Supported Communication to Improve Participation in Rehabilitation of people with moderate-severe aphasia after stroke: a pilot study (SCiP-R)

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Trial sites
Norfolk: Norwich Community Hospital, Mulberry Rehabilitation Unit (Beech Ward)
Cambridge: Addenbrooke’s Hospital, Lewin Stroke & Rehabilitation Unit

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Lay summary
About 150,000 people in the UK have a stroke each year, with significant cost to health and social care. A third of stroke survivors experience aphasia, a communication disorder which affects speaking, understanding, writing or reading. Aphasia is associated with longer stays in hospital and has severe consequences for all aspects of life.

People with aphasia may not fully benefit from stroke rehabilitation for a number of reasons to do with their communication. They may struggle to understand questions or follow instructions, or be unable to express their needs, leading to great frustration. Information must be communicated in particular ways to be accessible to them, or they may need additional help to set goals. Staff are not necessarily trained in the skills to support people with aphasia in these ways.

‘Supported communication’ uses a set of techniques to make communication accessible for people with aphasia. A skilled communication partner uses low-tech resources such as pen/paper, pictures, symbols, calendars, or gestures to break down barriers and enable understanding and expression. Research with community volunteers and students has shown that there are beneficial effects for conversation and engagement.

Supported communication could be used by any member of the stroke team to help patients with aphasia to engage more fully in rehabilitation. It has the potential to improve the quality of care, and address some of the key aims of stroke rehabilitation such as adapting to disability, and increasing quality of life and well-being. Previous studies have mostly focussed on its use outside the clinical context.

This study aims to build on this existing evidence and see whether supported communication is a technique that can be learned by stroke unit staff, and used during every day rehabilitation in order to enhance participation and improve outcomes for people with aphasia. The results of the study will be used to strengthen the design of a more comprehensive trial.

Every person (staff member or patient) recruited as a participant to this pilot study will first be required to provide written informed consent. No routine treatment will be withheld from patient participants whether they are receiving rehabilitation on the unit allocated to the supported communication intervention or on the unit allocated to the standard clinical practice condition.

Background to this pilot study
About 150,000 people have a stroke in the UK each year (1), with around 38% of cases attributable to recurrent stroke (1); they occupy around 20% of all acute and 25% of long term beds (2), with significant direct costs to health and social care (2). About a third of people after a stroke experience aphasia (3), a communication disorder which impairs speaking, listening, reading and/or writing. Aphasia has a substantial impact on all aspects of an individual’s life (4), and is associated with increased length of hospital stay (5). The level of communication disability experienced by a person with aphasia results from an interaction between the impairment itself, type or complexity of activity undertaken, and the healthcare or social environment (6). Participation, which is key to the success of most treatments in stroke rehabilitation (4) may be adversely affected by ‘barriers’ such as inaccessible information, negative staff attitudes, or unskilled communication partners (6,7). People with aphasia are particularly vulnerable to effects of these conditions (8). Participation in conversational interactions has been demonstrably enhanced for people with aphasia by providing ‘supported communication’ in the form of skilled communication partners and appropriate communication resources (9,10). Supported communication builds on the ability of many people with aphasia to capitalise on preserved cognitive and
interactional abilities in order to participate (9), and is premised on the view that interactional communication is collaborative and co-constructed (11), with the unimpaired communication partner (e.g. volunteer; healthcare practitioner) being jointly responsible for achieving exchange of information and sustaining participation (9). Proof of concept of a supported communication intervention implemented by community-based volunteers in Canada (9), and the UK (12), and by medical students in South Africa (13) has been established.

Studies of supported communication have mostly applied single case and small group methods (14) and current knowledge about implementation in clinical contexts is limited. This intervention, which is aimed at reducing barriers to communication and enabling the engagement of patients with aphasia through training team members and making services more accessible (15) has the potential to improve the technical quality of healthcare (16) and address key aims of stroke rehabilitation such as adapting to disability, and maximizing quality of life and well-being of patients (4). Although experienced stroke care practitioners might be expected to already possess the necessary skills, communication problems in healthcare settings do not necessarily resolve with clinical experience (17). Indeed, individual communication skills training may not in itself lead to improved patient outcomes if not supported by attention to the particular needs of the practice setting (8,18) and strategies for sustained implementation of the intervention in context (8,19). There are no UK studies to date evaluating supported communication in the context of stroke rehabilitation, or the impact of such an intervention on patient participation and patient-reported outcomes.

Introduction
This pilot study is directed at a key area of concern for people with aphasia, namely full participation. Participation in the specific context of stroke rehabilitation for people with aphasia started to receive research attention only relatively recently (8); indeed many previous studies of participation and stroke have specifically excluded people with aphasia (20). The principle of enabling people with aphasia to more fully participate initially focused on conversation/communication in family and community settings (21,22); a considerable body of developmental work on the principles and practice of supported conversation was carried out in North America and Canada, with the Aphasia Institute in Toronto (http://www.aphasia.ca/) becoming a key centre of excellence. In the UK, Connect – the communication disability network (http://www.ukconnect.org/index.aspx) has developed expertise in supported conversation initiatives for people with aphasia and extensive resources for implementation in the community (23).

While proof of concept of supported conversation/communication is now firmly established (9,12,13), as yet very little work has been carried out to examine how principles and practices may need to be adapted to the demands of communication contexts other than social conversation or the needs of communication partners other than community volunteers or family members (13,24,25). Principles to be taken into consideration when addressing access and social inclusion of people with aphasia in any context include the fact that activities and actions are negotiated on a moment-by-moment basis; are achieved collaboratively (i.e. through contributions of both parties); and are based on social dimensions such as power and authority (26). These will be key concerns in the investigation of supported communication in the context of stroke rehabilitation.

In line with recommendations for the development of complex interventions such as this one [Supported Communication to Improve Participation in stroke Rehabilitation – SCIP-R] a phased approach is being adopted (27). A pilot study is being carried out in advance of a main study in order to reduce some of the uncertainties associated with that study and to increase confidence that a subsequent research design will be appropriate and generate a successful result. Uncertainties in this case include: adaptation of the intervention to the context of stroke rehabilitation; application and acceptability of the intervention to stroke staff and patients; likelihood of and evidence for clinical efficacy; most appropriate (primary)
outcome measure and the application of existing measures not yet used with this population; cost-effectiveness.

In summary this study aims to examine the feasibility and provide initial evidence of clinical efficacy and value of a supported communication intervention aimed at improving the participation in rehabilitation activities of people with moderate-severe aphasia after stroke (SCIP-R), in order to strengthen the design of a subsequent cluster randomised observer blinded multi-centre Phase III trial. Results from a subsequent Phase III trial have the potential to impact positively on routine rehabilitation care and outcomes for all people with moderate-severe aphasia after stroke, addressing some of the key issues identified in the National Stroke Strategy (3), including workforce skills (28), quality of stroke unit and community rehabilitation (28), and patient participation.

Research objectives
The primary driver for this study is to investigate the implementation of supported communication in the clinical context of stroke rehabilitation to gain data for the development of a definitive RCT (Phase III trial). We believe that the intervention may produce direct and tangible benefit to patients with moderate-severe aphasia after stroke when deployed by members of the stroke team. It has the potential to reduce frustration of patients with aphasia and enable them to benefit more fully from the rehabilitation available, with improved physical, psychosocial and health-related outcomes. The research will generate data in order to: provide initial estimates of clinical efficacy; explore the views and experiences of stroke unit staff towards implementation of the intervention; examine the views and satisfaction of people with aphasia; evaluate the cost effectiveness of the intervention.

Feasibility will be evaluated in terms of: 1) training requirements of staff in order to use the intervention, and the process of training, including the involvement of service users with aphasia; and the impact of training on staff skills; 2) the process (nature and quality) of implementation of the intervention by staff; and the acceptability to staff of implementing the intervention in the context of stroke unit rehabilitation; 3) the rate of patient recruitment.

Clinical efficacy will be evaluated in terms of: 1) the impact of the intervention on the ability of patients with aphasia on a stroke unit to actively engage in their rehabilitation through optimum communication with health care staff; 2) the impact of the intervention on the quality of the patient experience; 3) the impact of the intervention on physical, communicative and psychosocial functioning, and well-being of people with moderate-severe aphasia at discharge from a stroke unit and at six months.

Value will be examined in terms of resource costs associated with the intervention and impact on quality of life. In addition the study will generate data in order to: 1) perform a formal sample size calculation for a subsequent Phase III trial; 2) provide additional evidence of inter-rater agreement for key measures; 3) provide evidence to identify a good primary outcome measure for a subsequent Phase III trial; 4) provide evidence of acceptability of measures for use by this patient group where there is no existing evidence.

Research design
An exploratory cluster controlled assessor blinded trial (supported communication enhanced care vs routine care) will be carried out. As described below the clusters will be based on the stroke unit from which the participants are recruited. Staff who take outcome measurements (Research Team) and staff that deliver the intervention or standard clinical practice (Clinical Team) will be kept separate; the Clinical Team will not take outcome measurements, but research staff who take outcome measurements will not be blind to the assignment of the participants. Outcome assessors and data analysts will be kept blind to the assignment of the participants.
Study population
Staff participants will be recruited from two stroke units from the East of England SHA, matched on the basis of: bed numbers; staffing levels; estimated stroke cases per year. Staff groups will comprise: nurses drawn from all day shifts (Bands 5-7); qualified therapy staff - occupational therapists; physiotherapists (Bands 5-7); therapy / healthcare assistants (Bands 2 – 4). Medical staff will be excluded because rotation of FY1 doctors makes it unlikely that they would be able to complete participation in the study.
To obtain unit-level comparisons routine anonymised data will be collected on discharge by the Clinical Team for all patients meeting the inclusion criteria before the commencement of the trial.

Patient participants with moderate-severe aphasia will be recruited from the two stroke units (intervention / standard clinical practice), and will be followed up at discharge from the unit and 6 months after discharge wherever they are living. Only patients who give individual informed consent will complete self-report measures and take part in observational assessment. Study criteria (combined inclusion and exclusion) are:

- People aged 18+ years, who have had a stroke (first or recurrent) and have moderate-severe aphasia established by a speech and language therapist (SLT)
- Aphasia type: expressive; receptive; or both, all at either a moderate or severe level
- Able to give informed consent

**Planned interventions**

After completion of Baseline 1 (staff skills measures), a training protocol will be developed based on the principles of Supported Conversation for Adults with Aphasia [SCA™] (9,21) in order to meet the specific needs of the stroke unit context. To this end, a focus group (29) of 6-8 nursing, therapy and assistant staff from the experimental unit will be conducted to explore the range of needs and contexts for implementation of the intervention. Participants will be asked to explore their own experiences of working with people with aphasia, and how their own or their patients’ communicative needs were / were not addressed and what might have helped. Focus groups will be researcher-facilitated, and audio-recorded for later transcription and analysis. Members of the Norfolk Conversation Partner Trainers (NCPT) group (service users with aphasia), and Connect – the communication disability network will also be consulted to inform development of the training protocol. It is anticipated that attention will need to be paid to application of the intervention in a range of contexts of care and therapy, including availability and use of resources on the unit, environmental adaptations and staff support systems.

**Experimental intervention**

The experimental intervention (Supported Communication to Improve Participation in Rehabilitation [SCIP-R]) is based on the principles of supported conversation (9, 21) where patient participation is enhanced by the unimpaired communication partner (i.e. staff member) acting as a resource for the aphasic person and actively sharing the communication load by asking appropriately phrased questions, allowing extra time or using low tech resources such as pen/paper, pictures, symbols, calendars etc to break down barriers to successful communication. The intervention is implemented in order to ameliorate routine rehabilitation activity and care – therefore all these activities will continue as normal. Participating staff from the experimental unit will be trained in use of the intervention. Training will consist of a theory lecture on the principles, values and practices of supported communication, and practical face-to-face training given by people with aphasia. During the course of the trial ongoing support concerning implementation of the intervention will be available from the research team.

**Control intervention**

On the unit where standard clinical practice is implemented training will consist of a theory lecture on communication in aphasia, which is the routine training provided to the majority of NHS staff working in stroke rehabilitation. All routine care and rehabilitation activities will continue.

**Length of intervention**

In both units all care will continue as normal for each patient participant from admission until discharge from the unit. Length of stay on units will vary from patient to patient according to need as assessed by the clinical team. It is anticipated that average length of stay will be 4-6 weeks. SCIP-R will continue for each patient for as long as they are on the unit.
Measurement battery

Outcome measures
As this is a pilot study one of the purposes is to collect data in order to establish a good primary outcome measure for a subsequent Phase III trial. Outcome measures used in this study have been selected on the basis of a number of considerations: 1) they are used in other trials so that future meta-analysis is enabled; 2) validated measures are used which capture the elements of communication (staff skill; patient participation and engagement) that the intervention is designed to change; 3) outcome assessors and data analysts are blinded to assignment of participants; and 4) validated measures are used which capture the level of change that participants may consider important e.g. in physical functioning; quality of life and well-being.

To this end key measures employed are: i) Measure of Skill in supported Conversation (MSC); ii) Measure of Participation in Conversation (MPC); iii) Stroke and Aphasia Quality of Life Scale (SAQOL-39g); iv) EQ-5D. In addition patient satisfaction with staff communication uses the Communicative Access Measure for Stroke CAMS3: Patient Satisfaction instrument developed by the Aphasia Institute in Toronto (http://www.aphasia.ca/research.html).

If the patient does not meet the inclusion criteria due to capacity impairments or declines to take part in the study the following routinely collected data will be anonymised by the clinical team and made available to the research team: sex, age, stroke type (Bamford Classification), date of admission, date of discharge (Length of Stay), Therapy Outcome Measures (TOMS) Impairment, Activity, Participation and Well-Being scores at admission and discharge; discharge destination. These data will be used as an adjunct to data from patients who have consented to participate. No personal identifiable information will be recorded, nor will any attempt be made in the future to use these data to link to any other identifiable record.

Assessment at baseline

1) Collection of demographic data and socioeconomic information; 2) Evaluation of staff skills by the Measure of Skill in Supported Conversation [MSC] (30); participating members of staff will be video-recorded in interaction with people with aphasia before (Baseline 1) and after (Baseline 2) their respective training sessions; 3) Comparability between stroke units: routine anonymised data (age, sex, type and severity of aphasia) collected at discharge, before the start of the trial (Baseline 1); 4) Patients' ability to actively engage in rehabilitation by the Measure of Participation in Conversation [MPC] (30). Video-recorded observations will be collected in the course of routine care within a maximum of twenty days of admission(Baseline 2); 5) Assessment of health-related quality of life by the Stroke and Aphasia Quality of Life Scale (SAQOL-39g) (31) (Baseline 2); 6) Assessment of health status (EQ-5D) to allow health economic evaluation (Baseline 2).

Assessment at follow-up

1) MPC – video observations will be collected in the course of routine care prior to discharge from the unit; 2) Evaluation of the quality of the patient experience of staff communication uses the Communicative Access Measures for Stroke: CAMS 3 Patient Satisfaction (32) at discharge from the unit; 3) Assessment of health-related quality of life (SAQOL-39g); and health status (EQ-5D) at discharge from the unit and after six months.

Assessment of efficacy

Measurement points are within a maximum of twenty days of admission to the unit (Baseline 2); at discharge from the unit (Follow-up) and after six months post discharge (Follow-up). Outcome assessors and data analysts will be blinded to assignment of participants.

Assessment of acceptability and feasibility

Due to the exploratory nature of this study, the process of implementing SCIP-R in the course of routine rehabilitation will be investigated. This will be carried out in three ways: 1) assessment of staff skills in implementing the intervention in day-to-day practice - the same video-recorded observations used for initial estimates of clinical efficacy (MPC) will also be used as the basis for rating staff skills using the MSC; this will not entail any additional video-recording; 2) completion of a monthly 'learning log' enabling staff at the intervention site to reflect on their experiences of implementing the intervention and indentifying the need for
additional support or training; 3) exploration of staff experiences - mixed profession focus group discussions (29) with at least two thirds of staff participants will be carried out. Focus groups should not include more than 8 participants and therefore two separate groups will be run. The focus groups will be researcher-facilitated and audio-recorded for later transcription and analysis. A topic guide and vignettes will be used to prompt and promote discussion. The focus groups will each take approximately 2 hours and will be arranged at a time and place to accommodate staff availability and ensure privacy.

Collection of data for Health Economic evaluation
In this study we seek to estimate the cost-effectiveness of providing supported communication training and intervention, compared to standard training and care. In order to determine the costs of each course of action key items of resource use associated with the intervention / standard care will be identified. In line with National Institute of Health and Clinical Excellence guidance (33), costs will be calculated from the perspective of the NHS and personal social services (PSS) and encompass those costs that are potentially related to the intervention. Thus, aspects to be monitored will include resources associated with each of the training regimes (e.g. staff time; room use; materials), recorded by the Research team; input by staff in each of the stroke units (e.g. additional time needed to implement the intervention), recorded using a short questionnaire (developed in the course of the study) to be completed by all participating staff. For patients any re-admissions to hospital, other health and non health care contacts (e.g. further therapy, social services, out-patient visits) and medication will be recorded at six month follow-up using a researcher enabled non-standardised Health Service Use questionnaire. Subsequently, appropriate unit costs will be assigned to each of these resources. The main measure of effectiveness, in the economic analysis, will be the EQ-5D. However, the EQ-5D may not be appropriate in all circumstances (33) and a key part of this study will be to assess the properties of the EQ-5D in this patient group.

Assessment of safety
No adverse events have been reported in any of the published studies of supported conversation/communication. Therefore it is assumed that there are no risks associated with implementation of the intervention in the context of stroke rehabilitation. The Trial Steering Committee will assume the role of the Data Monitoring and Ethics Committee in ensuring that the safety and wellbeing of participants is paramount at all times.

Sample size
Staff participants: twenty four staff involved in day-to-day rehabilitation care and therapy will be recruited from each unit. This number represents over half of all staff per unit with the estimated proportion of staff groups recruited (2/3 nursing; 1/3 therapy) reflect relative staffing levels on the units. As this is a pilot study assessing the feasibility of conducting a subsequent Phase III trial of supported communication a formal power calculation has not been carried out. A sample of 24 patients from each unit assessed at discharge is considered sufficient to allow reasonable baseline comparisons between units to be made before the trial begins. A sample of 50 patients from each arm assessed at discharge is considered sufficient to assess results on the outcome measures being used in the study. Of the fifty patient participants per unit, 12 per unit will be sampled for assessment on the Measure of Participation in Communication (MPC) and in order to carry out qualitative observational analysis of implementation of the intervention / standard clinical practice. A maximum variation sampling strategy (34) will be used to maximise the diversity of participants and contexts while ensuring a feasible level of data collection given the resources available. The sampling frame consists of: severity and type of aphasia (moderate expressive, receptive, mixed aphasia; severe expressive, receptive, mixed aphasia); point in the day (4 time periods - 7-9am; 10-12; 2-4pm; 6-8pm). Two patients from each aphasia category, in two different time periods each within a maximum of twenty days of
admission and prior to discharge yield 48 observations per unit. It is therefore anticipated that implementation and impact of SCIP-R / normal care will be measured with all participating staff and in an extensive range of rehabilitation care and therapy activities.

**Statistical analysis**
To develop understanding of key feasibility & acceptability issues qualitative data from focus groups will be transcribed and subject to thematic analysis, where themes are identified, grouped and relationships explored (29). Researcher interpretations will be subject to credibility checks through respondent validation (35,36) where findings are fed back to participants for comparison and re-interpretation as appropriate.

Comparison between the two arms of the study will compare SAQOL-39g, EQ-5D and CAMS3 (Patient Satisfaction) using a t-test. We will adjust the analysis for important individual characteristics if they are predictive of outcome, potentially: sex, age, socio-economic status and severity of impairment, using a regression-based analysis. MSC and MPC measures (obtained from video data) will be compared in a similar fashion, but we will also consider individual characteristics, such as grade of health care professionals, and severity of patient impairment. The analysis will be used to provide initial evidence of efficacy, but also to estimate the important characteristics that will be useful for designing a subsequent Phase III trial (e.g. variation in outcome measures, loss to follow-up).

In order to provide an in-depth fine-grained exploration of issues affecting implementation in day-to-day practice, purposively selected samples of video data will be subject to qualitative analysis using Conversation Analysis (37) and Discourse Analysis (38) methods.

An economic model will be constructed to estimate the overall cost and overall effect in each of the stroke units. If one of the two options were shown to be less costly and more effective then this would suggest that it ‘dominates’ the other, and represents a cost-effective use of scarce resources. Alternatively, the incremental cost-effectiveness ratio (ICER) will be estimated, and assessed in relation to a range of cost-effectiveness thresholds (e.g. at thresholds of £20,000 to £30,000 per Quality Adjusted Life Year (QALY)), in order to estimate the likely level of cost-effectiveness. The associated level of uncertainty will also be characterised by estimating the cost-effectiveness acceptability curve (CEAC) for each training option and the value of further research, through value of information analysis (39). Sensitivity analysis will also be undertaken to assess the robustness of conclusions to changes in key assumptions.

**Research Governance**
NHS South Norfolk Clinical Commissioning Group (CCG) is the named recipient of the grant and has overall responsibility for the trial. Appropriate management and governance arrangements with all institutions involved in the study will be secured. All research staff employed and trial applicants will have Good Clinical Practice training.

The RA based at the unit where standard clinical practice is implemented will be employed and managed by the NHS Trust; the RA responsible for research at the experimental unit will be employed by UEA and managed by the Chief Investigator (CI).

A research committee (Trial Steering Committee) will be established to manage the project. The committee will consist of the applicants, and two service user representatives who have experience of organisational management (from the Norfolk Conversation Partner Trainers group). The CI will chair the committee and take overall responsibility for the progress of the project. The TSC will meet every three months in the first year and subsequently twice a year. In addition there will be monthly research meetings involving all currently active researchers on the study. Weekly (teleconference) meetings between the CI, Helen Watson (Norwich), Deborah Stanton (Cambridge) and the research associates (RAs) will address issues of day-to-day management.
Project timetable and milestones
Recruitment of research staff (two RAs) will be undertaken before the trial begins. Recruitment of staff participants will take place within the first six weeks; intervention development, staff training and Baseline 1 & 2 staff skills measures will be completed by month six. Approximately 14 months will be needed for recruitment of the 100 patient participants across the two units (4 per month per unit). Six-month follow-up measurements will be conducted on a rolling timetable and will be completed by approximately month 30. A further six months will be required to complete data processing, write up results and prepare a range of dissemination resources. Consequently a total of 3 years will be needed to undertake this research.

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<th>Milestones</th>
<th>Project months</th>
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<td>Staff recruitment &amp; training</td>
<td>1-6</td>
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<tr>
<td>Intervention development</td>
<td>7-12</td>
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<tr>
<td>Staff skills Baseline 1 &amp; 2</td>
<td>13-18</td>
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<tr>
<td>Training measures analysis</td>
<td>19-24</td>
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<td>42 participants: baseline &amp; d/c follow-up measures</td>
<td>25-30</td>
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<td>84 participants: baseline measures &amp; d/c follow-up measures</td>
<td>31-36</td>
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<td>100 participants: baseline measures &amp; d/c follow-up measures</td>
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<td>Staff evaluative focus groups</td>
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<td>Six month follow-up measures</td>
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<td>Trial measures &amp; qualitative analysis completed</td>
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<td>Reporting and dissemination</td>
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Service user involvement
Priority areas for research and individual interest in research collaborations were explored by people with aphasia who are members of the Norfolk Conversation Partner Trainers group at a workshop in July 2007, and through subsequent consultation. Members identified research into NHS staff training in and implementation of supported communication skills as a priority area for improving stroke care and services for people with aphasia in the East Anglia region. All members of this group have expressed an interest in being involved in this study in various ways, such as staff assessment, training and/or project management group membership. Lay summaries and key points concerning the potential impact of the research have been written with the support of members of the group.

Service users with aphasia will contribute directly to the assessment of staff skills and training in the SCIP-R intervention. These service users will be invited to provide critical commentary on the process, and on any other of their experiences of involvement in the study, and to advise on dissemination of findings to service user groups in the region. All communication (oral; written) with service users with aphasia collaborating on the project will be made accessible through various appropriate means.

The inclusion of people with aphasia in development, delivery, dissemination and research committee roles is considered to be a key feature of the project. Funding to support their inclusion (i.e. travel; subsistence; and gifts in recognition of collaborative expertise) has been requested accordingly from the funding body.
References
13. Legg C Young I Bryer A (2005) Training sixth-year medical students in obtaining case history information from adults with aphasia. Aphasiology, 19, 6, 559-575