TRACS

TRAINING CAREGIVERS AFTER STROKE

Process evaluation embedded within a randomised trial of caregiver training after stroke

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Process evaluation embedded within a randomised trial of caregiver training after stroke

3.0 STUDY SUMMARY

Stroke remains a major health problem in the 21st Century with incident rates of 1.65 per 1000 population for first ever stroke (1). With the emphasis on shorter hospital stays, caregivers will play an increasingly important role in the care and continued rehabilitation of patients after stroke. Caregivers identify information and the skills training required to implement physical care as the most important pre-discharge needs (2). The proposed study is a process evaluation complementary to a multicentre cluster randomised trial evaluation of a caregiver training programme (TRACS).The intervention has been previously tested in a single centre and was effective in decreasing burden, anxiety and depression for the caregiver, improving psychological outcomes for patients and reducing overall costs (3,4). The process evaluation will comprise of non-participant observation of the general routines of the stroke units, more detailed and longitudinal non-participant observation of the care and therapy delivered to a small number of patient and caregiver dyads (participants in the TRACS trial), semi-structured interviews with members of the multidisciplinary teams, patients and caregivers, and the analysis of documents recording the delivery of care on the stroke units. This evaluation will enable greater understanding of the training process, for example, the staff training required and ease of delivery, and provide insight into patient and caregiver experience. The latter will include the acceptability of the intervention and extent to which their needs have been met. These experiences will inform and enhance the national implementation of the intervention if positive trial outcomes are reported. If the trial intervention is unsuccessful, it will help interpret results, providing possible reasons for the ineffectiveness of this intervention and enable modifications to be proposed to facilitate progress in research and service provision.

4.0 BACKGROUND

We are conducting a cluster randomised trial designed to investigate provision of training to caregivers of patients after stroke (the TRACS trial). The study will take place in 36 UK stroke units. The intervention (London Stroke Carer Training Course (LSCTC)) has been tested in a single centre and is complex and multifaceted. The caregiver training is structured in that it is focused on fourteen core competencies. Training is provided to the caregiver during the patient's time as in-patient on the stroke unit. Competency assessments are conducted and 'signed off' by a multidisciplinary team member prior to the patients discharge home.

Training in implementing the LSCTC has been provided at centrally organised training days to representatives from the stroke rehabilitation units randomised to the intervention arm. These staff will disseminate the intervention process to their multidisciplinary team colleagues; the team will then be in a position to train caregivers. The caregiver training should be responsive to the individual needs of the caregiver and patient with awareness of their level of understanding. Ultimately, it ought to improve outcomes after the patient has returned home, for instance, by improving patients' physical recovery and psychological wellbeing, reducing caregiver burden and decreasing caregiver anxiety and depression.

To inform and interpret the quantitative outcomes of the trial (5,6), we need to understand the process of the LSCTC as delivered in the intervention arm sites and have insight into the care provided in those stroke units randomised to the control arm of the study. Current practice on each of the stroke units has been documented through (single) structured interview and observation of multidisciplinary team meetings. To capture the elements of the intervention, or usual care as delivered, the staff's experiences of delivery and patients' and caregivers' views on the process and possible benefits or problems, we propose to conduct an embedded qualitative study based on overlapping fieldwork methods. These will include non-participant observation, interviews and documentary analysis (7). Data generated will be analysed by the constant comparative method (8,9).

Provision of advice and guidance to stroke patients and their caregivers is a component of good care. Within the context of the TRACS trial structured caregiver 'training' will only be given in the intervention sites, in control sites caregivers may

also be provided with information, advice and guidance. For ease of understanding in this protocol this range of activities in intervention and control sites are termed 'formal and informal' training.

5.0 AIMS

The aims of this study are to:

1. Comprehend the context in which formal and informal training is provided for caregivers after stroke in both intervention and control stroke units participating in the TRACS trial,
2. Understand patients', caregivers' and staff's experience of the formal and informal training process,
3. Understand patients' and caregivers' subjective views of the benefits of formal and informal training,
4. Provide data to assist in interpretation of the TRACS trial outcomes.

6.0 METHODS

6.1 Non-participant observation of ward practice

The interaction between staff, patients and caregivers is fundamental to delivery of the caregiver training programme. Observation of practice offers a direct view of behaviour as it captures events in their natural setting (10,11,12). The researcher will seek to examine all apparently taken-for-granted actions and the minutiae of behaviours, with the aim of gaining a more complete understanding of how training is delivered and the nature of the interactions between team members, patients and carers during this process. Participant observation would be inappropriate in this study as researcher participation could alter practice delivery in the stroke rehabilitation units, influencing delivery of the caregiver programme in the intervention units or highlighting the need for caregiver training in the control units. Observation will therefore be by a non-participant researcher.

The observation of the ward process is an agreed component of the TRACS trial protocol. Staff may already be aware of this, but will be advised of the intention to conduct the process evaluation through the use of ward posters and staff information sheets. Observations will be undertaken by researchers otherwise unconnected to the randomised trial. Access to the selected units will be facilitated by discussion with

senior ward staff. Sites will be visited prior to study commencement to familiarise the researchers with the staff, ward environment and work practice in order to facilitate subsequent observations and interpretations of events and interactions.

Preliminary work will be undertaken in two units (one from each arm of the trial) to develop a schedule for observations. Interaction with caregivers in both the treatment and control groups is likely to occur through planned and unplanned activities. Therefore, observations will encompass the day and evening. The observer will endeavour to remain separate from patients, staff, caregivers and visitors, finding a discrete location, for example, window bay area, or corner of a therapy room to reduce physical obtrusiveness. Components of previously developed systematic observational methods designed for stroke units (13,14,15), and for use in mental health settings (for example, 'dementia care mapping' (14,16) will be reviewed to inform development of an observational record. As all members of the multidisciplinary team may provide advice and guidance to caregivers on aspects of caring for their relative at home, staff observed will include, for example, physiotherapists, occupational therapists, speech therapists, nursing staff, doctors, dieticians. Analysis and review of this preliminary work will also provide guidance on practical aspects such as timing and length of observational periods, and indicate the range of observations required; these may include team meetings and in-service staff training in order to capture all components of caregiver training.

Informed by this preliminary work and using the purposively designed and piloted observational record, non-participant observation will then be undertaken in at least four units from the intervention arm and four from the control arm. The total time of observations will be equally balanced between the control and treatment units.
The observations will have two elements;

a) Firstly, general observation of the processes of therapy and care will occur throughout the period of observations in each unit.
b) Secondly, detailed and longitudinal case study observation of a small number of patient and caregiver dyads, participants in the TRACS trial (between 6 and 8) will be undertaken to develop understanding of, engagement with, and response to training over time in the intervention units and advice and guidance provided in control units.

Although we anticipate a period of three months of observations in the stroke units, the length of the observational period will depend on the data generated and will cease when it is perceived that data saturation has occurred (11,17). Additional observations may be undertaken by observing more patients on already observed sites.

The observational record will consist of concurrent field notes recording contextual and case based information, and the researchers' reflective account of the interactions observed (7,18). These will include the researcher's impressions and reactions to the observations since adopting such reflexive methods is an important element of demonstrating rigour and quality when undertaking qualitative research (19). Emerging categories or preliminary hypotheses about the data may be tested during fieldwork; and more cases or examples (or contradictory ones) may be sought. Field notes and observational records will be transcribed and entered into the qualitative data analysis tool NVivo (version 7.0) to facilitate data management and the constant comparative approach to data analysis (8).

6.2 Patient and caregiver interviews

To obtain insight into the patient and caregiver experience, including an understanding of the views of the training process or experience on the 'control' wards, semi-structured interviews will also be undertaken with the patient and caregiver dyads. Equal numbers of control and intervention group patients will be selected to allow comparison between the two groups. A topic guide will be devised drawing on relevant literature (3, 20) and previous work in this area (21, 22, 23). The interviews are likely to include questions on participants' views on the hospital experience, how the caregiver was prepared for the patients discharge home and immediate home settlement. The topic guide will be refined by pilot interviews with a small sample (approximately four) patient and their caregivers. The guide will then be used with approximately 40 patients and their caregivers (across the eight sites) with final numbers determined when 'data saturation' is considered to have been achieved through on-going analysis. Patients and caregivers will be offered the opportunity to be interviewed separately so that one respondent will not be constrained by the presence of the other (20, 24). These interviews will be undertaken at approximately 3 months after discharge from hospital, when patients and caregivers will be able to reflect on their hospital experience and potential benefits and disadvantages of their

pre-discharge preparation, which in the intervention wards will include caregiver training. Our experience from other studies has indicated that approaching stroke patients and their families soon after hospital discharge is generally unsatisfactory as there may be considerable upheaval associated with being discharged, and the prime focus is on gaining help and support to tackle practical everyday needs (25).

6.3 Interviews with stroke rehabilitation unit staff

Non-participant observations will be complemented by semi-structured interviews with members of the multidisciplinary team in units where observations have taken place. Interviews conducted during the recruitment may have the undesired effect of changing practice, for example, prompting staff in the control units to undertake more caregiver training. We anticipate that these interviews will be undertaken within 6 weeks of the end of the TRACS trial recruitment process. The observations will provide information on which members of staff have been involved in caregiver training.

In order not to prescribe boundaries to the exploration of issues around this new intervention, a small pilot sample of in-depth, unstructured interviews will be conducted with two staff members who have different roles within the multidisciplinary team, for instance a nurse and an occupational therapist, from two intervention and two control stroke units. These individual interviews, which will be conducted in a quiet private area, will, with participants' permission, be tape recorded and transcribed verbatim for analysis. The interviewer will seek to hear the staff's views regarding the preparation of patients and caregivers for discharge home. The researcher will be unblinded and will therefore explore with staff from the intervention sites their experience of providing the caregiver training. Questions are likely to explore their confidence in providing the programme, whether they were adequately prepared, their insights into giving the training and the responses of patients and caregivers. Data from these interviews will be analysed by two of the research team and used to inform development of a semi-structured topic guide.

Interviews will then be undertaken with approximately 3-4 members of the MDT in each of the stroke units. The semi-structured topic guide will be utilised but will be sufficiently flexible to allow respondents to introduce any issues they consider

relevant. At the end of the interviews respondents will be given a written contact name and address in case they have any questions about the research.

6. 4 Documentation of training inputs

A standard record sheet has been created for each patient and members of the multidisciplinary team on all participating stroke units this will note how long they spend with caregivers providing information and advice. In addition to this quantitative data, documents recording multidisciplinary delivery of care to patients and interactions with caregivers recruited to the trial will be reviewed as these documents commonly capture team members' perceptions of the engagement and response of patients and caregivers to therapy, formal and informal training. These documents will include for example, shared multidisciplinary notes and other records of care routinely kept by members of the multidisciplinary teams. Reviews of these data will be included in field notes and will also be entered into NVivo computer software to facilitate a constant comparative approach to data analysis (17).

7.0 SAMPLING

All the participating centres fulfil the study definition of a stroke unit. However, the participating stroke units can be expected to vary in terms of service organisation and processes of care – both of which are considered important influences on patient outcomes (26,27). Stroke rehabilitation units participating in TRACS have been stratified prior to randomisation by geographical site (Yorkshire, North West, South East, Peninsula), and by quality of care as measured by the key 12 indicators score of the 2006 National Sentinel Stroke Audit. Observations will be undertaken in a sub-sample of at least eight units, selected from a purposive sampling frame of control group/intervention; above/below the median on the National Sentinel Audit Score and geographical site. This selection will be undertaken by staff in the CTRU at the University of Leeds, who are unconnected to the research team.

7. 1 Screening

As part of the main TRACS trial the clinical research team, who are independent of the clinical team, will complete a log of all patients and caregivers screened for

eligibility for inclusion in the trial and the process evaluation including those who are not registered, either because they are ineligible or because they decline participation. Anonymised information will be collected including:

- the reason not eligible for trial participation or
- eligible but declined
- eligible and consented
- age
- gender
- ethnicity
- relationship of the patient to the caregiver
- living circumstances (live alone , co-habit or in residential/nursing home)
- living circumstances (caregiver co-resident or non-resident).
- length of hospital stay

7.2 Inclusion Criteria: Patient and Caregiver

The following criteria which are adopted for the TRACS trial will be utilised to identify the patients and caregivers who are eligible to participate in the longitudinal case study observations (specific patient and caregiver dyads) and process evaluation interviews following patient discharge from the stroke units:

- have a confirmed primary diagnosis of new stroke
- are medically stable
- are likely to return home with residual disability at the time of discharge
- have a caregiver available, defined as the main person other than health, social or voluntary care provider, helping with activities of daily living and/or advocating on behalf of the patient, who is willing and able to provide support to the patient after discharge
- written informed patient consent/a caregiver declaration and caregiver consent will be obtained prior to patient and caregiver specific observations and interviews.

Unless the patient exhibits the following characteristics:

7.3 Exclusion Criteria: Patient and Caregiver

- in need of palliative care
- if discharge is planned within one week of admission to the current stroke unit

- if the patient or caregiver was registered to the process evaluation on a previous admission
- patients involved in other stroke research network adopted studies will also be recruited into the study unless: 1) the patient is recruited into the ACTNoW study (which assesses intensive speech therapy versus no speech therapy); 2) the patient is first recruited into another trial involving six and 12 months follow-up questionnaires (currently only the STICH study).

7.4 Stroke unit team member eligibility

All stroke unit team members in each of the eight selected study sites are eligible for participation in the observational component of the process evaluation. The following team members are unlikely to be invited to participate in the interviews:

- the team member is allocated to the stroke unit for the purposes of a student training rotation
- the team member is allocated to the stroke unit on an ad hoc basis as a temporary or agency replacement team member
- the team member is expected to cease employment in the stroke unit before the process evaluation is completed

In a small number of cases, however, data analysis may suggest that interviewing temporary team members would add to our understanding of care and therapy processes within a particular unit.

8.0 RECRUITMENT PROCESS

The general non−participant observations on the stroke units will focus on processes rather than individuals, so written consent will not be obtained from every patient, caregiver and staff member on the unit at each observation. However, verbal consent will be sought from staff, patients and caregivers on each occasion the researcher plans to observe an instance relating to general care delivery, therapy or training, advice and guidance. The study and research methods will be fully explained to the stroke units' consultants and ward managers. Posters explaining the study will be displayed on the ward during the study period (Appendix 8)

8.1 Informed consent –patients and caregivers for more detailed, longitudinal non-participation and interviews

Recruitment will usually be undertaken by a member of the clinical research team or process evaluation team, (independent of the clinical team) who will visit the stroke rehabilitation units at least once a week to liaise with the clinical team, assess patient and caregiver suitability and obtain informed consent from both patients and caregivers to undertake longitudinal (case study) observations and follow-up interviews. A verbal explanation of the process evaluation as it relates to the main trial and Patient and Caregiver Information Sheets (Appendices 1 and 2) will be provided by either the clinical research team or members of the process evaluation research team for the patient and caregiver to consider. These will include detailed information about the rationale, design and personal implications of the study. Following information provision, patients and caregivers will be given sufficient time to consider and discuss participation in the process evaluation with their family and healthcare professionals before they are asked whether they would be willing to take part. Information about the process evaluation will be repeated again if the patients and caregivers require time to consider their participation and the participants (patient and caregiver) will again have the opportunity to ask questions and confer with other members of their family. The right of the patient and caregiver to refuse consent without giving reasons will be respected.

Assenting patients and caregivers will then be invited to provide informed, written consent for the longitudinal (case study) observations and follow up interviews (Appendices 3 and 4). For patients unable to read/sign the consent form due to stroke related disabilities, and for those with problems of comprehension, a caregiver declaration will be sought. For patients unable to consent for themselves, this study complies with the Mental Capacity Act (MCA) 2005. In such cases, the caregiver will act as consultee. The caregiver will be advised to set aside their own views and provide advice on the participation of the patient in the research, taking into consideration the patient's wishes and interests. Research participants will not be required to do anything which is contrary to any advance decisions or statements that have been made by them in relation to their treatment or any other matter. Advance decisions made by the patient about their preferences and wishes will always take precedence.

The caregiver will also be approached to provide consent on their own behalf. Formal assessment of eligibility and seeking informed consent will be undertaken by a member of the clinical research or process evaluation research team. The patient and caregiver will remain free to withdraw from the study at any time without giving reasons and without prejudicing any further treatment. The research fellows will check with the GP whether the patient and caregiver are alive prior to contact to arrange interviews. The original consent forms will be retained in the investigator site file. A copy of the patient and caregiver consent forms will be given to the patient and caregiver respectively. Further copies will be filed in the patient hospital notes and a fourth set of copies will form part of the central study archive and be returned to the Academic Unit of Elderly Care and Rehabilitation in Bradford (AUECR).

8.2 Informed consent- stroke unit staff

A verbal explanation of the process evaluation as it relates to the main trial and Staff Information Sheets (Appendix 5) will be provided by the clinical research team or process evaluation team for the stroke unit team member to consider. These will include detailed information about the rationale, design and personal implications of the study. Following information provision, stroke unit team members will be given sufficient time to consider participation and will be given the opportunity to discuss participation in the process evaluation with the clinical research team and their colleagues before they are asked whether they would be willing to take part. Information about the process evaluation will be repeated again if the staff require time to consider their participation. The right of the stroke unit team members to refuse consent without giving reasons will be respected.

Assenting stroke unit team members will then be invited to provide informed, written consent for longitudinal (case study) patient and carer specific observations and follow up interviews. If staff members wish only to participate in the observational aspect of the study and, therefore, do not consent to be interviewed, this will be respected and they will not necessarily be excluded from taking part in the study. Formal assessment of eligibility and informed consent will be undertaken by a member of the process evaluation research team. The stroke unit team member will remain free to withdraw from the study at any time without giving reasons. The original consent forms will be retained in the investigator site file. A copy of the stroke

unit team members' consent forms will be given to the team member. Further copies will form part of the central study archive and be returned to the AUECR.

9.0 DATA ANALYSIS

9.1 Observational data

Analysis of observational data will entail close reading of the observational records and all field notes, and an iterative process of coding, developing categories, and testing and refining them, identifying concepts and looking for similarities and differences in the phenomena being studied. A sub-sample of field note data will be independently analysed by a member of the research team, and compared to analysis undertaken by the researchers. The main premise of the approach is that the explanation of social processes (theory) emerges from, and is grounded in data (11). The key to allowing such emergence is by means of the method termed 'constant comparison' in which data collection and analysis are a cyclical process in which attempts are made to compare data segments with each other (17).

9.2 Interview data

Following transcription, the interviews will be checked and typographical errors corrected alongside contemporary field notes. There will be familiarisation with the material on first reading and the content will then be analysed to identify the main patterns of responses, consistencies and divergences across and within interviews and to identify similarities and differences between and within groups. Common experiences, outlier views and significant differences by category of respondent will be identified. A sub-sample of interview data will be independently analysed by a member of the research team, and compared to analysis undertaken by the researchers.

The honing of theory by constant comparison has been referred to as a process of 'theoretical sensitivity'. This means that preliminary analysis is undertaken immediately and is on-going alongside fieldwork. This involves continued analysis until a level of 'saturation' is reached (9,17). At this point, nothing new emerges from the data, merely repetitions of the theoretical relationship which have already been discovered. This process will inform the number of centres finally recruited, the overall duration of observation in the stroke units and the number of interviews undertaken. Field notes and observational records will be transcribed and entered into the

qualitative data analysis tool NVivo (version 7.0) to facilitate data management and the constant comparative approach to data analysis (8).

9.3 Trustworthiness and quality

Initial analyses of observational and interview data will be presented by the researcher to the consumer research advisory group, established as part of the Yorkshire Stroke Research Network, to discuss the interpretations made (a form of triangulation). We will adopt standard approaches to demonstrating rigour in qualitative research (19,28). This will include clear documentation of research methods and processes, transparency in the use of observation, interview and monitoring schedules, independent coding and analysis by researchers, systematic exploration of alternative explanations for the processes claimed to explain our findings and as far as possible and the involvement of study participants in a discussion of the initial analyses.

Data generated will cover a range of perspectives and describe the contexts in which this intervention was delivered. Data from intervention and control sites will inform interpretation of the TRACS trial outcomes and directly address the study aims.

10.0 SERIOUS ADVERSE EVENTS (SAE) PROCEDURES

In respect of the process evaluation of the TRACS trial we anticipate that the likelihood of serious adverse events occurring is very low.

Should an unexpected and related SAE occur to a research participant, where in the opinion of the chief investigator the event is related and unexpected this would be reported to the main Research Ethics Committee (REC). The TRACS trial protocol provides a detailed summary of reportable and non reportable events; these criteria define the action to be taken in instances when expected or unexpected adverse events occur.

11. 0 QUALITY ASSURANCE AND ETHICAL CONSIDERATIONS

11.1 Quality assurance

The process evaluation will be conducted in accordance with the NHS Research Governance Framework and through adherence to CTRU (University of Leeds) standard operating procedures (SOPs).

11.2 Ethical considerations

The process evaluation will be informed by the research ethics guidelines of the British Sociological Association and the Association of Social Anthropologists. The right of a staff member, patient and caregiver to refuse participation without giving reasons will be respected. The staff member, patient and caregiver will remain free to withdraw at any time from the study without giving reasons and without prejudicing the patient's further treatment. The study will utilise the Integrated Research Application System (IRAS) and submit documentation for approval to a main Research Ethics Committee (REC) identifying each stroke unit which will participate in the process evaluation prior to entering patients and caregivers into the study. The AUECR will provide the main REC with a copy of the final protocol, patient and caregiver information sheets, consent forms and all other relevant study documentation.

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11.3 Confidentiality

All information collected during the course of the process evaluation will be kept strictly confidential. Information will be held securely on paper and electronically at AUECR (in Bradford), and the CTRU. When observations are being carried out some information will be held on the researchers' laptop computers. This information will be password protected. Some of the analysis may be carried out at King's College London and the University of Leeds. Any data they receive will be completely anonymous. The AUECR, CTRU, King's College London and the University of Leeds will comply with all aspects of the 1998 Data Protection Act and operationally this will include for those patients and caregivers participating in the longitudinal case study observations and follow up interviews:

- consent from patients to record personal details including name, date of birth,

address and telephone number, NHS ID, hospital ID, GP name and address;

- consent from caregivers to record personal details including name, date of birth, address and telephone number, GP name and address;
- appropriate storage, restricted access and disposal arrangements for patient and caregiver personal and clinical details;
- consent from patients and caregivers for access to their medical records by responsible individuals from the research team or from regulatory authorities, where it is relevant to study participation;
- consent from patients and caregivers for the data collected for the process evaluation to be used to evaluate safety and develop new research;
- patient and caregiver name, address and telephone number will be collected when a patient and caregiver are registered into the process evaluation but all other data collection forms that are transferred to or from the CTRU will be coded with a process evaluation number and will include two patient and caregiver identifiers, usually their initials and date of birth.

If a staff member, patient or caregiver withdraws consent from further trial participation their data will remain on file and will be included in the final study analysis unless they specifically withdraw consent for their data to be used.

12.0 ARCHIVING

At the end of the process evaluation study, data will be securely archived at the AUECR, which is part of the Bradford Institute for Health Research, the CTRU and participating stroke rehabilitation units for a minimum of 5 years. Once the interviews have been fully transcribed, the audio recordings will be wiped. If a staff member, patient or caregiver withdraws consent for their data to be used, it will be confidentially destroyed.

13.0 STATEMENT OF INDEMNITY

This process evaluation is embedded within the TRACS trial, which is sponsored by the University of Leeds and the University of Leeds will be liable for negligent harm caused by the design of the process evaluation. The NHS has a duty of care to patients treated, whether or not the patient is taking part in a clinical trial, and the

NHS remains liable for clinical negligence and other negligent harm to patients under this duty of care.

14.0 STUDY ORGANISATIONAL STRUCTURE

14. 1 Responsibilities

Chief Investigator

As defined by the NHS Research Governance Framework, the Chief Investigator is responsible for the design, management and reporting of the study.

14. 2 Operational structure

Process Evaluation Management Group (PEMG)

The Process Evaluation Management Group which is a sub group of the TRACS trial management group comprises the Chief Investigator, research manager, expert advisor (Mary Godfrey, University of Leeds) and co-investigators; the PEMG will be assigned responsibility for the clinical set-up, on-going management, promotion of the process evaluation, and for the interpretation of results**.**

The **process evaluation research team** includes the process evaluation Research Manager and research staff undertaking the process evaluation in the identified centres. The Research Manager will be responsible for the day-to-day running of the process evaluation, centre set-up, liaison with, recruitment and supervision of the process evaluation research team and other clinical research team members.

Clinical research team includes the TRACS trial manager and researchers recruiting to the TRACS trial, many of whom are associated with the Stroke Research Network.

Members of the clinical research and process evaluation research teams will recruit patients, caregivers and staff to the process evaluation as described. Data collection will be undertaken by members of the process evaluation research team, who are unconnected to the TRACS trial.

15.0 PUBLICATION POLICY

The success of the process evaluation depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who

have collaborated in the process evaluation, through authorship and contributorship. Uniform requirements for authorship for manuscripts submitted to medical journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

- conception and design, or acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content;
- and final approval of the version to be published;
- and that all these conditions must be met (www.icmje.org).

In light of this, the Chief Investigator, research manager, research fellows, Co-Applicants and relevant senior CTRU staff will be named as authors in any publication. In addition, all collaborators will be listed as contributors for the main process evaluation publication, giving details of roles in planning, conducting and reporting the process evaluation.

To maintain the scientific integrity of the process evaluation, data will not be released prior to the end of the process, either for trial publication or oral presentation purposes, without the permission of the Process Evaluation Steering Committee or the Chief Investigator. In addition, individual collaborators must not publish data concerning their patients which is directly relevant to the questions posed in the process evaluation until the main results of the process evaluation have been published.

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A study of the information provided to caregivers of stroke patients

PATIENT INFORMATION SHEET

A large-print version of this sheet is available on request.

We would be grateful if you would consider taking part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

- **Part 1 tells you the purpose of this study and what will happen to you if you take part.**
- **Part 2 gives you more detailed information about how the study will be carried out.**
- **Part 3 gives information to caregivers who are considering this study on behalf of the patient (caregiver declaration).**

Please ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether you wish to take part. Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

This stroke unit is involved in a research project called TRACS, which you may have heard about. TRACS is looking at the guidance given to caregivers. Caregivers are people, usually a partner or relative, who will provide some help and support to people who have had a stroke.

This research project complements the TRACS project. We would like to understand more about what happens on stroke units by observing the daily routine of the unit including the therapy and care provided to you and your caregiver. We will also ask you and your caregiver to have an interview with a researcher after you have left the stroke unit so that we can find out about your experiences and what you really thought about the advice and guidance you received.

Why have I been chosen?

You have been invited to help us with the study because you are an inpatient on the stroke unit at ….. hospital, where the TRACS study is being carried out.

Do I have to take part?

No. It is up to you and your caregiver to decide whether or not to take part. If you do decide to take part you will both be asked to sign consent forms. You will be given copies of the consent forms and this information sheet to keep. You are still free to withdraw at any time and without giving a reason. A decision to withdraw, or a decision not to take part, will not affect the standard of care you receive in any way.

What will happen to me if I take part?

If you agree to take part, a researcher will observe you on the ward and in therapy sessions that involve you during your time on the stroke unit. The researcher will ask permission from you and your caregiver (if they are present) before every period of observation. The researcher will take written notes of the observations made. A range of documents relating to your care may also be reviewed.

After you have left hospital we will arrange a convenient time with you and your caregiver to complete an interview about your experiences when you were in hospital with your stroke. We may interview you separately so you can both tell us your views. This interview will take about one hour and will take place at a time and location (your own home for instance) of your convenience. You may find some of the questions quite sensitive. If you wish to pause or stop the interview at any point, you will be able to do so. The interview will be recorded using a Dictaphone/Tape recorder.

What are the possible disadvantages and risks of taking part?
We do not anticipate there will be any additional risk in taking part. Your care will not be affected.

What are the possible benefits of taking part?
The information we get from this study probably won't directly benefit you, however, it may help us to treat future patients and their caregivers after stroke.

What if there is a problem?
Any complaint about the way you or your caregiver have been dealt with during the study or any possible harm you might suffer will be addressed. Detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. All the information about you and your caregiver's participation in this study will be kept confidential and reported anonymously. The details are included in Part 2.

This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

Will my taking part in this study be kept confidential?
Yes. If you decide to take part in this study, all information which is collected about you during the course of the research will be kept strictly confidential. The information will be securely stored by the research team at your hospital and at the Academic Unit of Elderly Care and Rehabilitation. You will be given a unique study number and only researchers involved in this study will be able to identify you from this number.

While observing on the stroke units, the researchers' notes will be securely stored on laptop computers. Once the recordings of your interview have been typed up the actual recordings will be destroyed. Some of the anonymous information may be analysed at Kings College London and the University of Leeds.

What will happen if I do not want to carry on with the study?
If you withdraw from the study, the information collected from you for the study will remain on file and will be included in the final study analysis. At the end of the study, your information will be securely archived for a minimum of 5 years. If you withdraw consent for your information to be used, it will be confidentially destroyed.

What if there is a problem?
If you have a concern about any aspects of this study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Involvement of the General Practitioner /Family Doctor (GP):
Your GP will not be informed that you are participating in this study.
What will happen to the results of the research study?

We aim to publish the results of this study in a reputable medical journal. If you wish to obtain a copy of the report you can request one from Professor Anne Forster, the Chief Investigator for the study, telephone number 01274 383406 a.forster@leeds.ac.uk, or through the study website, www.tracstrial.co.uk. You will not be identified in any report/publication.

Who is organising and funding the research?
This study is being organised and run by the Academic Unit of Elderly Care and Rehabilitation at Bradford Teaching Hospitals NHS Trust. This study is being funded by the National Institute for Health Research, Research for Patient Benefit Programme

Who has reviewed the study?
This study has been reviewed by the Leeds (West) Research Ethics Committee.

This completes Part 2 of the Information Sheet.

Part 3 Caregiver Declaration:
Your relative/friend is unable to provide consent to participate in this research, therefore you have been identified as a person who we can consult about whether or not they would want to be involved. You are known as the consultee and have been provided with the same information about the research project as your relative/friend. If you are unsure you may seek independent advice about this role and what is expected of you or if you do not feel able to take on this role, you may identify someone else to take your place. The following website is a useful source of information about the role of the consultee: www.publicguardian.gov.uk/docs/making-decisions.

As consultee you should set aside your own views and provide advice on the participation of your relative/friend in the research, taking into consideration their wishes and interests. Advance decisions made by your relative/friend about their preferences and wishes will always take precedence.

If you decide that your relative/friend would not wish to take part in this study this will not affect the standard of care they receive in anyway.

Please discuss any questions you may have with your hospital contact or research study contact.

Your hospital contact is:

Name: **Contact phone number:**

Job title:

Your research study contact is:

Name: Contact phone number:
Job title:

If you decide you would like to take part, please read and sign the consent form. You will be given a copy of this information sheet and the signed consent form to keep.

If you need more time to consider this, please feel free to think this over.

Thank you for taking the time to read this information sheet

Delete this line, and then print on Hospital headed paper

A study of the information provided to caregivers of stroke patients

CAREGIVER INFORMATION SHEET

A large-print version of this sheet is available on request.

We would be grateful if you would consider taking part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

- **Part 1 tells you the purpose of this study and what will happen to you if you take part.**
- **Part 2 gives you more detailed information about how the study will be carried out.**

Please ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether you wish to take part. Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

This stroke unit is involved in a research project called TRACS, which you may have heard about. TRACS is looking at the guidance given to caregivers. Caregivers are people, usually a partner or relative, who will provide some help and support to people who have had a stroke.

This research project complements TRACS. We would like to understand more about what happens on stroke units by observing the daily routine of the unit including the therapy and care provided to you and your relative/friend. We will also ask you and your relative/friend to have an interview with a researcher after your relative/friend has left the stroke unit so that we can find out about your experiences and what you really thought about the advice and guidance you received.

Why have I been chosen?

You have been invited to help us with the study because you are a relative/friend of an inpatient on the stroke unit at ….. hospital, where the TRACS study is being carried out.

Do I have to take part?

No. It is up to you and your relative/friend to decide whether or not to take part. If you do decide to take part you will both be asked to sign consent forms. You will be given a copy of your consent form and this information sheet to keep. You are still free to withdraw at any time and without giving a reason. A decision to withdraw, or a decision not to take part, will not affect the standard of care your relative/friend will receive in any way.

What will happen to me if I take part?

If you agree to take part, a researcher will observe your relative/friend on the ward and in therapy sessions that involve your relative/friend and perhaps yourself, during their time on the stroke unit. The researcher will ask permission from your relative/friend and yourself if you are present, before every period of observation. The researcher will take written notes of the observations made. A range of documents relating to your relative's/friend's care may also be reviewed.

After your relative/friend has left hospital we will arrange a convenient time with you and your relative/friend to complete an interview about your experiences while your relative/friend was in

hospital. We may interview you separately, so you can both tell us your views. This interview will take about one hour and can take place at a time and location (your own home, for instance) of your and your relative/friends convenience. You may find some of the questions quite sensitive. If you wish to pause or stop the interview at any point, you will be able to do so. The interview will be recorded using a Dictaphone/Tape recorder.

What are the possible disadvantages and risks of taking part?
We do not anticipate there will be any additional risk in taking part. The care given to your relative/friend will not be affected.

What are the possible benefits of taking part?
The information we get from this study probably won't directly benefit you, however, it may help us to treat future patients and their caregivers after stroke.

What if there is a problem?
Any complaint about the way you or your relative/friend has been dealt with during the study or any possible harm you might suffer will be addressed. Detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. All the information about you and your relative/friend's participation in this study will be kept confidential and reported anonymously. The details are included in Part 2.

This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

Will my taking part in this study be kept confidential?
Yes. If you decide to take part in this study, all information which is collected about you during the course of the research will be kept strictly confidential. The information will be securely stored by the research team at your hospital and at the Academic Unit of Elderly Care and Rehabilitation. You will be given a unique study number and only researchers involved in this study will be able to identify you from this number.

While observing on the stroke units, the researchers' notes will be securely stored on laptop computers. Once the recordings of your interview have been typed up the actual recordings will be destroyed. Some of the anonymous information may be analysed at Kings College London and the University of Leeds.

What will happen if I do not want to carry on with the study?
If you withdraw from the study, the information collected from you for the study will remain on file and will be included in the final study analysis. At the end of the study, your information will be securely archived for a minimum of 5 years. If you withdraw consent for your information to be used, it will be confidentially destroyed.

What if there is a problem?
If you have a concern about any aspects of this study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Involvement of the General Practitioner /Family Doctor (GP):
Your GP will not be informed that you are participating in this study.

What will happen to the results of the research study?
We aim to publish the results of this study in a reputable medical journal. If you wish to obtain a copy of the report please ask your doctor or you can request one from Professor Anne Forster, the Chief Investigator for the study, telephone number 01274 383406, a.forster@leeds.ac.uk, or through the study website, www.tracstrial.co.uk. You will not be identified in any report/publication.

Who is organising and funding the research?
This study is being organised and run by the Academic Unit of Elderly Care and Rehabilitation at Bradford Teaching Hospitals NHS Trust. This study is being funded by the National Institute for Health Research, Research for Patient Benefit Programme

Who has reviewed the study?
This study has been reviewed by the Leeds (West) Research Ethics Committee.

Contacts for further information:

Please discuss any questions you may have with your hospital contact or research study contact.

Your relative/friend's hospital contact is:

Name:	**Contact phone number:**
Job title:	

Your research study contact is:

Name:	Contact phone number:
Job title:	

If you decide you would like to take part, please read and sign the consent form. You will be given a copy of this information sheet and the signed consent form to keep.

If you need more time to consider this, please feel free to think this over.

Thank you for taking the time to read this information sheet

Appendix 3 Patient consent form

Patient ID:	Initials:
Date of Birth:	Hospital Number:
Principal Investigator:	

A study of the information provided to caregivers of stroke patients

PATIENT CONSENT FORM Version 1.0 21st August 2008

		Please initial the boxes
1.	I confirm that I have read and understand the Information Sheet dated…… (Version…….) for the above study and have had the opportunity to ask questions.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected.	
3.	I understand that my medical notes may be looked at by responsible individuals from the research team, regulatory bodies or Sponsor where it is relevant to my taking part in the research; I give permission for these individuals to have access to my records.	
4.	I understand that my data will be collected for this study and may be used to help develop new research, and that data protection regulations will be observed, and strict confidentiality maintained.	
5.	I understand that even if I withdraw from the above study, the data already collected from me will contribute to the study unless I specifically withdraw consent for this. I understand that my identity will remain anonymous.	
6.	I agree for my details, which will include my name and address, to be passed to the Academic Unit for Elderly Care and Rehabilitation, University of Leeds for the administration of the study.	
7.	I understand that a copy of this Consent Form will be stored at the Academic Unit for Elderly Care and Rehabilitation, University of Leeds	
8.	I agree to take part in the above study	

PATIENT:

Name of patient (IN CAPITALS)	Date	Signature

RESEARCHER:

Name of Researcher	Date	Signature

(1 copy for the patient; 1 for the AUECR; 1 for filing in the patients medical records;
Original stored in Investigator Site File)

Appendix 4 Caregiver consent form

Caregiver ID:	Initials:
Date of Birth:	
Principal Investigator:	

A study of the information provided to caregivers of stroke patients

CAREGIVER CONSENT FORM Version 1.0 21st August 2008

Please initial the boxes

1. I confirm that I have read and understand the Information Sheet dated…… (Version…….) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without affecting my and my relative's / friends medical care or legal rights. ☐
3. I understand that even if I withdraw from the above study, the data already collected from me will contribute to the study unless I specifically withdraw consent for this. I understand that my identity will remain anonymous. ☐
4. I understand that any data collected from me for this study may be used to help develop new research, and that data protection regulations will be observed, and strict confidentiality maintained. ☐
5. I agree for my details, which will include my name and address, to be passed to the Academic Unit of Elderly Care and Rehabilitation, University of Leeds for the administration of the study. ☐
6. I understand that a copy of this Consent Form will be sent to Academic Unit of Elderly Care and Rehabilitation, University of Leeds ☐
7. I agree to take part in the above study. ☐

CAREGIVER:

Name of Caregiver (IN CAPITALS)	Date	Signature

RESEARCHER:

Name of Researcher	Date	Signature

(1 copy for the caregiver; 1 for the AUECR; 1 for filing in the patients medical records;
Original stored in Investigator Site File)

Appendix 5 Caregiver declaration form

Caregiver ID:	Initials:
Date of Birth:	
Principal Investigator:	

A study of the information provided to caregivers of stroke patients

CAREGIVER DECLARATION FORM Version 1 21st August 2008

		Please initial the boxes
1.	I confirm that I have read and understand the Information Sheet dated ……. (Version …….) for the above study and have had the opportunity to ask questions.	
2.	I understand the purpose of the study and know what my relative's/friend's involvement will be. In my opinion, my relative/friend does not object to taking part in this study.	
3.	I understand that my relative's/friend's participation is voluntary and that I and my relative are free to withdraw our declaration/consent for participation at any time without giving any reason and without my relative's/friend's medical care or legal rights being affected.	
4.	I understand that my relative's/friend's medical notes may be looked at by responsible individuals from the research team, regulatory bodies or Sponsor where it is relevant to my relative/friend taking part in the research; I give permission for these individuals to have access to my relative's/friend's records.	
5.	I understand that my relative's/friend's medical data will be collected for this study and may be used to develop new research, and that data protection regulations will be observed, and strict confidentiality maintained.	
6.	I understand that even if I and my relative /friend withdraw from the above study, the data already collected from me and my relative/friend will be used in analysing the results of the trial, unless me and my relative/friend specifically withdraw consent for this. I understand that my and my relatives/friend's identity will remain anonymous.	
7.	I agree for my relative's/friend's details, which will include my relative's/friend's name and address, to be passed to the Academic Unit for Elderly Care and Rehabilitation, University of Leeds for the administration of the study.	
8.	I understand that a copy of this Declaration Form will be sent to the Academic Unit for Elderly Care and Rehabilitation, University of Leeds.	
9.	I agree to my relative/friend taking part in the above study	

RELATIVE/FRIEND: Name of Patient (IN CAPITALS): _____

Name of Caregiver (IN CAPITALS)	Date	Caregiver's Signature

RESEARCHER:

Name of Researcher	Date	Signature

(1 copy for the relative; 1 for the Clinical Trials Research Unit; 1 for filing in the patients medical records; Original stored in Investigator Site File)

Appendix 6 Staff information sheet

Delete this line, and then print on Hospital headed paper

A study of the information provided to caregivers of stroke patients

STAFF INFORMATION SHEET

A large-print version of this sheet is available on request.

We would be grateful if you would consider taking part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

- **Part 1 tells you the purpose of this study and what will happen to you if you take part.**
- **Part 2 gives you more detailed information about the conduct of the study.**

Please ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether you wish to take part. Thank you for reading this information sheet.

Part 1

What is the purpose of the study?
As a member of the multidisciplinary Team (MDT) on the stroke unit at <name of hospital> you may already be aware of the TRACS research study. The aim of the TRACS study is to evaluate different ways of providing information and guidance to patients and their families.

The present qualitative study is complementary to TRACS. We would like to find out how care is delivered and your own personal experiences as a member of the MDT on the stroke unit. The researcher will observe the daily routine on the stroke unit. We also plan to observe the care and therapy delivered to a small number of patients and caregivers on a regular basis throughout their stay on the stroke unit. In addition, we will ask some members of the MDT to have an interview with a researcher so that we can find out in detail about their experiences.

Why have I been chosen?
You have been invited to help us with the study because you are a member of the MDT on a stroke unit that is taking part in the TRACS study.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to sign a consent form. You will be given a copy of the consent form and this information sheet to keep. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect you in any way.

What will happen to me if I take part?
You may be observed during your everyday involvement in care delivery on the stroke unit. If you agree to take part in this research project, we may also ask to observe you working with the patients and caregivers we plan to follow throughout their stay. The researcher will take written notes of the observations made. We may ask to see a range of documents relating to care and therapy processes.

Following the completion of the observations, the researcher will arrange a convenient time with you to complete an interview about your experiences as a member of the MDT on the stroke unit. This interview will take about one hour and will be conducted in a private room in or near to your stroke unit. The interview will be recorded using a Dictaphone/Tape recorder.

What is being investigated?
We are interested in processes of care and therapy on the stroke ward and the MDTs experiences of providing advice and guidance to caregivers before the patient goes home

What are the possible disadvantages and risks of taking part?
We do not anticipate there will be any additional risk in taking part.

What are the possible benefits of taking part?
The information we get from this study may not benefit you in the short term, however, it may help us to understand how stroke units could develop the care of patients and their caregivers after stroke.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. All the information about your participation in this study will be kept confidential and reported anonymously. The details are included in Part 2.

This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

Will my taking part in this study be kept confidential?
Yes. If you decide to take part in this study, all information which is collected about you during the course of the research will be kept strictly confidential. This information will be securely stored by the research team at your hospital and at the Academic Unit of Elderly Care and Rehabilitation. You will be given a unique study number and this will be used as a code to identify you on all study forms. Only the researchers involved with this study will be able to identify you from this number.

When observations are being carried out some information will be held on the researchers' laptop computers. Once the recordings of your interview have been typed up the actual recordings will be destroyed. Some of the anonymous data may be analysed at Kings College London and the University of Leeds.

What will happen if I do not want to carry on with the study?
If you withdraw consent from further participation in the study, the information collected from you for the study will remain on file and will be included in the final study analysis. At the end of the study, your information will be securely archived for a minimum of 5 years. If you withdraw consent for your information to be used, it will be confidentially destroyed.

What if there is a problem?
If you have a concern about any aspects of this study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

What will happen to the results of the research study?
We aim to publish the results of this study in a reputable medical journal. If you wish to obtain a copy of the report please ask your doctor or you can request one from Professor Anne Forster, the

Chief Investigator for the study, telephone number 01274 383406, a.forster@leeds.ac.uk or through the study website, www.tracstrial.co.uk. You will not be identified in any report/publication.

Who is organising and funding the research?
This study is being organised and run by the Academic Unit of Elderly Care and Rehabilitation at Bradford Teaching Hospitals NHS Trust. This study is being funded by the National Institute for Health Research, Research for Patient Benefit Programme

Who has reviewed the study?
This study has been reviewed by the Leeds (West) Research Ethics Committee.

This completes Part 2 of the Information Sheet.

Contacts for further information:

Your research study contact is:	
Name:	Contact phone number:
Job title:	

If you decide you would like to take part, please read and sign the consent form. You will be given a copy of this information sheet and the signed consent form to keep.

If you need more time to consider this, please feel free to think this over.

Thank you for taking the time to read this information sheet

Appendix 7: staff consent form.

Patient ID:	Initials:
Date of Birth:	Hospital Number:
Principal Investigator:	

A study of the information provided to caregivers of stroke patients

MDT STAFF CONSENT FORM Version 1.0 21st August 2008

Please initial the boxes

1.	I confirm that I have read and understand the Information Sheet dated…… (Version…….) for the above study and have had the opportunity to ask questions.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my legal rights being affected.	☐
3.	I understand that my data will be collected for this study and may be used to help develop new research, and that data protection regulations will be observed, and strict confidentiality maintained.	☐
4.	I understand that even if I withdraw from the above study, the data already collected from me will be used in the study, unless I specifically withdraw consent for this. I understand that my identity will remain anonymous.	☐
5.	I understand that a copy of this Consent Form will be stored at the Academic Unit of Elderly Care and Rehabilitation, University of Leeds.	☐
6.	I agree to take part in the above study	☐

STAFF:

Name of staff (IN CAPITALS)	Date	Signature

RESEARCHER:

Name of Researcher	Date	Signature

(1 copy for the patient; 1 for the AUECR; 1 for filing in the patients medical records;
Original stored in Investigator Site File)

Appendix 8: WARD POSTER to be displayed one week before process evaluations commence.

INFORMATION FOR PATIENTS

From xxday xxth you may see someone walking around the ward, making notes and talking to staff. They may also observe the delivery of care in different areas of the ward, for example the therapy rooms, the ward, the dining room and day room. They are researchers looking at the process of care on the ward.

Unless you have agreed to participate in the TRACS project, the researcher will not record any personal information relating to you or your care. For example they will not record your name.

When the researchers are on the ward they will introduce themselves and ask if their presence is acceptable to you. Please let them or the ward staff know if you have any concerns.

The lead researcher would be happy to provide more information if you wish.

Thank you

For more information contact Anne Forster, telephone: 01274 383406 or write to: Academic Unit of Elderly Care, Temple Bank House, Bradford Royal Infirmary, Duckworth Lane, Bradford, BD9 6RJ

The research is funded by the National Institutes for Health-Research for Patient benefit Programme