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Study Protocol

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Protocol Approval

The return to work experiences of people with communication disorders post-stroke: a qualitative study – ConQueSt

Signatures

By signing this document I am confirming that I have read, understood and approve the protocol for the above study.

Emma Coutts		5th October 2022
Chief Investigator	Signature	Date

1.0 Title

The return to work experiences of people with communication disorders post-stroke: a qualitative study

2.0 Summary

With an estimated incidence of 15 000 in Scotland every year, stroke is the most common cause of severe physical disability among adults in Scotland. As approximately a quarter of stroke survivors are of working age, a significant proportion of the considerable financial burden of stroke can be attributed to difficulties to returning to work because of the ensuing disabilities. Stroke-related disabilities may be obvious and physical, such as reduced mobility or limited movement in the upper limb on the affected side. However, other disabilities such as communication disorders including aphasia (language processing difficulties) and dysarthria (speech articulation difficulties) may be less apparent but equally significant, because of the importance of communication across a vast range of work activities. There has been little research into the barriers and facilitators affecting people with post-stroke communication disorders endeavoring to return to work. This study aims to address this issue by conducting semi-structured interviews with people with post-stroke communication disorders to explore their experiences of returning or attempting to return to the workplace. This study will generate important knowledge that will help inform the development of a targeted intervention for this population, which will be evaluated in a future study. It therefore represents the vital first step in understanding the problem (return to work for people with post-stroke communication disorders), which is key to the development of complex health interventions.[1]

3.0 Background and rationale

Approximately a quarter of stroke survivors are of working age,[2] and while estimates of return to work rates following stroke vary considerably, ranging from around 11% to 85%,[3] it has been estimated that over 9 million workdays are lost in the UK alone each year because of stroke, with 26% of the total annual cost of stroke being due to loss of productivity.[4] In addition to the economic cost, being out of the workplace due to disability has major psychosocial costs for the individual, causing reduced social capital, sense of purpose, quality of life and standard of living.[5-6] Return to work following illness or injury is therefore an important factor in reducing these economic, social and personal consequences.[7] Communication disorders resulting from a stroke are very common: an estimated 21-38% of stroke survivors are affected by aphasia (which can affect comprehension of the spoken and written word, as well as the production of speech and writing),[8] and 20-30% by dysarthria.[9] Because of the importance of spoken and written communication in work activities, such impairments can cause considerable barriers to return to work.[10] One review found that the return to work rate for people with post-stroke aphasia averaged 28% across the included studies, a significantly lower rate than that for the general population of working-aged stroke survivors, which was 45%.[8]

We recently carried out a scoping review[11] which found that while there has been a significant amount of research in the last ten years on factors, barriers and facilitators impacting on return to work for people following a stroke, there has been little research specific to people with post-stroke communication disorders: only two records were identified in the scoping review, one of which was a narrative review on rates of return to work[8] and one of which was a single case study on a person with aphasia's experiences of return to work.[12] Therefore, there is a need to carry out research in this area, to explore issues which are unique or particularly pertinent to people with post-stroke communication disorders. This

is especially important, given the necessity of effective communication in a wide range of work-related activities, for example as a means to engage with colleagues, to share information in order to solve problems and resolve conflicts,[13] and as a means to ensure health and safety.[14]

4.0 Public involvement

People with lived experience were engaged in the design of this study and will continue to be engaged throughout its implementation. This will help to ensure that the study is relevant, the design is acceptable, the information is understandable and the results are effectively communicated at the end of the study.[15] For the design stage of the project, three people from across Scotland who were known to the Chief Investigator (CI) as having the experience of attempting to return to work with post-stroke communication disorders were contacted by letter and invited to contribute to development of this proposal. An outline of the study including the proposed research questions and methodology, written in accessible language, was sent by post or email to the two people who responded. A video call (via Microsoft Teams) was arranged with each person at least 5 days later in order for them to give their comments and make further suggestions from the perspective of their lived experience of the issue. These comments and suggestions were subsequently incorporated into the design of the study which is described below. Specific examples include explicit mention that communication refers to reading/writing as well as speech, and the inclusion of National Stroke Voices as a vehicle for recruitment. These two advisors also participated in further stages of the design, as described in the relevant sections below.

5.0 Aims and research questions

This proposed research aims to investigate the experiences of people with post-stroke communication disorders who are attempting or have attempted to return to work. The specific questions are:

i) What are people with post-stroke communication disorders' experiences of attempting return to work?

ii) What barriers and facilitators are experienced by people with post-stroke communication disorders when attempting to return to work?

iii) What do people with post-stroke communication disorders perceive their informational and support needs to be in relation to return to work?

iv) How and by whom do people with post-stroke communication disorders perceive that any informational and support needs could be met?

6.0 Methodology and methods

6.1 Study design

A qualitative descriptive study design will be used. This methodology seeks to discover and understand a phenomenon from the perspectives of those experiencing it.[16] It falls within the naturalistic approach[16] and attempts to interpret findings while staying close to the surface of the data.[17] It is appropriate to this study because it offers the opportunity to gather rich descriptions of a phenomenon about which little is currently known,[16] and the use of knowledge gained may influence interventional approaches aimed at the participant population.[16] Interviews will be carried out using a semi-structured format in order to allow flexibility to explore aspects of importance to the participants while having focus maintained by the guide questions.[18]

6.2 Setting

The study will take place within Scotland. The focus will be the area covered by NHS Grampian, NHS Greater Glasgow and Clyde, and NHS Highland health boards. Participants can also take part from elsewhere in Scotland where they are recruited via social media or through public adverts. This cohort is of sufficient size to make recruitment viable and feasible, and it also represents a range of geographical areas in terms of urban/rural classification to allow for generalizability of the findings to elsewhere in Scotland and beyond.

6.3 Participants

Adults (aged 18 years of age and over) will be eligible for inclusion if:

- they have had an ischaemic or haemorrhagic stroke (excluding Transient Ischemic Attacks, or mini strokes) within the last 3 years
- they self-identify as having communication difficulties as a result of the stroke
- they were in paid employment or actively seeking work at the time of their stroke
- they are attempting or have attempted (whether or not successfully) to return to paid employment since their stroke.

Individuals will be excluded if:

- they lack the capacity to consent
- they are considered to have insufficient English language skills to be able to engage effectively in an interview, given that this is a small-scale study which will not have the resources to fund interpreter services

- they have a diagnosis of a learning disability, dementia or another comorbidity deemed to be as or more significant than the stroke in their experience of return to work.

6.4 Recruitment

Sampling will be purposive and include more than one pathway in order to recruit a wide range of participants. In one pathway, individuals will be recruited through Speech and Language Therapy services in NHS Grampian, NHS Greater Glasgow and Clyde, and NHS Highland. Speech and Language Therapists (SLTs) will identify potential participants, discuss the project with them, and give them the information pack. This pack, which was designed in consultation with the two advisors with lived experience mentioned above (Section 4.0), will include an invitation letter, Participant Information Sheet (PIS), and reply slip with a stamped addressed envelope. In a second pathway, advertising notices (again designed in consultation with the advisors mentioned in Section 4.0) will be given to groups for stroke survivors run by organisations such as the Chest Heart and Stroke Scotland and the Stroke Association across Scotland, inviting individuals to contact the research team if they wish to be considered for the study. They will then be sent an information pack including a PIS, and a reply slip with a stamped addressed envelope. In either pathway, the individual can then reply to the research team by post, email or telephone if they wish to proceed with involvement.

We will aim for a total sample size of 18 participants. We will aim to recruit 12 participants initially. If data saturation has not been reached, a further three participants will be recruited, then further groups of three until data saturation has been reached. If data saturation has been reached before 18 participants have been recruited, we will close the study early. This number is based on evidence that a sample size of 12 has been found to be the minimum for data saturation in an interview study[19] and also for pragmatic reasons (e.g. the predicted

availability of eligible participants within the region, and the time and resource limitations of the study.) If recruitment numbers are low, a third recruitment pathway will utilise the vehicle of the National Stroke Voices public involvement group and/or social media (Twitter/Facebook accounts for relevant NHS Grampian and Robert Gordon University (RGU) departments and professional contacts of the research team). Participants will be recruited via advertisements and will be asked to contact the research team in the same way as the first and second recruitment pathways.

6.5 Eligibility screen and informed consent

A member of the research team will make contact with each potential participant who has consented to the initial contact or responded to an advertisement to screen against the inclusion and exclusion criteria for eligibility, discuss the study further and answer any questions about it. If the person still wishes to be involved in the study, a member of the research team will arrange to meet them at a mutually agreed venue or, where a face to face meeting is not possible, via a digital interface such as NearMe or Microsoft Teams (in the case of people recruited from the NHS Greater Glasgow and Clyde and NHS Highland areas, all meetings would be conducted via a digital interface rather than face to face). Written informed consent will be obtained before conducting the interview. The participant will initial, sign and date two copies of the consent form, one of which they will keep, the other being retained by the researcher team. Where the meeting is conducted via a digital interface,. the participant will be provided with a copy of the consent form by email or post, according to their preference, and each point will be read aloud to the participant for them to indicate their consent to participate verbally. The researcher will initial each point of the consent form as the participant agrees, and will retain this hard copy. A copy of this will be sent to the participant. This meeting would be recorded, and the recording stored (see section below on data protection).

6.6 Ineligible and non-recruited patients

Participants recruited via SLTs will have been identified as eligible by the SLTs, so it is unlikely that they will then be found to be ineligible for inclusion when screened by a member of the research team. It is possible however that individuals who respond to advertisements may be found to be ineligible when screened. In this event, they will be thanked for their interest and their time, and it will be explained to them why the current study is not appropriate for them. They will be directed to sources of support as appropriate. A screening log will be kept, recording how many individuals have been approached about the study; how many individuals have contacted the research team to request an interest in participating; and how many of these have been screened as eligible for inclusion.

As involvement will entail a single interview, it is highly unlikely that a participant would have to be withdrawn by the research team. If a participant chooses to withdraw when data collection has already begun (e.g. when the interview has commenced), they will be asked if they consent to the data already collected being retained by the research team for analysis. Their wishes in this regard will be respected.

6.7 Data collection

In the case of face to face interviews, these will be arranged with participants in a venue suitable for them (e.g. in their own home or in a clinic or a mutually convenient community location). The sponsor's Lone Working Policy will be adhered to, with risk assessments carried out as appropriate, in order to reduce the risk of harm to members of the research team. While it would be more beneficial to carry out face to face interviews because of participants' communication problems and the potential barriers caused by digital

technology, interviews could be carried out using digital interfaces such as Microsoft Teams or NearMe if necessary. As noted above, in the case of participants recruited from NHS Greater Glasgow and Clyde and NHS Highland areas, although it would be ideal to conduct face to face interviews, this is not practical outside of the Grampian area, therefore all interviews will be conducted via a digital interface. The interview will be informed by a topic guide with items probing the overarching research questions (e.g. questions about pre-stroke employment/job seeking activity; feelings on considering returning to work/job seeking after stroke (especially with regard to communication problems); support from health services/third sector; discussions with employer/employment services; nature of return and adjustments made; feelings about return (especially with regard to communication problems). The topic guide questions were informed by consultation with the advisors with lived experience mentioned above (Section 4.0). In addition, they were piloted with a colleague.

The interviews will last approximately 60 minutes, but the time will vary depending on the individual and their communication needs and skills (e.g. how much information they are able to provide; whether additional time is required for them to respond to questions). Additional communication support will be given if necessary (e.g. use of writing, drawing and gesture, and communication technology). If a participant would like to take a break from the interview it can be paused, as necessary, and a further session can be arranged to complete the interview at a convenient time for the participant. Participants will be given a shopping voucher as a thank-you for taking part in the study.

The interviews will be digitally recorded on a password-protected NHS iPad (with automatic cloud storage having been disabled). The recordings will be immediately transferred onto an NHS password-protected computer and deleted from the portable device.

6.8 Data analysis

The audio-recordings will be transcribed by an NHS Grampian-approved transcription service. Thematic analysis will be undertaken, using the procedure outlined by Braun and Clarke.[20] The CI will generate the initial codes on the basis of content pertinent to the research questions. A research fellow will assist with the coding process. In order to ensure rigour, The CI, one of the collaborators (a research professor), and the research fellow will code 2-3 transcripts independently and review agreement/disagreement. This may result in refinement of the coding index and further coding and reviewing agreement, until agreement is sufficiently high for coding to be conducted by the CI or the research fellow.

An audit trail will be kept in the form of Microsoft Word documents recording discussions and decisions that are made. The data management software system NVivo will be used to facilitate data analysis. Participants will be sent a summary of the initial findings and asked if they have anything further to add. They will be able to provide this by filling in a feedback form supplied with a stamped addressed envelope. This will be an optional activity and all responses will be fully anonymous. Any additional information provided by the participants in this feedback will be incorporated into the final analysis.

7.0 Project management

The project will be overseen by a steering group comprised of the research team, 1-2 healthcare professionals with specialist knowledge of return to work (e.g. a vocational rehabilitation specialist and/or a physiotherapist or occupational therapist with relevant expertise) and 2-3 lay advisors with lived experience (invited from the pool of advisors who participated in the design stage, as discussed above in section 4.0). This group will meet every 3 months to discuss progress and to agree on any further decisions that require to be

made during the course of the project. In keeping with current guidance, lay members will be reimbursed for their time and travel.

A study-specific Delegation Log will be prepared, detailing the responsibilities of each member of staff working on the study.

8.0 Inspection of records

The CI, collaborators and all institutions involved in the study shall permit study related monitoring, audits, and Research Ethics Committee (REC) review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.

9.0 Good clinical practice

9.1 Ethical issues

The study will be conducted in accordance with the principles of good research practice (GRP). In addition to Sponsorship approval, a favorable ethical opinion will be obtained from the appropriate REC, and appropriate Research and Development (R&D) approvals will be obtained prior to commencement of the study.

Potential participants will be given clear verbal and written information in an accessible format (for example large font size, pictorial support) as appropriate to the nature of their communication disorders. This information will highlight that participation is entirely voluntary

and participants can withdraw at any point without needing to give a reason and without it affecting any healthcare or return to work support they may be receiving.

We believe that there is a low burden or risk of harm to participants. Any unexpected distress experienced when describing the emotional impact of the stroke or any difficulties that ensued will be minimised by sensitive and sympathetic listening, acknowledging the distress and offering to discontinue the interview. In addition, the participant information sheet will signpost people to sources of support, for example Chest Heart & Stroke Scotland, or the Stroke Association.

9.2 Confidentiality

All data will be identified in a manner designed to maintain participant confidentiality. All records will be kept in a secure storage area with limited access to study staff only. Clinical information will not be released without the written permission of the participant, except as necessary for monitoring and auditing by the Sponsor or its designee. The CI and study staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee will be obtained for the disclosure of any said confidential information to other parties.

9.3 Data protection

The CI and study staff involved with this project will comply with the requirements of the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. The Health Research Authority (HRA) recommended wording to fulfil transparency requirements under the GDPR for health and care research has been included in the PIS.

The CI and study staff will also adhere, if appropriate, to the current version of the NHS Scotland Code of Practice on Protecting Patient Confidentiality. Access to collated participant data will be restricted to the CI and appropriate study staff.

Computers used to collate the data will have limited access measures via user names and passwords.

Published results will not contain any personal data that could allow identification of individual participants.

Participants will be assigned a code in order to de-identify them for the purposes of transcription and analysis. A separate file containing the participants' names and contact details will be stored separately and accessed only by the research team if necessary, e.g. for sending the summary of initial findings or final report. All identifiable study data (i.e. signed consent forms, the coding information with participants' details), will be stored on password-protected NHS computers (electronic data) and/or locked filing cabinets (hard copies consent forms) on NHS premises that are only accessible to members of the research team and destroyed at the end of the study.

Anonymised data may be analysed on university computers as well as NHS computers during the course of the study. This anonymised data will be transferred between institutions using a dedicated Microsoft Teams page. Anonymised transcriptions may be printed out to facilitate the process of data analysis. These hard copies will be stored in a locked filing cabinet in NHS or university offices which are locked outwith working hours. Audio

recordings will be destroyed at the end of the study. Anonymised research data will be stored for ten years in an NHS-approved storage facility.

Consent procedures will seek permission to use direct quotations from respondents. Any identifying material (e.g. names of people/employer) will be removed from the quotation.

10.4 Insurance and indemnity

Grampian Health Board is sponsoring the study.

10.4.1 Insurance – Grampian Health Board will maintain its membership of the Clinical Negligence and Other Risks Insurance Scheme ("CNORIS") which covers the legal liability of Grampian in relation to the study.

10.4.2 Indemnity: Grampian Health Board does not provide study participants with indemnity in relation to participation in the study but has insurance for legal liability as described above.

11.0 Output and dissemination

11.1 Authorship policy

Ownership of the data arising from this study resides with the study team and their respective employers. Following the analysis of the study data described above in section 6.7, a final report will be prepared.

11.2 Dissemination

The findings from the study will be presented via the following channels:

Academic: a peer-reviewed manuscript in high-impact journal aimed at rehabilitation professionals and academics; a presentation at a relevant international or national conference such as the UK Stroke Forum Conference.

Lay: a summary of findings provided to the study participants.

Professional: presentations to relevant NHS Grampian, NHS Greater Glasgow and Clyde, and NHS Highland rehabilitation professionals involved in managing post-stroke communication disorders and/or return to work, e.g. Occupational Therapists, Physiotherapists, Speech and Language Therapists, Vocational Rehabilitation specialists.

As indicated above (section 2.0), the findings will be used to progress a programme of research that will benefit people who have had a stroke. It will be combined with the findings from our earlier scoping review[11] to provide important knowledge about barriers and facilitators to return to work for people with post-stroke communication disorders. This knowledge will then be used in a co-production that will follow on from this study. In this co-production, based on the facilitators identified and using strategies to overcome the barriers, a targeted intervention will be developed to support people with post-stroke communication disorders attempting to return to work.

12.0 Study conduct responsibilities

12.1 Protocol amendments, deviations and breaches

The CI will seek approval for any amendments to the protocol or other study documents from the Sponsor (in the first instance), REC and NHS R&D Office(s). Amendments to the protocol or other study documents will not be implemented without these approvals.

In the event that the CI needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the Clinical Report Form, documented and submitted to the Sponsor. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to the appropriate REC and NHS R&D Office(s) for review and approval.

In the event that a serious breach of GCP is suspected, this will be reported to the Sponsor immediately using the form “Breach Report Form”.

12.2 Study record retention

Archiving of study documents will be on NHS Grampian premises in line with the Sponsor’s Standard Operating Procedure (SOP). At the end of the study the NHS Grampian archivist will be contacted to arrange appropriate archiving.

12.3 End of study

The end of study is defined as the last participant interview. The Sponsor, CI and/or the steering group have the right at any time to terminate the study for clinical or administrative reasons. The end of the study will be reported to the Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely. The CI will ensure that any appropriate follow up is arranged for all participants. A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study.

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