



STUDY PROTOCOL

REVISED Exploring the perspectives of key stakeholders on the design and delivery of an intervention to rehabilitate people with cognitive deficits post-stroke [version 2; peer review: 1 approved, 2 approved with reservations]

Previous title: Exploring the perspectives of people post-stroke, carers and healthcare professionals to inform the development of an intervention to improve cognitive impairment post-stroke

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Abstract

Background: Stroke is a leading cause of death and disability worldwide. Cognitive impairment is common post-stroke and can result in negative sequelae such as a lower quality of life, increased carer burden and increased healthcare costs. Despite the prevalence and associated burden of post-stroke cognitive impairment, there is uncertainty regarding the optimum intervention to improve cognitive function post-stroke. By exploring the perspectives of people post-stroke, carers and healthcare professionals on cognitive impairment, this qualitative study aims to inform the design and development of an intervention to rehabilitate cognitive impairment post-stroke.

Methods: A qualitative descriptive approach will be applied, using semi-structured interviews with people post-stroke, carers and healthcare professionals. People post-stroke will be recruited via gatekeepers from a local stroke support group and Headway, a brain injury support service. Carers will be recruited via a gatekeeper from a local carers branch. Healthcare professionals will be recruited via gatekeepers from relevant neurological sites and via Twitter. The final number of participants recruited will be guided by information power. Data will be collectively analysed and synthesised using thematic analysis. The Consolidated Criteria for Reporting Qualitative Studies (COREQ) guidelines will be used to standardize the conduct and reporting of the research.

Open Peer Review

Approval Status

	1	2	3
version 2 (revision) 08 Jul 2021	 view		 view
version 1 22 Dec 2020	 view	 view	

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2. **Margaret McGrath** , The University of Sydney, Sydney, Australia
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Any reports and responses or comments on the article can be found at the end of the article.

Conclusions: It is anticipated that exploring the perspectives of people post-stroke, carers and healthcare professionals on cognitive impairment post-stroke will inform the development of an evidence-based optimal intervention to rehabilitate cognitive deficits post-stroke. This study was granted ethical approval from the Faculty of Education and Health Sciences Research Ethics Committee at the University of Limerick. Study findings will be disseminated locally through presentations at stroke support groups, as well as internationally through academic conferences and peer-reviewed journals.

Keywords

Stroke, cognition, cognitive impairment, rehabilitation, qualitative, interviews

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REVISED Amendments from Version 1

We have carefully considered reviewer comments and feedback. Having reflected upon reviewer comments, we have revised the manuscript in accordance with their useful feedback and suggestions and believe this has resulted in a more coherent piece of work. Specifically, we addressed key points relating to the aim of this study, issues around eligibility and recruitment of people post-stroke with cognitive deficits, and also the manner in which we will facilitate participation in the study. We also clarified that perspectives of relevant stakeholders will be used to inform the development and design of a future feasibility study to rehabilitate cognitive deficits post-stroke.

Any further responses from the reviewers can be found at the end of the article

Introduction

Stroke is one of the leading causes of death and disability adjusted life years on a global scale¹. Cognitive impairment post-stroke is reported in up to 60% of ischemic stroke survivors² with varying incidence rates between 20–80% of individuals post-stroke^{3–5}. A qualitative study involving 142 individuals post-stroke analysed data from follow-up assessment of functional outcomes and found that over half of individuals post-stroke who exhibit favourable recovery from physical deficits continue to experience cognitive deficits in the longer term⁶. Indeed, cognitive deficits post-stroke are seen in 22% of individuals at 5 years post-stroke and 21% of individuals at 14 years post-stroke⁷. Cognitive impairment post-stroke is shown to be independently associated with a lower quality of life⁸, higher rates of mortality and institutionalisation⁹, increased carer burden¹⁰ and increased healthcare costs¹¹.

A priority setting partnership in the UK, the James Lind Alliance, identified that cognitive impairment post-stroke was the leading priority among the top 10 research priorities in relation to life after stroke¹². Despite this, much rehabilitation focus is placed on the improvement of physical deficits post-stroke, with a neglect towards cognitive deficits^{13,14}. In their updated review examining the effects of physical fitness training post-stroke, Saunders *et al.*¹⁵ noted that outcomes of cognitive function in particular lack investigation. Peoples *et al.*¹⁶ reported from their synthesis of qualitative studies that people post-stroke report a focus during rehabilitation on physical needs over social re-integration and psychological support. These non-physical needs were perceived as factors that could facilitate empowerment and enable people post-stroke to regain control over their everyday life¹⁶. Similarly, McKeivitt *et al.*¹⁷ estimated the prevalence of self-reported unmet needs in community-dwelling stroke survivors (n=799) across the United Kingdom and found that 60% of those surveyed reported memory problems after stroke as an unmet need. The lack of focus on cognitive deficits is further acknowledged by the Intercollegiate Stroke Working Party national clinical guidelines which highlight gaps in cognitive rehabilitation after stroke¹⁸.

Cognition is not a unitary concept, as evidenced by the variety and breadth of neuropsychological assessments available¹⁹. Cognitive impairment post-stroke involves a variety of deficits across multiple domains of cognition function²⁰ which allow an individual to select and process information within their environment²¹. Previous Cochrane reviews have explored the effectiveness of cognitive rehabilitation interventions on a specific domain of cognitive function post-stroke, such as attention, memory, executive function, limb apraxia, neglect and perception^{22–27}. These reviews each concluded that while there are some short-term benefits arising from cognitive rehabilitation for attention and executive functioning, the effectiveness of cognitive rehabilitation aimed at each of these cognitive domains has yet to be established. An overview by Gillespie *et al.*²⁸ synthesised evidence across these Cochrane reviews and reported favourable outcomes of cognitive rehabilitation across the domains of attention, spatial neglect and motor apraxia immediately post-intervention, but these improvements were not likely to persist in the long-term and did not improve the everyday functioning of the individual post-stroke²⁸. Gillespie *et al.*²⁸ also noted the methodological shortcomings of trials within reviews and argued for the need for more robust clinical trials in this area.

Beyond the definition of specific “cognitive rehabilitation” interventions, a breadth of interventions can affect cognitive function in people post-stroke ranging from virtual reality training²⁹ to physical activity interventions³⁰ to neurofeedback therapy³¹ and many more. A systematic review and meta-analysis was conducted by O’Donoghue *et al.*³² to examine the totality of evidence with regard to interventions which rehabilitate cognitive deficits post-stroke. This review identified 64 studies and an extensive range of interventions including multiple component interventions, physical activity interventions, cognitive rehabilitation interventions, non-invasive brain stimulation (NIBS) protocols and occupational-based interventions. The protocol for this systematic review has been published³² and the systematic review is under review in a specialist stroke journal. Our systematic review found evidence to support multiple component interventions, physical activity interventions and NIBS protocols leading to improved cognitive functioning post-stroke. Findings must be interpreted with caution, given the heterogeneity of interventions and outcome measures across studies.

Living with memory deficits may result in negative effects on the stroke survivor and their family once in the community³³. A recent systematic review and meta-ethnography found that stroke survivors and carers can feel abandoned as a result of becoming marginalised by healthcare services³⁴. This marginalisation occurs due to lack of continuity of care, limitations in access to services and inadequate information provision to re-engage with services during different stages of recovery post-stroke. The lack of follow-up services was also noted³⁴. Specifically, people with memory problems post-stroke and their carers have identified barriers that may prevent them engaging with a healthcare professional such as

fear of a dementia diagnosis, the denial of cognitive deficits and the lack of familiarity with HCPs to comfortably discuss their memory problems³⁵. These perceived unmet needs and inequities in accessing rehabilitation services are challenges that require attention. Moreover, given that research focused on the improvement of cognitive impairment post-stroke is considered as the top research priority among people post-stroke, carers and healthcare professionals, the design of an effective intervention and feasible intervention is an urgent issue.

The Medical Research Council's (MRC) guidelines for developing complex interventions details the importance of identifying the current evidence base³⁶. The identification and engagement of stakeholders is essential to the development of a cohesive stroke system of care³⁷. Moreover, qualitative research methods have been proposed as key components in the conduct of research into complex interventions by increasing knowledge of intervention components and mechanisms of action^{38,39}. Thus, in accordance with the MRC framework for developing and evaluating complex interventions³⁶, perspectives of relevant stakeholders will be used to inform the development and design of a feasibility study to rehabilitate cognitive deficits post-stroke.

Given that key features of cognitive intervention design have yet to be established⁴⁰, it is imperative to explore the insights of key stakeholders regarding their engagement with such interventions and their perceived effectiveness. To this end, this study aims to elicit the perspectives of key stakeholders on the design and delivery of an intervention to rehabilitate cognitive deficits post-stroke. Qualitative findings from this proposed study will enable realistic plans for intervention design, taking into account feasibility and acceptability of any intervention, based on views from key stakeholders to rehabilitate cognitive deficits post-stroke. Taken together with quantitative evidence from our systematic review, the findings will inform the development of an evidence-based and stakeholder informed feasibility study to rehabilitate cognitive deficits post-stroke.

Methods

Study design

This study will employ a qualitative descriptive approach with thematic analysis of data^{41,42}. A qualitative descriptive approach was chosen so that broad and rich information would be gathered in relation to descriptions of participants' attitudes towards the development of a complex intervention³⁹. The study will be reported in line with the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist⁴³. The perspectives of key stakeholders will be gathered using a semi-structured interview protocol via telephone or telecommunication platform such as Microsoft Teams.

Research team roles

All interviews will be conducted, transcribed and analysed by the researcher (MOD), a physiotherapist and a PhD candidate at the University of Limerick. MOD has completed training in a qualitative research methodology module and

also completed a training workshop for Nvivo software. Dr Sara Hayes (SH) is a lecturer in physiotherapy and an experienced quantitative and qualitative researcher. As the principal investigator, SH has led the conceptualisation of this research and will contribute to the data analysis and write-up of the manuscript. Dr Pauline Boland (PB) is an occupational therapist who has worked extensively in stroke rehabilitation including delivery of cognitive rehabilitation and an experienced qualitative researcher. Dr Rose Galvin (RG) is a senior lecturer in physiotherapy and experienced researcher in quantitative and qualitative research. Dr Siobhan Leahy is a lecturer in physiotherapy and an experienced quantitative and qualitative researcher. PB, RG and SL will contribute and provide critical feedback throughout the analysis, write-up and dissemination stages of this research. A third of the transcripts will be analysed by co-authors (SH, PB, SL) for peer coding and collaborative framework development. Another co-author (RG) will contribute to the clarification of themes at a later stage in the analysis

Sampling and recruitment

A pragmatic mixed purposive sampling technique will be used in this study. Participants will include key stakeholder groups: people post-stroke, carers, healthcare professionals (HCPs), academics and academicians with an interest in stroke rehabilitation. Purposive sampling and snowball sampling will be used to recruit stakeholders^{44,45}. Given our sampling methods and due to the remote nature of data collection due to Covid-19 restrictions, participants could feasibly be recruited nationwide and/ or internationally.

For people post-stroke, invitation letters and participant information leaflets will be sent via a gatekeeper from Volunteer Stroke Scheme and Headway in Limerick respectively. Both organisations are the key services supporting people post-stroke outside of health services. The gatekeepers of these organisations will identify individuals that may be suitable to participate based on eligibility criteria. People post-stroke will be included if they meet the following inclusion criteria:

- Aged 18 years or older with a diagnosis of ischaemic or haemorrhagic stroke
- Self-reported cognitive problems post-stroke
- In the acute, subacute or chronic stage post-stroke
- Have the ability to verbally communicate over the phone/ via telecommunication platform.*

*In cases where an individual has difficulty understanding the interview questions, a proxy respondent may be used. The proxy respondent may be a spouse or a carer of the individual post-stroke

People post-stroke will be excluded if:

- Individuals are unable to provide informed consent. Ability to provide consent will be determined at eligibility checking stage though the gatekeeper and/or proxy respondent.

Carers will include caregivers, spouses or family members who provide care (paid or unpaid), support or assistance to people post-stroke⁴⁶. In accordance with this definition, there is no set amount of care that needs to be provided by carers for them to be deemed eligible. Invitation letters and participant information leaflets will be sent through a gatekeeper from The Carers Association Limerick, a local carers' branch in the Limerick area (see extended data⁴⁷). Carers of eligible people post-stroke are also eligible for inclusion. Carers will be eligible for inclusion if they have been involved/ are currently involved in the care of an individual post-stroke with cognitive impairment.

HCPs will be recruited from relevant neurological clinical sites i.e. those working in stroke units of acute hospitals, rehabilitation units of subacute hospitals or community settings, and Twitter. HCPs will be eligible for inclusion if they have treated or are treating people post-stroke with cognitive impairment. HCPs will include medical staff, physiotherapists (PTs), occupational therapists (OTs) psychologists and speech and language therapists (SLTs) working in the provision stroke rehabilitation services. Academics and academicians will include those affiliated with the University of Limerick with an interest in stroke rehabilitation research who will be invited through relevant research clusters within the University of Limerick such as the Ageing Research Cluster (ARC) and the Physical Activity for Health Research Cluster (PAfH). Potential for conflict of interest due to existing relationships between academicians will be acknowledged and addressed by allowing for sufficient time to be given to academicians to consider their participation in the study. We will reiterate that involvement is voluntary and participants can withdraw at any stage.

Once prospective participants express an interest in engaging with the study, a phone call will be scheduled to discuss what participation entails, ensuring that the potential participant has read and understood the participant information leaflet already supplied. MOD will discuss the eligibility criteria with each participant and determine whether or not eligibility criteria has been met prior to data collection.

The participant will be required to complete a consent form and a brief demographic information form prior to their interview/focus group (see extended data⁴⁷). The researcher will orally present the participant information leaflet and offer to email/ post it. The researcher will arrange a follow-up call a minimum of one week later to allow time to consider participation in the study. During the follow-up call, if the individual wishes to participate, verbal informed consent will be confirmed orally and audio recorded. Alternatively, if the individual wishes to read the participation leaflet and sign the consent form themselves, the researcher will post the participant information leaflet and informed consent form to the individual (using a pre-paid postage stamped letter; see extended data⁴⁷). The individuals will then send the signed consent form back to

MOD. Completion of the written informed consent form, either by written or digitally signed signature, will be a prerequisite for participation in the study in accordance with the Health Research Regulations (2018)⁴⁸.

Participation in interviews and/or focus groups will only commence once informed consent from all participants is received. According to the Assisted Decision-Making Capacity Act (2015)⁴⁹, individuals should be assumed to have the capacity to consent unless otherwise demonstrated. A key issue in the context of this study is the manner in which the capacity for informed consent is established and how potential changes in capacity are identified. To this end, the capacity of participants with cognitive impairment post-stroke to consent to participate in the study will be assessed on a continual basis, with regular reiteration of the rights of participants as the study progresses.

The impact of cognitive deficits post-stroke on decision-making around participation in research must be considered⁵⁰. For this reason, informed consent will be conducted as an ongoing process i.e., where consent will be obtained prior to participation, reviewed on the day of participation and reviewed again immediately once the interview has been conducted. Moreover, the content of all consent forms will be discussed with participants in line with best practice to ensure participant understanding of the nature of their participation in this study and any risks associated with same⁵¹. Participants will be given the option to opt out of the study for any reason at any stage. MOD will refer to the INVOLVE guidelines regarding the knowledge, skills and experience required to participate in PPI when addressing participant queries⁵².

Sample size

The sample size for this study will follow guidance from Malterud *et al.* (2016) regarding "information power." According to this model, criteria such as the aim of the study, the specificity of the sample of participants, the use of established theory, the quality of dialogue and the analysis strategy should ascertain whether sufficient information power will be achieved with less or more participants included in the study sample⁵³. In the context of this study, "information power" appears more suitable than "data saturation" in the process of decision-making regarding sample sizes, given that the concept of data saturation is often poorly defined within qualitative studies and the methods by which authors claim data saturation are not always transparent⁵⁴⁻⁵⁶. In accordance with this model and in consideration of the current study, it is anticipated that approximately ten interviews will be conducted with individuals post-stroke, ten interviews with caregivers and ten interviews with healthcare professionals.

Data collection

The qualitative research interview is a highly utilised data collection tool in health research⁵⁷. The most common type of interview used in qualitative research and the healthcare

context is the semi-structured interview which enables an in-depth exploration into the experiences of interviewees and offers the insights into how difference phenomena of interest are perceived^{58,59}. This study will employ both telephone-based and online methods of data collection, wherein face to face contact may not be possible due to COVID-19.

Semi-structured interviews and focus groups will be conducted using a semi-structured interview protocol (see extended data⁴⁷) via telephone or via a telecommunication platform such as Microsoft Teams, as per the participants' preferences and in accordance with the tools that are licensed and supported by ITD, University of Limerick.

The telephone interview is an effective method for collection of qualitative data which facilitates flexible interview scheduling, less time-consuming for both the researcher and participant, enhanced access to geographically dispersed regions and more cost-effective⁶⁰. Furthermore, telephone interviewing can mitigate against some of the negative aspects of face-to-face interviewing; it is argued that telephone-based interviews offer a more balanced distribution of power between researcher and participant and offer a greater level of anonymity and privacy than with face-to face interviews^{61,62}. Interviews are expected to last no more than one hour. Participants will be encouraged to take breaks where necessary to mitigate against cognitive fatigue. Furthermore, interviews may be conducted in 2–3 shorter sessions if required. This be discussed in detail with participants prior to participation.

Proxy respondents

In cases where the individual post-stroke is unable to effectively communicate in a semi-structured interview setting, proxy respondents may be used. Given that post-stroke aphasia occurs in up to 42% of people post-stroke in the acute setting and up to 50% in rehabilitation or community settings⁶³, it is important that these individuals are empowered to express their views⁶⁴. Responses from a proxy respondent will be used when the interviewer or caregiver has concerns about the capacity of the person post-stroke to communicate and/or when the person with stroke nominates such a person. The proxy respondent will be giving their own responses to questions asked during the interview about the issues as related to the person with stroke. The person post-stroke may be present if they wish. However, proxy ratings must be interpreted with caution given that proxy respondents are likely to overestimate the level of impairment of the individual, compared to self-reported measures⁶⁵. Therefore, all summaries of data collected by the proxy respondent will be summarised and relayed back to the individual post-stroke who may wish to add their views to the reported carer data.

As well as the use of proxy respondents, this study will employ a number of adjustments to the qualitative interviewing skill in order to be as facilitating and inclusive as possible. Strategies such as reducing the cognitive load on individuals by lessening the content of the interview line of questioning and utilising clear and visual forms of communication where possible

will be used⁶⁶. Furthermore, people post-stroke will be interviewed remotely while situated in their home to provide a familiar and relaxed environment to facilitate open communication during the interview process and in which individuals are more likely to disclose information relating to the nature of their lived experiences⁵¹.

Focus groups

A focus group may be conducted with carers or HCPs who work on the same clinical site. While focus groups are a popular method of data collection in health research⁶⁷ maintaining privacy and anonymity within a focus group setting raises potential challenges due to the limited control over what participants may communicate outside of the focus group. To mitigate against this, the researchers will ensure that informed consent is obtained from all participants and that sufficient information is provided to potential participants to facilitate autonomous decision-making before partaking in the study⁶⁸. We will reiterate our processes for ensuring anonymity as detailed in the participant information leaflet provided. Please see extended data for participant information leaflet. Both one to one interviews and focus groups will follow the same topic guide. Where a focus group is not possible, individual interviews will be conducted with these stakeholders. Due to remote nature of data collection methods as a result of Covid-19 restrictions, people post-stroke will be interviewed on a one-to-one basis only.

Topic guides

The interview topic guide and questions were developed by the research team by reviewing existing literature regarding the engagement with rehabilitation services post-stroke. The interview questions were based on the principles of developing semi-structured interviews in qualitative research and health research respectively^{57,69}. The template for intervention description and replication checklist for reporting of interventions (TIDieR) was used to frame questions relating to the design and delivery of a future intervention to rehabilitate cognitive deficits post-stroke⁷⁰. The interview guides for each stakeholders group are available as extended data⁴⁷. An advocate for people with stroke was contacted to review the interview schedule. During this process, this person made amendments to the interview guide itself and aided in the phrasing of interview questions to facilitate clear and concise questioning. Supportive communication strategies such as reducing the cognitive load on individuals by lessening the content of the interview line of questioning and utilising clear and visual forms of communication where possible will be used^{66,71}. Furthermore, individuals post-stroke will be interviewed remotely while situated in their home to provide a familiar and relaxed environment to facilitate open communication during the interview process and in which individuals are more likely to disclose information relating to the nature of their lived experiences⁵¹.

In order to garner perspectives on a proposed cognitive intervention, items in the interview include questions around single and multiple component interventions, as well as basing our definition of cognition in line with the latest Australian Clinical Guidelines for Stroke (2020) which details the cognitive

domains of attention, memory, executive function, apraxia, perception and neglect, under the remit of the term “cognition”. The interview guides for each stakeholders group are available as extended data.

Piloting

A piloting phase will be undertaken to assess the acceptability of the semi-structured interview for stakeholders. An individual from each stakeholder group will be asked to provide feedback on the flow of questions, the relevance of questions and their overall experience of the interview process focusing on emotional impact and feelings of fatigue or overload. Following this, these individuals will participate in cognitive interviews centred on their experience of completing the semi-structured interview. Cognitive interviewing is a pre-testing strategy that explores how respondents interpret and attribute meaning to individual questions^{72,73}. It can identify issues regarding the terminology of questions which could lead to potential misinterpretations, resulting in incomparable responses and missing data⁷². While this strategy is primarily used in questionnaire design⁷², it was deemed useful in this qualitative interview study as, given the likely age, health status, cognitive and communication difficulties, there is a risk of misinterpretation of interview questions associated with stakeholders in this study. The following techniques guide cognitive interviewing: think/read aloud, cognitive verbal probing and observation⁷². Given that respondents will have completed the pilot interview, it is important to consider the cognitive load associated with the subsequent cognitive interview. Therefore, cognitive verbal probing will be used as the main approach to guide the cognitive interview and will be guided using a brief list of prompts.

Data protection

All data will be handled confidentially and will be stored in accordance with the Data Protection Policy at the University of Limerick. All consent forms will be stored in a locked cabinet in the Principle Investigator’s office in the School of Allied Health Building, University of Limerick. Participants will be assigned a unique participant number when data are transcribed. A separate, password-protected Excel file will hold participants’ details and their unique participant number on a password protected laptop. Audio files will be destroyed after being transcribed and the research team will only have access to anonymised transcripts. These transcripts and descriptive statistics will be stored on a password-protected laptop.

Data analysis

Nvivo software package (Version 12 QSR International) will be used to import transcripts, organise and retrieve data to be analysed. Data will be analysed and collectively synthesised using reflexive thematic analysis⁷⁴. Reflexive thematic analysis was chosen for its theoretical flexibility as well as its ability to provide a rich and detailed account of a large dataset^{74,75} and is a useful approach for evaluating the perspective of different research participants, highlighting the similarities and difference between groups and generating a rich and detailed account of the data⁷⁶. Data will be analysed through an iterative process where data collection and data analysis will occur concurrently and recursively to integrate the development of themes grounded in the primary data⁷⁷. The flexibility of this approach,

while useful, also has the potential to lead to inconsistencies in the development of themes derived from the data⁷⁸. To reduce this risk, this study will adhere to standardised criteria promoting trustworthiness as outlined by Nowell *et al.* (2017). This step by step procedure aims to guide qualitative researchers to meet the original trustworthiness criteria outlined by Lincoln and Guba (1985). Peer debriefing will be conducted throughout the analysis on all transcripts, where preliminary codes and themes will be discussed and reflected upon with co-authors^{79,80}. Data will be analysed using an inductive approach, where generated codes will be based on the content of the primary data rather than existing theories or concepts.

Reflexive thematic analysis will be conducted in accordance with the steps outlined by Braun and Clarke (2019) which will be applied to the current study: (i) data familiarisation, involving repeated active engagement with notes and transcripts. Initial theoretical and reflexive thoughts will be documented to inform the next step, (ii) generation of initial codes; all segments of data which may be relevant to the research question will be coded, (iii) conceptualisation of themes, involving the identification and interpretative analysis of the collated codes (iv) reviewing themes, involving the refinement of themes identified. This will require in-depth interpretation and reviewing of the boundaries of each theme and probing to decipher if there is sufficient data to support the theme. There should be a clear and identifiable distinction between themes and data within these themes should cohere in a meaningful manner (v) defining and naming of themes, requiring clear and descriptive working definitions to be generated for each theme and potential subthemes within the data, (vi) producing the final report, involving the transformation of the analysis into the publication of a journal article.

Ethics approval

Ethical approval for this study has been granted by the Faculty of Education and Health Sciences Research Ethics Committee at the University of Limerick [Ref 2020_03_05_EHS].

Dissemination

Study findings will be submitted for publication in peer-reviewed journals and will be disseminated through relevant research clusters in the University of Limerick. We will engage with participating networks such as the Volunteer Stroke Scheme, Headway Limerick and University Hospital Limerick to disseminate the results of our study. This will be done through a public talk in the community involving all stakeholders and their families. Abstracts will be submitted to relevant national and international conferences. Findings will also be disseminated through the use of social media such as Twitter.

Study status

Recruitment and data collection for this study commenced in November 2020.

Conclusion

This research will highlight the views of key stakeholders who are often unrepresented in intervention design. Combined with the existing empirical evidence from a quantitative review, perspectives of relevant stakeholders will be used to inform the

development and design of a feasibility study to rehabilitate cognitive deficits post-stroke.

Data availability

Underlying data

No data is associated with this article.

Extended data

Figshare: Exploring the perspectives of people post-stroke, carers and healthcare professionals to inform the development of an intervention to improve cognitive impairment post-stroke. <https://doi.org/10.6084/m9.figshare.13332923.v1>⁴⁷

This project contains the following extended data:

- Appendices.docx (recruitment letters/emails, participant information leaflets, consent forms and demographic data collection form)
- Interview guide.docx (cognitive interview guide and semi-structured interview guides for individuals post-stroke, carers and healthcare professionals)

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](#) (CC-BY 4.0).

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Salvatore Facciorusso

Villa Beretta Rehabilitation Center, Universita degli Studi della Campania Luigi Vanvitelli, Caserta, Campania, Italy

The study protocol provided aims to explore the perspectives of key stakeholders on the design and delivery of an intervention to rehabilitate people with cognitive deficits post-stroke. However, i have some concerns.

1. The major concern: Considering the study was initially designed under the constraints of COVID-19 restrictions, which influenced its methodological choices, it is now advisable to adapt the study protocol to reflect the current context where these restrictions have been eased. You wrote "This study will employ both telephone-based and online methods of data collection, wherein face to face contact may not be possible due to COVID-19."Therefore, it would be prudent to revisit and modify the methods accordingly. Below are some recommendations for adaptation::
 - Consider adding face-to-face interviews or focus groups to capture richer data, including non-verbal cues.
 - Develop protocols for in-person, remote or hybrid interactions to ensure the safety and comfort of participants, offering them the choice of communication mode.
 - The changes in data collection methods and recruitment strategies might necessitate adjustments to the project's feasibility and timeline.
 - Allocate resources for logistical and technological support required for face-to-face data collection.
 - **Data Collection:**The choice of telephone and online interviews, while practical in the context of COVID-19 restrictions, may limit the depth of interactions compared to face-to-face interviews. Non-verbal cues are lost, which can be particularly relevant when discussing sensitive topics like cognitive impairments post-stroke. COVID 19 restrictions are now limited. Thus, If feasible, offer participants the option of face-to-face interviews in addition to telephone and online interviews. This would accommodate participants' preferences and potentially enhance the depth of qualitative data collected. The reliance on technology may exclude participants who are not comfortable with or do not have access to the necessary tools.
 - **Proxy Respondents:**The use of proxy respondents introduces another layer of

complexity, as proxies may not accurately represent the experiences and perspectives of the stroke survivors themselves. This methodological choice could affect the validity of the data collected, especially considering the potential overestimation of impairments by proxies compared to self-reports. Whenever possible, include direct assessments or observations of stroke survivors alongside proxy reports. Offer guidance for proxy respondents on how to accurately represent the experiences and perspectives of the stroke survivors they are speaking for.

Finally, In the context of your study, the utilization of teleconsultation methods has proven to be an invaluable tool, especially given the constraints imposed by the COVID-19 pandemic in these years. However, with the progressive easing of these restrictions, it presents an opportune moment to reassess and update your study protocol to reflect the current landscape and emerging needs.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Partly

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Stroke rehabilitation

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 12 July 2021

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Sinéad Hynes 

Discipline of Occupational Therapy, National University of Ireland, Galway, Ireland

Thank you to the authors for clarifying the questions I had and for adding additional detail in areas that were requested.

There is one typographical error in heading that should read "Focus groups".

Is the rationale for, and objectives of, the study clearly described?

Not applicable

Is the study design appropriate for the research question?

Not applicable

Are sufficient details of the methods provided to allow replication by others?

Not applicable

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cognitive rehabilitation, community-based rehabilitation, intervention development.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 27 January 2021

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Margaret McGrath 

Sydney School of Health Sciences, The University of Sydney, Sydney, NSW, Australia

This qualitative study sets out to explore experiences of post-stroke cognitive impairment and perspectives on the optimum approach to cognitive rehabilitation after stroke from the perspective of stroke survivors, carers of stroke survivors and health care professionals working in stroke rehabilitation.

The authors suggest that the findings of the study, when combined with findings from a systematic review of interventions to address post stroke cognitive impairment will 'inform the design and development of an intervention to rehabilitate cognitive impairment post stroke'.

I have noted below some points for consideration by the authors.

Rationale and objectives:

- The authors present a compelling case for the research. The research is complemented by an earlier systematic review of interventions for post stroke cognitive impairment.
- There are two different research aims and it would be helpful for the authors to set out these aims more explicitly before addressing the research design - one to describe the experience of post stroke cognitive impairment from the perspective of the stroke survivor/care and health care professionals. A second aim is to explore these stakeholders views on interventions to address cognitive impairment.
- There are three distinct groups of potential participants: stroke survivors; carers of stroke survivors and health care professionals. The inclusion of multiple perspectives is helpful given the complexity of post stroke cognitive impairment.
- An estimated 10 stroke survivors will be recruited to the study. The authors refer to purposive sampling but it is not clear how this will be enacted - beyond fulfilling the inclusion criteria how will participants be selected?
- I am not entirely clear how the authors propose to include the perspectives of people with communication impairment - it is likely that using supportive communication strategies participation of this cohort could be facilitated rather than relying on a proxy respondent. It may be useful to draw on the expertise of a speech and language pathologist to support this.
- Given that many stroke survivors/carers have unmet needs relating to cognitive impairment I am not clear how they will be expected to give informed answers about their preferences for intervention approaches, timing or delivery methods. It seems more likely that their opinions will be based on a hypothetical 'if services were available' and this limitation should be acknowledged.

Health professionals:

- It seems as if most of the health professionals will be recruited from a local health service and it is not clear if the health professionals will have direct clinical experience in addressing cognitive impairment post stroke. It may be worth considering expanding the scope of potential recruitment to address this gap.
- It is not clear why you have chosen not to include nursing staff among HCP to be recruited?

Data collection:

- It would be helpful for the reader to clarify which participants will be offered the opportunity to engage in a focus group and which participants will be interviewed.
- The process for data analysis is clear and comprehensive.

General comments:

- The methods section would benefit from further editing as at times information is

repeated.

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Occupational Therapy; Neurorehabilitation; Chronic Disease and Disability;

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 31 Mar 2021

mairead o donoghue

Many thanks to the reviewers for their comprehensive feedback and comments on this protocol paper. We really value this feedback. As we are currently submitting a review paper that informs this qualitative work, we have decided to delay our response to reviewer comments for a month or so. We will respond in full after this time. Thank you again for your valuable feedback.

Kind regards,
Mairéad O' Donoghue.

Competing Interests: None declared.

Author Response 02 Jul 2021

mairead o donoghue

Thank you for taking the time to review this protocol. I apologise for the delay in response.

Point 1: The authors present a compelling case for the research. The research is complemented by an earlier systematic review of interventions for post stroke cognitive impairment.

Response 1: Thank you.

Point 2: There are two different research aims and it would be helpful for the authors to set out these aims more explicitly before addressing the research design - one to describe the experience of post stroke cognitive impairment from the perspective of the stroke survivor/care and health care professionals. A second aim is to explore these stakeholders views on interventions to address cognitive impairment.

Response 2: Thank you for highlighting this. We agree that the research aim needs to be set out more explicitly. To this end, and in accordance with changes to the manuscript title, the manuscript has been amended to reflect one specific aim of this study, "to elicit the perspectives of key stakeholders on the design and delivery of an intervention to rehabilitate cognitive deficits post-stroke." Please see Introduction section Line 149-151.

Point 3: Rationale and objectives:

- There are three distinct groups of potential participants: stroke survivors; carers of stroke survivors and health care professionals. The inclusion of multiple perspectives is helpful given the complexity of post stroke cognitive impairment. An estimated 10 stroke survivors will be recruited to the study. The authors refer to purposive sampling but it is not clear how this will be enacted - beyond fulfilling the inclusion criteria how will participants be selected?

Response 3: Thank you for requesting clarity on this. We have added a sentence to outline how we will work with gatekeepers of organisations supporting people post-stroke to facilitate purposive sampling. Please see Methods, subheading: Sampling and recruitment, Line 200-201;

Point 4: I am not entirely clear how the authors propose to include the perspectives of people with communication impairment - it is likely that using supportive communication strategies participation of this cohort could be facilitated rather than relying on a proxy respondent. It may be useful to draw on the expertise of a speech and language pathologist to support this.

Response 4: Thank you for requesting clarity on this. We have added to the manuscript outlining supportive communication strategies that will be used in order to be as inclusive as possible. Any issues that do arise regarding cognitive communication difficulties will be factored in the feasibility study. Please see Methods section; Topic Guides and Piloting, Line 372-377.

Point 5: Given that many stroke survivors/carers have unmet needs relating to cognitive impairment I am not clear how they will be expected to give informed answers about their preferences for intervention approaches, timing or delivery methods. It seems more likely that their opinions will be based on a hypothetical 'if services were available' and this limitation should be acknowledged.

Response 5: Thank you. A similar comment was raised by both reviewers regarding the

“hypothetical, ideal world” situation versus “real world” situation. Yes, we agree that stakeholders may have unmet needs relating to cognitive impairment. We aim to illicit their views on the gaps in the services received and their experience of cognitive intervention to date i.e. the “real world” experience. We also hope to garner perspectives on the design of a “hypothetical, optimal” intervention in line with the “who, what, where, when and why” line of questioning of the TIDER framework (Hoffmann *et al.* 2014). We will acknowledge opinions based on a hypothetical view as a limitation in the main results study.

Point 6: Health professionals:

- It seems as if most of the health professionals will be recruited from a local health service and it is not clear if the health professionals will have direct clinical experience in addressing cognitive impairment post stroke. It may be worth considering expanding the scope of potential recruitment to address this gap.

Response 6: Thank you for this comment. One means of recruiting health professionals is from a local service, and another is through social media (Twitter) with no limit on geographical location. Given the use of Twitter as a platform to advertise our study, and that data will be collected online due to Covid-19 restrictions, we foresee recruitment extending far beyond local health services.

We have edited the inclusion criteria for health professionals to outline that health professionals must have experience in the treatment of individuals post-stroke with cognitive impairment in order to be eligible. Please see Methods, subheading: Sampling and recruitment.

Point 7: It is not clear why you have chosen not to include nursing staff among HCP to be recruited?

Response 7: Thank you for this question. We aimed to include HCPs most likely to delivery such an intervention but we recognise that some were not included e.g. nursing staff. This will be acknowledged as a limitation in the results manuscript.

Point 8: Data collection:

It would be helpful for the reader to clarify which participants will be offered the opportunity to engage in a focus group and which participants will be interviewed.

Response 8: HCPs alone, if working on the same clinical site and if deemed more feasible to facilitate, will be offered to engage in a focus group. People post-stroke and caregivers will be interviewed. This has been clarified in the Methods, subheading: proxy respondents.

Point 9: The process for data analysis is clear and comprehensive.

Response 9: Thank you.

Competing Interests: I have no competing interests to declare.

Reviewer Report 18 January 2021

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Sinéad Hynes 

Discipline of Occupational Therapy, National University of Ireland, Galway, Ireland

Summary:

This protocol of a qualitative study examines the perspectives of key stakeholders on cognitive rehabilitation for people post-stroke. Through a series of interviews (with people who have had a stroke and are experiencing cognitive difficulties, healthcare professionals, carers, and academics), the authors aim to gather data that will be used to inform the development of a cognitive rehabilitation intervention for people post-stroke. The protocol provides a good level of detail, including supporting material, that allows for replication of the research. The authors make reference to the use of the template for intervention description and replication checklist for reporting of interventions (TIDieR) and The Consolidated Criteria for Reporting Qualitative Studies (COREQ) guidelines which are good to see in the development of the research protocol. There are a number of areas that I think need clarification or some additional detail in order for the protocol to be complete.

Aim:

Given that the title states that the study will *"inform the development of an intervention to improve cognitive impairment post-stroke."* there is not adequate discussion with regards to how the results of this research will be used to inform an intervention.

The research aim in the manuscript is a better match with the focus of what is proposed: *"The aim of this study is to examine the perspectives of key stakeholders on the design and delivery of an optimal intervention to rehabilitate cognitive deficits post-stroke."*

Background:

There has been much done in this field in the past- how will previous research be integrated into the planned intervention? The background should provide more detail on cognitive rehabilitation interventions that have a promising/proven evidence base. There is reference to a not-yet published review on the topic which is not sufficient, given the aim of intervention development.

It would be useful to have a stronger rationale for the current study, given that there is an extensive literature base in the area. What was the rationale for focusing on stakeholder views on intervention? Is the specific focus here on the feasibility in practice or is it something else- it would be good to see this clarified. Given the broad range of cognitive deficits seen in people post-stroke, will the proposed cognitive intervention focus on all areas proposed here or will it be specific to an area- e.g. memory, neglect, etc. Some clarification would be beneficial for the reader.

Eligibility:

People post-stroke- How will the inclusion criteria of "self-reported cognitive problems" be met?

What are the limitations of not including people post-stroke who cannot provide informed consent?

With regards to “changes to capacity” and this being “assessed on a continual basis” and “reviewed again after participation has occurred”- is it not a one-off involvement for participants? Why is there a need for monitoring of capacity in this study?

Proxy respondent- will they be assisting the person post-stroke to answer the questions or giving their own responses? When and how will the decision be made to use a proxy? Would be good to get more detail of what this would look like in practice- will the person post-stroke be present for the interview?

Caregiver criteria- is there a minimum amount of care that needs to be provided by carers for them to be deemed eligible? “Have been involved in care”- does it matter how long ago this might be? Given that data is being collected remotely had you thought about recruiting from outside of Limerick?

Academics- How will the authors deal with a potential conflict of interest or coercion when recruiting researchers from their own research group to participate in the study? How might this affect the data collected?

Data collection:

There are a number of references to focus groups in the manuscript- “semi-structured interviews and focus groups”. The rationale and methodology for focus groups and interviews is distinct. Need to see a clearer rationale for the use of interviews/focus groups with different groups in the study. Privacy and anonymity are mentioned (column 2, top of page 5) and this would not be guaranteed with focus groups.

Interview guide:

Participants post-stroke

- Interview guide- questions are very specific for someone with cognitive difficulties- e.g. exact details of materials used in previous rehab programmes.
- In the “what” section – are participants asked about each of these intervention types? Are they Yes/no responses? It would be good to have more clarification here as there is a danger of leading participants through some of the suggestions.
- Some of the questions are quite complicated.
- Would the participant be expected to know who would best deliver the intervention?

How long on average are the interviews? Seems quite a substantial amount of material for someone with cognitive difficulty (and potential cognitive fatigue).

Is the same guide used for focus groups?

Guide for HCPs- are you interested in “the ideal world” or what is feasible in their own clinical practice?

Data analysis:

How will the separate data sets be integrated? Will the data be analysed separately for each of the

groups or will this be integrated? Will interview and focus group data be analysed in the same way? Will member-checking only be used with proxy interviews? There is reference to "trustworthiness" but not adequate detail in relation to how this will be ensured.

Conclusion

How exactly will the findings be used to inform an intervention? This needs to be clearer given the title and aim of the research. The impact and need for the research should be clear.

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Partly

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cognitive rehabilitation, community-based rehabilitation, intervention development.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 02 Jul 2021

mairead o donoghue

Thank you for reviewing this protocol. I apologise for the delay in response.

Point 1: Given that the title states that the study will "*inform the development of an intervention to improve cognitive impairment post-stroke.*" There is not adequate discussion with regards to how the results of this research will be used to inform an intervention. The research aim in the manuscript is a better match with the focus of what is proposed: "*The aim of this study is to examine the perspectives of key stakeholders on the design and delivery of an optimal intervention to rehabilitate cognitive deficits post-stroke.*"

Response 1: Thank you for this valuable feedback. We have added further discussion outlining how stakeholder perspectives will inform the development of an intervention to improve cognitive impairment post-stroke in more detail. Please see Introduction section, Line 142-145, Line 147-156. We have also changed the title of this manuscript to reflect a clearer message of the study.

Point 2: Background:

There has been much done in this field in the past- how will previous research be integrated into the planned intervention? The background should provide more detail on cognitive rehabilitation interventions that have a promising/proven evidence base. There is reference to a not-yet published review on the topic which is not sufficient, given the aim of intervention development.

Response 2: Thank you for this question. We have added additional text and referenced additional sources to outline previous research on cognitive rehabilitation interventions. We have added evidence from previous Cochrane reviews. Please see Introduction, Line 93-105. We have also expanded on the findings of our quantitative systematic review. Please see Introduction, Line 116-119. The referenced systematic review protocol is for a systematic review which is currently under review with *Stroke AHA*. We hope to hear a decision on this soon. For now, we have referenced the published systematic review protocol.

Point 3: It would be useful to have a stronger rationale for the current study, given that there is an extensive literature base in the area. What was the rationale for focusing on stakeholder views on intervention?

Response 3: Thank you. The rationale for focusing on stakeholder views is that we wish to elicit the perspectives of key stakeholders on the design and delivery of an intervention to rehabilitate cognitive deficits post-stroke. Such a starting point will aid early knowledge on feasibility and acceptability of future interventions. We have clarified this in the manuscript. Please see Introduction, Line 147-154.

Point 4: Is the specific focus here on the feasibility in practice or is it something else- it would be good to see this clarified

Response 4: The specific focus is to gain the perspectives of key stakeholders to inform the development phase of the MRC framework. In accordance with the MRC framework, perspectives of relevant stakeholders will be used to inform the development and design of an evidenced-based and stakeholder informed feasibility study rehabilitate cognitive deficits post-stroke. This has been clarified in the Introduction, Line 150-156.

Point 5: Given the broad range of cognitive deficits seen in people post-stroke, will the proposed cognitive intervention focus on all areas proposed here or will it be specific to an area- e.g. memory, neglect, etc. Some clarification would be beneficial for the reader.

Response 5: We agree that cognitive functioning is very diverse. The findings from this qualitative study will help determine what specific domain/ domain(s) of cognitive impairment our intervention will focus on, or indeed if a domain will be focused on. The content of the proposed intervention will be prioritised based on the findings of our previous quantitative systematic review, coupled with our future qualitative findings. We have added to the manuscript to outline items in the interview schedule which include

questioning around a breadth of rehabilitation interventions and multiple domains of cognitive functioning. Please see Methods section, subheading: Topic Guides, Line 393-397.

Point 6: People post-stroke- How will the inclusion criteria of “self-reported cognitive problems” be met?

Response 6: The gatekeepers of both the Stroke Support Group and Headway are in a position to identify people with cognitive difficulties post-stroke and as such, will identify individuals that may be suitable to participate based on pre-defined eligibility criteria.. Once potential participants have been identified, and have received and understood the participant information leaflet, the researcher will re-assess eligibility based on inclusion criteria as outlined in the manuscript. A line has been added to the Methods section to demonstrate the role of the researcher in confirming the eligibility of the potential participant during the recruitment process. This will entail the person with stroke confirming they have cognitive issues as a result of their stroke. Please see Methods, subheading: Sampling and Recruitment, Line 243-245.

Point 7: What are the limitations of not including people post-stroke who cannot provide informed consent?

Response 7: Thank you for requesting clarity on this. The inability to include people unable to consent, due to clear ethical concerns, means that their perspectives on intervention design will be missing from this study, which we will acknowledge as a limitation of this study.

However, we have attempted to address this via the use of proxy respondents, by including the views of caregivers and reducing the cognitive load on people post-stroke using. Please see details of how we aim to facilitate people post-stroke during the interview in Methods, subheading: Proxy respondents.

Point 8: With regards to “changes to capacity” and this being “assessed on a continual basis” and “reviewed again after participation has occurred”- is it not a one-off involvement for participants? Why is there a need for monitoring of capacity in this study?

Response 8: Thank you for this question. “Reviewed again after participation has occurred” refers to immediately after the interview had been conducted. We are not following up at a later date. The monitoring of capacity is only relevant for people post-stroke. People post-stroke will be assessed for capacity to consent on a continual basis throughout the interview given that cognitive deficits may interfere with the decision making process regarding participation in research. We have clarified this in Methods, Line 273. We have also added that participants may withdraw from the study at any time. Please see Methods, subheading: Sampling and recruitment, Line 276-277.

Point 9: *Proxy respondent*- will they be assisting the person post-stroke to answer the questions or giving their own responses? When and how will the decision be made to use a proxy? Would be good to get more detail of what this would look like in practice- will the person post-stroke be present for the interview?

Response 9: Thank you. We have clarified the role of proxy respondents in the manuscript. Please see Methods, subheading: proxy respondents, Line 327-331.

Point 10: Caregiver criteria- is there a minimum amount of care that needs to be provided by carers for them to be deemed eligible? "Have been involved in care"- does it matter how long ago this might be?

Response 10: No, there is not a minimum amount of care that needs to be provided by carers for them to be deemed eligible. In accordance with the definition used to identify caregivers, "Carers will include caregivers, spouses or family members who provide care (paid or unpaid), support or assistance to people post-stroke (Greenwood *et al.* 2008)". This has been clarified in the Methods, subheading: Sampling and recruitment, Line 220-221.

Point 11: Given that data is being collected remotely had you thought about recruiting from outside of Limerick?

Response 11: Yes, we had considered recruiting outside of Limerick. This study will use both purposive and snowball sampling of participants. Snowball sampling of participants would permit recruitment to extend beyond the Limerick area. The use of Twitter will also allow recruitment to extend beyond the Limerick area also. We have added to the manuscript outlining that participants will be recruited outside the Limerick area. Please see Methods, 193-195.

Point 12: Academics- How will the authors deal with a potential conflict of interest or coercion when recruiting researchers from their own research group to participate in the study? How might this affect the data collected?

Response 12: We will acknowledge the potential relationship between the researchers and academicians recruited. We have added to Methods to outline how this potential conflict of interest will be managed. Please see Methods, Sampling and Recruitment, Line 236-239.

Point 13: Data collection:

There are a number of references to focus groups in the manuscript- "semi-structured interviews and focus groups". The rationale and methodology for focus groups and interviews is distinct. Need to see a clearer rationale for the use of interviews/focus groups with different groups in the study. Privacy and anonymity are mentioned (column 2, top of page 5) and this would not be guaranteed with focus groups.

Response 13: Thank you. We plan to conduct focus groups only for health professionals working on the same clinical site. Due to the remote nature of conducting our data collection due to Covid-19, people post-stroke and caregivers will be interviewed in their own homes and as such, a focus group will not be conducted with these groups. We have amended the text to clarify this. Please see Methods, subheading: proxy respondents, Line 349.

We agree that focus group methodology raises ethical challenges with regard to the

preservation of privacy and anonymity. We have added to the manuscript to outline the means of addressing these issues. Please see Methods, subheading: Focus Groups, Line 350-358.

Point 14: Interview guide:

Participants post-stroke

- Interview guide- questions are very specific for someone with cognitive difficulties- e.g. exact details of materials used in previous rehab programmes.
- In the “what” section – are participants asked about each of these intervention types? Are they Yes/no responses? It would be good to have more clarification here as there is a danger of leading participants through some of the suggestions.

Response 14: Thank you for requesting clarity on our interview guides. The “what” section of the interview would open up responses on the experience or knowledge of the individual regarding a particular intervention, if they are able to recall this. In some cases, specific intervention examples may be helpful to assist with gathering of information i.e. people with recall issues. If they are not able to recall these details, more general information will be gathered. These are suggested questions and not all are mandatory, the interviewer will adapt to the communication ability and preference of the interviewee on a case by case basis. If the participant wishes to answer in a yes/ no format, the researcher will probe using prompts as detailed in the interview scripts. If the probing does not result in an expanded answer, then a yes/no answer will suffice. The interventions listed in the “what” section are based on a systematic review and meta-analysis completed by our research team. This systematic review evaluated the effectiveness of these interventions to rehabilitate people with cognitive deficits post-stroke. However, there remains unanswered questions about these interventions with regard to their optimal mode of delivery, timing of intervention etc. Where possible, these details will be gathered but we acknowledge that specifics of intervention design and delivery may not be possible to ascertain.

Point 15: Some of the questions are quite complicated. Would the participant be expected to know who would best deliver the intervention?

Response 15: Based on their experience of stroke rehabilitation as a person post-stroke, a caregiver or a health professional, their opinion on who they perceive as best to deliver the intervention would be valuable information for the design of a programme, where they have an opinion on this topic based on their experience. As discussed, we will pilot the interview on a participant from each stakeholder group and modify the script as required as well as allow for different administration between participants as their communication and cognitive issues require. Please see Methods, subheading: Piloting.

Point 16: How long on average are the interviews? Seems quite a substantial amount of material for someone with cognitive difficulty (and potential cognitive fatigue).

Response 16: Interviews are expected to last no more than one hour. Breaks will be given as required/requested, interviews may be conducted in 2-3 shorter sessions if required e.g. if cognitive fatigue is an issue. This has been addressed in the manuscript. Please see Methods, Data Collection, Line 317-319.

Point 17: Is the same guide used for focus groups? 19:

Response 17: Yes. This has been clarified in Methods. Please see Methods, Focus Groups, Line 357-358.

Point 18: *Guide for HCPs-* are you interested in "the ideal world" or what is feasible in their own clinical practice?

Response 18: We aim to explore both of these areas. As seen from our interview guide, we pose questions to gain perspectives on a hypothetical "ideal world" intervention. Given that there are substantial gaps in the literature to date regarding the optimal intervention to rehabilitate people with cognitive deficits post-stroke, we are interested in gaining these perspectives to fill the gap in the literature. In the closing questions of the interview, we pose a question regarding practicalities of delivering the intervention(s). Participants are encouraged to speak about their own clinical practice and what they perceive as working/not working regarding the feasibility of interventions to rehabilitate cognitive impairment post-stroke. This will be vital to develop understanding of feasibility and acceptability of a potential intervention. Please see "interview guides" for further clarification on our line of questioning (available as extended data).

Point 19: Data analysis:

How will the separate data sets be integrated? Will the data be analysed separately for each of the groups or will this be integrated? Will interview and focus group data be analysed in the same way? Will member-checking only be used with proxy interviews? There is reference to "trustworthiness" but not adequate detail in relation to how this will be ensured.

Response 19: Datasets from each stakeholder group will be analysed using reflexive thematic analysis. Therefore, each transcript will be analysed separately at first and then integrated in accordance with each stage of reflexive thematic analysis i.e. where data will be synthesised across groups. Yes, interview and focus group data will be analysed in the same way. We have added detail to the manuscript outlining how peer debriefing will be conducted to enhance the credibility and trustworthiness of data analysis. Please see Methods, Data Analysis, Line 437-439.

Point 20: How exactly will the findings be used to inform an intervention? This needs to be clearer given the title and aim of the research. The impact and need for the research should be clear

Response 20: Thank you. We have added a sentence to clarify the impact of these research findings. Please see Conclusion, Line 478-481.

Competing Interests: I have no competing interests to declare.