

BMJ Open Why do patients with stroke not receive the recommended amount of active therapy (ReAcT)? Study protocol for a multisite case study investigation

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ABSTRACT

Introduction: Increased frequency and intensity of inpatient therapy contributes to improved outcomes for stroke survivors. Differences exist in the amount of therapy provided internationally. In England, Wales and Northern Ireland it is recommended that a minimum of 45 min of each active therapy should be provided at least 5 days a week provided the therapy is appropriate and that the patient can tolerate this. Sentinel Stroke National Audit Programme (2014) data demonstrate this standard is not being achieved for most patients. No research been undertaken to explore how therapists in England manage their practice to meet time-specific therapy recommendations. The ReAcT study aims to develop an in-depth understanding of stroke therapy provision, including how the guideline of 45 min a day of each relevant therapy, is interpreted and implemented by therapists, and how it is experienced by stroke-survivors and their families.

Methods and analysis: A multisite ethnographic case study design in a minimum of six stroke units will include modified process mapping, observations of service organisation, therapy delivery and documentary analysis. Semistructured interviews with therapists and service managers (n=90), and with patients and informal carers (n=60 pairs) will be conducted. Data will be analysed using the Framework approach.

Ethics and dissemination: The study received a favourable ethical opinion via the National Research Ethics Service (reference number: 14/NW/0266). Participants will provide written informed consent or, where stroke-survivors lack capacity, a consultee declaration will be sought. ReAcT is designed to generate insights into the organisational, professional, social, practical and patient-related factors acting as facilitators or barriers to providing the recommended amount of therapy. Provisional recommendations will be debated in consensus meetings with stakeholders who have not participated in ReAcT case studies or interviews. Final recommendations will be disseminated to therapists, service managers, clinical guideline developers and policymakers and stroke-survivors and informal carers.

Strengths and limitations of this study

- This is the first in-depth ethnographic case study investigation of factors that act as barriers and facilitators to providing the recommended intensity and frequency of inpatient stroke therapy in England.
- Combining non-participant observations, analysis of therapy records and interviews with stroke staff, stroke survivors and their informal carers, will provide detailed insights into the ways in which therapists conceptualise, organise and provide stroke therapy. Organisational, professional and patient factors influencing therapy provision will also be identified.
- Examining stroke therapy provision in units which are performing well and less well according to the Stroke Sentinel National Audit Programme will highlight examples of good practice and areas where improvements can be made to bring about an increase in the frequency and intensity of therapy provision.
- A limitation of the ReAcT study is that a maximum of nine stroke units, predominantly in the North of England will participate in the study. This may mean that elements of good practice in achieving the stroke therapy recommendations in other units are not available to the research team.
- Consensus meetings to refine study recommendations with different stakeholder will ensure that final recommendations are clinically relevant and feasible to implement in other stroke units.

INTRODUCTION

Worldwide it is estimated that up to 17 million people will experience a stroke every year.^{1 2} Stroke is the most common cause of disability in England with more than 110 000 people having a new stroke each year, and over 1 million people living with longer-term disability in the community.³ Stroke can

result in impairments affecting upper and lower limb function, vision, swallowing, cognition and speech and language. Assessment and treatment by multidisciplinary teams (MDTs) in a stroke unit improves patient outcomes⁴ which brings benefits for individuals, health services and the economy by enabling patients to leave hospital earlier, to return to work or to other activities and live independent lives. A fundamental element of stroke unit care is assessment and patient specific therapy provided by physiotherapists (PTs), occupational therapists (OTs) and speech and language therapists (SALTs). There is increasing evidence demonstrating the effectiveness of a range of interventions and that increased frequency and intensity of therapy leads to better outcomes.^{5–7}

However, the evidence base underpinning guidelines regarding frequency and intensity of therapy has been questioned. Foley *et al*⁸ identified six international clinical guidelines which made recommendations for the minimum daily dose of stroke therapy, 37 studies were cited as support for the recommendations. In-depth review of 15 of the studies cited found that a significant difference in favour of increased intensity was reported between experimental and control groups in only five studies. Foley *et al*⁸ concluded that the evidence base reviewed could not support a specific (time-based) recommendation for stroke therapy intensity. A more recent systematic review and meta-analysis of the evidence for physiotherapy interventions post-stroke included 467 randomised controlled trials.⁷ The evidence favoured intensive, high repetition, task-oriented and task-specific training in all phases of post-stroke rehabilitation. However, Veerbeek *et al*⁷ recognised that more research was still required to investigate dose–response relationships in exercise therapy. A Cochrane review of aphasia therapy post-stroke⁹ reported that pooled data from five trials indicated improvements in severity of aphasia following high-intensity SALT. However, these results were confounded by significantly higher numbers of participants dropping out from high-intensity SALT groups compared to low-intensity SALT groups. Brady *et al*⁹ noted some benefits of intensive approaches to SALT in relation to functional communication, writing and severity of impairment, but suggested, based on the small number of trials reviewed, that intensive approaches may not suit all patients. These findings broadly support earlier claims that intensity of practice is a key factor in meaningful training after stroke, and that more practice is better.^{5 6 9} However, there is a clear need for further evidence relating to frequency and intensity of stroke therapy, especially as clinical guidelines continue to recommend minimum time-specific periods.

The National Clinical Guidelines for Stroke¹⁰ for England, Wales and Northern Ireland recommend that:

Patients with stroke should be offered a minimum of 45 minutes of each appropriate therapy that is required,

for a minimum of 5 days a week, at a level that enables the patient to meet their rehabilitation goals for as long as they are continuing to benefit from the therapy and are able to tolerate it.

Similar guidelines are evident in the USA, Canada, Australia and elsewhere in Europe although the recommendation varies between 1 and 3 h per day.^{11–13} Studies in Canada, the Netherlands and other European countries indicate that these recommendations are not often met.^{14–16} Research in four European stroke units (the CERISE group) identified important variations in therapy provision in the units studied.^{16–19} The CERISE group investigated one established and respected stroke unit in each country comparing therapists' activity and the impact on patients. Notable findings included that in the English unit, patients with stroke received on average 1 h of therapy daily compared with 1:59, 2:20 and 2:46 in Belgium, Germany and Switzerland respectively. Functional recovery was significantly better in German and Swiss units compared to England when confounding variables were controlled for (eg, initial stroke severity); this was attributed to increased therapy contact time. Lower contact time in the English unit was reportedly not due to lower staffing levels, but was related to the organisational culture of the rehabilitation service.¹⁹ In England, Wales and Northern Ireland the Stroke Sentinel National Audit Programme (SSNAP) prospectively collects a minimum data set for every stroke patient to measure processes of acute care, rehabilitation and care in the community. This self-reported audit includes data from each participating stroke unit on the number of minutes of therapy that were provided by OT, PT and SALT and on how many days. The 2013 and 2014 SSNAP reports identified that the 45 min per day recommendation was not being achieved for most patients.²⁰ While the proportion of patients considered to require therapy remained relatively constant during 2013–2014 (80–85% for PT and OT and just under 50% for SALT), the (national) median number of minutes of therapy received each day remained stubbornly lower than recommendations (OT at 40 min, PT and SALT at 30 min, with significant between and within region variation evident). When the median percentage of days therapy was received is considered, these figures give further cause for concern. There are some units where a higher frequency is achieved, but national figures indicate therapy is received on less than 30% of the days recommended for SALT and on 59% and 69% for OT and PT respectively.²⁰ These findings raise important questions about why the recommendation is not being met and indicate the need for a better understanding of factors influencing therapy provision in English stroke units.

Therapy provision is complex; it involves not only direct therapeutic contact with patients but also patient assessment, communication and joint assessment with other MDT members and interaction with patients and

their families. Clinical decision-making involves targeting the most appropriate intervention for each individual. This must take account of patients' stroke-related disability and also their premorbid health status, which may include comorbidities such as dementia, chest or heart disease and current health status (eg, post-stroke pneumonia or depression). After stroke, patients may have communication, swallowing and cognitive impairments which add to the complexity of therapy assessment and provision. Patients' motivation and engagement with therapy and family and other social support are factors that can influence stroke rehabilitation.^{21 22} Service provision (eg, 7-day stroke services, staffing levels) and organisational issues may also impact on therapy provision.¹⁰

Research on patient and therapy activity in stroke units has relied almost exclusively on behavioural mapping techniques (recording actions at timed intervals) to document patients' location, activity and interaction, time spent in therapy and content of therapy.^{17 23–25} Other studies have used retrospective chart audit to report on frequency, duration and intensity of therapy.²⁶ While these studies have consistently identified low levels of patient activity and time spent in therapy after stroke, they have not explained why this occurs. These studies have not explored how therapists understand and manage their practice, or explained factors influencing therapists' decision-making regarding therapy provision. Patients' views about therapy received have had little attention.^{27 28}

In England, approximately 85% of all stroke-survivors will spend >90% of their stay in a stroke unit where inpatient therapy is provided.¹⁹ Stroke units must meet defined minimum criteria (figure 1) but vary according to whether they focus on hyper-acute care, rehabilitation or a mixture of hyper-acute, acute and rehabilitation care in the same or separate units. Data from SSNAP indicate significant variation between stroke units on performance in providing stroke therapy at levels consistent with national guidelines. The ReAcT study aims to develop an in-depth understanding of stroke therapy provision, including how the recommendation of 45 min

of each relevant therapy (PT, OT and/or SALT) a day, is interpreted and implemented by therapists and is experienced by patients and their informal carers in stroke units (figure 2).

METHODS

The ReAcT study will employ a multisite ethnographic case study design in a minimum of six stroke units in the North of England. Ethnography in general is concerned with describing and explaining the particular culture and operation of social settings.²⁹ Typically case studies are understood as bounded entities in which particular behaviours, activities or social process are occurring and can be studied.³⁰ The cases, that is, stroke units participating in this study, are potentially representative of stroke therapy provision in the UK. The multisite ethnographic case study approach will allow generation of in-depth contextualised descriptions of stroke units reported as performing well and less well against the national guidelines, and development of understanding of factors which influence therapy provision in stroke units. Data generation in each site will include modified process mapping, non-participant observations and documentary analysis; these will be undertaken over a period of up to 4 months in each unit. This will be followed by in-depth semistructured interviews with therapists and managers and with patients and informal carers. The approach to sampling, data generation methods and data analysis are described below.

Site selection and sampling

A purposive, non-probability sampling³¹ approach will be used. In purposive sampling participants or settings, are chosen for their experience of a phenomenon or specific characteristics of a setting which ensure that research questions can be directly addressed and an in-depth understanding can be developed of, in this case, factors influencing therapy provision against the national guidelines. Representativeness and generalisability of the study population are not the primary consideration in non-probability sampling. However, we adopted a typical case sampling approach to the

Stroke Unit Criteria
<p>Patients who need ongoing inpatient rehabilitation after completion of their acute diagnosis and treatment should be treated in a specialist stroke rehabilitation unit, which should fulfil the following criteria:</p> <ul style="list-style-type: none"> -it should be a geographically identified unit -it should have a coordinated multidisciplinary team that meets at least once a week for the interchange of information about individual patients -the staff should have specialist expertise in stroke and rehabilitation -educational programmes and information are provided for staff, patients and carers -it has agreed management protocols for common problems, based on available evidence. <p>(Intercollegiate Stroke Working Party. National Clinical Guidelines for Stroke, 4th edition. London: Royal College of Physicians, 2012).</p>

Figure 1 Stroke unit criteria.

Study objectives:	
1)	To identify and explore current practice in a minimum of six stroke units which are divergent in the level of therapy provision reported in the Sentinel Stroke National Audit Programme;
2)	To explore the decision making of stroke unit professionals relating to therapy provision to stroke survivors;
3)	To describe the amount and content of therapy provided to individual patients using the broad categorisations developed by Langhorne et al (2009) (physiotherapy), Brady et al (2012) (speech therapy), and Legg & Drummond et al (2007) (occupational therapy);
4)	To understand the contexts, facilitators, and barriers to providing and receiving therapy in an inpatient stroke unit from the perspective of therapists, patients and stroke service managers;
5)	To explore the experience of providing and receiving therapy from the perspective of therapists, patients and carers, and patients and carers, stroke unit staff and stroke service managers;
6)	To refine the study findings through three iterative expert seminars to inform development and testing of evidence based implementation strategies to optimise therapy provision for in-patients after stroke.

Figure 2 Study objectives.

selection of stroke units and a heterogeneous sampling approach to staff, patient and informal carer sampling in order to explore therapy provision in stroke units with characteristics likely to be similar to others in the UK. A sampling frame has been created based on high and low performance ratings in SSNAP reports (July–September 2013) for therapy provision against the 45 min standard. Two stroke units from each of the Yorkshire; North East and North West regions have been identified and approached to participate. Three units reported as having a higher level and three reporting a lower level of compliance with the 45 min therapy guideline form the initial sample. Within each site purposive sampling will be used to identify potential participants who have inpatient, informal carer, clinical or managerial experience in the stroke unit. We aim to recruit up to 210 participants including 90 staff members, 60 patients and up to 60 informal carers in total from the 6 units (figure 3). We aim to sample a heterogeneous population of stroke survivors with a range of stroke severity levels as measured by initial National Institutes of Health Stroke Scale (NIHSS) score and modified Rankin Score (mRS).^{32 33} Recruitment began in October 2014 and will continue in the initial units until the end of August 2015. Further theoretical sampling may be employed if other key informants are identified during the conduct of the semistructured interviews. Based on review of the emergent data, and in consultation with the expert advisory group for the study, an additional unit in these or other regions may be recruited if it is considered that the explanation for factors influencing therapy provision, including the 45 min guideline, requires further development.

Modified process mapping

Process mapping is a commonly used tool in healthcare environments.^{34 35} The technique is designed to examine part or all of a patient journey through a particular inpatient, outpatient or diagnostic service with the objective of understanding patients' experiences. It can capture the reality of a process as experienced by

patients and identify duplication, variation and unnecessary steps. Process mapping is often used to help teams decide where to start to make improvements that will have the biggest impact for patients and staff.^{34 35} In the ReAcT study, modified process mapping will be used to develop insight into how therapists in each stroke service assess need for and then manage provision of therapy. A process mapping meeting will be convened with 10–15 stroke unit team members (in each unit) to develop a map of what therapists and MDT members perceive to be a standard therapy journey and what factors they believe influence therapy provision across the inpatient stay. We will identify points in the patient journey at which specific aspects of therapy practice are informed by National Clinical Guidelines,¹⁰ informed by individual patient needs and/or influenced by local organisational contexts. Process mapping will be used to focus non-participant observations of stroke unit processes and individual therapy sessions in order to develop understanding perceived and actual 'therapy journeys'.

Non-participant observations

Observation is a key element of ethnographic research and offers a direct view of behaviour, capturing events as they occur in their natural setting.^{36 37} There is continuum from full participant to non-participant observational roles. Although it is acknowledged that the presence of an observer will inevitably have some impact on the behaviour and interaction of those being observed,³⁷ this impact diminishes over time, and will be considered in data analysis. Researchers will adopt a non-participant role and will examine all actions and behaviours, formal and informal interactions between team members and between team members and patients and informal carers. Observations will have two elements: an initial focus on stroke unit contexts including the built environment and facilities within the units, how therapists' time is managed and spent, approaches to MDT working and specific instances of therapy planning and provision. These observations will include therapy and MDT meetings, joint therapy provision or

Eligibility Criteria
<p>Stroke survivors:</p> <ul style="list-style-type: none"> - Aged 18 years or over - Confirmed primary diagnosis of new stroke - Receiving active therapy provided on the stroke unit
<p>Carers:</p> <ul style="list-style-type: none"> -Aged over 18 years -A family member/close friend of a stroke survivor receiving active therapy provided on the stroke unit
<p>Stroke service managers, therapists and other multidisciplinary team members</p> <ul style="list-style-type: none"> - A stroke service manager, registered therapist [physiotherapist, occupational therapist, speech and language therapist] or other multidisciplinary team member working on the stroke unit for three or more days in each week [or the equivalent level of contact for stroke service managers]
<p>Exclusion Criteria:</p>
<p>Stroke survivors</p> <ul style="list-style-type: none"> - Aged less than 18 years - Do not have a confirmed primary diagnosis of new stroke - Not receiving active therapy provided on the stroke unit
<p>Carers:</p> <ul style="list-style-type: none"> - Less than 18 years -Not a family member/close friend of a stroke survivor receiving active therapy provided on the stroke unit
<p>Stroke service managers, therapists and other multidisciplinary team members</p> <ul style="list-style-type: none"> - A stroke service manager, registered therapist [physiotherapist, occupational therapist, speech and language therapist] or other multidisciplinary team member working on the stroke unit for less than three or more days in each week [or the equivalent level of contact for stroke service managers]

Figure 3 Eligibility criteria.

unit based staff providing early supported discharge services. Observations will then become progressively more focused. Longitudinal non-participant observation of a small number (up to 10) of a purposively selected group of patients in each unit will be undertaken to develop in-depth understanding of therapy provision. We will seek to recruit patients based on differences in stroke severity and nature of post-stroke impairments informed by patients' NIHSS scores and other measures of disability and impairment including the mRS score.^{32 33}

A qualitative observational framework developed for use in a process evaluation of caregiver training in stroke units³⁸ will be adapted following a 2-week period of pilot observations in three participating stroke units. The framework is underpinned by detailed guidance on preparation of field notes in general and in rehabilitation settings specifically. Researchers will meet to compare and contrast observational and field notes to ensure consistency in areas of observational focus and in the depth and detail of field notes.^{38–40} Timing of observations will be tailored depending on when therapy is carried out. Early mornings, meal times, evenings and weekends, traditionally outside standard therapy time, will be included if these are considered integral to therapy provision. Active therapy has been defined as face-to-face contact, which may be individual or group treatment, and may include tele-therapy.⁴⁰ In this definition therapy does not include administrative tasks related to patients. This definition will be compared with practice-based understandings reported by therapists, MDT members and patients during fieldwork.

Observations will be undertaken in blocks of up to 16 consecutive weeks per unit, with observations normally taking place for up to 4 h per day on 3 or 4 days per week. The exact length of the observational period will depend on the data generated and will cease when it is perceived that no new relevant information is emerging. After each therapy session therapists will be asked to briefly describe the aims of the session, the type of intervention(s) and to explain their rationale for their actions and decisions. These, together with the record of time spent documented in therapy or MDT notes, will be recorded in a therapy category schedule developed from one used in the CERISE studies and drawing on relevant systematic review findings.^{9 16 41–43} Patients' informal comments made during or after observations in respect of their experiences of therapy will also be summarised in field-notes.

Documentary analysis

Researchers will review current SSNAP data for each stroke unit,^{20 41} which continuously audits stroke services' self-reported performance against national clinical guideline recommendations. We will review professionals' records of therapy provision for up to 10 patients in each unit. This will include those with mild, moderate or severe impairment in order to capture how therapy and activity included in meeting the 45 min recommendation is recorded. This will follow observations and will enable a check for discrepancies between the process maps, therapy recorded, therapy observed and staff and patients' perceptions. In addition, unit policies or protocols relating

to therapy provision will be reviewed. Organisational management structures and policies, staffing levels and skill mix will also be recorded and reviewed.

Semistructured interviews

Semistructured interviews will be conducted with up to 10 patients and their informal carers in each unit, normally in their own homes 4–6 weeks after discharge using a topic guide drawn from previous research.³⁸ Interviews will focus on expectations of therapy, patients' recollections of the frequency and content of therapy and informal carers' perceptions of therapy frequency and contribution of therapy to recovery. Patients and informal carers will be offered the opportunity to be interviewed jointly or separately.

Semistructured interviews will also be conducted with a minimum of 15 therapists, other MDT members and stroke service managers in each unit to clarify organisational structures and local policies and to explore therapy provision-related questions emerging from periods of observation. Sampling of (staff) interviewees will be guided by individual unit observations and will include those responsible for service delivery and evaluation; therapists with differing levels of experience and other MDT members engaged in facilitating, providing or continuing therapy, related to the 45 min recommendation. An interview topic guide informed by previous literature, revised if necessary following observations, will explore understanding of facilitators and barriers to implementing the therapy recommendation. Perceptions and experiences of working towards the recommendation will be captured. Interviews will explore the decision-making processes used when planning therapy (including prioritisation, mode, format, intensity, personnel delivering) for patients with differing severities of stroke impairment, or therapists' decisions not to provide therapy. Interviews will explore issues relating to service structure including, where appropriate, 6 or 7-day therapy services, hours of working and staff skill mix.

DATA ANALYSIS PLAN

The multisite case studies of stroke units will be subject to within, and cross case analysis^{30 31} to develop a robust explanation of contemporary therapy provision in these units including how staff interpret and engage with the 45 min therapy guideline. Process mapping, field notes,

observational records and interviews will be transcribed and entered into the qualitative data analysis tool NVivo (V.10.0) to facilitate data management and support an iterative approach to data analysis. Data will be analysed using the Framework approach,³¹ which has five stages (figure 4). An iterative approach will be used to develop a plausible and coherent explanation of processes underpinning therapy provision with patients, and factors that act as barriers and facilitators to this. Analysis will also focus on understanding the perceived impact of these factors on patients' experience of therapy. Observational, documentary and interview data will be coded; related codes will be grouped together under thematic headings that convincingly capture and explain the relationship between coded elements of text. The purpose of this element of data analysis is to contribute an overarching explanation of the contextual, organisational and professional processes evident within and across the units. This will identify and examine factors in individual unit variation as well as providing insight into factors influencing all units in terms of the 45 min therapy guidelines. The Framework approach enables development of matrices for data coded to each key theme.³¹ This element of the data analysis will facilitate close examination of patterns, relationships and discrepancies in the data related to the research objectives. Emerging explanations arising from the data may be explored further during fieldwork; and more examples (or contradictory ones) sought in observations of current and of subsequent units.

Researchers will meet to discuss data analysis every 4-to-6 weeks and report findings to an expert advisory group. Standard approaches to demonstrating trustworthiness and quality in qualitative research^{29 31} will be used, including: the clear documentation of the research process (methods, analysis and any problems encountered and solutions found); transparency about the development of the thematic framework and matrices and their use in analysis; documentation of the contextual features in which the research was carried out; the exploration of contradictory cases and alternative explanations, and discussions of emerging findings among the research team.

Consensus meetings

Once data analysis is completed in the participating stroke units, groups of stroke service providers, stroke-survivors and informal carers and researchers, who

Stages in the Framework approach:	
1)	Familiarisation with the data,
2)	Identifying a thematic framework
3)	Indexing (applying the framework to the data)
4)	Charting
5)	Mapping and interpretation
(Ritchie et al, 2014)	

Figure 4 Stages in the framework approach.

have not previously been involved in the ReAcT study will be invited to participate in up to three separate consensus meetings lasting up to 2 h on each occasion. These will be held in three regions in England and will involve a different group in each meeting. The research team will present the findings and provisional recommendations from the multisite case studies and, using an iterative process across the three meetings, engage participants in discussion to refine the study recommendations. Meetings will progressively focus on how barriers may be prevented or addressed and how facilitators and good practice can be effectively shared nationally. The output from the consensus meetings will be stakeholder consensus on recommendations to support delivery of optimum levels of stroke therapy provision in stroke units.

ETHICS AND DISSEMINATION

The ReAcT study has no interventional component and no risk of harm is anticipated for participants. However, observations in the stroke units could be intrusive and the subsequent interviews with stroke survivors, informal carers and with staff could result in some distress. Participant information sheets detail how researchers will manage these processes and will proceed only with the express approval of participants. All participants will provide written informed consent to participation, except where stroke-survivors lack capacity, when a consultant declaration will be sought. Process consent will be sought on each occasion that non-participant observation is requested. The study received a favourable ethical opinion from the National Research Ethics Service (reference number: 14/NW/0266) and local Research and Development department approval in each of the six initial participating sites.

During the ReAcT study a newsletter will be produced and made available to participants while a website provides more general information (http://medhealth.leeds.ac.uk/info/621/stroke_projects). Target audiences for the dissemination of findings and recommendations are therapists, service managers, clinical guideline developers (Intercollegiate Stroke Working Party and National Institute for Health and Care Excellence) and policymakers, the Stroke Association (UK) and stroke survivors and informal carers. The findings will be presented at national and international stroke meetings and conferences, including the UK Stroke Assembly, a stroke survivor and carer led conference, and published in peer reviewed journals and on the website.

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