COMmunicating in STroke cAre and Rehabilitation (COM-STAR): Improving staff communication skills for better access to and inclusion in care and rehabilitation for stroke survivors with communication impairments

Short Study Title/ Acronym
COM-STAR

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Contents

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Study Summary

Study Title	COMmunicating in STroke cAre and Rehabilitation (COM-STAR): Improving staff communication skills for better access to and inclusion in care and rehabilitation for stroke survivors with communication impairments
Short Title	COM-STAR
Study Design	Mixed methods study design
Study Participants	Work package 1 strand 1: Online survey of national stroke professionals Work package 1 strand 2: Structured interviews with people with communication disorders, family members and stroke professionals Work package 1 strand 3: Systematic review of staff communication training interventions and implementation strategies Work package 2: Co-design of new communication training package Work package 3: Evaluation of implementation and impact of the training package
Planned Size of Sample	Total: n=902-1135 (plus unknown n choosing to participate in staff training) Work package 1 strand 1: 800-1000 survey respondents Work package 1 strand 2: 10 staff and 10-15 people with communication disorders and family members Work package 2: 18 co-design members Work package 3: Training completion rates of staff from 4 sites (n unknown) Interviews and video observations: 20-28 staff, 20-28 patients/family Staff Focus group: 4 groups of 6-9 staff - 24-36 participants
Planned Study Period	March 2024 - Feb 2027
Research Aims	The overall aim of this research is to develop and evaluate a theoretically-underpinned, co-designed communication skills training package for stroke staff working with communication impaired patients

Funding

FUNDER	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
National Institute for Health and Care Research, Health and Social Care Delivery ResearchProgramme	Funders of the research programme

Role of Study Sponsor and Funder
Neither the funder nor the Sponsor has had any role in study design, data collection and analysis, decision to publish, or preparation of manuscripts.

This project is funded by National Institute for Health and Care Research, Health and Social Care Delivery Research Programme [NIHR 155921]. The views expressed are those of the authors and not necessarily those of the National Institute for Health and Care Research, Health and Social Care Delivery Research Programme.

Role and responsibilities of Study Management Group and Steering Committees
The overall responsibility for the study will be with Sheffield Teaching Hospitals NHS Trust who will act as sponsors for the study. The study will be conducted in accordance with the protocol and good clinical practice (GCP). The two committees which will govern the conduct of the study are:

1. **Study Steering Committee (SSC)**

The SSC will be responsible for the overall conduct of the COMSTAR study and consists of an independent chair and up to seven other members including stroke specialists, methodologists and PPI representatives (adhering to the 75% independent requirement). The committee will meet approximately every 6 months to monitor the study.

2. **Study Management Group (SMG)**

The role of the SMG is to monitor all aspects of the conduct and progress of the research, ensure that the protocol is adhered to, and take appropriate action to safeguard participants and the quality of the research itself. The SMG will comprise of the Chief Investigators and all co-investigators. The SMG will meet on a regular basis (every two months) to monitor the day-to-day running of the study.

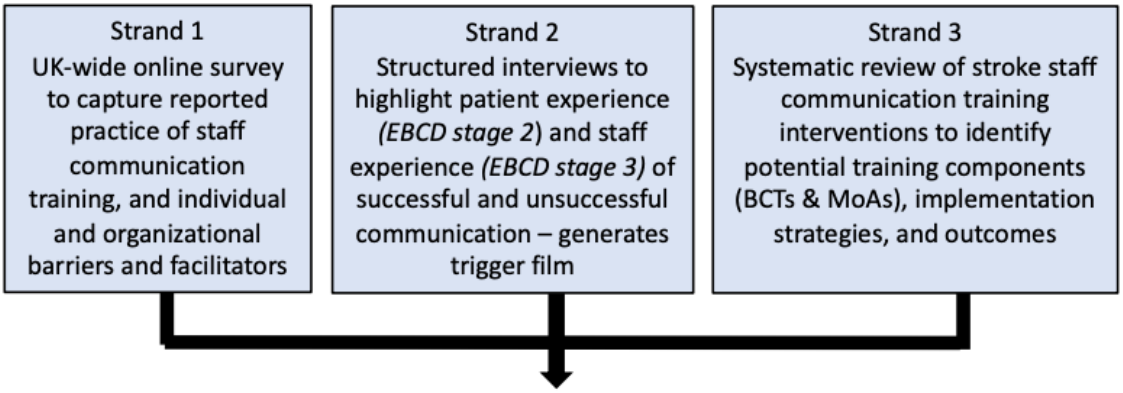
Protocol Contributors
All co-investigators contributed to the development of the protocol. The protocol was reviewed and the final version approved by Professors Rebecca Palmer and Madeline Cruice.

KEY WORDS:	Stroke Communication disorders Staff communication training

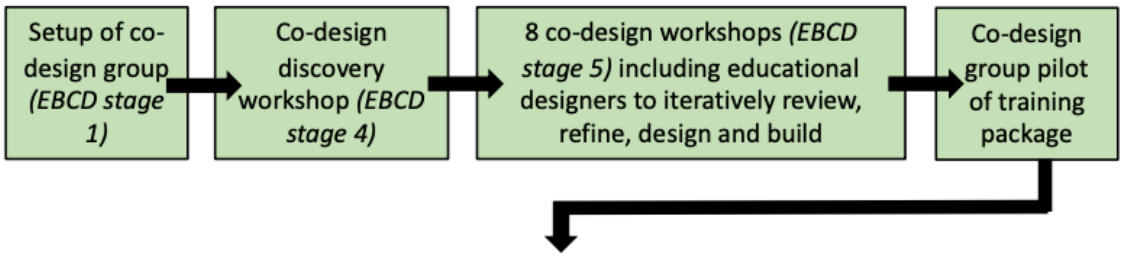
COM-STAR work package content and interaction

(Diagram identifies the 6 Experience-Based Co-Design stages from Bate and Robert 2007)

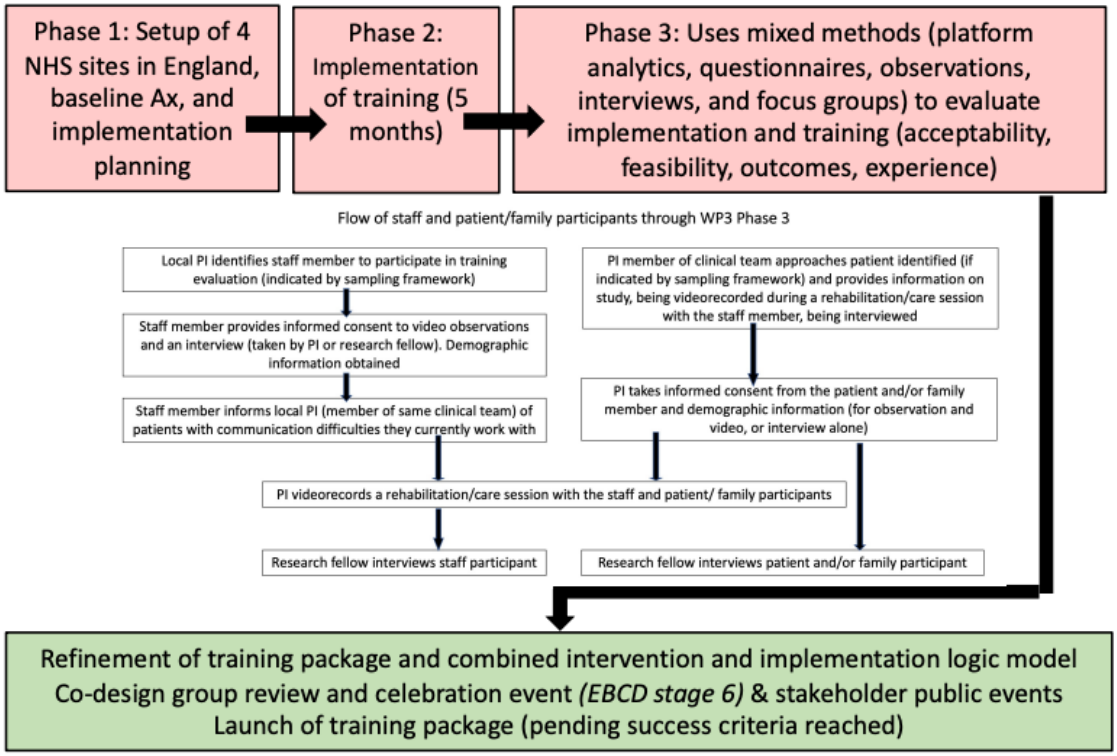
Work package 1: Preparatory work [Months 1-11]



Work package 2: Co-design of training package [Months 9-22 & 34-36]



Work package 3: Evaluation of implementation and training [Months 20-33]



NB. This protocol refers only to work package 1 and 2.

1. Background and Rationale

Stroke patients with communication impairments and stroke health and social care professionals have difficulty communicating together, with negative consequences. Throughout this protocol, the term 'patients' is used to refer to stroke survivors with aphasia, dysarthria, dyspraxia and/or cognitive communication difficulties in hospital or community rehabilitation; and 'staff' refers to the full multidisciplinary team including healthcare/rehabilitation assistants, involved in rehabilitation. Staff and patients experience challenging and frustrating communication breakdowns causing stress and anxiety[1,2,3]. Staff lack knowledge and confidence and feel ill-equipped to communicate with these patients; and consequently dread, limit, and avoid communication interactions[2,3,4]. Patients and families feel frustrated, in denial, fear, panic, depression, confusion, and uncertain when they are not able to communicate effectively with staff[5]. They become disempowered and minimally involved in their care and rehabilitation[1,6] with increased risk of preventable adverse events in hospital and poor outcomes[1,7]. This problem is substantial, as the majority of stroke survivors in UK hospitals have communication impairments: 64% of 88,974 patients[7]. As such, there is a sustained need for a workforce skilled in communicating with these patients.

National and international[2,4,8,9,10,11] research conducted with patients, family members, and speech and language therapists (SLTs) confirms that staff (across the stroke pathway) need greater awareness of communication impairments and how to support communication. Staff have expressed they want to know how to support communication-impaired patients and want more training on how to use communication strategies, tools and resources[2,4]. In the UK, anecdotally, SLTs deliver communication training to stroke multidisciplinary team (MDT) colleagues, however staffing issues/pressures reduce SLTs' capacity to deliver this within their role leading to high variability within services. SLTs elsewhere have also reported insufficient resources to provide training themselves and would value freely accessible, manualized resources including tip sheets and instructional videos[12].

The Stroke Specific Education Framework (SSEF) expects staff to understand stroke communication impairments and adapt their communication to patients' needs. However, there is no evidence-based national training for staff identified and/or provided by SSEF or NHS England that includes communication training and resources to adapt healthcare communication and make it accessible. SSEF has indexed a small number of courses that include communication, however these are not deemed fit for purpose because: they are very short (e.g., 2 mins 38 seconds for assistants); they are too long (2 or 3 days with e.g., 5 hours homework) and taught face-to-face only; or are no longer available. One course has relevant content on types and effects of communication impairments and strategies, and is available online; however it does not consider dyspraxia or cognitive communication impairment; is not theoretically underpinned by behaviour change theory; and has not been evaluated.

Existing training packages also substantially focus on knowledge. Whilst knowledge is a necessary precondition for behaviour-change, education-in-isolation interventions are ineffective in changing staff practices in stroke[13] and are likely ineffective in changing staff communication behaviours with patients[14]. In addition, delivery (by SLTs) and adoption of communication training by staff is affected by a range of factors including staff self-efficacy, time pressure, and managerial and organisational support[13,15,16,17]. Factors shown to be effective in changing behaviour in stroke care/staff communication include site facilitation and ongoing support, local site tailoring, iterative tailoring, audit feedback, specialist feedback, physical resources, educational lectures paired with patient interactions, and electronic reminders[13,15,17].

There is currently no evidence or agreement on what behaviour change techniques are most effective at changing staff communication with patients with communication impairments. Evidence for what intervention components should be incorporated into staff training, what range of outcomes should be targeted, and how best to ensure delivery and uptake of training in practice is lacking. Evidence syntheses of stroke-specific[18] and general healthcare professional education[19,20] recommend interactive training, delivered to multidisciplinary groups, and training that exploits the use of technology (e-learning) for standardisation and access[18,20]. It should attend to known facilitators and barriers relating to the learner, as well as design, delivery, and implementation of online training[19].

This programme of research will create a communication skills training package (inclusive of online training, local skills practice, resources, implementation toolkit, and communication checklist) for staff (qualified and assistant) tailored specifically for their use in stroke care and rehabilitation in UK NHS hospital and community stroke services. The training package will be evidence-based and theoretically designed to change clinicians' communication behaviours with appropriate regard for the organisational context in which clinicians practise and in which patients receive services. The research will evaluate both the implementation of training in four NHS sites which have been selected to reflect different stages of the stroke pathway and varying organisational complexity, and the outcomes and impact of the training on staff communication behaviour, and staff and patient experience.

2. Aims and objectives

Aim: To develop and evaluate a theoretically-underpinned, co-designed communication skills training package for stroke staff working with communication impaired patients.

Objectives:

1. Understand the context of communication and communication training in stroke care
    a. Map current practice in stroke staff communication training in the UK including individual and organisational barriers to, and facilitators of, implementing training and changing communication behaviour in practice
    b. Highlight the impact of unsuccessful and successful communication on both patients and staff
    c. Identify potential training components (behaviour change techniques), implementation strategies and outcomes from the literature
    d. Create a type 4 logic model[21] combining a theory driven intervention logic model[22] and an implementation research logic model[23] defining the training and implementation impact
2. Co-design a novel standardised communication training package (including training, resources, communication checklist and implementation toolkit) and mode of delivery
3. Evaluate feasibility of training implementation in 4 different NHS sites, training acceptability and impact on staff-patient communication behaviours and care experiences

3. Study Design and Data Collection, Analysis and Storage

This is a mixed methods study that will draw on:
(i) Theory and evidence approaches[24,25,26]
(ii) Partnerships informed by the 6 stages of Experience-Based Co-Design (EBCD - (1) project set up; (2) gathering staff experiences; (3) gathering patient and carer experiences; (4) bringing staff, patients and

carers together in a first co-design event; (5) sustained co-design work in small groups; (6) celebration and review event[27]), and
(iii) Behaviour change theory and Mechanisms of Action (MoA)[28,29] using the Theory and Techniques tool[30] combined with the Consolidated Framework for Implementation Research (CFIR)[31] to account for both individual communication behaviour change and individual and organisational barriers and facilitators to training uptake in the development and evaluation of the training.

The study is composed of three work packages (WP) using a combination of quantitative and qualitative research methods to help achieve each of the objectives: WP1 is preparatory and involves scoping practice context across the UK (individual and organisational factors), illustrating staff and patient experience, and synthesising the evidence base in communication training for potential training components, implementation strategies, and outcomes. Findings will directly inform WP2 which develops the training and resource content and delivery through co-design with a range of stroke staff and patient and family members. We anticipate this will result in a high quality e-learning resource hosted on a UK-wide platform coupled with local skills practice. WP3 evaluates organisational elements (adoption, implementation, sustainability) and the training package (acceptability, feasibility, outcomes, impact) in four sites in the North and South of England. The details of the sampling, recruitment, data collection and analysis processes for each of the work packages are now described in sub-sections 3.1-3.5. Details of data storage procedures are detailed in section 3.6. Please refer to appendix 2 for the timeline (Gantt chart).

3.1 Work Package 1 strand 1: National survey of current communication training (empirical research, non NHS, university ethics permission required)

3.1.1 Overview
Addressing objective 1a): Map current practice in stroke staff communication training in the UK including individual and organisational barriers to, and facilitators of implementing training and changing communication behaviour in practice.

An online survey will be conducted to investigate current communication training practice, reported training needs and demand, and barriers and facilitators to providing/accessing training and using new communication behaviours. We will also capture data on how staff currently support stroke survivors who do not speak English as their first language as this may highlight strategies and/or resources that could be incorporated into the future training package. In addition to collecting relevant demographic information, survey content will be informed by selected constructs in the CFIR and linked BCT taxonomy and MoA framework[30] relevant to training implementation and use of new behaviours, with tailored construct descriptions to be meaningful to communication training and context in which it is/needs to be delivered.

3.1.2 Sampling
A survey of approximately 800-1000 healthcare professionals working in stroke care will be conducted. We will target registered practising stroke staff including doctors, nurses, Allied Health Professionals, assistants, domestic staff and managers working in the UK NHS, in order to capture both individual staff perspectives and organisational barriers/ potential solutions.

3.1.3 Eligibility and recruitment
All NHS and social care staff working with stroke patients in the UK will be eligible to participate in this survey. This will include medical, nursing or Allied Health Professional staff, as well as rehabilitation or healthcare assistants, domestic staff and those managing stroke services.

Survey participants will be recruited via personal and professional networks, special interest groups and social media. We will seek access to participants through national Royal Colleges/ Societies/ Associations/ Forums including (but not limited to) the RCSLT stroke clinical excellence network, British Aphasiology Society, Association of Chartered Physiotherapists in Neurology, Royal College of Occupational Therapists specialist section on neurological practice, National Stroke Nurses Forum, Scottish Allied Health Professional Forum, Scottish Stroke Nurses Forum, British and Irish Association of Stroke Physicians, British Psychological Society Division of Neuropsychology, UK Stroke Forum, and RCSLT managers group. The co-applicant team (SMG) has contact with all the above-named groups and will facilitate and promote their participation. We will intentionally link in with these organisations' diversity and inclusion networks and groups so that we can be sure the survey is promoted to staff from ethnic minority backgrounds and staff for whom English is not their first language. We will share survey information/invites via the twitter accounts of project team members and the aforementioned professional organisations. We will also make use of the team's wide personal network amongst stroke staff and ask our contacts to cascade the survey amongst their networks.

Information about the project and the purpose of the survey, and consent to complete the survey will be embedded into the beginning of the survey itself.

3.1.4 Data collection

The survey will use the Qualtrics platform and consist mainly of closed questions as this has been shown to increase likelihood of complete responses[32]. However, free text boxes will also be used to capture more in-depth responses to selected questions. We will also request demographic data including staff participants' ethnic group backgrounds, first languages, and additional languages spoken to characterise our sample, in addition to data on professional group, gender and number of years working in stroke care.

The survey will be piloted with representatives from different stroke rehabilitation disciplines (n=5; including staff whose first language is not English) who will be asked to provide feedback (via a bespoke, user-friendly feedback form) on the wording of questions, format, completion time, and usability to ensure we have a clear and accessible Plain English survey. A revised version will be piloted with a different representative group (n=5; same as above) using the same feedback form to inform final revisions.

In order to maximise response rates we will advertise in the above mentioned organisations' bulletins, offer voucher incentives to complete the survey, ensure it takes no more than 20 minutes to complete and be transparent about this in the introductory information, enable the opportunity to complete it in more than one session and access it from different devices[32,33,34]. The survey will be open for approximately 12 weeks.

3.1.5 Data analysis

Closed responses will be analysed using descriptive statistics and responses between participant sub-groups will be compared. Analysis of open-ended responses will be informed by conventional content analysis[35]. Exact words or phrases capturing key concepts and terms relevant to CFIR and Theory and Techniques tool constructs will be highlighted and collated, and will be iteratively reviewed, discussed, and coded within relevant constructs.

This work will be led by Palmer and Scobbie with quantitative support from Hilari, representing SLT and OT professions with good links to other networks, and experience in online multidisciplinary staff survey

methods. Survey development, advertising and data analysis will be conducted by Harrison (experienced research fellow) with supervision and input from Strand 1 leads.

3.2 Work Package 1 strand 2: Interviews with people with communication disorders, family and stroke staff (empirical research, non NHS, university ethics permission required)

3.2.1 Overview

This strand addresses objective 1b) to highlight the impact of unsuccessful and successful communication on both patients and staff.

Structured interviews about communication experiences and impact on care/rehabilitation with people with communication impairments, family members and staff (EBCD stages 2 and 3) will be conducted. We will aim to interview 10 staff and 10-15 people with communication impairments and family members.

3.2.2 Sampling

A sampling framework will ensure representation from a wide range of patients/families (age, communication impairment type and severity, ethnicity, first language) and staff (profession, grade/role, setting, ethnicity, first language). We note that incidence of stroke is higher in Black and South Asian individuals[36], and that ~24% of the NHS workforce are from ethnic minority groups[37]. We will ensure representation from all 4 UK nations.

Following our EDI commitment, we will invest time and have budgeted resources to ensure we can recruit at least 3/10-15 stroke survivors with communication impairments and family members and 2/10 staff whose first language is not English for the interviews; in this way, their experiences will be captured and included in the data, as well as reflected in the trigger film which contextualises the WP2 co-design.

3.2.3 Eligibility and recruitment

Patient participants will be eligible if they have had one or more strokes, received stroke care from the NHS, and have post stroke dysarthria, dyspraxia and or mild to moderate post stroke aphasia (as indicated by the ability to understand and read a minimum of 2 key words in a sentence on the Consent Support Tool screen, CST[38]). Patient participants will be excluded if they have severe receptive aphasia (less than 2 key word understanding or reading ability on the CST) and or have cognitive difficulties that would make participation difficult, as judged by a family member and the recruiting research fellow.

Family members will be eligible if they are relatives (or very close friends) of a person with post stroke communication disorder(s) who has received NHS stroke care, and if they have had contact with the care team or been present during stroke care contacts/visited in inpatient stroke settings.

Staff will be eligible if they currently work with stroke survivors in the NHS.

Patient and family participants will be identified and invited to take part through ‘Say Aphasia’, a national charity founded by one of our PPI group members, with over 200 members in 14 hubs across the UK. Following our EDI commitment, we will monitor our recruitment if the demographics of members of Say Aphasia will not adequately support recruitment of diverse stroke survivors and family members, and recruit from other avenues; notably the team has first hand experience of diverse London groups of e.g., Different Strokes. For people with communication impairments, the research fellows will use the CST to indicate eligibility to participate (mild and moderate impairments) and inform choice of communication

strategies that best support the individual during informed consent and the interview. Experiences of people with severe impairments will be represented in interviews with family members.

Informed consent will be taken from all participants, using accessible information sheets and consent forms, and will be made available in participants' first languages upon request. On first contact, the research fellow will use the CST to indicate whether an individual will be best supported by patient information sheet 1 (lay language), 2 accessible information sheet, 3 accessible powerpoint slides presentation delivered by the research fellow using additional supportive communication techniques (e.g. rephrasing, gesturing, discussing each point, using pictures), or 4 narrated accessible powerpoint slides. If version 3 or 4 is used, the participant will also be given version 2 to keep for reference. The participant will be given up to a week to decide whether they would like to participate after which the research fellow will contact them to learn their decision and arrange an interview if they wish to participate. Participants will provide written or audio informed consent prior to conducting the interview. If audio consent is provided this will be documented on the audio consent form and also recorded using the same mode of recording as the interview itself (separate file).

Professionals will be identified through the networks listed in Strand 1, provided with a written information sheet in their first language and asked to provide written informed consent.

All interviewees will be offered a voucher for participating.

3.2.4 Data collection

Interview questions will be designed by the work strand leads together with the PPI group to elicit descriptions of memorable communication experiences, both positive and negative, between stroke staff and patients with communication impairment and the impact of these experiences.

Interviews will be conducted by the research fellows who both have skills and experience of interviewing people with communication disorders. The communication profile established from the CST at the time of recruitment will be used to indicate the communication support strategies to be used to support people with communication disorders in the interviews. Interpreters will be employed for staff, patient, and family members whose first language is not English. In-person or videoconference interviews will be offered. Interviews will be no more than an hour long. A range of strategies will be used to both minimise and support the potential distress and emotional experiences for both stroke survivors and staff, including offering breaks and ensuring people know they do not have to answer any questions they would prefer not to. Both research fellows have advanced skills in handling interviews sensitively. Interviews will be video recorded for analysis.

3.2.5 Data analysis

Video recorded interviews will be analysed using a rapid deductive framework analysis approach informed by the Picker Institute principles of person centred care[39]. The interviews in languages other than English will be professionally transcribed and translated into English for analysis purposes, with first languages retained in video excerpts included in the eventual film (see below). This method has been found to be effective and rigorous whilst being time efficient and eliminating standard transcription costs[40]. The research fellow who has not conducted the interview will watch the video and write detailed notes on the videoed interview and immediately code these into an Excel matrix. The research fellow who has conducted the interview will then review the videos and edit the matrix. During analysis, both fellows will identify potential touchpoints. The PPI group will watch the recordings of potential touchpoints with both

fellows and co-applicants representing different MDT professions and select clips to produce a joint film of patient and staff experiences (trigger film) for use in WP2 (EBCD stage 4).

This work strand will be led by Palmer and Cruice, research SLTs with experience of interviewing stroke survivors with communication impairments, and PPI lead McKevitt who has experience of producing EBCD trigger films. Kellar and Jones (WP2 leads) will input into the WP1 trigger film as this links to the WP2 co-design process.

3.3 Work Package 1 strand 3: Literature review and synthesis (non empirical research)

3.3.1 Overview

This strand addresses objectives: 1c) to identify potential training components (behaviour change techniques), implementation strategies, outcomes from the literature, and 1d) to create a type 4 logic model defining the training and implementation impact.

This strand involves a systematically-conducted narrative review of staff communication training interventions in stroke peer-reviewed articles with structured data extraction and narrative synthesis to identify components that change staff behaviour for potential inclusion in training, outcome measures used, outcomes reported, and implementation strategies (and also reported implementation barriers and facilitators).

3.3.2 Data collection

In conduct and reporting, we will follow the PRISMA extension for Scoping Reviews (PRISMA-ScR)[41] and seminal literature by Arksey and O'Malley[42], and will also draw on methodological guidance from the JBI Scoping Review Methodology Group (https://jbi.global/scoping-review-network).

To efficiently undertake this strand, we will update and expand the findings from two existing systematic reviews in communication partner training undertaken in 2010 and 2016[43,44], wherein peer-reviewed articles reporting on staff communication training interventions in stroke have already been identified. We will search for staff communication training interventions in:

(1) aphasia to capture articles published after the most recent review[44] (search 1), and
(2) dysarthria, dyspraxia, and cognitive communication disorder with no time frame imposed (search 2).

Searches will conducted in the following nine databases - Cinahl, Medline, Embase, Sociology Source Ultimate, APA Psycinfo, APA Psycarticles, Communication Source, Cochrane Database of Systematic Reviews, Web of Science - and the following search terms will be used:

- Search 1 from August 2015 onwards: team* OR staff OR personnel OR assistant* OR student* OR volunteer* AND aphasi* OR dysphasi* AND conversation* OR communicati* OR language OR speech OR interacti* OR pragmatics OR "functional communication" OR relationship OR social AND therap* OR treatment OR rehabilitation OR intervention OR strateg* OR train* OR coach* OR inservice OR in-service OR educati* OR information OR behavio* OR skill* [terms based on review[40]]
- Search 2 with no time frame was imposed: is as above, except [aphasi* OR dysphasi*] will be replaced with dysarthri* OR dyspraxi* OR apraxi* OR "apraxia of speech" OR "cognitive communication" OR cognitive-communication.

Polyglot software (https://sr-accelerator.com/#/polyglot) will be used to ensure search terms are correctly formatted for each database. Inclusion criteria include: published in the English language, peer-reviewed, report original data, and report on staff and/or student health care professional training in communication skills in relation to stroke survivors. Exclusion criteria include: published in languages other than English; non-peer reviewed articles, conference abstracts, literature reviews; and staff training in communication skills that targets populations other than stroke. Searches will be conducted through EPPI REVIEWER and duplicates will be removed through the automation tool and manual checks. Title, abstract, and full text screening will be completed by lead research fellow (Shiggins). 20% of articles will be checked at title and abstract level, and again at full text level, by the other research fellow (Harrison). Percentage agreement will be calculated, and a minimum of 70% considered sufficient reliability.

Data will be extracted from journal articles on:
(1) training description (using the TIDieR[45])
(2) behaviour change techniques (BCTs)[30] and mechanisms of action (MoA)[30] (following the Theory and Techniques Tool)
(3) outcome measures
(4) reported outcomes (content analysis)
(5) implementation strategies (following Expert Recommendations for Implementing Change; ERIC[46])
(6) and age, ethnicity, first language, and other languages of staff and stroke survivor participants, by the lead research fellow (Shiggins).

The lead fellow will undertake training in the BCTT via the self-study online training https://www.bct-taxonomy.com/ and follow the protocol for identifying BCTs and MoAs written for the NIHR 202607 PDG, and complete training on practice articles with input from Kellar, Cruice and Beeke. Familiarisation with key TIDieR and ERIC literature will be undertaken.

Regarding data extraction, 20% intra-rater reliability checks (complete one month apart), and 20% inter-rater reliability checks with the other research fellow (Harrison) will be undertaken, and discrepancies checked with the WP1 strand 3 team.

3.3.3 Data analysis

Data will be extracted and tabulated against the relevant constructs within templates/ tools outlined above e.g., 12 items in the TIDieR checklist and a narrative synthesis written. Data on outcomes will be summarised by conventional content analysis[35]. Findings will comprise a synthesis of staff communication skills training interventions; a long list of candidate intervention components (BCTs and MoA); summary of outcomes; and a long list of implementation strategies. Findings will be used as the basis for co-producing meaningful potential training content and implementation options with the co-applicant team and PPI group for use in WP2.

A draft programme theory and tentative logic model populated with a framework of candidate BCTs/MoAs, outcomes, and modes of delivery and implementation strategies will be generated from WP1 knowledge. This will serve as the basis for mode 2 knowledge mobilisation[47] summarising evidence from research and practice to support NHS staff and people with communication impairments and family to utilise this knowledge in their co-design activities (WP2). Additionally, we will map literature-reported outcomes and implementation strategies to practice-reported positive and negative communication (interviews) and barriers/ facilitators (survey) respectively, forming a draft implementation toolkit that will be iteratively developed and evaluated in WP2 and 3.

This strand will be led by Cruice and Beeke, research SLTs with experience of systematic reviews, data extraction against TIDieR, BCTs and MoAs, and of communication training; with Shiggins as lead research fellow. It will be supported by behavioural scientist, Kellar, who will use his extensive experience of intervention development to support development of the programme theory and logic model.

3.4 Work package 2 Co-design of communication training package (development, University ethics permission required)

3.4.1 Overview

This work package addresses objective 2: Co-design novel standardised communication training package (including training, resources, communication checklist and implementation toolkit) and mode of delivery.

NHS stroke staff from different professions and grades, people with communication impairments and family members (innovation recipients), service managers and policy makers (innovation leaders and facilitators), will be identified to be involved in a series of 10 three hour co-design workshops (EBCD stage 1). Nine co-designers (6 staff and 3 people with communication impairments/family members) will meet in person in London, and the same (n=9) will meet in person in Sheffield with a remote link connecting the two groups. Research team and speech and language therapy facilitators will be physically present in each location for facilitation of the co-design activities. Our PPI group decided that people with post-stroke communication impairments and family members could be supported to commit to and attend regular three hour workshops by having meetings in the middle of the day in accessible and consistent locations, with support for travel and refreshment/ comfort breaks.

3.4.2 Co-designers

We will identify potential stroke survivor and family co-designers through voluntary aphasia/ stroke groups and through PPI group members links with other community groups/settings of culturally diverse communities. We will identify potential professional co-designers through professional bodies, and special interest groups.

We will employ a sampling strategy to ensure wide representation of the co-design group: Stroke survivors with communication disorder/families with NHS stroke care experience (age, communication impairment type and severity, ethnicity, first language) and staff (profession, grade/role, setting, ethnicity, first language). We note that incidence of stroke is higher in Black and South Asian individuals[36], and that ~24% of the NHS workforce are from ethnic minority groups[37], therefore we will ensure co-designers represent these groups and include representation from all 4 UK nations. Co-designers whose first language is not English will be included but they will need to be able to speak some English in order to participate in sessions. Communication-impaired people will be supported by experienced SLTs (co-applicants and research staff) using evidence-based communication-support approaches.

The workshops proposed require a large time commitment and therefore all co-designers will be paid for their time. Before committing to be a co-designer, potential members will be provided with information about the role both in written summary and through discussion with the research team (using accessible materials and support techniques where needed). As all members – stroke survivors, family members, professionals and researchers from the study team are of equal importance and have an equal relationship in the co-design process, the co-designers will be colleagues rather than participants. We

will work together to produce a training programme, but individual contributions will not be recorded, analysed or published. Therefore, written consent to be a co-designer will not be sought.

3.4.3 Co-design process

Firstly, a joint co-design event 'discovery workshop' will be held (EBCD stage 4) in which people will view the trigger film developed from the WP1 Strand 2 (EBCD stages 2 and 3). We will employ co-design techniques[25] including journey mapping, pain-point analysis, and stakeholder prioritisation to identify key priorities to take on to EBCD stage 5.

A series of 8 further joint co-design workshops (EBCD stage 5) will follow during which co-design members will work in small groups to design solutions to problems identified and prioritised in the discovery workshop (e.g training components, content and mode of delivery with attention to implementation context, implementation strategies and communication resources). Co-produced WP1 component descriptions will provide examples of potential behaviour change techniques and implementation strategies. Existing training examples and materials will also provide inspiration for the training and resources, and existing implementation tools such as the CFIR card game[48] will provide inspiration for the implementation toolkit. The first stage 5 workshops will promote creative thinking around solutions, using warm-up activities, ideation, sketching and drawing, and prototyping[25]. We envisage that elearning may be discussed as a solution to providing standardised training - designers from project collaborators eLearning for health at NHS England (NHS E) will attend later stage 5 workshops to inform design of a prototype. SLTs, research fellows and elearning designers from NHS E will produce the training package and engage co-design members in iterative prototype review and refinement. Staff members of the co-design group will pilot the training prior to its final refinement and launch for evaluation (WP3). See Gantt chart for designated co-design, development and piloting time.

The logic model will be refined throughout WP2. The PPI group will help create a communication checklist informed by communication behaviours/outcomes identified in the model for use in WP3 evaluation.

Review and celebration (EBCD stage 6): After the evaluation of the training package at 4 sites in WP3, the findings will be reviewed by the co-design group and stimulate ideas for further refinement (workshop 10). Two in person celebration events are planned (in addition to the 10 co-design workshops), one in Sheffield and one in London to enable a wide geographical spread of stakeholders to attend.

This work package will be led by Jones and Kellar with their extensive expertise and experience of EBCD to design interventions and Isaksen with her experience of developing stroke staff communication training in Denmark. It will be supported by PPI lead McKevitt who also has extensive experience of EBCD with stroke teams, the SLT researchers and clinicians from the co-applicant team, and research fellows.

3.5 Work package 3 Evaluation of communication training package (empirical NHS research – NHS Ethics permission required)

Work Package 3 (WP3), originally documented here, was designed to evaluate the feasibility, acceptability, implementation and impact of the co-designed communication training package across four NHS stroke care sites, using a theory-informed, multi-method approach. It aimed to investigate organisational readiness, implementation processes, staff behaviour change, and patient communication experiences through observations, surveys, and interviews with staff, patients, and families. However,

WP3 has now been removed from this protocol, as the empirical NHS research it involves will be submitted separately through the NHS Ethics review process in a dedicated protocol.

3.6 Data management

On grant submission to funder (11/11/2022), a high level Data Management Plan (DMP) was written by City, covering Data Collection, Documentation and metadata, Ethical and legal compliance, Storage and backup, Selection and preservation, Data sharing, and Responsibilities and resources (this is stored under City Worktribe Project ID: 669899). Once the project has commenced (01/03/2024), in the first month, fellows will lead on refining the DMP. Monitoring data management will be a continuous process across the duration of the project; and considered regularly at Study Management Group meetings; and reported at Study Steering Group meetings.

We will collect, use and store research data in accordance with the Data Protection Act 2018 and the General Data Protection Regulation (UK). We will complete Data Protection Impact Assessment Threshold Tests on all activities involving personal data, through City St George's, University of London and/or the University of Sheffield. We will observe Safe Data Handling practices for Equipment, Tools, and Working Environment; Email; File Storage and Data Sharing; and Secure Use of the Internet (see City St George's https://staffhub.city.ac.uk/information-technology/data-protection/safe-data-handling). We will observe institutional requirements regarding recommended practices around Data Breaches, and requirements for reporting. Data that is shared between organisations (Sheffield and City St George's) and/or amongst organisations involved in the research, including collaborators, will be subject to a data sharing agreement informed by Working with Third Parties documentation (City St George's) https://staffhub.city.ac.uk/information-technology/data-protection/working-with-third-parties#5. No data will be shared until agreements are approved.

Physical data

Physical data (e.g., Consent Support Tool screens, completed paper consent forms, clinical test forms) will be stored in the site files in a locked filing cabinet at the City St George's, University of London and University of Sheffield, as will any notes taken during the codesign groups by the researchers/ facilitators. The notes will be written up into electronic format and anonymised, and the originals subsequently destroyed as soon as possible. Access to this data will be limited to appropriate members of the research team (within the study management group) only.

Physical data collected in WP3 sites will be stored securely in locked drawers/ filing cabinets on site until collected by the fellows; and preferably scanned prior to physically leaving the site to mitigate loss in transit.

Electronic data

In the case of remote consent, recording of consent will be stored on a secure server.

The majority of data will comprise electronic data which will be stored securely on password-protected hardware and encrypted drives and/or devices, and accessed through secure researcher institutional log-in details. Data will be stored within the OneDrive (City St George's) which is encrypted and automatically backed-up; and within project specific X drive space at Sheffield. With two bases supporting the research (Sheffield and City St George's), it will be important to establish appropriate and secure data sharing between fellows and joint leads; supported through secure institutional access and approved data sharing

agreement. Access to this data will be limited to appropriate members of the research team (within the study management group) only.

Electronic data collected in WP3 sites will be stored securely following local NHS policy and procedures for site research data; and transferred to research staff physically (e.g., encrypted device) or electronically through a secure file transfer.

Electronic data pertaining to WP1 Strand 2 and/or WP3 site participant interviews which are conducted in a language other than English with an interpreter and require translation for analysis by the research team - professional translation services will be used and subject to a confidentiality agreement in the conduct of the work.

Archiving

Physical data will be scanned and stored electronically, and securely disposed of following local institutional policy and procedures. Electronic data will be stored for the length of time mandated by the local institution, and thereafter destroyed following institutional policy and procedures.

4 Ethics

4.1 Assessment and management of risk

On grant submission to funder (11/11/2022), a high level risk assessment was completed by City St George's, which identified (1) human participants involvement, and (2) off-site and lone working for researchers; and confirmed that no security sensitive/ obscene material/ sensitive projects/ hazardous materials/ additional specialist facilities and resources for health and safety/ and environmental risks were implicated in this research (this is stored under City St George's Worktribe Project ID: 669899).

Once the project has commenced (01/03/2024), in the first month, fellows and Joint Leads will complete a detailed risk assessment covering risks to the organisations involved, the environment, the research, and the health, safety and wellbeing of researchers and research participants (including those involved in PPI). Institutional guidance (e.g., Framework for Good Practice in Research), templates and procedures, general national guidance (e.g., GDPR, Good Clinical Practice), and national guidance on research integrity https://ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research.pdf will be drawn on to complete this, and to guide the research overall. We will assess the project against the UKRIO Code of Practice Recommended Checklist for Researchers, and observe the commitments of The Concordat to Support Research Integrity, and observe Code's the Standards for Organisations and Researchers. In brief, the research will comply with ethical, legal and professional standards and requirements; and relevant ethical approvals will be sought for research involving human participants and personal data within the university sector (WP1 and 2) and within the NHS (WP3).

Health and safety risk assessments will be completed by research fellows with oversight from Joint Leads for in-person human participant involvement activities within WP1 Strand 2, WP2, and WP3, following recommended institutional templates and procedures. Per work package, this will involve description of activities, identification of hazards and rating of their likelihood and severity using the matrix provided, and rating without and with control measures in place; and opportunity to incorporate additional control measures and any personal protective equipment; approval for Head of Department or other relevant senior staff member; and archiving with the local/ Departmental Liaison Safety Officer. A similar process will be followed for off-site and lone working of research staff whilst undertaking research activity away from their own institutions.

Risk monitoring and management will be a continuous process across the duration of the project; and considered regularly at Study Management Group meetings; and reported at Study Steering Group meetings.

4.2 Research Ethics Committee (REC) and other regulatory review

REC and HRA approvals

The study will not be initiated before the protocol, informed consent forms and participant information sheets have received approval from a University Research Ethics Committee (REC) for WP1 strands 1 and 2, and from an NHS REC, the Health Research Authority (HRA) with local Capacity and Capability confirmation by the relevant NHS Research & Development (R&D) departments for WP3.

MHRA approval is not required for this study.

For WP1 strands 1 and 2, an application will be made to the University of Sheffield Ethics Committee. For WP3 an application will be submitted through the IRAS central allocation system.

Regulatory review and compliance

This study will be conducted in accordance with Good Clinical Practice Guidelines and CTRU standard operating procedures. The study will be conducted subject to Research Ethics Committee favourable opinion including any provisions for site specific assessment. Local research governance approvals will be sought from all participating research sites. The approval letter from the ethics committees and copy of approved patient information leaflets, consent forms and any ethically approved data collection tools will be present in the site files before initiation of the study and patient recruitment.

Amendments

Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval/ favourable opinion from the relevant REC and/or HRA. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

Peer review

This study has undergone extensive peer review as part of the Health Service and Delivery Research (NIHR) application process. Key collaborators have been involved in developing the research proposal with specialist expertise in communication disorders and research methods. The PPI group made up of people with communication disorders and family members, and clinical partners were also involved in the development of the procedures. The protocol and associated documentation for this study was peer reviewed within the study team prior to submission.

Protocol compliance

This study will be conducted in compliance with the protocol, GCP and regulatory requirements.

Data protection and patient confidentiality

Participant confidentiality will be respected at all times. Study documents (paper and electronic) will be retained in a secure location during and after the study has finished. All source documents will be retained for a period of 10 years following the end of the study. Where study related information is documented in the medical records – those records will be retained for 10 years after the last patient visit. Each

site is responsible for ensuring that records are archived and the information about the location of this supplied to the Chief Investigator.

All electronic data will be accessed on university computers that are password protected and maintained within university servers with encrypted off/cross-site backups.

Indemnity

The study has been financed by the NIHR and details have been drawn up in a separate agreement. This is an NHS sponsored study. If there is negligent harm during the research project when the NHS body owes a duty of care to the person harmed, NHS Indemnity will cover NHS staff, medical academic staff with honorary contracts and those conducting the trial. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim. The University of Sheffield has in place insurance against liabilities for which it may be legally liable and this cover includes any such liabilities arising out of this research project.

Access to the final study dataset

Access to the study data will be granted to members of the research team to ensure that they only have access to the data required to complete their tasks. All electronic data will be accessed on university computers that are password protected and maintained within university servers with encrypted off/cross-site backups. Specifically, the data gathered via The Portal website will be maintained in an encrypted database with encrypted off/cross site backups at the University of Sheffield.

4.3 Patient and Public Involvement (PPI)

Extensive patient and public involvement was conducted in instigating and shaping the application for this study.

Patients and the public will be involved in delivering the study in 3 main ways:

1. PPI group focussing on research processes
2. Members of the staff communication training co-design group
3. Representation on the project management and independent steering groups

Co-applicant, McKevitt with lived experience of communication impairment after a recent stroke is on the study management group (SMG) and leads the PPI group. He is an experienced stroke PPI leader (pre stroke). He will be supported by project leads Palmer and Cruice who are both speech and language therapists with extensive experience of conducting PPI with people with communication difficulties.

The group will comprise 10 members, plus McKevitt, large enough to represent people from different locations, genders, ages, under-represented groups, types and severities of communication disorder and small enough for discussion. Eight PPI members have agreed to be part of the group. Five have worked together with this team in a previous project and 3 are new for the proposed project. The group includes 4 males and 4 females, members from South-East England, Yorkshire, Wales, 3 members whose first language is not English, 2 members from an ethnic minority background, 3 people with aphasia, and 1 with dysarthria, and 4 family members. Two had strokes relatively recently (within the last 2-3 years). We will recruit 3 more PPI members to join this group and increase representation of recent stroke experience, dysarthria and ethnic minority backgrounds.

The group will meet 5 times a year for 2 hours with between meeting tasks of approximately 5 hours a year. They will meet face-to-face to get to know each other in meeting 1. One further face-to-face meeting is planned in year 3. Other meetings will be by videoconference to enable diversity in membership. The team have experience of facilitating people with communication difficulties online: we will provide support for using videoconferencing prior to meetings if needed and support those with communication difficulties by using a total communication approach – sharing screens with short, written sentences, picture support and using online communication tools e.g. drawing, polls, post-its.

The group will engage in:

- agreeing meaningful training component descriptions in WP1
- ensuring accessible informed consent materials for recruitment of people with aphasia being interviewed in WP1 and participating in the evaluation (WP3)
- identifying participants with communication disability for video interviews in WP1 and helping develop interview questions
- identifying touch points from interviews in WP1 to make a trigger film
- reviewing interview schedules and observation checklists WP3, and
- leading on the dissemination of findings to people with communication disability including the design of accessible promotional materials, film and involvement in presentations/workshops.

Co-design
Six people with communication difficulties and family members will also be invited to 10 face-to-face co-design workshops (WP2) to inform the staff communication training from a patient/carer perspective. Speech therapists from the research team will facilitate their inclusion.

All involved will be paid expenses and an honorarium based on INVOLVE recommended rates.

To enable clear reporting of PPI impact the PPI lead, supported by a co-lead or research fellow, will complete an impact template based on GRIPP2 (Staniszewska et al 2017) reporting checklist and INVOLVE recommendations after each PPI and co-design meeting.

5 Dissemination, outputs and anticipated impact

5.1. Outputs of this research

This research will yield a number of outputs including:

(1) A communication training package comprising
    (a) a standardised communication training which is acceptable, feasible, freely available (HEE will host on elearning for health - elfh - platform, available to all UK nations and internationally), approved and promoted by project partners HEE, SSEF and professional bodies (if supported by the evaluation outcome), and
    (b) a linked communication resource pack that supports healthcare and general communication (freely downloadable from elfh)
(2) A checklist to guide observations and reflection on patient-staff communication interaction
(3) An implementation toolkit for NHS stroke services, and
(4) A film and sketches that illuminate the impact of staff communication on the care and rehabilitation of people with communication impairments after stroke and the need for training (both will reflect the diversity of stroke survivors and staff).

5.2 Dissemination methods

Dissemination will occur throughout the project timeline, and the team has a strong track record of establishing national and international project identity using the following mechanisms:

(1) A dedicated project website and X account to actively promote the project (e.g., blog postings with email address sign-up to website to receive these automatically); advertise survey, interview, and co-design opportunities; and widely disseminate findings and resources. We will use various strategies for creating an active X community (e.g., polls, threads, etc.) that keep stakeholders engaged for the project duration.

(2) We will explore other social media preferences e.g., Facebook, with PPI at project start to reach stroke survivor and family stakeholders. Various analytics will help us understand our reach and impact through channels in (1) and (2).

(3) We will create a stakeholder network (email addresses) of individuals and organisations to provide regular e-newsletter updates; this will include the Integrated Stroke Delivery Networks workforce lead for each UK region.

(4) We will work with co-applicant institutions' and project partners' public relations teams to maximise media coverage and public engagement opportunities, and capitalise on existing initiatives e.g., Make May Purple, international Aphasia Awareness Month (June). MDT co-applicants will be instrumental in championing the project in their professions. To ensure we reach a diverse range of stakeholders, we will also partner with ethnic minority groups e.g., Egality Health to raise awareness and share findings.

Dissemination will also occur at specific time points to varied audiences, including:

- A webinar to launch the project across the four UK nations (and promote the staff survey) for stroke health care professionals, stroke survivors and family members, service managers, commissioners, policymakers
- Open-access journal articles from each work package in high impact journals
- Conference presentations and workshops specifically the UK Stroke Forum which attracts ~1700 multidisciplinary NHS stroke professionals, researchers, and industry; International Stroke Conference; and the Royal College of Speech and Language Therapists conference for SLTs who are key to championing and supporting the training with their local stroke MDTs across the UK
- Service user forums e.g., UK Stroke Club Conference, Aphasia Forum (with whom the lead investigators have links) and magazines e.g., Stroke News
- Two end-of-project engagement events (one in London, one in Sheffield) to disseminate findings to stakeholders and the public, and celebrate the outcomes (EBCD Stage 6). All stakeholders who participated in the project will be invited: co-applicants, steering group, PPI, co-design group, managers/implementation leaders, staff and patients at the evaluation sites. Key policy leaders e.g. NHS England national clinical directors and speciality advisors for stroke, relevant HEE/ NHS England leads will also be invited.

5.3 The role of PPI in dissemination

The PPI group will collaborate with the research team to ensure that project engagement and dissemination strongly represents the voices and interests of stroke survivors, family members, and importantly meets users' needs including accessible communication, first languages, and a range of ethnic groups. The research team and PPI group will work in partnership to maximise impact of the WP1 trigger film made for WP2 co-design, by using selected clips widely in dissemination, including in an end-of-project film, to increase awareness and visibility of communication impairment after stroke, and the impact of staff communication in care and rehabilitation. This may for example include film screenings.

PPI will collaborate with our artist-in-residence sketcher (WP2 co-design sessions) to inform, review and choose sketches/infographics, for inclusion in training and dissemination, and advise on how these are best shared. PPI will also coproduce accessible dissemination materials e.g., accessible results flyers, video-abstracts, with translations, foreign language subtitles, and printed materials available.

5.4 Reaching a diverse range of stakeholders

Following further reflection on EDI, we will explore and agree with the PPI group on the value of, and subsequent actions, in:

a) working with community support workers/ bilingual health advocates and interpreters who are local to our sites to make findings accessible to local communities
b) targeted liaison with relevant stroke groups i.e., the Black Asian and Minority Ethnic Stroke Support online group within the Stroke Association (https://www.stroke.org.uk/finding-support/clubs-and-groups/bame-stroke-support-online-group) and the Black and Asian Stroke Survivors Project in Different Stroke (https://differentstrokes.co.uk/ethnicity-stroke/) to support awareness raising of the project at inception and dissemination of findings at project end
c) partnering with organisations that support ethnically-minoritized groups and address health inequalities in the UK e.g., Social Action for Health in East London https://www.safh.org.uk/, Rotherham Ethnic Minority Alliance https://rema-online.org.uk/) and more widely Egality Health https://egality.health https://twitter.com/EgalityHealth who the Stroke Association have previously partnered with for project work to support the same objectives as (a)
d) partnering with specific community groups across the UK, who the Stroke Association have again previously partnered with, to support the same objectives as (a), and
e) pursuing options to make dissemination products available in other languages, such as free foreign language subtitling on dissemination videos and/or low-cost commercial foreign language voice overs on videos.

5.5 Anticipated impact of COM-STAR

The anticipated impact of this research and its outputs will be significant for healthcare in terms of improving stroke professionals' communication in care and rehabilitation of stroke survivors with communication impairments, and improving the experience that communication-impaired stroke patients and families have from stroke services.

New knowledge: This research addresses gaps in knowledge around communication skills training in stroke in the UK, and the lack of theoretically-underpinned and standardised training to upskill stroke staff to have effective health care and rehabilitation conversations with patients and families. It will also provide knowledge of how to best implement communication skills training in a wide range of clinical services, and will therefore be of interest nationally and internationally to healthcare services, researchers, and policy makers.

Engagement in training: This research provides two key mechanisms for large-scale uptake of training for stroke staff to communicate with stroke survivors with communication impairment (1) Stakeholder co-design of the training package to ensure its relevance for stroke staff and patients and feasibility for organisations to implement. (2) Communication about the training package by project partner Health

Education England and hosting on the established HEE elearning for health platform to facilitate extensive use. Engagement in training and some acceptability data can be captured via the HEE elfh platform e.g., number and type of staff, geographical spread and settings across England, Wales, Northern Ireland and Scotland, access and completion of training and feedback from users. This will enable monitoring and insights into sustainability and spread of the training in the UK, and inform longer term training package updates and future research.

There is also potential for international impact as HEE can make the training available outside of the UK. International impact would be assisted by links with international organisations, specifically the Collaboration of Aphasia Trialists (Hilari, Beeke, Isaksen in Executive Committee), International Speech and Language Therapy Association (IALP), and the Communication Disorders special interest group of the World Federation of Neurorehabilitation (Palmer chairs this group). Power (Australia) and Isaksen (Denmark) are well placed to support wider impact activity, with the latter potentially through an existing international collaboration for staff communication training[55].

Improved staff experience: Providing high-quality training and communication resources that change staffs' skills will enable them to provide more accessible and inclusive care and rehabilitation reducing the negative consequences that communication challenges and breakdowns have on staff (stress, anxiety).

Improved patient and family experience: Providing high quality staff communication training will contribute to increased understanding and inclusion of patients and families in their care and rehabilitation, improving their experience, safety, and recovery.

6. Equality, Diversity, and Inclusion Statement

The COM-STAR Equality, Diversity and Inclusion Statement

We have consulted various documentation (NIHR Equality, Diversity and Inclusion Strategy 2022-2027[56]; the INCLUDE project[57]; the NIHR and NHS Race and Health Observatory Statement of Intent[58]), and consulted with the team to develop the following statement:

The COM-STAR team commits to considering equality, diversity and inclusion during the preparation for, and the conduct, delivery, and dissemination of this research project. We recognise the responsibility and the value of undertaking inclusive stroke research that represents the interests and needs of a wide range of stroke survivors and family members, and the stroke rehabilitation workforce across the four nations in the United Kingdom. We acknowledge as a team that we need to develop and continue to develop in this area. We recognise our privilege and that we will continue to acknowledge this in meetings, and intentionally consider how our decisions could further marginalise a group or further widen health inequalities. By stopping and considering this frequently across the project, we can address this from the outset.

We commit to:

- becoming more informed and inclusive researchers as we engage with the increasing literature, guidance and training available on diversity and inclusion in research and apply this in stroke research

- creating a psychologically safe space within the team to engage in discussions around equality, diversity and inclusion
- using evidence-led and PPI generated-and-agreed approaches/ toolkits/ resources to improving diversity and inclusion, working in respectful and collaborative ways with all stakeholders
- respecting the dignity and individuality of every stakeholder we work with
- doing everything we can not to further widen health inequalities and/or place additional burden on marginalised groups
- diversifying our research participants by investing time, effort, and resources into recruiting appropriately and actively seek to remove or minimise the barriers that prevent research participation
- becoming more informed in stroke as we navigate stroke research data, literature, policy, guidelines and other information sources to better understand the associations between protected characteristics (as per the Equality Act 2010) (and other contributing factors) and health inequalities in stroke
- contributing to the stroke research evidence base generating new knowledge about diversity in stroke participants, by collecting demographic information in a robust but sensitive manner throughout the project, and
- sharing our practices and resources in supporting diversity and inclusion with others

Additionally, to underpin the project, we will undertake a brief literature review to identify relevant literature on limited English proficiency, non-English speaking backgrounds, and languages other than English in relation to patient-provider communication, access, and mis-communication and adverse events in healthcare to underpin the project (we will also review discipline-specific literature[59,60] as an example).

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Appendix 1: Study Gantt chart