined a homogenous 'sample universe' of physiotherapists (PTs) and family members with rich experiences of participation in the pilot RCT, PS use, and proxy decision making on behalf of people with reduced capacity (please see the supplementary materials for further details).

Quantitative Phase

Data collection included demographic information, clinical outcome measures, and feasibility measures at the time points displayed in figure 1. Protocol feasibility measures were descriptively reported as relative frequencies. Due to the nature and size of this feasibility study, no efficacy testing was undertaken. Please see the supplementary materials for the full RCT protocol.

[Figure 1]

Qualitative Phase

Video focus groups and interviews used a semi-structured topic guide (please see the supplementary materials) and triangular question structure (Plummer-D'Amato, 2017) to explore the acceptability of including adults with reduced CTC in randomised research. An inductive and experiential perspective facilitated interactive discussions which elicited individual stories and co-created meaning between the researcher and participants (Braun and Clarke, 2022; Plummer-D'Amato, 2017).

Where focus group participation was not possible or desired, one-to-one interviews were conducted instead. It was not expected or wanted to develop a consensus of perspectives but rather to develop a richer understanding of this complex question (Ormston, Spencer, Barnard, and Snape, 2014).

Principles of information power and meaning sufficiency were utilised to assess sample size as they better matched the studies epistemological underpinnings, plurality, and reflexive nature than data saturation. These principles were applied iteratively to assess when sufficient data was obtained (Braun and Clarke, 2021; Malterud, Siersma, and Guassora, 2016). Our specific objectives, exploratory design, and the unique experiences of the sample suggested 6-10 interviews and/or 2-4 focus groups would offer an adequate data set (Braun and Clarke, 2021).

Data Analysis

Reflexive thematic analysis (RTA) was used for its theoretical flexibility, subject empowerment, ability to analyse across data types, and draw links in under researched areas for question development (Braun and Clarke, 2022; Trainor and Bundon, 2021). The six phases of RTA were applied in a non-linear and recursive fashion. Data collection and analysis were conducted concurrently. Interviews/focus groups were recorded and transcribed by the PI shortly after completion using Braun and Clarke's (2013) method of orthographic transcription and combined with notes and early analytic ideas. Coding was done by hand, searching for meaning and repetition. Initial themes were developed by physically grouping codes by shared meaning and visually mapping them alongside reflexive diary, field notes, and the researcher’s knowledge and insights. Candidate themes were continually refined until clearly demarcated and constructed around a central organising concept. The research team included varying expertise of the population and phenomenon under study, with each researcher bringing a different

perspective. The PI was employed at the research site and immersed in the area of clinical practice whilst the rest of the research team were more distant. This allowed for both insider and outsider perspectives which added to theme development (Hayfield and Huxley, 2015). Theme names were finalised and defined with a brief synopsis.

Results

Quantitative Phase: Pilot Randomised Controlled Trial

Data collection occurred for six months between January and June 2021. Twenty-six potential participants were screened and twenty-four excluded (recruitment rate 8%). A summary of reasons for exclusion can be found in table 2. Two people were successfully recruited. A participant flow diagram is available in the supplementary materials.

[Table 2]

Recruitment was an outcome of interest and recorded on recruitment logs. Of the 24 people excluded, 16 received BoNT treatment to muscles other than the hamstring. 8 received an eligible hamstring BoNT treatment but were excluded: multiple exclusion factors (2), PS treatment was deemed not in their best interests (1), more than six months since their brain injury (5). This research was conducted during the Covid-19 pandemic when admissions to the rehabilitation hospital were delayed. Without this delay, recruitment would have been increased to an estimated seven people, increasing the recruitment rate to 27%.

Clinical outcome measures (Leg Activity measure (LegA), Modified Ashworth Scale (MAS) and Goal Attainment Scale (GAS)) were reliably completed at each time point (figure 1). No participants were withdrawn. There were no significant safety concerns.

Neither participant experienced lasting AEs. Both experienced minor STI (self-healing skin abrasion), consistent with evidenced AE rates in this population (Pohl, Mehrholz, and Rückriem, 2003). Independent oversight was achieved through reporting of safety and withdrawal outcomes to an appointed person separate to the study. Due to low recruitment, it was not possible to conduct statistical data analysis.

Qualitative Phase: Focus Groups and Interviews

Two focus groups and two interviews were conducted involving 12 physiotherapists, each lasting approximately an hour. There was wide ranging experience in the sample, from 4-24 years in clinical practice. The demographics of the Physiotherapy sample are presented in table 3. Focus groups were formed pragmatically, according to the timing of the groups and who had consented to participate. Ten physiotherapists participated in the focus groups (six in group one, four in group two). An additional two participants were more directly involved in the research project. They were individually interviewed to prevent the differences in their exposure from affecting focus group dynamics (Barbour, 2005).

[Table 3]

Two eligible family members were approached to participate and showed initial interest, but neither consented to participate. The perspectives of family are essential to this question but remain unknown.

The four final themes (figure 2) discuss the feasibility of conducting randomised PS research through reflection on PS complexity, the nuances of working with people with PSBI and reduced CTC, the specific context of their care provision and potential incompatibilities between ‘good’ clinical care and randomised research design.

[Figure 2]

Theme 1: The complexity of contracture management

This theme reflects the complexities of contracture management decisions in this vulnerable population from the perspective of expert physiotherapists. For those with severe brain injury and a limited prognosis, physiotherapists portrayed hopelessness in their capacity to influence recovery but highlight contracture as one area where they can help and prioritised patient comfort as an essential act of compassion.

> PT5: I guess a lot of the time with our patients that's like one of the last things that they feel like you might be able to make improvements with or like maintain (.) when they've lost so much else already (all PTs nod). FG1

> PT: but you know no one as a basic sort of human need, no one wants to be in continuous discomfort and surely everyone wants to be comfortable. You know if they have no other options then surely you don't want to be in pain (.) continuously. Interview 1

Physiotherapists saw few generalisable factors in contracture treatment, highlighting variability and unpredictability across clinical cases. Physiotherapists limited understanding of the contributors to treatment success or failure presented as low confidence in their ability to predict outcomes and adverse events.

> PT3: ... reassure them that even when you think everything's gonna be okay these problems still happen sometimes ((PT 2 and 4 laugh)) because I think we've all probably all cast someone who we thought was going to be okay and they still ended up with problems (PT 2 and 4 nod) and you just can't tell sometimes and so those risks are always going to be there ((laughs)). FG2

Theme 2: The burden of decision making

This theme encompasses the ethical and legal complexities of making best interests' decisions and the emotional burden on physiotherapists to get it right for the individual.

Making treatment decisions in the ‘best interests’ of someone else requires physiotherapists to balance the available evidence and formulate individualised decisions alongside family members (MCA, 2005), setting a perceived impossible threshold of truly knowing what the person would want.

> PT: I think it’s just so hard. Unless you’ve specifically ((laughs)) spoken about it ((laugh)) ‘so you’re in this brain injured state, and you ((laugh)), what treatment would you want and what treatment wouldn’t you want’. Like it’s really difficult to you know to be - and try and put yourself in that patients’ um shoes at that very particular time. Interview 1

Contracture treatment decisions appeared influenced by the need to allow space for hope and support family members suddenly confronted by ambiguous loss and the assumption of a caregiving and advocacy role for their loved one (Soeterik, Connolly, and Riazi, 2018).

> PT2: I think well often for family members in particular they they just want their relative’s arm or leg to appear normal (PT 1 and 4 nod). I don't know whether sometimes people transfer their own sort of emotions on to that. FG2

This particularly influenced treatment discontinuation decisions, which could be perceived as ‘giving up’ by family members.

> PT5: You might just try I think like sometimes you keep trying longer or try different things where in your heart of hearts you know and you’ve probably told them – unlikely to make any difference but (.) you can keep going (PT 1 & 2 nod). FG1

Making PS treatment decisions in evidentiary uncertainty appeared strongly influenced by risk management and fears of professional vulnerability. Important positive risk-taking thought processes (to offer treatment when potential benefits for the individual appear to outweigh the risk of harm) appeared intuitively led but had to overcome a

starting point of ‘do no harm’.

> PT4: ‘Cos (sic) we have to datix [hospital incident report] it then you’re like oh it’s a naughty thing I’ve given them I’ve given them a sore (all PTs laugh). It’s like you feel like you’ve done something wrong as a physio when you’ve done it (PTs 1 and 5 nod) when actually I think just from even talking about it now it’s like what it’s going to heal it’s fine. Probably ok at least we tried (PT6 nods). FG1

> PT1: […] let say you can achieve a lot let’s say someone you might be able to get them to stand or walk or something like that that's a huge gain to be made then I think even though the evidence is sort of against you yeah I think it's worth giving it a try […] see what happens. FG2

Physiotherapists evidenced the use of a complex decision-making safety net. Featuring their own knowledge supported by the collaborative ethos of multi-disciplinary teams, where trust and respect support a unified process of shared decision-making. Sense-making and shared responsibility appeared integral to good decisions and proportionate risk management.

> PT6: um well because I’ve been here a while I’ve often had staff ask me if they should do it … they often seem quite worried to do it (PT 4 and 5 nod) so, I think um, there’s a bit of lack of confidence in making a serial cast. FG1

Theme 3: Lack of evidence and uncertainty.

Physiotherapists consider PS a valuable treatment but do not know who will respond, how they will respond, or who will be harmed. Physiotherapists find the existing scientific evidence base weak and poorly generalisable so use broader evidence in their decision making, including their own experience and shared decision making with colleagues and local experts. This emphasis on shared experience and expertise creates a localised epistemic pyramid of knowledge, with the experts at the top of the pyramid responsible for individual decisions but also strongly influencing wider clinical practice.

Less experienced physiotherapists hierarchically defer their decisions to more experienced clinicians, sometimes with little understanding of how those decisions were made.

> PT3: I don't think there is a lot of evidence out there. Just from the, mostly from my own experience and experience of my colleagues and just ah yeah um, (.) what works best. FG1

> PT4: I was just thinking that I've never probably never gone through that process of that like that journey on my own. It's always been other influences like other people's thoughts influencing that. And it does feel to me like, generally, serial casting is at the end of the journey but also I don't really know why and perhaps I was just thinking it would really nice to have a bit more back up to say actually lets try this earlier on like its really effective its worth the risks sort of thing. FG1

Experienced physiotherapists highlight the importance of experience and intuition in PS decisions, indicating that to wholly rely on scientific evidence could lead to harm, no effect, or a failure to provide appropriate treatment.

> PT2: yeah I mean if you if you decided to serial cast someone whose skin integrity was really poor who couldn't consent who was in lots of pain I don't know if you made that the wrong decision based on the evidence and you hadn't considered all the other factors around that patient and their situation which evidence can't ever really sort of point to and you'd have made a really big big mistake, so you can't fall totally on evidence can you (PT 3 and 4 nod). FG2

In evidentiary uncertainty, ensuring patient comfort was returned to repeatedly and used to defend decisions to both intervene or do nothing.

> PT: what we're looking to do is to maintain it [the contracture] to prevent it from getting any worse. So to prevent care of burden or pain or discomfort becoming worse from a worsening contracture over time. Interview 2

Theme 4: Challenges to randomised controlled trial acceptability and feasibility

Physiotherapists were asked about their experience in treating muscle contractures in this population, and about their experiences and/or feelings of the ethical acceptability and practical feasibility of a trial with a randomised PS intervention (in an inpatient rehabilitation setting). They highlighted key variables of real-world contracture and PS practice which would threaten RCT success and require methodological consideration. This included challenges to equipoise, high levels of variability and the need for individualised treatment, the specific expertise needed for safe and effective PS interventions (which may not be available in other settings), paternalistic recruitment biases, and the likelihood of a time intensive PS research intervention being deprioritised in a busy rehabilitation environment through competing demands.

Ethical RCTs must start from equipoise, an absence of evidence or belief that one treatment is superior. This allows RCTs to evidence causality through repetition, and assumption that *'ceteris paribus'* (all other things being equal), the same cause (i.e. PS intervention) will always produce the same effect (i.e. contracture change) (Freedman, 1987). Equipoise in PS treatments appears uncertain. Generally, physiotherapists expressed a consensus of uncertainty and unpredictability in PS outcomes consistent with equipoise. However, for some people physiotherapists expressed a clear belief that one treatment was better than another, highlighting variability across clinical cases which requires an individualised approach for safety and effectiveness. Physiotherapists could not identify the characteristics of these patients, instead relying on experience and intuition. This unquantifiable sub-group would be disadvantaged by randomisation (as one treatment could be superior) suggesting it would be an ethically inappropriate and scientifically ineffective way to assess PS causal relationships. Future RCTs would be strengthened if this subgroup could be identified and isolated for separate consideration.

> PT3: I can't see a huge difference between, just from my experience, between the casting and the (splinting), it's probably just a, difference of a few degrees. FG1

> PT5: I can think of specific people where you were like definitely serial casting is going to be tolerated better or definitely splinting (PT2 nods). And so you choose that because you're quite sure that that's what's going to work for them. So if they were randomly allocated to something that's going to be more difficult I could see that being tricky ((laughs)) (PT 1 nods). FG1

Involving their own patients who lacked capacity in randomised research challenged physiotherapists boundaries of professional comfort. The responsibilities of research participation heightened when making recruitment choices for those with reduced CTC, a situation where physiotherapists felt forced to take on extra responsibilities for patient safety with ambiguous levels of professional culpability. Physiotherapists support research participation but also appeared to wrestle with their responsibility to protect the patient, mitigate their own uncertain accountability to adverse outcomes, and manage potential repercussions to family relationships. Physiotherapists perceptions of threat and risk (with potential repercussions for both themselves and the patient) manifested as paternalistic attitudes which could introduce consent-based recruitment biases.

> PT2: It does feel like you know at the end of the day it's my name that's on that Patient's physio records and actually if an interventions been put in place at random it's still my name that's on there. […] So, I think whilst we're all comfortable making decisions in patient's best interests actually I'd I guess I'd feel almost slightly more uncomfortable having that control taken away (PT 1 and 5 nod). FG1

Physiotherapists felt PS interventions were an area of expertise requiring significant time and resources. Contracture treatment is provided in an unpredictable, hypercomplex and non-linear rehabilitation setting, and in competition with other organisational and patient priorities. The complexity and adaptability which makes rehabilitation 'work' risks derailing a PS RCT through prioritisation of need(s).

> PT2: …I think the amount of time you invest into it probably has a big impact on the outcome I suppose and whether you've got that time. FG2

> PT6: you can have all these factors at ward level that might interfere with your [research] results. FG1

Physiotherapists were concerned that research participation presented an additional load to family members and physiotherapists, which might influence therapeutic relationships. Physiotherapists expressed the importance of maintaining relationships with families and supporting them through grief and uncertainty. Physiotherapists communicated concerns that research recruitment presents an extra burden for grieving families but would also require increased bandwidth from physiotherapists who prioritise family support within their care.

> PT1: when you're discussing it [research randomisation] with them, you don't want to be misleading, um, in what you're saying, ah, and so if they bring up the question about 'do you think this is the best option for the patient', (PT 2 nods) I think that's a genuinely hard question to answer then, at that point. FG1

> PT4: You know it's gonna be a lot of work if you do include a certain family [in research] (PT 5 nods). ((pause)) Very time consuming and like. FG1

> PT1: It will be a very easy discussion [about the research] with the majority of families they'll be definitely a select few where it will be a difficult decision well a difficult discussion. FG2

One interviewee met with family members during the RCT. Contradicting fears, they found minimal difficulties but highlighted the importance of experience and skilled communication. They felt the challenges resembled normal clinical practice and did not feel research recruitment placed extra burden on family members.

> PT: I mean obviously they're going through difficult times already these family members and this was another decision that they had to to mull over. [….] I wouldn't have said it caused any more distress. Interview 2

Discussion

Quantitative and qualitative findings were crystallised alongside the PI's research journal and experiences of conducting this study to develop an understanding of the population specific factors pertaining to the acceptability of research inclusion and potential barriers.

Positionality

I (first author, TC) am a female physiotherapist with more than 20 years' experience working with PSBI and reduced CTC and an expert in contracture treatment (including BoNT and PS). I started from a post-positivist perspective which evolved as I realised my research objectives required a more inductive exploration. My changing positionality (position held on the topic) was essential to the outcomes of this study.

I began thinking that scientific comparison free of confounding was needed to develop probabilistic conclusions for improved patient care. I was frustrated that research did not exist about the condition specific needs of PSBI and believed the solution was to develop methods of including people with reduced CTC into robust RCTs.

As the project progressed, I became increasingly discomfited by the inclusion of such vulnerable adults into a RCT and struggled to understand why. Both arms of the trial represented standard practice with minimal risk of harm, but an awareness was developing that this study could not achieve the beneficent or social justice outcomes needed to influence practice change. I was challenged by the power imbalances and motives of my own study and forced to reflect on the underpinning theory. I adopted an increasingly experiential orientation, underpinned by a critical realist ontology (Braun

and Clarke, 2022; Krauss and Putra, 2005). As data collection continued, I reflexively considered; how can research better serve the specific needs of this population, and what lessons have we learned within this project to support that goal.

Complex Population

Within healthcare research there is increasing emphasis on the use of pragmatic RCTs to evaluate treatments and guide decision making (Goldstein et al, 2018). This research quantitatively and qualitatively explored the inclusion of a specific population of PSBI, profound physical disability, and reduced CTC in a pilot pragmatic RCT.

They share common characteristics with other conditions where research inclusion and reduced CTC has been explored (i.e., dementia, critical illness, intellectual disabilities, and palliative care) but have significant differences. Their brain injury and loss of decision-making capacity is often abrupt, unexpected, permanent, and traumatising for those around them. Family members find themselves violently thrust from being an equal to a protective advocate, whilst processing their own ambiguous loss and grief (Soeterik, Connolly, and Riazi, 2018). In severe brain injury there is little ability to prognosticate recovery, and death lingers menacingly. The seeming futility and unpredictability of their condition is an underlying and often unspoken aspect to all decisions (theme 2). Many will live for an extended period with limited recovery of their decision-making capacity. Despite high care needs and unpredictable outcomes to treatment, people with reduced CTC are commonly excluded from trial research (National Institute for Health, 2020; Shepherd, 2020). A literature review of research in neurological conditions found three quarters of potential participants were excluded. Reasons for exclusion were rarely explained but commonly related to decisional capacity (Trivedi and Humphreys, 2015). Consent based recruitment biases, research exclusion, and the resultant absence of evidence places this group in a ‘knowledge

shadow,', leaving them at risk of 'evidence-biased care' with health inequities and potential harm (Shepherd, 2020; Trivedi and Humphreys, 2015).

Their complexity has spawned an inverted research state, where despite the desperate need for research about their condition they are the least likely to be participating in research (Shepherd, 2016). Their research needs are stuck in a circular paradox. The methodological, practical, and ethical challenges of involving those who lack CTC has led to a rarity of trials which include them, which perpetuates the lack of methodological knowledge to support their inclusion and their exclusion persists (Shepherd, Hood, and Wood, 2022).

Research Inclusion

The lack of inclusivity in experimental research for those with reduced CTC is well documented and topical. A survey of experimental research inclusion in adults with intellectual disability revealed that 73% of RCTs passively and 20% actively excluded those with reduced CTC through inaccessible consent and recruitment processes, much of which could be adapted to improve inclusion (Hamilton et al, 2017). NIHR-INCLUDE and the Consult project have recently emerged as forerunners, leading the way in research inclusivity methods (table 3).

Inclusivity findings from our research correlate with research from similar populations. Inclusion is affected by restrictive inclusion criteria, recruitment biases, decision making burden, paternalistic gate keeping attitudes, varied UK legal and ethical frameworks, inadequate methodological knowledge, resourcing and skill challenges, and the disconnect between EBM and patient centred care devaluing research findings (Shepherd, 2020; Shepherd, Hood, and Wood, 2022).

Research ethics arguably disproportionately prioritises protection from harm over the benefits of research inclusion (Douglass and Ballantyne, 2019). The inclusion of people

with reduced CTC requires evidence an intervention offers potential benefit to participants or minimal/no risk of harm, and presents less risk than standard care (MCA, 2005; The Medicines for Human Use (Clinical Trials) Regulations 2004). In complex, under researched conditions research participation rarely benefits the individual, so by default, must present negligible risk of harm and less risk than standard care. Standard care is rarely researched, making its risks of benefit/harm unknown for comparative assessment (Hamilton et al, 2017; Shepherd, 2016). This sets difficult standards for the inclusion of people with brain injuries in research and risks opposing their fundamental rights to participate in public life, including research (Hamilton et al, 2017; NHS Constitution for England, 2012; United Nations General Assembly, 2006). Disability advocates argue for research ethics with a social justice focus, which prioritises the social value of research and inclusion over protection. They highlight healthcare inequities and harms which arise from research exclusion and the denial of evidence-based medicine (Douglass and Ballantyne, 2019).

This research began with emancipatory goals, to improve the inclusion of PSBI in research better able to meet their specific healthcare needs, like contracture management. We gained ethical approval to run a RCT comparing two PS interventions in adults with reduced CTC and successfully recruited all eligible participants (n=2) through a consultee process. The expertise of our recruiting research team may have helped our recruitment rates. Recruitment may be less feasible in other settings. We overcame the challenges outlined above to evidence equipoise (there is no robust efficacy evidence to support either intervention, yet both are standard care) and low risk. Our attempt to develop a qualitative understanding of inclusion acceptability was limited by recruitment, with family perspectives remaining unknown and essential to progression of this topic. Studies examining family experiences of involvement in

research inclusion decisions suggests this can be a stressful and complex process, and suggests methods to prevent misconceptions and support decision making (Shepherd et al, 2019).

Our physiotherapy sample reported reservations in recruiting patients without CTC (theme 4) which may cause selection bias through exclusion and impact recruitment. In contradiction with qualitative findings two patients participated in the pilot RCT, suggesting some acceptability of the RCT protocol in practice but supports the belief that expert physiotherapy characteristics were essential. Our pilot RCT suggested these highly vulnerable patients could be successfully recruited but that this was likely reliant on the expertise of the clinical setting.

To meet the methodological and ethical requirements of a RCT, our study used inclusion/exclusion criteria to narrow our sample to PSBI and potentially reversible hamstring contracture who could receive PS interventions with minimal/no risk. 24 of 26 potential participants were excluded, with a recruitment rate of 8%. On reflection, our attempts to isolate cause/effect relationships and protect from harm led to the exclusion of the more complex and research relevant participants and a denial of opportunity (Oliver et al, 2002). If we consider this potentially discriminatory and risk avoidant disconnect between our RCT sample and the population under study, we can see how vulnerable patient groups are harmed by research exclusion and how such research is unlikely to yield clinically useful conclusions. Research should aim for samples which resemble the complexity of the population, to achieve greater heterogeneity for improved generalisability (Trivedi and Humphreys, 2015; Witham et al, 2020). As demonstrated by our high exclusion rate, improving the diversity of research participants needs movement away from current overprotective ethical standards and rigid methodologies towards a more nuanced approach to risk which

resembles the more pragmatic nature of risk management within clinical care (Douglass and Ballantyne, 2019).

Decision Making Burden

Research conducted with people accessing palliative care services highlighted that despite the gatekeeping fears of researchers and health care workers, most people wanted to be involved in research but needed researchers to reduce the burden of participation (Dewhurst et al, 2022). In our population, proxies and healthcare workers carried the decisional burden of research participation. Good proxy decisions aim for a substituted judgement that represents being in the persons shoes (Shepherd et al, 2021). Our research highlighted the impossibility of approximating this for a person with a sudden loss of decisional capacity and the burden of joining up often wildly disparate decisional dots (theme 2).

Our observations of the interactions between emotional burdens and research participation decisions have similarities and differences compared to other populations with reduced CTC. The relative burden of a decision relates to how confident the proxy decision maker feels that they are making the 'right' decision for the person and how impacted the decision is by uncertainty, fallibility and what can be known (Reich, 2020). When making difficult proxy decisions for a loved one, family members strive for authenticity, a process of holding true to what the person would want (Shepherd, 2022). Uncertainty complicates this in severe brain injury. The course of recovery is unknowable, and prevents decisions being assessed against a predicted outcome (Reich, 2020). With the sudden onset of their condition, they will rarely have discussed relevant preferences with family members and frequently lack any decisional capacity, making substituted judgement an impossible standard. Correlating with our qualitative findings (theme 1 and 2), proxy decisions are biased by the values and beliefs of decision

makers, hope for recovery versus futility and nihilism, risk perception, and the need to 'do something' (Reich, 2020; West et al, 2017).

Family members of people with dementia who participated in proxy research inclusion decisions report wide ranging experiences. Proxies form a constructed judgement which balances harms and benefits of participation and prioritises authenticity over attempting to predict preferences (Shepherd et al, 2019). Decision-making was described as a 'tough job' with decisions relationally formed through trust, love, and responsibility. The authors concluded proxy decision making was far more complex than described in bioethics literature (Shepherd et al, 2019). We observed our physiotherapy focus groups evaluating decisions in similar ways but being confronted by not knowing the person before their injury and the added challenge of preserving relationships with family members in challenging times. Physiotherapists worried research participation would oppose individualised care and add stress to grieving families (theme 4). Adding research to this complex scenario felt a step too far for some physiotherapists, resembling the 'emotional labour' in Boulton and Boaz (2019) with research acceptability potentially influencing physiotherapy engagement, recruitment, and protocol fidelity.

Participation in palliative care and dementia research appears similarly affected by gatekeeping behaviour by healthcare workers and family members. Representatives of the patient worry about the burden on the person and the fear of making decisions the person would not agree with. In agreement with our qualitative findings (theme 2 and 4), protective recruitment biases have been observed to skew recruitment towards people with less severe illness (and less impaired cognitive ability) who do not represent the population with non-generalisable research results (Dewhurst et al, 2022; West et al, 2017).

The burden of proxy decision-making could be improved through supported deliberation strategies which form decisions congruent to the persons beliefs. Good congruence appears to reduce decisional conflict and regret (Shepherd, 2022). We observed the importance of congruent decision-making processes in our physiotherapy focus groups, enacted through shared decision-making and collaborative practice with families and team members. Correlating with what we observed, Shepherd et. al. (2019) advocate for enhanced proxy support which reflexively orientates research participation decisions towards the values and preferences of the person. To ensure a balance of best interests (welfare) and substituted judgement (autonomy) with transparent acknowledgement of protective biases, decision-making processes should support the normal interdependent, negotiable, and occasionally conflictual nature of complex decision-making by actively engaging with the persons wider family network and clinical team (Largent et al, 2022).

Risk

Clinical error is an unavoidable and necessary fallibility, arising from the limitations of science (what can be known) and what is possible to predict (Gorovitz and Macintyre, 1975). The risk of error is an intrinsic but challenging aspect of clinical practice which can cloud decision-making. In contradiction with the good safety record demonstrated in our pilot RCT, our focus groups demonstrated putative beliefs about PS risk driven by emotional biases towards harm minimisation and comfort prioritisation (theme 2 and 3) which may challenge RCT feasibility. Risk perception, do no harm, and the prioritisation of comfort weighed heavily on our physiotherapy participants. Similar concerns exist in different populations with reduced CTC. Research recruiting people with critical illness noted families were more likely to decline research when they perceived risks (Burns et al, 2017), and beliefs that research participation is burdensome

manifest as low willingness for recruitment in palliative care RCTs (Visser, Hadley, and Wee, 2015).

These emotive drivers increase the decision making burden and contribute to heuristics tending towards research exclusion (Zinn, 2008), with emerging incompatibilities between RCT design and the components of good, individualised risk management in clinical practice. Correlating with risk literature (Bodemer & Gaissmaier, 2012; Zinn, 2008), physiotherapists found 'experts' and shared decision making essential to risk management in evidentiary uncertainty, similar to using 'provisional' decision making strategies (Griffiths, Green, and Tsouroufli, 2005) or Bolam's Test (evaluating decisions against common professional opinion or standard practice) to evidence reasonable judgement (Samanta and Samanta, 2003) (theme 2 and 3). RCTs limit this fluid decision-making space, making physiotherapists fearful of error, personal risk, professional liability (theme 4), and potentially research avoidant (Zinn, 2008). Whilst essential to good care, clinical safety nets introduce variability and biases which challenge RCT reproducibility, generalisability and external validity, and weaken the causal link RCTs aim to evidence (Creswell and Creswell, 2018).

Research exclusion presents its own risks. It perpetuates a limited evidence base for treatment, limits the development of therapies, and sentences these populations to receive rarely researched 'standard care' (Shepherd, Hood, and Wood, 2022; Trivedi and Humphreys, 2015). Exclusion is described as 'neither kind, nor caring but irresponsible' (Shepherd, 2016 pp. 3). The link between healthcare inequity and an absent evidence base can be seen within an ethnographic study in severe stroke (a similar population with reduced CTC). Without evidence to advocate for their needs, the care of those with the most severe disability appeared heavily influenced by therapeutic nihilism. They received less treatment and fewer resources, with appropriate

treatment more reliant on chance interactions with experts than evidence (McGlinchey, Faulkner-Gurstein, Sackley, and McKevitt, 2023). The risks of excluding this population from research were not raised by our physiotherapy participants suggesting clinicians are unaware of the risks of exclusion, or these are obscured by the worries and responsibilities of research inclusion.

Complex interventions: limitations of EBM and Randomised Controlled Trials

Our experiences of running a small pilot RCT of an isolated rehabilitation intervention suggested some aspects were feasible, but our qualitative analysis and literature review questioned the beneficent and social justice capacity of this methodology and the capability of the EBM paradigm to examine complex rehabilitation interventions in this population with reduced CTC. Our physiotherapy participants highlighted multiple real-world factors which may threaten a RCTs success and raised important epistemological questions for research and knowledge progression.

The attractive and valuable effectiveness information offered by RCTs relies on a reality containing equipoise, regularity, and reproducibility, where interventions can be isolated for cause-and-effect testing. Testing is supported by rigorous standardisation methods which simplify populations down into comparable samples through the removal of variability. Results obtained from large (but narrowed) samples are aggregated to create statistical inferences and probabilistic outcomes (Davidoff, 2011). Our research suggests neither this population nor the nature of PS interventions within rehabilitation appear to meet the requirements for a RCT. Physiotherapists intuitively recognised a group of patients who would be disadvantaged by randomisation but struggled to identify them (theme 4), highlighting an absence of equipoise methodologically mismatched to randomised research. Their discussions suggested unpredictability in PS outcomes related to unknown patient and healthcare setting

characteristics (complexity factors including context expertise, established practice norms, and collaborative decision-making practices). In our pragmatic trial design PS end points were decided by clinicians. Our qualitative results suggest discontinuation would be influenced by risk perception and families (theme 2), introducing biases which limit reproducibility and external validity and cast doubt over knowledge claims. Rehabilitation settings (where PS is administered) represent a complex adaptive system with a reality mismatched to RCT ideals. Outcomes are produced by actors (i.e., patients, carers, clinicians, and managers) acting within a self-organising mesh of interrelated political, cultural, and biopsychosocial factors. Outcomes result from uncontrollable, non-linear relationships which cannot be distilled down to component parts (Stockley and Graham, 2022). Rehabilitation settings are wildly varied social entities which bring their own heterogeneity and poorly understood mechanisms influencing intervention success (Davidoff, 2011). Attempts to simplify this level of complexity through isolated probabilistic methods risks heterogeneity blindness, an obscuration of the reality that treatment only worked for some people and only under ideal test conditions, with an inability to explain variation, and resultant sub-optimal care (Davidoff, 2011). The hunt for linear causal inferences simplifies complex rehabilitation interventions beyond recognition and relegates useful examination of interactions between an intervention and its context. Understanding these interactions is essential to predicting when an intervention will cause benefit or harm in the individual patient, and the enablement of wider success and implementation in clinical practice (Stockley and Graham, 2022). Improving our understanding of these interactions and how they manifest within PS interventions should be a goal for future research. Research commentary from other complex populations bemoans the mismatch between real life practice and the application of EBM. They plead a need for varied and

pragmatic research methods capable of answering complex questions for greater individuation and clinically relevant outcomes (Visser, Hadley, and Wee, 2015). Research methods which facilitate the inclusion of complex/rare populations or seek mechanistic or interaction-based evidence are often deemed methodologically 'weaker' by EBMs evidentiary hierarchy and relegated to a lesser position (Davidoff, 2011; Douglass and Ballantyne, 2019). Useful mechanistic knowledge remains lost, the 'knowledge shadow' (Shepherd, 2020) is perpetuated and due to a lack of knowledge about treatment outcomes in this complex patient group, therapeutic nihilism continues to bias treatment decisions (Fins and Bernat, 2018). The gap between EBM and day-to-day PS practice was apparent in our focus group. Physiotherapists expressed distrust in the available PS evidence due to its poor generalisability and perceived invalidity. Their experiential knowledge evidenced differing responses in their patients to those included in PS research and made them sceptical. Instead, they preferentially used experts and collaborative processes to arrive at decisions (theme 3 and 4). Extracting and understanding this expertise as potential mechanisms of the intervention may improve intervention efficacy.

RCTs purify and exclude heterogeneity (as confounding variables) for probabilistic cause and effect knowledge claims but are confounded by the complexity of rehabilitation and overlook the roles of context and behaviour. When a treatment fails or causes harm in the real world, clinicians are not armed with enough mechanistic understanding (the why's) to adapt an individualised approach at the ground level, and instead default to the heuristic decision-making processes with a return to status quo and failure to reduce the research-practice gap (Davidoff, 2011; Fraenkel and Fried, 2010). To achieve practice change, rehabilitation research needs a paradigm capable of reducing uncertainty. Realist ontologies which embrace messiness through pluralistic

and complexity focussed approaches would allow adaptive RCTs and exploratory designs to work together and better explore phenomena of interest (Greenhalgh et al, 2022; Skivington et al, 2021; Stockley and Graham, 2022). The tools for improved clinical decision making are likely to be found within a richer real world mechanistic understanding of PS intervention and population heterogeneity.

Conclusion

In our research we used a seemingly simple research question (comparison of two PS interventions which resemble standard care) to explore the inclusion of a complex population with reduced CTC within experimental research. This study suggests a RCT could feasibly be done but casts doubt on whether it should be.

Our results highlight the limitations of a RCT when faced with complexity and variability. Experimental methods alone appeared disempowered to usefully compare two PS interventions. Without attention to complexity and context, a RCT (in isolation) cannot reduce uncertainty sufficiently to drive practice change in this complex population. Randomised testing may have a useful role within a PS research portfolio but needs an increased understanding of causal mechanisms and complexity factors to isolate and prioritise factors for comparison and contextualised findings. This involves a methodological re-think and a change of lens. EBM is challenged to consider reflexive and pluralistic approaches to knowledge acquisition in complex questions, with the epistemic potential for mechanistic understanding and critical, socially responsible conclusions (Greenhalgh et al, 2022). Based on this, research must shift its current paradigm towards personalised, pragmatic, and patient participatory research capable of ground-up illness management.

To exit the circular paradox and achieve equitable evidence-based healthcare for this population we need new inclusive trial designs and methods which bridge the gap

between the trial world and the real world and incorporate complexity theory (Long, McDermott, and Meadows, 2018; Subbiah, 2023; Visser, Hadley, and Wee, 2015). Recent Medical Research Council (Skivington et al, 2021) and National Institute for Health and Care Research (2020) recommendations present a mandate for non-reductionist research designs in complex questions. This change in the metaphorical research waters emphasises a shift in how we approach complexity, away from the description-explanation divide. They posit that complexity can neither be controlled nor eradicated and steer researchers away from RCT idolatry and towards understanding complexity by studying its context (Skivington et al, 2021). RCTs will always have an important role in measuring effectiveness but alone, cannot understand complexity. Realist or open world ontologies allow RCTs to work alongside theoretically-grounded and ecologically focussed approaches which deal with uncertainty and unpredictability by examining interactions and mechanisms (Greenhalgh et al, 2022; Greenhalgh and Papoutsi, 2018). This allows RCTs to be combined with approaches that study the mechanism-in-situ and bridge the research-practice gap. Pluralistic and exploratory designs such as pragmatic and critical realist RCTs, mixed-methods, qualitative designs, ethnography, and case studies can all contribute to the crystallisation of knowledge (Long, McDermott, and Meadows, 2018; Rocca, 2017; Stockley and Graham, 2022). Research priorities should be co-produced by patients (where possible), families and health care workers, using inclusive, participatory research strategies.

Strengths and Weaknesses

The perception of strength and weaknesses within this study depend on the readers' ontological perspective. Although this research set out to explore the practical feasibility of conducting a RCT for a complex intervention in PSBI and reduced CTC, it ended in an ethical and theoretical exploration of how questions pertinent to patient care

can be better answered. The RCT design had several inherent weaknesses (including its low recruitment rate, single site nature, and recruitment and cessation biases) which contribute to the discussion of RCT limitations. This research was strengthened by its highly reflexive and adaptive processes and its theoretical grounding in a critical realist ontology which allowed the inclusion of multiple realities and perspectives to draw multi-dimensional conclusions. The overall findings of this research are significantly weakened by the absence of patient and family perspectives.

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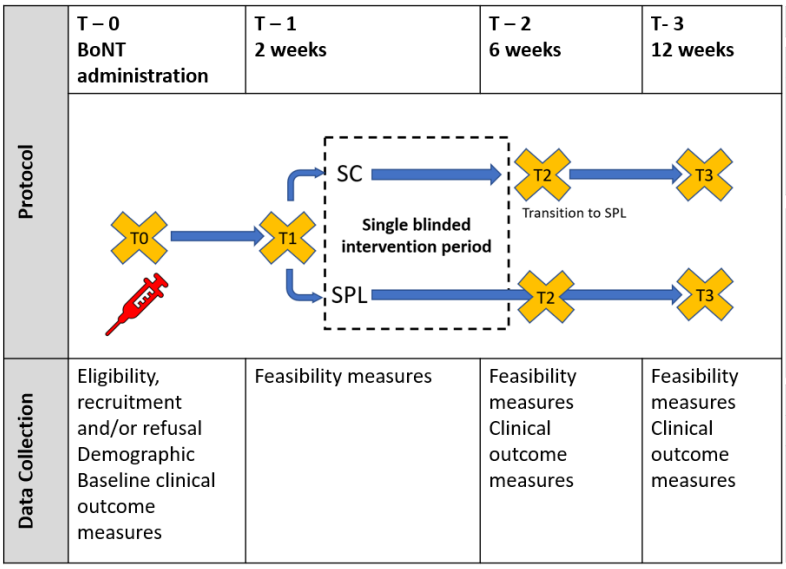
Tables and Figures

Figure 1: Pilot randomised controlled trial (RCT) protocol



Data Collection

Demographic Characteristics

Age and Sex	Leg -
BoNT treatment	Left/Right/Bilateral
Time since injury	NPDS
Spasticity medications	Knee PROM
	Cause of brain injury

Feasibility Measures

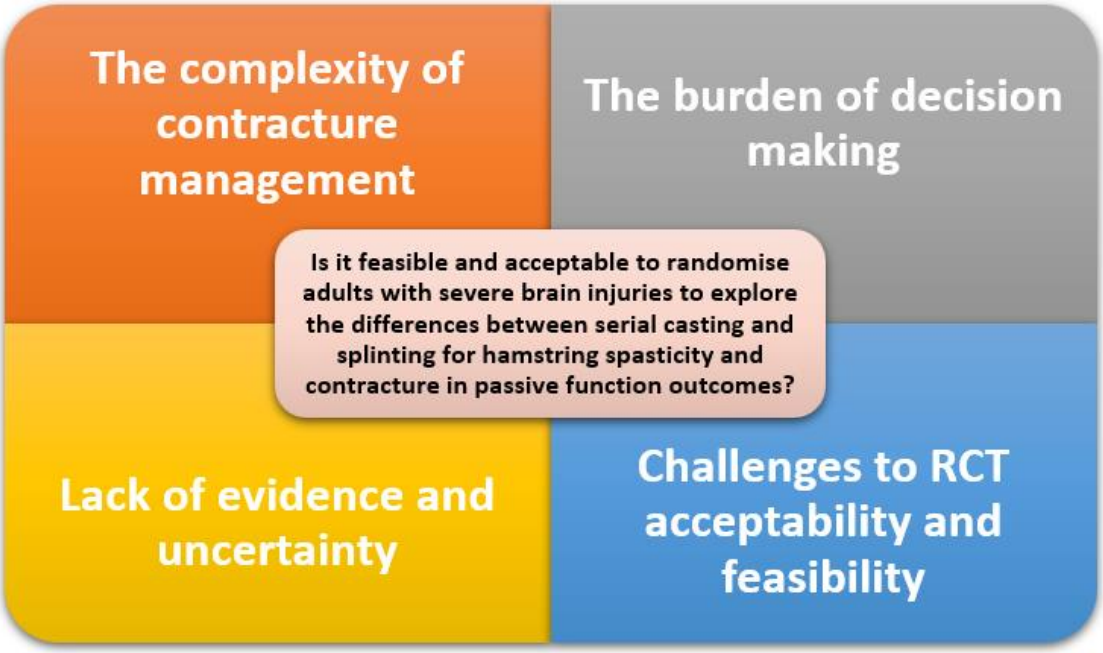
Eligibility, recruitment and withdrawal rates
Adverse event occurrences
Safety concerns
Protocol deviations
Outcome measure completion
Treatment end points

Clinical Outcome Measures

Outcome:	Measure:
Passive function	LegA
PROM change	Goniometry
Spasticity	MAS
Goal Achievement	GAS

(BoNT – Botulinum Neurotoxin, GAS – Goal Attainment Scale, LegA – Leg Activity measure, MAS – Modified Ashworth Scale, PROM – Passive Range of Movement, NPDS – Northwick Park Dependency Score, SC – Serial Cast, SPL - Splint)

Figure 2: Final themes developed from focus groups and interviews



(RCT- randomised controlled trial)

Table 1: Randomised control trial inclusion/exclusion criteria

Inclusion Criteria	**Exclusion Criteria**
- Lower limb passive function treatment goal - Northwick Park Dependency Score (NPDS) > 25[1] - Brain injury < 6 months ago - Hamstring spasticity (Modified Ashworth Scale (MAS) score of 1-3/4) [2]	- Current wounds/skin disorder - Known allergy to casting material - Uncontrollable movements in leg being treated - Heterotrophic ossification or bone deformity in treated leg - Likely irreversible hamstring contracture (MAS=4 and/or knee flexor contracture > 90^{o})[2]
[1] NPDS scores range from 0-100 with higher scores indicating greater dependence on nursing care. Scores of > 25 indicate the person requires help from at least two people with all daily activities. [2] MAS scores range from 0-4, with 0 suggesting no spasticity and 4 indicating fixed joint contracture. Scores of 1-3 were used to indicate problematic spasticity capable of responding to treatment.	

Table 2: Summary of reasons for exclusion from pilot randomised controlled trial at screening

Did not receive hamstring botulinum toxin treatment	16
Received eligible hamstring botulinum toxin treatment but > 6 months since brain injury	5
Received eligible hamstring botulinum toxin treatment but not appropriate for serial casting or splinting interventions	1
Received eligible hamstring botulinum toxin treatment but has multiple exclusion factors	2

Table 3: Qualitative study physiotherapist participant demographics

Age range (years)	Years practicing as a Physiotherapist	Years practicing in neurological rehabilitation
27-51	4-24	1.5-15

Table 4: Current research inclusion research and resources

NIHR INCLUDE	Improving inclusion of under-served groups in clinical research	National Institute for Health and Care Research (NIHR)	NIHR (2020) Improving inclusion of under-served groups in clinical research: Guidance from the NIHR-INCLUDE project. UK: NIHR. Available at: www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435
CONSULT	Capacity and consent to research	Consult Project	https://www.capacityconsentresearch.com/