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

Guidance notes and non-participant observation framework: This summary sheet refers to non-participant observations and documentary analysis only

The overall aims of the study are to:
- 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,
- Understand patients’, caregivers’ and staff’s experience of the formal and informal training process,
- Understand patients’ and caregivers’ subjective views of the benefits of formal and informal training,
- Provide data to assist in interpretation of the TRACS trial outcomes.

General guidance relating to non participant observations in stroke units:
The purpose of this guidance is not to constrain the research fellows who will generate data, but rather to provide some common areas of initial and ongoing focus so that there is some agreed structure for our observational records. We anticipate that all data collection will begin with a small number of (2-3) visits to all study units; these will be periods of orientation to a unit to begin to comprehend the way these work and social spaces are organised. This will help establish the pattern of future visits and ways of working which will facilitate data generation. After these initial orientation periods, individual researchers will develop field notes and linked memos which both relate to but also extend and add to the areas of focus identified below and on the observation record sheet.

We have identified two broad but overlapping areas for non participant observation, these are:
- General stroke unit observations
- Case based patient, carer and staff member(s) observations

General stroke unit observations
The purpose of these observations is to:
- develop understanding of the organisational and social context within which stroke care in general and more specific training related activity takes place
- develop understanding of the regularities and irregularities of work and social interaction which can inform the process evaluation
- recognise the activities, interactions or processes we need to sample more specifically in these and also the case based observations

Case based patient, carer and staff member(s) observations
The purpose of these observations is to:
- identify, describe and explain the activities, events and interactions which represent TRACS training (intervention units) or more general advice and preparation for discharge from hospital (control units).
- develop understanding of the contextual, social and organisational factors influencing or impacting on training/advice and preparation for discharge
- focus in detail on the interactions between the social actors who represent the case (patient, carer(s), staff member(s)
- identify and develop topics or questions to explore in semi-structured interviews
Areas to be routinely captured on the observation record:
Record once for each centre:

<table>
<thead>
<tr>
<th>Item</th>
<th>Specify/List</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Urban or suburban location</td>
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<tr>
<td>Unit Type: (e.g. acute, mixed, rehabilitation)</td>
<td></td>
<td>The label ‘stroke unit’ may be variously interpreted around the country, so we are looking at local understanding, context and organisation. This will need to be reflected in the observational schedule.</td>
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<tr>
<td>Number of Beds</td>
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<td>Average Length of Stay (in days)</td>
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<tr>
<td>Staff Profile</td>
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<td>Record here any information that will aid interpretation of the observation and interviews</td>
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<tr>
<td>List professional Groups (actual numbers as well as types), Describe shift numbers, management and organization of staff (including staff physical location)</td>
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<td>Record timing/frequency of routine activities: For example MDT meetings, Patient conferences, home visits, meal times, ward rounds, work patterns across professions</td>
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<td>Outline local catchment area population size and make-up</td>
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<td>Identify and outline local and national policy initiatives or requirements impacting on the context and operation of the unit</td>
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| **Locations for observations (with time spent if appropriate)** | Locations for general unit observations will include:  
- the central work or nurses station or any area where staff routinely congregate to discuss patient activity or meet with patients and carers  
- staff meeting rooms (this can include attending multidisciplinary team meetings)  
- therapy rooms/gymnasiums/occupational therapy kitchens or facilities which allow patients and carers to spend time independence of stroke unit staff in preparation for discharge home  
- patient dining areas  
- day rooms or other social communal areas  
- bed areas  
- any additional areas where the researcher determines that it would be appropriate and gains consent to engage in non participant observation  
**Case based observations may also include most of the above areas, but will require written informed consent to undertake observations during specific activities taking place in defined areas of the stroke units** |
| **Focus of non participant observation** | **Areas of focus for general unit observations will include:**  
- description of general activities routinely involving interaction between staff, patients and carers  
- description of what appears to be important and meaningful for staff, patients and caregivers for instance staff concerns, beliefs and preoccupations where these are verbalised  
- description of specific activities focusing on TRACS training (intervention units) or advice and preparation for discharge home (control units)  
- description of the conditions under which patients, carers and staff members conduct their activities and interactions in the units, including constraints and pressures  
- description of staff interactions  
- description of patient to patient, carer with patient and carer with staff interactions  
- description of informal unplanned activity, which appears to contribute to or reinforce TRACS training (intervention units) or advice and preparation for discharge home (control units)  
- summary records of dialogue between participants may also be recorded when this is considered appropriate. Where verbatim recording of dialogue
is considered important then written informed consent will be required from the participants. In the case of recurring dialogue, content which relates broadly to meeting the aims of the study, should not require consent. Additional areas of focus will clearly emerge in each study unit—researchers will develop field notes in these areas and should share/discuss these areas, with the other researchers generating data.

**Focus of non participant observation**

*Case based observations*

The *case based non participant observations* will include the above, but here we are seeking more fine-grained and detailed description (and later explanation), which will aid in understanding:

- the context of the activity
- who is participating in the activity
- the nature and purpose of the activity
- how the participants appear to respond to, participate in, feel about, describe, explain and make sense of the activity
- the researcher's perceptions of the relationship of the activity to the aims of the study

Additional areas of focus will clearly emerge in each study unit—researchers will develop field notes in these areas and should share/discuss these areas, with the other researchers generating data.

**Documents reviewed in relation to the case based observations only (written consent will be needed)**

Documentary analysis is designed to capture any textual information which will aid in understanding how TRACS training (intervention units) or more general advice and preparation for discharge is reported upon by stroke unit staff or patients and carers in situations where this is recorded. Documents reviewed may include:

- shared patient records (for example, multidisciplinary team notes)
- individual patient records (for example, the medical notes, the nursing notes or notes, developed by therapists or any other stroke unit team member working with patients and carers)
- information sheets or posters describing TRACS training or more general advice and preparation for discharge
- any other formal or informal documentation, which is considered relevant to illuminate the process of TRACS training or more general advice and preparation for discharge
- caregiver/family contextual information for example discussions in MDT meetings, records of home visits, social work/OT assessments of preparedness

**Open field note record**

*Detailed notes and reflections* of the researcher completed during the period of non participant observations or documentary analysis (these will of course be written up in more detail following the period of observation). Researchers may choose to use notebooks in the field, but overall observation records should be completed and saved (securely) electronically using this document.

**Linked memo number**

Researchers will be encouraged to record and develop memos. Memos are not simply "ideas." They are involved in the formulation and revision of explanations for the processes observed and later in the development of theory during the research process. Writing theoretical memos is an integral part of doing grounded theory and we are adopting this approach for our data analysis. Since the analyst cannot readily keep track of all the categories, properties, hypotheses, and generative questions that evolve from the analytical processes involved in recording and analysing fieldwork, there must be a system for doing so. The use of memos constitutes such a system (Strauss & Corbin, 1998).

We will encourage researchers to share and copies of memos, within the group discussion area of the Blackboard VLE at Leeds.
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<tr>
<th><strong>Other relevant information</strong></th>
<th><strong>Record as appropriate</strong></th>
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