Rehabilitation for Elderly Patients: Day Hospitals Compared to Rehabilitation at Home

This project comprises two phases: phase 1 is an initial scoping study with pilot work and phase 2 is a proposed randomised controlled trial. Phase 1 is now complete and the results and their implications for the proposed randomised controlled trial are presented here.

First we will outline the background to the project as a whole and the hypotheses to be tested. Then we will describe the phase 1 study and it's results. Finally we will present an amended trial protocol, which is modified to take account of the lessons learnt in Phase 1. The trial protocol is now accompanied by a proposed add on study which addresses key issues related to the context and generalisability of the trial results.

The structure of this document in therefore as follows

1) Background
2) Literature
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1. Background

There is current debate as to the most appropriate setting for rehabilitation, with Health Trusts increasingly providing community based services. This has been a response to evidence from randomised controlled trials showing the need for and effectiveness of alternatives to acute hospital care for the health of elderly patients, and the practical need to relieve the pressure on hospitals, bought on partly by the ageing population, for which the NHS was not originally designed to cope with(1), and evidence that older people prefer community based care (find reference2). One of the concepts to emerge and develop from this has been 'intermediate care', a phrase coined to describe the gap being bridged between primary and acute care. In clinical terms the challenge this creates is for providers to develop a holistic approach to rehabilitative care at or near the patients home. In research terms the challenge is to develop methods to evaluate this fast changing and complex system (1).
Home-based rehabilitation (HBR) for older people is considered to be appropriate and effective because it is provided within the patient's usual environment rather than an institution, arguably reducing the need to generalise learning from one environment to another. Support for this view underpins the wider development of hospital at home and early discharge schemes (3). In addition to this the day hospital has long been regarded as a central resource in medicine for older people, and almost every health district in the UK has one. Although there are considerable variations in practice, most day hospitals provide functional and medical assessment, rehabilitation, physical maintenance, and medical and nursing procedures within an ambulatory care setting as an alternative to community based or hospital inpatient care. The majority of day hospital patients receive rehabilitation (DHR) and the majority of day hospital resources are consumed by rehabilitation patients(4).

2. Literature

Despite long-standing concerns over cost and effectiveness (5,6) and a number of descriptive studies of day hospitals (7,8), the question "what is the best setting for rehabilitation for older people with disability and rehabilitation needs?" has only ever been partly addressed in well constructed controlled trials. We propose a pragmatic randomised controlled trial (RCT) in which HBR will be compared with DHR as it is usually delivered.

A 1998 systematic overview of systematic reviews in rehabilitation has confirmed evidence for the efficacy of comprehensive multidisciplinary assessment and rehabilitation in care of the elderly and particularly those having suffered a stroke (9). Little evidence in respect of setting for rehabilitation was available and no systematic reviews of DHR were included. In a recent systematic literature review, day hospital care (10) was compared with comprehensive care, no comprehensive care, or domiciliary alternatives. Day hospitals were shown to provide services that were as effective as other forms of comprehensive care and more effective than no comprehensive care.

A systematic review of day hospitals as a setting for rehabilitation was carried out as part of the Best Place of Care (BPOC) commission (HTA project 96/43/01) (11). The main conclusions of the BPOC review were that overall, the day hospital has not yet been adequately evaluated as a *setting* for rehabilitation. It is unlikely that the day hospital offers significant advantage over alternative settings for delivering comprehensive care for the outcomes considering mortality, hospital bed use or gross disability. However, it is possible that the day hospital impacts differentially over alternative settings for delivering comprehensive care for quality of life, quality of life for patient and carer, or health care provider costs. Costs for patients, carers and social care providers have not been adequately evaluated, and neither have patient and carer preferences for day hospital or alternative comprehensive care settings. Trials comparing home rehabilitation to other forms of rehabilitative care have so far been condition specific and not generalisable to the elderly rehabilitation population as a whole.

This literature review was last formally updated in the original application for funding for this study.

3. Best Place of Care research programme

As part of the iterative commissioning programme 'Best Place of Care for Older People' the National Health Service Research and Development Health Technology Assessment Programme placed a call for proposals for a randomised controlled trial comparing day hospital with home based rehabilitation. The successful bid was for a two-phase research proposal. Phase 1 of the project was a pilot study designed to establish the continuing relevance of the research question and feasibility of an RCT in this area. Phase 1 is now complete. Phase 2 was proposed as a mutli-centre pragmatic randomised controlled trial with health economic analysis, comparing day hospitals to home based rehabilitation for elderly patients. Phase 2 would, however, be influenced by the outcomes of Phase 1. We will now report on Phase 1, before outlining the design modifications that it suggests are necessary for Phase 2.

4. Overview of the project

Phase 1 consisted of a National Survey of Trusts in England to find out about current rehabilitation services and identify possible trial sites for a RCT, a pilot study in local trusts to test out the suitability of the research questionnaires and iron out any problems, and the gathering of feedback on the usefulness of the trial and it's methodology.
Phase 2 is a proposed RCT comparing Day Hospital to Home Based Rehabilitation for elderly patients, with health economic analysis.
In addition, for reasons disussed in detail below, we are also proposing an additional Observational Study of Day Hospitals and Home Based Rehabilitation services, to elucidate the philosophy, processes and outcomes associated with different provision within health trusts in England.

5. Phase 1. A scoping study and pilot work for the proposed RCT

a) A National Survey of NHS Trusts in England

Objective

The objective of the survey was to create a picture of current service provision in rehabilitation, and to identify potential trial sites for a RCT.

Methods

All trusts in England were identified by contacting each of the 28 Strategic Health Authorities for a list of their Primary Care and Hospital Trusts. Where this information was difficult to obtain, the Department of Health website was consulted. 578 trusts were identified but 44 (such as children's and ambulance trusts) were excluded as irrelevant. A 1st contact questionnaire, which simply asked whether or not the trusts provided home based and/or day hospital rehabilitation for elderly patients. (see appendix 1) was sent out to 534 trusts 13 were later found to no longer exist or have merged with another trust, leaving 521 possible replies. 391 trusts replied (75%). In the responses we received information on a total of 400 trusts (77%). See table 1 for results.

We then sent out a second contact questionnaire (see appendix 2) asking for more detail about these services, initially to those trusts with co-existing HBR and DHR and later to all trusts, to enable us to identify the range of provision in more detail and to identify potential trial sites from information about the service characteristics. See Table 2 for results.

Results

Service provided	Number	Percentage%
HBR and DHR	184	46
HBR no DHR	80	20
DHR no HBR	60	15
Neither	48	12
Incomplete	8	2
Irrelevant	20	5
Total	400	100

Table 1. Trusts providing home based and / or day hospital rehabilitation. Forty six percent of trusts responding to the first contact questionnaire reported providing both types of service.

2nd contact questionnaire					
	Home based		Day hospital		
Replies received	150		114		p-value
SERVICES	***n***	***%***	***n***	***%***	
Fn Assessment	115	77%	108	95%	<0.01
Medical assessment	53	35%	102	90%	<0.01
Rehabilitation	103	69%	94	83%	<0.01
Respite & Social Care	45	30%	32	28%	>0.2
Specialist medical assessment	33	22%	69	61%	<0.01
Nursing procedures	87	58%	104	91%	<0.01
Specialised Stroke	61	41%	76	67%	<0.01
Specialised TIA	35	23%	61	54%	<0.01
PD	45	30%	74	65%	<0.01
Movement disorders	31	21%	49	43%	<0.01
Falls	69	46%	91	80%	<0.01
Continence	50	33%	50	44%	>0.05
Physical maintenance	34	23%	43	38%	<0.01
STAFF					
Other	77	51%	75	66%	<0.05
Community Nurse	65	43%	18	16%	<0.01
GP	32	21%	21	18%	> 0.1
Hospital nurse	11	7%	62	54%	<0.01
Hospital Doctor	14	9%	70	61%	<0.01
OT	103	69%	99	86%	>0.2
PT	100	67%	97	84%	>0.2
Therapy assistant	88	59%	81	70%	>0.2
Admin staff	63	42%	82	71%	>0.2
Other	59	39%	54	47%	<0.05
Time limited service	75	50%	54	47%	>0.2

(P-value refers to the significance of the difference in provisions between home based and day hospital service (chi))

Table 2. Results of 2nd contact questionnaire received from trusts providing home based and / or day hospital rehabilitation. Note that day hospitals are very much more likely to provide medical or specialised medical services and, home based services are more likely to be provided by community practitioners (GP and Nurse).

b). Pilot work in 3 Trusts to prepare for the RCT

We have piloted the research in 3 trusts, to enable us to establish and resolve practical difficulties in conducting the trial.

Methods

Ethical approval was sought and granted to work in 3 sites, Sheffield, Barnsley and North Tyneside, using both day hospital and home based rehabilitation services. It was agreed that a pre-pilot was necessary, the main purpose being to test out the length and difficulty of the economic questionnaire which had been developed from that used in a RCT on cardiac pace making of older people at CHSR, University of Newcastle, and the Northern Region Day

Hospital Audit (NRDHA). 10 Pre-pilot interviews were done with day hospital rehabilitation patients in Barnsley.

Pre-pilot Interviews

Patients receiving rehabilitation in the day hospital were eligible for inclusion. The researcher approached the patients in the day hospital, explained the research and asked if they would be willing to be interviewed. Patients who agreed were taken to a private consultation room and given an Abbreviated Mental Test (AMT). If their AMT score was below 7, it would be explained that the assent of their carer was also needed. Otherwise, consent was taken and the interview performed then and there.

The economic questionnaire (see Table 5 for detail) was found to be of suitable length and some minor alterations to some questions were made. It was decided that certain information e.g. tests undergone (x-rays etc), should be checked against hospital notes due to problems for some patients in remembering. From the other standardized measures we had originally included both the HADS and GHQ (for full list of measures used see Table 5, for justification of measures used see appendix 3). The GHQ proved to be too upsetting and therefore unsuitable with this group of patients, so was excluded. When we were satisfied that these questionnaires were suitable we continued onto pilot research, in North Tyneside Jubilee Day Hospital, Sheffield Assessment and Rehabilitation Centre, and Barnsley Community Rehabilitation Service.

Staff were consulted and recruitment/consent procedures modified in Sheffield to fit in with local concerns. Staff were then left with Patient Information Sheets (see appendix 4) and Consent Forms (see appendix 5), which they passed on to the researcher when patients were recruited. The researcher then contacted the patients in their own homes. This recruitment procedure would be necessary for the blinding of the researcher in the RCT.

If the patient had an informal carer (e.g. spouse, child), they would be approached if permission was given by the patient, and asked to be interviewed. The interview included the General Health Questionnaire and economic data (see Table 1 for detail).

Location	Number of subjects
Pre-pilot	
Barnsley Day Hospital	10 (5 FU)
Pilot	
Barnsley HBR	7
Sheffield Day Hospital	11
North Tyneside Day Hospital	8
Total	36

Table 3. Completed Pilot Interviews

c) Dissemination and feedback to inform protocol development

Objectives
An integral part of Phase 1 was to gather feedback as to the usefulness and feasibility of the proposed RCT, as well as to seek opinions regarding outcome measures and methodological issues.

Methods
Views were actively sought through:

- *Conferences and presentations*

Poster at BGS Conference Spring Meeting
Poster at Trent Research Unit Conference
Presentation at Newcastle University
Poster at September 2003 BSG Conference
Presentation at Barnsley Research and Development Unit

Information received from these sources has been fed back to the trial management team and was used to inform the recommendations for alterations to the second stage protocol and suggestions for add on studies.

- *A staff and Patients Advisory Group*

An advisory group has been formed, comprising 6 members, consisting of patient representatives and healthcare staff. The group has been consulted separately (either patient representatives or healthcare staff), by holding small informal meetings. This group has been consulted on a variety of issues, including design of patient information leaflets, and for feedback on trial as a whole.

- *Patients and Health care professionals in the pilot sites*

Patients and staff involved in pilot have been asked for feedback on practical matters (e.g. consent procedures and questionnaire length) and for feedback on trial as whole.

Key Concerns
Trial Usefulness and Feasibility

- Many people we have spoken to (e.g. at the BGS conference) see this as a useful trial.
- Feedback has suggested that the current climate is of continual change, and this is confirmed by our survey. 36 of the 63 replies (57%) to 2nd contact questionnaires returned by trusts providing both HBR or DHR state than one or both of the services will be undergoing significant change in the next 3 years.

Methodological Concerns

- Our measures may not detect the holistic gains of rehabilitation, or pick up on small but important changes. To understand the key difference in therapy outcomes between HBR and DHR we need to understand the aims. These may differ between HBR and DHR, and between different trusts, dependant on local factors, and on an individual patient level. This concern has been addressed by including the use if Therapy Outcome Measures.In terms of the economic evaluation, staff at South West Primary Care Trust felt that services, which seemed to incur more extra costs may do so through having good relationships with other organisations (e.g. referring patients on), and there was concern that this would be seen in a negative light. However, we feel that this will be accounted for by considering extra costs against positive outcomes.

6. Interpretation of the results and experience of phase 1 of the project.

Key findings

Scoping study:

- 46% of trusts provide home based and day hospital rehabilitation, and the majority of the remaining trusts provide one or the other, implying that decisions about settings are still current. Elderly rehabilitation is not yet a standardised service.
- Due to the marked heterogeneity of services the number of sites involved in the RCT needs to be higher, to allow broader representation of services.
- Marked heterogeneity and rapid service development and change suggest that observational studies would be of value alongside an RCT.

Pilot:

- The research has been found to be feasible in the settings piloted (including day hospital and home based rehabilitation teams), and flexible to differential local needs, suggesting that it will be practically possible to incorporate the research into a variety of rehabilitation teams.

- Recruitment processes and inclusion criteria are appropriate and can be managed. A recruitment and consent procedure has been designed that can be flexible if necessary due to local issues:

    1. Rehabilitation staff explain research to patient
    2. Rehabilitation staff assess cognitive function as part of usual professional interaction, using usual local method supplemented by AMT as necessary

    (1 and 2 could be other way around depending on preference of staff)

    3. If patient willing consent will be taken, either from patient alone, or from patient with carer assent if AMT score below 7 or professional doubt.
    4. Use of pre-interview questionnaire to determine patients understanding of the type of questions being asked.

- Questionnaires are acceptable to research subjects in terms of both duration and content, and yield a satisfactory level of response and data completeness (out of 43 patients recruited, 35 were interviewed (81%)).

	Patient questionnaire schedule		**Patient economic questionnaire**		**Carer questionnaire**	
Number of questions	**N=54**	**%**	*N=360*	*%*	*N=60*	*%*
Average numbers of questions complete per questionnaire	53.4	99	355.5	99	53.4	99
Minimum number completed	49	91	322	89	49	97
Maximum number completed	54	100	360	100	54	100

Table 4. Patient questionnaire response rates.

The questionnaires have been developed as a result of piloting, and the main differences before and after piloting are shown in the table below.

	Before piloting	After piloting
Questionnaire 1 – Patient	Nottingham Extended Activities of Daily Living Scale	Included
	Hospital Anxiety and Depression Scale	Both were included to see which was most suitable, with the intention of choosing just one for the main trial. HADS was decided upon as many patients found the GHQ distressing.
	General Health Questionnaire	
	Euroquol 5D	Included
Questionnaire 2 – Patient – Economic Data (for full copy see appendix 6)	Use of health and social services, excluding rehabilitation	Included with minor changes
	Use of NHS transport, excluding that used for rehabilitation	Included with minor changes and checked against medical records
	Use of private treatment	Included
	Use of medication	Included and checked against medical records
	Acquiring of aids and equipment/alterations to house, excluding that which has been provided by rehabilitation service	Included with minor changes
	Costs of moving house or residential care	Included
	Travel Costs and other expenses	Included
	Assistance at home other than NHS and Social Services	Included with minor changes
	Social class, married status and use of benefits.	Included with minor changes
Questionnaire 3 – Carer (see appendix 7)	Social class and effect of caring on work status/costs to carer	Included with minor changes
	General Health Questionnaire 30	Included
Proforma for rehabilitation service use (see appendices 8 and 9)	Staff seen, for how long, and what grade, and mileage per patient	Included, but mileage worked out retrospectively later.
		Use of special equipment e.g. ultrasound, and aids/alterations provided for the home, and personal services such as bathing.
Additional	Need identified for holistic goal related measurement (see section 4.3.3.3)	Therapy Outcome Measures (12) See appendix 10.
	No specific provision	Semi structured Interview for determining patient and carer views of treatment.

Table 5. Changes to research instruments.

Feedback:

- The current policy environment continues to stimulate change in healthcare provision in the area, and the results of this trial will be informative in evidence-based policy making.
- Our methodology may not be sensitive to key differences between the 2 groups at the level of achieving rehabilitation goals.. When the protocol was originally proposed there was no practical research tool which would take into account the aims of rehabilitation. Goal Attainment Scaling was available but time consuming for professionals and researchers. Since this time, Therapy Outcome Measures has been validated with this patient group, therefore will be included. TOMS is based on observations of the goals of therapy and aims to provide a reliable and valid way of collecting data for the purpose of outcome measurement. It is administered by rehabilitation staff, who will be trained in it's use.

Protocol modifications suggested by Phase 1 data.

The Trial Management Group has met to consider findings of Phase 1 and the implications of this to Phase 2. Table 2 outlines the main changes to the protocol which the trial management team believe are suggested by the pilot work

Key Finding	Original Protocol	Recommendation
There is considerable heterogeneity between potential trial sites which is independent of the urban / rural setting. Less than 10% of potential trial sites satisfied explicit inclusion criteria based on throughput and range of services.	3 trial sites, 460 patients (after allowing for attrition and non-response).	6-8 trial sites, with a smaller number of patients in each site, to better represent the range of services provided. Total sample size remains the same.
The majority of sites with co-incident day hospital and home based rehabilitation services report ongoing or imminent changes to their service. This suggests that previous descriptive work is likely to be, or soon to become out of date.	Not addressed.	Add-on contextual study. A descriptive analysis of service models and processes across a range of sites will be essential to accurately contextualise the findings of a contemporaneous trial.
Concern from health workers in trial sites that we needed to know aims of rehabilitation to understand whether rehabilitation had been effective, and that our measures did not take account of the many factors affecting the rehabilitation process.	No goal attainment measure and no qualitative data collection.	Use of Therapy Outcome Measures (TOMS) as an alternative to goal attainment measurement, and semi-structured interviews with patients and carers (interview schedule attached).

Table 6. Proposed changes to study protocol.

Phase 2. A proposed randomised controlled trial

Revised protocol

For key differences between this and the original protocol, see table 6.

Hypotheses

Older people and their informal carers:

- are not disadvantaged by home based rehabilitation (HBR) relative to day hospital rehabilitation (DHR) and
- HBR is less costly.

Research Sites

Research sites are being selected from the national survey of trusts. Those identified as potential trial sites are contacted and if willing, visited by the Principle Investigator and the Project Manager, to gather further information and further assess suitability. We aim to recruit 8 research sites (allowing for possible loss of sites during trial), recruiting a total of 640 patients, in order to meet a sample size of 460 patients (allowing for attrition). At the time of writing, 5 sites have given positive responses to our approaches for recruitment. The recruitment process continues, and the protocol revision, expanded recruitment process and multi-centre research ethics application are running in parallel. As this is a pragmatic trial, we wish to compare existing services, and so no service recruited to the trial will undergo major changes to participate in the trial.

The length of the intervention will be determined according to patient need by the local clinical team. Data from the Northern Regional Day Hospital Study (unpublished data) indicates a median length of time receiving the service as 7 weeks. We would expect 95% of subjects to have been discharged within 16 weeks.

Inclusion/exclusion criteria

Subjects should have a permanent address within the defined catchment area of the service. No age criteria will be used for inclusion but in practise 90% of patients will be over the age of 70. As this is a pragmatic trial exclusion criteria will be kept to a minimum. No more than a 3rd of patients will be from one single diagnostic category (e.g. not more than a third being stroke patients). We will record the presence of cognitive difficulties but will endeavour not to exclude patients because of such difficulties.

Recruitment

When referred for rehabilitation the patient will be assessed for suitability for rehabilitation and if defined as suitable, will be informed of the research with the help of a Patient Information Sheet (Appendix 4). If the patient agrees to research, then consent will be taken. Staff will make a professional judgement about whether assent of carer would be appropriate, (e.g. in cases of cognitive impairment), with the use of an Abbreviated Mental Test (assent taken if score below 7), or their instrument of choice. Where the AMT is not used to determine this, the researcher will perform the AMT to confirm the staffs decision.

Carers will be approached by a researcher with the permission of the patient following the baseline interview, and informed of the research with a Carer Information Sheet (appendix 6). If they agree to research consent will be taken and they will be interviewed at the 3 month follow up point.

A chart of anticipated recruitment is shown below which makes the following assumptions: Six sites. First site begins data collection in August 2004. Sites enter trial at 2 monthly intervals during 2004/5. Average 50 subjects per randomisation arm per calendar year available from each site. Assume start at smallest site. Figures adjusted for each site in proportion to annual day hospital rehabilitation throughput. This represents recruitment of about one third of potentially eligible patients from participating day hospitals and one seventh of potentially eligible patients from participating home rehabilitation services.

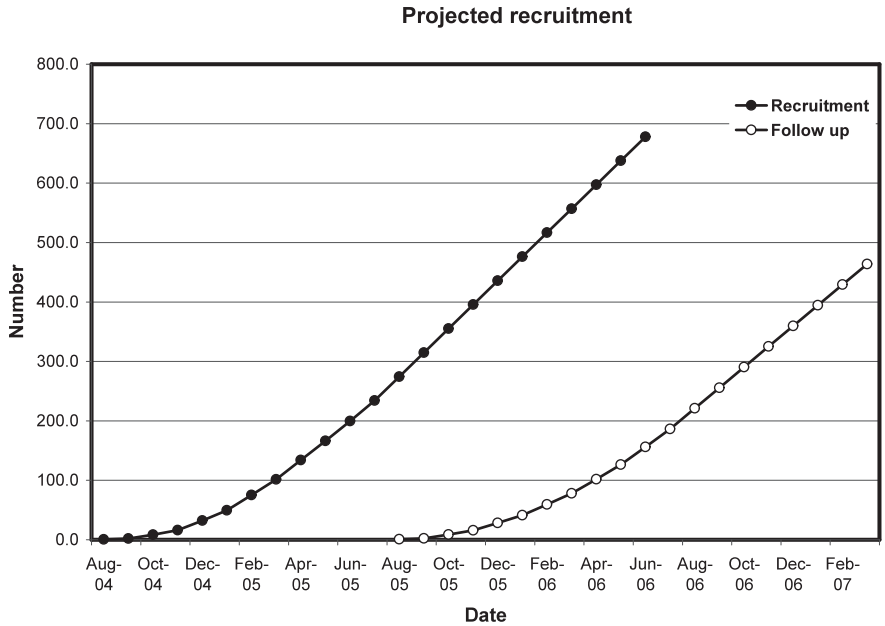

Figure 1. Chart of recruitment expectations

Milestones

A suggested table of milestones is shown below:

June 04	MREC Approval
Aug 04	LREC and local research governance approval(s)
Aug 04	1st Ra appointed*
Aug 04	Begin data collection Site 1**
Oct 04	Begin data collection Site 2**
Nov 04	2nd RA Appointed*
Dec 04	Begin data collection Site 3
Feb 05	Begin data collection Site 4
Mar 05	3rd RA appointed*
Apr 05	Begin data collection Site 5
Jun 05	Begin data collection Site 6
July 06	End of randomisation all sites
July 07	Complete 12 month follow up all sites
Nov 07	Complete date prep
Feb 07	Complete analysis
Aug 08	Complete final report

**RA appointments for data collection will vary between sites. The project milestones assume 3 appointments, but multiple part time appointments may be made across 6 (or more) sites to achieve projected recruitment rates within the budget.*

***Sites 1 and 2 are in close proximity (<10 miles) and subject to the same local ethics process. Data collection may be able to begin almost simultaneously on these sites if necessary.*

Randomisation, stratification and assessment
Patients referred for rehabilitation will be routed through a central point. They will be assessed for their need for rehabilitation and the assessor will complete the Oxford Handicap Scale and Abbreviated Mental Test. The patient will be informed of the research using a Patient Information Sheet. If the patient consents to research they will be randomised to home based or day hospital rehabilitation following a baseline interview,using computer generated block randomisation within each centre, managed by an independent member of the research team and available during the normal opening times of conventional day hospital services. Feasibility of randomisation has been explored with professionals working in pilot and potential trial sites, and while there were some concerns there was a level of understanding about the necessity of randomisation. Time for piloting randomisation processes is built in to the running time in each site to accommodate local issues, and in the first sites to begin randomisation an initial period of piloting will test and resolve any problems in procedures. The scoping study will have identified variation between sites on a number of key variables (e.g. age distribution, range of clinical conditions, sources of referral), which will inform a final decision about stratification. Eligible patients will be stratified by source of referral (hospital inpatient or primary health care team) and the Oxford Handicap Scale using a cut point of 2/3. It is possible that patients will be referred for rehabilitation more than once in the course of the year that they are part of the research. Subjects re-referred to the trial will continue treatment in the arm of the trial to which they were first randomised and study follow-up will continue from the point of randomisation.

Informing GPs about the research
Prior to patient recruitment we will inform all GP surgeries local to the trial site about the research. As patients are recruited we will inform their GP's individually that they are a participant in the trial and that we will contact the GP prior to contacting the patient for follow-up, to check for death.

Outcome measures
Outcomes will be assessed by interview but in addition (to assess potential bias due to ineffective blinding of interviewers) self-completed questionnaires will be completed by a randomly selected 50% of surviving subjects at 6 months and by the other 50% at 12 months. The primary outcome will be functional health status as measured using the Nottingham Extended ADL scale13. All outcomes will be measured at base line and at 3, 6 and 12 months after recruitment by interviewers who are unaware of the treatment allocation (see below). Carer interviews will take place within 1 month of patient interviews. Secondary outcome measures will include survival (death certifications) and changes in subject's perceived mental state (Hospital Anxiety and Depression Scale(14)), change in household or residential or nursing home circumstances (study records), informal caregiver's psychological health (General Health Questionnaire (GHQ(15)) and patient's and informal caregiver's views of 'treatment' (semi-structured interviews). Therapy Outcome Measures (TOMS) will be used to measure outcomes in relation to rehabilitation aims.

Assessment of quality of life is implicit within the choice of outcome measures, (including EuroQOL). No generic and comprehensive quality of life measure is proposed since there is no evidence that a suitable measure exists for this particular patient group. Taken together the proposed outcome measures cover the traditional domains of quality of life included in generic measures. In the absence of reliable patient reported data, data collected from informal caregivers will be substituted where appropriate since previous studies have indicated that informants are a source of reliable data(16 17 18) . The applicants have used all the proposed outcome measures identified in recent studies and found them to be appropriate to the study.

Patient Interviews
Patients will be interviewed in their own homes, following prior arrangement by telephone or letter, by a researcher unaware of their treatment allocation. The interviews have been shown in the pilot to take between 30 minutes to an hour. Patients' welfare will be considered of paramount importance at all times. Proxy information will be used if the interviewer feels that the patient is not capable of answering questions accurately. This will be judged by a combination of AMT score and ability to answer pre-interview questions. The interview will

consist of the instruments outlined in Table 2, and a short semi-structured interview to ascertain views of treatment.

Carer Interviews
It was found in the pilot study that many carers are present at the patient's interview, in which case consent will be taken then and their (see appendices 6 and 7 for Carer Information Sheet and Consent Form) and the interview carried out, in private with the carer where possible. If not, the researcher will ask permission to contact the carer, and then arrange with the carer to visit them at their home. The interview will consist of the instruments outlined in Table 5, and a short semi-structured interview to ascertain views of treatment. In the pilot this was estimated to take about 30 minutes.

Education of data collectors
The data collectors will be trained and monitored to ensure inter rater and intra rater reliability. There will be a 3-day training course at the start of the trial and refresher days will be organised during the trial. There was some discussion about the possible use of videos for this, but it was felt that the effort and expense of producing a video was likely to be more than organising a venue and travel for data collectors.

Data collectors/interviewers will be taught a standard procedure when asked to respond to or faced with a clinical problem during the interview (experience is that this is an uncommon occurrence). In addition, each data collector will be assigned an experienced mentor, who will be available for counselling over unfamiliar and/or potentially distressing experiences during interviews, and can be contacted in cases of concern and these will be logged.

Generalizability, cost and compliance
Variability between centres in terms of size of day hospital and patient case mix will provide a robust basis for generalisability. Variability between services will be documented as part of a description of resource use in each centre. Case mix will be monitored during the trial to ensure comparison with other centres. An additional observational study will also provide a context for the research and the research team are currently designing a potential "add-on" study. The impact of services will be measured in terms of both resource use and cost. Costs to patients, informal caregivers and health and personal social services will be estimated. The unit of analysis will be "cost per patient" (see below). Sub-group analysis, will examine the costs and benefits to specific patient groups. The records of patients recruited to the trial will be reviewed independently by one of the applicants (PE), plus an appropriate dual observer, in order to assess differences in professional inputs within and between centres. Where subjects fail to comply with treatment but where compliance with continuing data collection is achieved subjects will be analysed on an intention to treat basis. Clinician compliance, including nursing and therapist involvement will be given high priority by the project manager. A member of the rehabilitation professions among the applicants (PE) will provide support and encouragement for all centres. We will provide regular newsletters to each centre showing target and actual response rates as well as visits from the research team, as mechanisms for encouraging staff compliance.

Sample size
We estimate a sample of 460 patients (230 propositi and 230 controls) will have 90% power to detect a difference of two points on the Nottingham EADL scale(19) using a significance level of 5%. NRDHS data estimates about a 10% attrition over the course of the study but we have used the more conservative estimate of 15% in estimating sample size, throughput and budgeting for data collection. Therefore allowing for initial non-response of 20% and attrition between times 1 and 2 of 15% we need to recruit 680 patients, probably from 6-8 participating clinical centres.

Analysis
Analysis of the trial data will be on an 'intention to treat' basis. Univariate and multivariate techniques including survival analysis, non-parametric analysis of variance and log-linear modelling will be used to evaluate the relationships between inputs and outcomes. Interim analysis of throughput, case mix and difference in primary outcome will be done by an independent data monitoring committee 9 and 21 months after recruitment has begun (at the end of the first and second year of the study). We will monitor throughput but all other analysis will wait until the end of data collection.

Economic Evaluation
Perspective of the study
An economic evaluation will be conducted alongside the clinical trial to compare home-based rehabilitation (HBR) vs. day hospital rehabilitation (DHR). DHR is considered to be the current practice. The aim of the study is to test the hypothesis that for older people requiring rehabilitation, HBR: (i) is not less effective than DHR, (ii) is not less preferable than DHR to the patients and their carers, (iii) is less costly than DHR.
The economic evaluation will address the study question from the NHS decision making and societal perspectives (20). We recognise that a decision making perspective is particularly suitable to address the study questions posed by the NHS research programme. However, we believe the societal perspective to be also important because the problem under investigation has an impact on other agents beyond the health service, and the decision maker may want to be informed about such implications.
The societal perspective is aimed at including all costs and health effects regardless of who incurs the costs and who obtains the benefits (21). We will try to make the collection of the most important data to address the societal perspective practically feasible, without making the data collection instruments too cumbersome. Therefore, we will consider the costs (and benefits) to the providers of health and social services, the patients and their carers. Although a wide range of cost items and outcomes will be included, the core analysis will focus on the subsets of costs and effects relevant for allocating the health service budget.

Measures of benefits used and study type
A Cost consequences analysis and a Cost-effectiveness analysis (which will become a Cost minimisation analysis if no significant difference in costs will be found) will be conducted. In Cost consequences analysis all the outcome results from the clinical study will be listed and will not combined with the (incremental) costs. In Cost effectiveness analysis the benefits will be measured in terms of the primary clinical outcome (functional ability score measured by the Nottingham EADL scale). Patients included in the study sample will be comparable in terms of clinical and prognostic features across sub-samples.
We are aware that the use of specific-condition health status measures in economic evaluations has some limitations, given the assumption of no interactions between dimensions. Alongside the specific-condition health status measure, a generic validated instrument which allows to combine different aspects of health status will be adopted (EQ-5D). We will investigate the nature of the correlation within and between instruments.

Resource data collection and costing methods
The use of health and social services will be monitored and costed. These services will include not only the therapy and direct costs related to the rehabilitative interventions ('packages of care') under investigation, but also those related to any subsequent use of health care and social services. Any difference in carers' use of time will also be considered.
<u>Estimation of resources included in 'packages of care':</u> It is expected that day hospital interventions will vary within and between centres. The contents and quantities of service inputs used in relation to the packages of care delivered in day-hospital (local geriatric day hospital service) or at home (own home or residential and nursing homes) will not be established by rigid protocols within the study. The present trial is in fact pragmatic; moreover, we think it may not be practically feasible to obtain health care professionals' compliance to the protocols, given the nature of the interventions and actual variety of care.
The contents of the packages of care and their measurements will therefore be assessed by observation. Data will be collected prospectively for each patient in each centre. Pro-formas for data collection will be completed by the NHS staff. The final aim is to estimate a cost per patient day in both DHR and HBR, in relation to the provision of physiotherapy, occupational

therapy, speech therapy, nursing, medical assessment and intervention, and transportation costs of patients/carers to and from day hospital centres; and of health care professionals to and from patients' homes; use of special aids and equipment; introduction of home alterations; personal care received through rehabilitation service. The provision of social and personal services which do not contribute directly to the rehabilitation process is excluded from the evaluation of these packages of care. However, they will be considered within the economic evaluation:
Information on personal and social services received at home will be collected through interviews (see below); information on personal and social services provided in day hospital will be monitored in each centre.
To estimate the use of resources made by the rehabilitation team, service elements will be recorded for each patient in a proforma. These will include date of visits, job title of the health care professional(s) seen on that day, the grade, the length of visit, the mileage per patient. The total time per patient will be the time spent on all service elements for that patient. This will allow to estimate labour costs. All material items/ equipment used during each action will be also be recorded. Fixed costs, such as overheads and general costs will be allocated pro-rata according to relevant parameters such as floor area used, number of staff, throughput.
Estimation of subsequent use of resources. Use of services - other than those included as part of the packages of care - to be monitored in both patient groups via questionnaire include: outpatient visits and hospitalisations, investigations, A&E admissions, use of ambulance services, visits and telephone consultations to and from the general practitioner and any other health care professionals, use of medications, personal and social services, attendance to day care centres, short-term respite or permanent care.
Details on procedures/investigations undertaken in hospital (eg, during hospitalisation or casualty attendance) will be extracted from patients' records, at 3, 6, 9, 12 months post-randomisation, as well as being including in questionnaire, to double check. Records will be reviewed over the previous three months.
Data on the use of all the other services/resources will be collected through questionnaire interviews to the patients. The interviews will be carried out at 1, 3, 6 and 12 months post-randomisation. Patients will be asked which services they used, and how often, over the previous month. Manpower data will be collected separately for each main category of staff. Moreover, the interview will collect information on the patients' expenditures due to travel, use of any equipment/special aids, changes introduced to accommodations/living environments, private medical/paramedical visits, assistance received by informal caregivers, any other out-of-pocket expenditures. Whenever practically feasible, patients will be asked to provide details for their financial expenditures and quantities separately.
Data collection instruments (hospital, patients and carers) have been prepared adapting those used in a randomised controlled trial on cardiac pacemaking of older people being carried out at CHSR, University of Newcastle(22). Questions on modifications of living environments have been adapted from a questionnaire used in a study of early supported hospital discharge for stroke(23). Questionnaires have been prepared thinking of the clinical management strategies and event pathways.

Costing methods: Costing of health and social care will be undertaken in a parallel study and a mixed approach using microcosting and gross costing methods will be used(24). The perspective used in the study affects the way in which resources have to be costed (25). Generally, resources should be valued at their (marginal) opportunity costs, and market prices are usually used as a proxy measure. We will cost resources using national average cost figures (26);(27);(28). We expect scarcity of published cost data in relation to rehabilitative care. Whenever necessary, cost estimation procedures will be developed and local NHS and social service accounting figures will be used to estimate total costs. Then, two methods of costing will be used and compared as suggested by the methodological literature(29): at first, unit costs averaged across centres will be applied to centre-specific volume of resources used; therefore, these results will be compared with those obtained using centre-specific information for both the unit costs and the resources volumes, and averages across centres will be calculated. Where relevant, costs will be broken down into capital, staff, consumable and overhead costs. This will aid the production of different cost scenarios, and the understanding of the implications on the marginal cost evaluation.
Other costs to carers: The impact of the interventions on carers' daily activity and their use of time will also be monitored. Informal carers will be identified through the patients' interviews.

Questionnaires will be interview administered up to one month after the patients' interview, to allow adequate time to identify, locate and contact the carers.
For carers in paid/unpaid work (eg. doing housing or voluntary work), time will be valued in monetary terms. Carers' lost leisure time will also be measured. However their impact will be assessed through HRQoL instruments(30), and therefore will not be valued in monetary terms.

Methods of data analysis
Average total costs between groups will be compared at the time points of data collection, in relation to the outcome results. Costs will be expressed in UK pounds sterling. No conversion to other currencies will be made. Costs will be expressed in the prices of the year in which the final analysis will be carried out and inflation method will be used to update costs data. Given the length of follow-up period, no discounting will be necessary.

We expect skeweness in the distribution of use of resources/costs(31). In the presence of skeweness, the logarithmic transformation of data is not recommendable, and the application of non-parametric tests can provide misleading results (in fact economic studies should aim to base the analysis on arithmetic means and not median values) (32);(33). The non-parametric bootstrap test can be the most appropriate (34), since it does not require any assumptions about the normality of data and equality of the variance or shape of the distributions. The t-test can be safely used if the sample size is not too small (33). Therefore, depending on the level of skeweness of data we will obtain and our sample size, we will make a judgement on which of these two methods can be safely applied.

Synthesis of costs and benefits
Summary results will be presented in aggregate and for each sub-group of analysis (groups will be defined in terms of severity and functional disability). Depending on the outcome measure, if there will not be evidence that one strategy is more effective than another, a cost-minimisation framework will be used and the less expensive form of care expressed in terms of cost per patient will be recommended. If one strategy appears to be dominant (ie. to be more effective and less costly than the alternative), its' uptake will be recommended. If one form of care appears to be more effective and more expensive than the comparator, the results of the study will provide useful information, and a judgement will be required in a decision making context to establish whether the additional benefits should be achieved sustaining the additional costs. In any case, recommendations will be made taking into account of the generalisability of the results. Incremental costs will be calculated overall and in relation to any reduced use of services included in the packages of care.

Sensitivity analysis
To handle uncertainty not related to sampling variations and to enhance the generalisability of the results, one-way; multi-way and extreme scenario analysis will be undertaken as appropriate, and Confidence Intervals for cost-effectiveness ratios will be estimated under different scenarios (34). A sensitivity analysis taking into account differences in resource use which are practically significant (i.e. potentially costly) but which have not been shown to be statistically significant, will also be undertaken. The sensitivity analysis will also make explicit all the simplifying assumptions made to collect the data, and will allow for 'learning effects' in HBR service provision.
Particular attention will also be given to whether the costs data used reflect the (marginal) opportunity costs of the resources used. When more than one reliable source of information will be available, such data will be used as a term of comparison. In this way, the sensitivity analysis will also be aimed to inform decision making at different levels and therefore to make the findings relevant to other perspectives. Finally, the use of different costing methods for multi-centre studies will be explored, as suggested by the recent literature (30).

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A RANDOMISED CONTROLLED TRIAL

OF DAY HOSPITAL REHABILITATION

COMPARED WITH

REHABILITATION AT HOME

QUESTIONNAIRE FOR TRUSTS:
1st Contact

Name of trust

Location

Name, address and telephone number for:

Lead clinician for rehabilitation for older people

Name: **Address:**   **Tel:** **Fax:** **Email:**

Research Department

Contact Name: **Address:**   **Tel:** **Fax:** **Email:**

Person filling in this form, if not one of the above

Name: **Address:**   **Tel:** **Fax:** **Email:**

Please could you fill in the following questionnaire as discussed in the accompanying letter?

(Questionnaire for trusts)

1. Is your trust a District General Hospital? YES ☐ NO ☐

   Primary Care Trust? YES ☐ NO ☐

   Other(please specify)_____

2. If a District General Hospital, which Primary Care Trusts do you serve?

   _____

   _____

   _____

   _____

   _____

   If a Primary Care Trust to which District General Hospital do you principally refer?

   Main_____

   Other_____

3. Does your trust provide a home based rehabilitation service for elderly patients?

YES ☐ NO ☐

IF YES please answer the following:

a) is this service restricted to older patients YES ☐ NO ☐

or

b) open to other age groups YES ☐ NO ☐

IF NO which trust(s) provide this in your area?

_____

4. Does your trust provide a day hospital rehabilitation service for elderly patients?

YES ☐ NO ☐

IF YES please answer the following:

a) is this service restricted to older patients YES ☐ NO ☐

or

b) open to other age groups YES ☐ NO ☐

IF NO which trust(s) provide this in your area?

_____

Thank you for your cooperation. Please return questionnaire in the envelope provided. You may be contacted again regarding this issue in the future.

2nd contact questionnaire for trusts

	Home based rehabilitation service		Day hospital rehabilitation service	
1. Does the service provide:				
1a. Functional assessment (assessment of personal independence)?	Yes	No	Yes	No
Medical assessment?	Yes	No	Yes	No
1b. Rehabilitation (a co-ordinated approach to the assessment and treatment of physical, cognitive, psychological impairment and disability)?	Yes	No	Yes	No
1c. Respite and social care?	Yes	No	Yes	No
1d. Specialist doctor related to rehabilitation?	Yes	No	Yes	No
1e. Nursing procedures?	Yes	No	Yes	No
1f. Specialist assessment services for specific groups of patients: ***Please circle***	***Stroke*** ***TIA*** ***Parkinsons*** ***Movement Disorder*** ***Falls*** ***Continence*** ***Other (please specify)*** ***Physical Maintenance*** ***Other (please explain)***		***Stroke*** ***TIA*** ***Parkinsons*** ***Movement Disorder*** ***Falls*** ***Continence*** ***Other (please specify)*** ***Physical Maintenance*** ***Other (please explain)***	
2. Approximately how many new elderly (e.g. over 55) patients have been referred to the service in the past 12 months?				
3. How many patients can the service provide for on any one day?				
4. Who delivers the service: ***Please circle***	**Community Nurse (s)** ***G.P(s)*** ***Acute hospital nurse (s)*** ***Acute hospital doctor (s)*** ***Occupational Therapist (s)*** ***Physiotherapist (s)*** ***Assistant (s)*** ***Administrative Staff*** ***Other (please give details)***		**Community Nurse (s)** ***G.P(s)*** ***Acute hospital nurse (s)*** ***Acute hospital doctor (s)*** ***Occupational Therapist (s)*** ***Physiotherapist (s)*** ***Assistant (s)*** ***Administrative Staff*** ***Other (please give details)***	
5. Does the service have defined time limits for the attendance of it's patients?	Yes	No	Yes	No
6. What proportion of the patients in the service are stroke/non-stroke?	Stroke	Non-Stroke	Stroke	Non-Stroke
7. Are there any major plans to change the service within the next 3 years?	Yes Please explain over leaf	No	Yes Please explain overleaf	No

- Would you be interested in taking part in a Delphi survey? Yes/No
- Would your trust be interested in the possibility of taking part in a randomised controlled trial? Yes/No
- **Thank you for your help. If you wish to elaborate on any questions please do this overleaf, numbering accordingly.**

Justification of measures used

Hospital Anxiety and Depression Scale

HADS was developed by Zigmond and Snaith (1983), to identify anxiety disorders and depression among patients in non-psychiatric hospital clinics. It contains an anxiety subscale and a depression subscale. They reported it to have good reliability and validity and be unaffected by the presence of physical illness. They found it to be easily understandable by and acceptable to patients (Bowling 1995).

Other studies since have confirmed it's usefulness. Aylard et al (1987, cited in Bowling 1995) found it to have good correlations with other well known scales. Mykletun et al (2001), tested the psychometric properties of HADS in a large population and found it to be good in terms of factor structure, intercorrelation, homogeneity and internal consistency. They also found that these properties were robust across a wide spectrum of sub-samples, including age, gender and education. Mykletun et al (2001) studied HADS as a self-administered scale, but Zigmond and Snaith (1983) recommend it to be interviewer administered (Bowling 1995).

Bjelland et al (2002) reviewed 747 papers on the validity of HADS. A 1996 review by Herrmann, had concluded that "HADS is a reliable and valid instrument for assessing anxiety and depression in medical patients" (cited p3). Since this was published however, the number of papers on HADS had increased four fold. Bjelland et al concluded that HADS has good internal consistency in the hospital population, with substantial evidence to support that it works well in general and other populations. They felt is was at least as good a screening tool and other similar screening instruments.

HADS has been used extensively in studies of patients receiving rehabilitation, recent examples include Wolf et al's (2001) study to establish the effect of an exercise intervention on balance dysfunction in elderly rehabilitation patients, and Wade et al (2003)used HADS in a study to determine the effect of a rehabilitation and support group on people with Parkinson's disease.

Therefore we can conclude that HADS will be a reliable and valid measure of anxiety and depression and is considered acceptable for use with elderly and rehabilitation patients patients.

General Health Questionnaire

Bowling (1995), describes the GHQ as "The most commonly used international scale of general psychiatric morbidity, across a wide range of patients" (p76). Specifically the GHQ-30 is the most popular, for it's good psychometric properties and brevity.

Bowling stated that it has been extensively tested for reliability, validity and sensitivity to change with good results. It has also been used with elderly populations successfully, including where help has been needed to fill it in.

It has recently been used by Watts et al (2002) in their study of mental health problems in older people in primary care, and by Bautz-Holter et al (2002) in their study of Early Supported Discharge following acute stroke compared to a normal rehabilitation package.

The reliability and validity of the GHQ is well documented, and specifically the 30 question version is most popular. It has been well used with elderly populations and is acceptable for use with rehabilitation patients.

Nottingham Extended Activities of Daily Living

The EADL was designed by Nouri and Lincoln in 1987 for use with stroke patients. I-Ping et al (2000) state that "The EADL is one of the most popular IADL scales used in rehabilitation

centres in the UK" (p449), it is recommended for use in clinical and research settings and includes items which are suitable for patients living at home. Bowling (1995) had found evidence for the reliability of EADL but found that few studies had evaluated it's validity.

Studies since though, have established the validity of the EADL, for example I-Ping et al's (2000) study evaluating it's use with stroke patients in Taiwan. They have also shown it to be sensitive to clinically important changes.

Other studies have also evaluated it's usefulness with non-stroke patients. Harwood et al (2002) concluded that EADL is valid for use with patients with arthritis of the hip, and Nichol et al (2002) evaluated it's usefulness with Multiple Sclerosis patients. Both of these studies support the reliability and validity of the method, and suggest that this is a useful tool for a wider rehabilitation population that stroke patients.

Euro-quol

Euro-quol was designed to provide a standardised non-disease-specific instrument for assessing health related quality of life (Bowling 1995), and has been widely used in health economic evaluation. The EQ 5-D has been widely used in rehabilitation studies, including a 2003 RCT by Wade et al, looking at rehabilitation for Parkinson's patients.

Schrag et al (2000) state that the EQ-5D "has been extensively validated and been shown to be sensitive, internally consistent and reliable in the general population and other patient groups".

Summary Table

	Reliability	**Validity**	**Appropriate to population**
HADS	Zigmond and Snaith (1983) Bjelland et al (2002)	Zigmond and Snaith (1983) Bjelland et al (2002)	Bjelland et al (2002) Wolf et al (2001)
GHQ	Bowling (1995)	(Bowling 1995)	Watts et al (2002) Bautz-Holter et al (2002)
NEADL	Bowling (1995)	I-Ping (2000)	Harwood et al (2002), Nichol et al (2002)
EUROQUOL	Schrag et al (2000)	Schrag et al (2000)	Wade et al (2003)

Patient Information Sheet

University of Sheffield

Rehabilitation for the elderly. Day hospitals compared to rehabilitation at home. A randomised controlled trial.

Invitation to participate in the above study
You are being invited to take 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 your time to read the information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything which is not clear or if you would like more information. Take time to decide whether you wish to take part.

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You'. This leaflet gives more information about medical research and looks at some questions you may want to ask. A copy may be obtained from CERES, PO Box 1365, London, N16 0BW.

Thank you for reading this.

What is the purpose of this study?
We want to compare elderly patients who are having rehabilitation in a day hospital, to those having rehabilitation in there own homes, and see if there are any advantages of one over the other in terms of cost or patient and carer preference. The study is a National Randomised Controlled Trial, which means it is taking place nationally, and patients who agree to be involved are randomly assigned to receive either home based or day hospital rehabilitation. From previous studies we don't expect there to be any difference in effectiveness between these two, so you will not be disadvantaged by being assigned to either one. What we hope to find out is which of these is preferable according to the patient and carer, and which is most cost effective.

Why have I been chosen?
You have been chosen because you are an elderly person who has been identified as needing rehabilitation.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?
If you agree to take part in this study, you will be randomly assigned to receive either day hospital or home based rehabilitation. Then your rehabilitation will start and the service you receive will be unaffected by your taking part in this study. A researcher will come to your home, at your convenience, and interview you within the next 2 weeks. This interview will involve questions about how you feel in yourself and what you can and can't do, and also questions about your use of health services. The interview will take between half an hour and an hour. This interview will be repeating in 3 months, 6 months and 12 months time. The researcher will always make an effort to fit around your commitments and your health and welfare will always be the top priority.

What do I have to do?
Taking part in the study does not require you to make any changes to your lifestyle, and the researcher will arrange to see you at a time convenient to you.

What is the procedure being tested?
The study aims to find any differences between home based and day hospital rehabilitation.

What are the alternatives to being involved in this study?
If you choose not to be involved in this study, you will receive rehabilitation, and if you have a preference to being treated at home, or in a day hospital, this can be taken into account.

What are the possible disadvantages or risks to being involved in this study?
We don't think there are any risks or disadvantages for being involved in this study, but you have the option to withdraw at any time, for any reason.

What are the possible benefits of taking part?
Information we get from this study will help us to find out the best way of treating patients in the future.

What happens when the research stops?
When the research stops we will analyse the information we have gathered, and report our findings, which may have implications for funding and resources in the future.

What if something goes wrong?
We don't think that being part of this study will cause you any problems, and the researchers will do there best to make sure we interrupt your day to day life as little as possible. However, if you are unhappy about the way you have been approached or treated during the study, there will be complaint procedures that you can follow.

Should you have a complaint about anything during the course of the research, please phone SISA on :
0114 271 5924

Will my taking part in the study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which we take away from the hospital/scheme will have your name and address removed from it so that you can not be recognised.

What will happen to the results of the study?
We hope that the results of this study will be published in journals and conferences, and help to decide on future policy development. There will be an opportunity for you to see the results of the study when it is completed.

Who is organising and funding this study?
The research is funded by the Department of Health, and organised by researchers at the Universities of Sheffield, Newcastle and Leicester.
If there is any else you would like to know please contact me.

Kate Fryer
Project Manager
Sheffield Institute for Studies on Ageing
Community Sciences Centre
Northern General Hospital
Sheffield
S5 7AU
Phone: 0114 XXXXXXX
Mobile:
Email:

Consent form. Rehabilitation of older patients:
day hospital compared to rehabilitation at home.
Randomised controlled trial.

Centre No. Patient ID No.

Name of researcher:

I have spoken to…….about the study. ☐

This conversation took place on ……(date). ☐

I have read the information sheet ☐

I know enough about the study ☐

I have had the chance to ask questions ☐

I have been told that I don't have to take part if I don't want to ☐

I have been told I can change my mind at any time if I don't want to carry on ☐

I have been told that what I decide to do will not effect any help I get now or in the future ☐

I understand that if I agree to take part in the study, I will be randomly assigned to receive rehabilitation either in the day hospital or at my home ☐

I have been told I will be asked to meet with the researcher in my own home up to 4 times ☐

I have been told my name will not be used in anything written about the study ☐

I have been told that nothing I say will be repeated to anyone else unless it is discussed with me first ☐

I am happy for my GP to be informed of my participation in the study ☐

I am happy for the researcher to contact my GP or other relevant health professional, in the event that they visit me ay my home and feel that is necessary ☐

Name of patient	Date	Signature

Name of person taking consent (if not researcher)	Date	Signature

Researcher	Date	Signature

(If AMT below 7)

Primary Informal Carer	Date	Signature

1 for patient, 1 for researcher, 1 to be kept with hospital notes

Carer Information Sheet

UNIVERSITY OF SHEFFIELD

Rehabilitation for the elderly. Day hospitals compared to rehabilitation at home. A randomised controlled trial.

Invitation to participate in the above study

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Why have I been chosen?

You have been chosen because you are the carer of an elderly person who has been identified as needing rehabilitation.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason.

What will happen to me if I take part?

If you agree to take part in this study, a researcher will come to your home, at your convenience, and interview you in about 3 months time. This interview will involve questions about how you feel in yourself and how you have been

affected by the illness of the person you are caring for. The interview will take about half an hour. This interview will be repeated 6 months and 12 months time from now. The researcher will always make an effort to fit around your commitments and your health and welfare will always be the top priority.

What do I have to do?
Taking part in the study does not require you to make any changes to your lifestyle, and the researcher will arrange to see you at a time convenient to you.

What is the procedure being tested?
The study aims to find any differences between home based and day hospital rehabilitation.

What are the alternatives to being involved in this study?
If you choose not to be involved in this study neither you or the person you are caring for will be affected. The person you are caring for can still be part of the study if you decide not to be.

What are the possible disadvantages or risks to being involved in this study?
We don't think there are any risks or disadvantages for being involved in this study, but you have the option to withdraw at any time, for any reason.

What are the possible benefits of taking part?
Information we get from this study will help us to find out the best way of treating patients in the future.

What happens when the research stops?
When the research stops we will analyse the information we have gathered, and report our findings, which may have implications for funding and resources in the future.

What if something goes wrong?
We don't think that being part of this study will cause you any problems, and the researchers will do there best to make sure we interrupt your day to day life as little as possible. However, if you are unhappy about the way you have been approached or treated during the study, there will be complaint procedures that you can follow.

Should you have a complaint about anything during the course of the research, please phone SISA on :
0114 271 5924

Will my taking part in the study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which we take away from the hospital/scheme will have your name and address removed from it so that you can not be recognised. We will not share anything you tell us with the person you are caring for unless you ask us to.

What will happen to the results of the study?
We hope that the results of this study will be published in journals and conferences, and help to decide on future policy development. There will be an opportunity for you to see the results of the study when it is completed.

Who is organising and funding this study?
The research is funded by the Department of Health, and organised by researchers at the Universities of Sheffield, Newcastle and Leicester.
If there is any else you would like to know please contact me.

Kate Fryer
Project Manager
Sheffield Institute for Studies on Ageing
Community Sciences Centre
Northern General Hospital
Sheffield
S5 7AU
Phone: 0114 XXXXXXX
Mobile:
Email:

Consent form. Rehabilitation of older patients:
day hospital compared to rehabilitation at home.
Randomised controlled trial. Carer.

Centre No. Patient ID No.

Name of researcher:

I have spoken to…….about the study. ☐

This conversation took place on ……(date). ☐

I have read the information sheet ☐

I know enough about the study ☐

I have had the chance to ask questions ☐

I have been told that I don't have to take part if I don't want to ☐

I have been told I can change my mind at any time if I don't want to carry on ☐

I have been told that what I decide to do will not effect the person I care for now or in the future ☐

I have been told I will be asked to meet with the researcher in my own home up to 3 times ☐

I have been told my name will not be used in anything written about the study ☐

I have been told that nothing I say will be repeated to anyone else unless it is discussed with me first ☐

Name of carer	Date	Signature

Name of person taking consent (if not researcher)	Date	Signature

Researcher	Date	Signature

University of Sheffield **Sheffield Institute for Studies on Ageing** **Rehabilitation of Older Patients: day hospital compared to rehabilitation at home – HTA Project No: 97/26/01**	
Patient Interview Schedule 2 – Economic	
Patient study number	1
Interviewer (Kate=1)	2
Interview done in home(1)/hospital(2)	3
Date	4
Baseline(0)/3 months (1)/6 months(2)/1 year(3)	5
Proxy? Yes(1)/No(2)	6
Relationship of proxy to patient Husband/wife (1) Son/daughter (2) Grandchild (3) Other relative (4) Friend (5) Paid carer (6)	7

0	So, when did you start your rehabilitative treatment (date)?	8
	*Now I will ask you a series of questions about the use of health and social services through the NHS. I only want to know about things you have had **in addition to** your rehabilitation treatment:*	
1	In the last 8 weeks have you done any of the following because of your condition or other health reasons? Can you please also remember how many times these events have happened? Please do not count visits you have made as part of your rehabilitation treatment.	
a)	**Have you been seen by the family doctor or another GP at a doctor's surgery?** Yes.....1 no. times ☐☐	9 10

	No 2	
b)	**Have you been seen by a nurse at a surgery?** Yes .....1 no. times ☐☐ No 2	11 12
c)	a) **Did you or anyone else speak to a nurse from a doctor's surgery about you on the telephone?** Yes .....1 no. times ☐☐ No 2	13 14
d)	**Did you or anyone else speak to a doctor at the surgery about you on the telephone?** Yes .....1 no. times ☐☐ No 2	15 16
e)	**Did you or anyone else telephone NHS Direct?** Yes .....1 no. times ☐☐ No 2	17 18
f)	**Have you visited an emergency doctor at an "out of hours" clinic?** Yes .....1 no. times ☐☐ No 2	19 20

2	In the last 8 weeks, have you been seen in an outpatient department at a hospital because of your condition or other health reasons? Please do not count the times you went there for tests/investigations only, I will ask you about these later. Only count those in addition to your rehabilitation treatment. Can you remember which hospital/clinic departments you have been seen as an outpatient? I will also ask you how many times this has happened. I have a list, which might help you.	
a)	**Have you been seen in a geriatric department?** Yes .....1 no. times ☐☐ No 2	21 22
b)	**Have you been seen in an orthopaedics department?** Yes .....1 no. times ☐☐ No 2	23 24
c)	**Have you been seen at a rehabilitation/physiotherapy department?** Yes .....1 no. times ☐☐ No 2	25 26

d)	**Have you been seen at a generic medical department?** Yes.....1 no. times ☐☐ No 2	27 28
e)	**Have you been seen at a neurology department?** Yes.....1 no. times ☐☐ No 2	29 30
f)	**Have you been seen at an ophthalmologist department?** Yes.....1 no. times ☐☐ No 2	31 32
g)	**Have you been seen at an ENT department?** Yes.....1 no. times ☐☐ No 2	33 34
h)	**Have you been seen in an Accident and Emergency department?** Yes.....1 no. times ☐☐ No 2	35 36
i)	**a) Have you been seen in any other department?** Yes.....1 Specify where…….no. times ☐☐ No 2	37 38

3	In the last 8 weeks, have you had to stay in hospital as a day patient or overnight because of your condition or other health reasons? **(RECORD GENDER OF PATIENT).** Yes (1) No (2) If yes ask name of hospital**……**	39
4	In the last 8 weeks, did you have any tests/investigations because of your condition or any other health reasons? Please do not count those you have had while admitted to hospital or those you have had during the outpatient visits you reported earlier on. I have got a list of tests and investigations some people might have had. You may be familiar with some of the words, but don't worry if you do not recognise all of them. Can you please tell me if you have any of the following and how many times? **Ring all that apply**	
a)	***Blood tests*** Yes (1) No (2) no. times ☐☐	40 41
b)	**Urine test** Yes (1) No (2) no. times ☐☐	42 43
c)	**X-ray** Yes (1) No (2) no. times ☐☐	44 45
d)	**CT (computerised tomography) brain scan**	46

	Yes (1) No (2) no. times ☐☐	47
e)	**MRI (magnetic resonance imaging) brain scan** Yes (1) No (2) no. times ☐☐	48 49
f)	**ECG, Heart tracing** Yes (1) No (2) no. times ☐☐	50 51
g)	**Ultrasound** Yes (1) No (2) no. times ☐☐	52 53
h)	**EEG (brain wave recording)** Yes (1) No (2) no. times ☐☐	54 55
i)	**Other (SPECIFY):** Yes (1) No (2) no. times ☐☐	56 57
j)	**Other (SPECIFY):** Yes (1) No (2) no. times ☐☐	58 59

5	In the last 8 weeks, have you used an emergency ambulance service because of your condition or any other health reasons? Can you please remember the number of times? (please count journeys both to and from the hospital as separate journeys) Yes (1) No (2) no. times ☐☐	60 61
6	In the last 8 weeks, have you used a pre-booked NHS transport service (e.g. minibus, ambulance, taxi) because of your condition or any other health reasons? Can you please remember the number of times? (please count journeys both outwards and inwards journeys as separate journeys) Yes (1) No (2) no. times ☐☐	62 63

	Now I will ask you about visits you have received at home through the NHS or the social services.	
7	In the last 8 weeks, have you received any visits at home because of your condition or other health reasons and can you remember how many times? Please do not include the visits you have had as part of your rehabilitation treatment since we will get this information from the Centre.	
a)	**Have you been seen by your GP or another doctor at home?** Yes (1) No (2) no. times ☐☐	64 65
b)	**Have you been seen by a health visitor at home?** Yes (1) No (2) no. times ☐☐	66 67

c)	**Have you been seen by a social worker at home?** Yes (1) No (2) no. times ☐☐	68 69
d)	**Have you been assisted by a home carer?** Yes (1) No (2) no. times ☐☐	70 71
e)	**Have you been seen by a disablement resettlement officer at home?** Yes (1) No (2) no. times ☐☐	72 73
f)	**Have you been seen by a psychologist at home?** Yes (1) No (2) no. times ☐☐	74 75
g)	**Have you been seen by a counsellor at home?** Yes (1) No (2) no. times ☐☐	76 77
h)	**Have you been seen by a district nurse at home?** Yes (1) No (2) no. times ☐☐	78 79
i)	**Have you been seen by some other person at home?** Yes (1) No (2) no. times ☐☐	80 81
j)	**Have you received meals on wheels?** Yes (1) No (2) no. times ☐☐	82 83
8	In the last 8 weeks, have you seen anybody privately (e.g. at your expenses or through a private insurance scheme) because of your condition or other health reasons? Yes (1) No (2) **If no skip to question 10**	84
9	*Who have you seen privately?* **Fill in the second column first, then fill in each applicable row.** Tick=1 No tick=2	

	(TICK ALL THAT APPLY).	How many times did this happen since in the past 8 weeks.	How much did it cost altogether? £		
A physiotherapist					85 86 87
A speech therapist					88 89 90
A chiropodist					91 92 93
An occupational therapist					94 95 96
An osteopath					97 98 99
					100 101 102

		A chiropractor					103 104 105
		An acupuncturist					106 107 108
		A psychologist					109 110 111
		A counsellor					112 113 114
		A naturopathologist					115 116 117
		Other **(SPECIFY):**					
10	In the last 8 weeks, have you taken any medications because of your condition or other health reasons? Yes (1) No (2) **If no skip to question 12**						118
11	I would like to ask you some detailed questions about your medication(s). **Go to medications list on next page**						

What is the **name** of the medication and **type of preparation** (e.g. tablets, capsules, syrup, inhaler, drops etc)? *(Brand name if possible)*	What is the strength of the medication taken? *(as written on the pack)*	For how many days have you been taking this medication? *(Please ask this question even if the respondent is not taking the medication now)*	What is the dose taken in a day (e.g. number of tablets, capsules, drops or puffs of inhaler)?	Did you buy the medication over the counter? *(Please write 'yes' or 'no')*	
Example: Nurofen tablet	400mg	Five	3 tablets per day	No	119 120 121 122
					123 124 125 126
					127 128 129 130
					131 132 133 134
					135 136 137 138
					139 140 141 142
					143 144 145 146
					147 148 149 150
					151 152 153 154
					155 156 157 158
					159 160 161 162
					163 164 165 166
					167 168 169 170
					171 172 173 174
					175 176 177 178

					179 180 181 182

12	In the last 8 weeks, have you had to get any special aid/equipment (e.g. wheelchair, zimmer frame, walking stick, special shoes because of your condition or other health reasons)? Yes (1) No (2) **If no skip to question 14**	183
13	Over the last 8 weeks what type of aid/equipment did you get?	

(FILL IN THE SECOND COLUMN FIRST, THEN FILL IN EACH APPLICABLE ROW).

Tick=1 No tick=2	**Tick all that apply**	**If there was a charge how much was it? If no charge write N/A and stop here.** **£**	**If someone else paid for it how much was paid? If the patients paid the total amount write N/A and stop here.** **£**	**Who made the payment?**	
Manual Wheelchair					184 185
Electric Wheelchair					186 187
Zimmer Frame					188 189
Walking Stick					190 191
Walking Trolley					192 193
Crutches					194 195
Helping Hand					196 197
Special Clothing					198 199
Special Footwear					200 201
Sheepskins					202

					203
Mattresses					204 205
Cushions					206 207
Special Chair					208 209
Chair Raise					210 211
Bed Table					212 213
Kitchen Gadgets					214 215
Special Cutlery					216 217
Special Crockery					218 219
Feeding Tubes					220 221
Commode					222 223
Bedpan					224 225
Catheter					226 227
Incontinence aids					228

					229
Book Rests					230 231
Typewriter/ Lightwriter					232 233
Talking Books					234 235
Page turners					236 237
Alarm system (personal)					238 239
Telephone					240 241
Special telephone					242 243
Door answering unit					244 245
Door opening unit					246 247
Hearing Aid					248 249
Other …….					250 251
Other …….					252 253

Other ……					254 255

14	In the past 8 weeks have you had to make any alterations to your house because of your condition or other health reasons? Yes (1) No (2) **If no skip to question 16**	256
15	In the past 8 weeks, what type of alteration did you make?	

(FILL IN THE SECOND COLUMN FIRST, THEN FILL IN EACH APPLICABLE ROW).

	Tick all that apply	**If there was a charge how much was it? If no charge write N/A and stop here.** **£**	**If someone else paid for it how much was paid? If the patients paid the total amount write N/A and stop here.** **£**	**Who made the payment?**	
Bath rails					247 248
Grab rails (bath)					249 250
Special taps					251 252
Shower					253 254
Bath hoist (mechanical)					255 256
Hoist with slings					257 258
Bath seat/board					259 260
Grab rails (toilet)					261

					262
Raised toilet seat					263 264
Toilet on bedroom/ living level					265 266
Bed hoist					267 268
Bed raise					269 270
Special bed					271 272
Fracture board					273 274
Widened doorways					275 276
Banisters					277 278
Stair lift					279 280
Ramp at front/rear					281 282
Grab rails (external doors)					283 284
Other ……					285 286
Other ……					287

					288
Other ……					289 290

16	Because of your condition or other health reasons have you had to either rent new accommodation or sell your house since in the last 8 weeks? Yes (1) No (2) **If no skip to question 19**	291
17	Has this caused a financial loss to you or your family? Yes (1) No (2) If yes how much was the loss? **£…….**	292 293
18	How much did it cost you to move your furniture and personal things? **£…….**	294
19	In the last 8 weeks, have you moved into residential/nursing home or made use of day care centres/sitting services at home because of your condition or other health reasons? Yes (1) No (2) **If no skip to question 22**	295
	How many days in the last 2 months? *Permanently* *Short stay* *Day care centre* *Sitting services*	296 297 298 299
20	*Do you pay personally for you to stay in residential/nursing care or make* use of day care centre/sitting services? Yes (1) No (2) If no, who pays?**……..**	300
21	How much are your bills monthly? **£……**	301

22	In the last 8 weeks, did you have to meet any travel costs because of your condition or other health reasons (e.g. to attend clinical appointments, or to get the prescribed treatment/equipment)? Yes (1) No (2) **If no skip to question 26**	302
23	n you please provide as much information as you can about the travel	

sts you had to meet because of your condition or other health reasons?
ease include costs for return journeys).

Can you tell me how you travelled? Tick=1 No tick=2	Please tick all that apply.	**How many miles did you travel overall** *(If you can't remember exactly, can you please estimate it)*	How much did these journeys cost you **altogether**? *(If you can't remember exactly, can you please estimate it)*	
			£	**p**
By train/metro				
By bus				
By private car				
By taxi				

303 304 305
306 307 308
309 310 311
312 313 314

24 If you travelled by car, did you have to pay any tolls or parking fees? Yes (1) No (2) — 315

If no skip to question 26

25 How much did you pay for tolls or parking fees? **£……** — 316

26 In the last 8 weeks, did you have any other extra expenses because of your condition or other health reasons (e.g. purchase of books or videos about your condition)? Yes (1) No (2) — 317

If no skip to question 28

27 If yes, please tell me the item and how much you have spent on each item: — 318

Item 1:

Description of item……

Amount spent……

319

Item 2:

Description of item……

Amount spent……

28 *In the last 8 weeks have you received any assistance at home to help in* your personal care or home care because of your condition or other — 320

	health reasons? Please exclude the visits through the NHS and social services you have already mentioned earlier on. Yes (1) No (2) **If no please go to question 30**	
29	If yes, who helped you?	

	Partner/Spouse (1)	**Relative (2)**	**Friend (3)**	Nurse (4)	**Paid Home carer (5)**	**Other e.g. grand child(6)**	**Other (6)**
Tick							
For how long in total?							
Days							
Hours							
Minutes							
Total cost	£	£	£	£	£	£	£
Paid by? (Tick)							
Patient							
Other (please state)							

321 Helper 1
322 Total hours
323 Cost
324 Paid by Patient – 1 Other – 2
325 Helper 2
326 Total
327 Hours
328 Cost
329 Paid by Patient – 1 Other – 2
330 Helper 3
331 Total hours
332 Cost
333 Paid by Patient – 1 Other - 2

30	Now I will ask you a few questions about your work. If you are retired, please answer these questions about your **last main** job. **If the patient has never worked please tick this box and skip to question 32** ☐ a) What is your job title? b) What do/did you actually do? c) What does the firm or organisation you work(ed) for make or do? d) Are/were you?: An employee 1 or self-employed..... 2 e) Are/were you a manager, foreman or supervisor of any kind? Yes, manager..... 1 Yes, supervisor..... 2 No, neither..... 3	Tick = 2 No tick=1 334 335 +336
31	Because of your condition or other health reasons have you done any of the following in the last 8 weeks? Gone on sick leave? 1 Gone on long-term sickness benefit(s)? ..... 2 Retired early from work? ..... 3 Given up work altogether? ..... 4 Already retired? 5	337

	None of these happened? 6	
32	Who do you live with at home? With your husband/wife or a partner ..... 1 With your children ..... 2 With your parents ..... 3 With a brother or sister ..... 4 With some other person ..... 5 No one - I live alone 6	338
33	Are you: Married or living with a partner ..... 1 Divorced or separated ..... 2 Widowed ..... 3 Single 4	339
34	Are you or your family members currently receiving any of the following allowances? Jobseeker's allowance (Ex-Unemployment benefit) ..... 01 Income support ..... 02 Working tax credit (Ex-working families tax credit) ..... 03 Statutory sick pay ..... 04 Incapacity benefit (Ex-Invalidity benefit) ..... 05 Severe disablement allowance ..... 06 Health benefits ..... 07 Attendance allowance ..... 08 Carers allowance (Ex-Invalid care allowance) ..... 09 Council tax benefit ..... 10 Housing benefit ..... 11 Disability living/allowance ..... 12 State retirement pension ..... 13 Disabled persons tax credit ..... 14 Other (*Please write in what*) ..... 15 Not receiving any 16	340 341 342 343 345 346 347 348 349 350
35	What is your date of birth? **.....**	351
36	(Record gender of patient). Male (1) Female (2)	352

Carer questionnaire

University of Sheffield **Sheffield Institute for Studies on Ageing** **Rehabilitation of Older Patients: day hospital compared to rehabilitation at home – HTA Project No: 97/26/01**	
Carer Interview Schedule	
Patient study number	1
Interviewer (Kate=1)	2
Interview done in home(1)/hospital(2)	3
Date	4
Baseline(0)/3 months (1)/6 months(2)/1 year(3)	5

1	So, when did you start to assist Mr/Mrs (Patients name) ……..	6
2	What is your relationship to the person you are assisting? Are you: His/her spouse/partner 1 His/her child 2 His/her grandchild 3 A friend 4 A paid carer 5 Other (*please write in relationship*) 6	7

3	Which of the following **best** describes your **current** position about work? (*Please ring one number only).* Full or part time 1 Retired 2 At home and not looking for paid employment 3 (eg looking after your home, family or other dependants) Unable to work due to illness or disability 4 Unemployed and looking for work 5 Other *(please write in*) 6 ……	8
4	Now I will ask you a few more detailed questions about your work. If you are not working at present for any reason, can you please tell me about your last main job. **If the carer has never worked, please tick this box and go to Q15** ☐ How many hours do you/did you work? ☐☐ hours per week	9 10
a)	How many hours do you/did you work? ……..hours per week	11
b)	Can you please tell me your job title? ……	12
c)	What do/did you actually do? ……	13
d)	What does the firm or organisation you work(ed) for make or do? ……	14
e)	Are/were you? An employee 1 or self-employed 2	15
f)	Are/were you a manager, foreman or supervisor of any kind? Yes, manager 1 Yes, supervisor 2 No, neither 3	16
5	In the past 8 weeks, have you been in paid employment/self employment at all? Yes 1 No 2 **If no skip to Q10**	17

6	In the past 8 weeks, have you taken any time off work as a carer *(eg to look after* *him/her at home or to accompany them to the doctor or hospital*)? Do not include times when you took work home or made up the time later. Yes 1 No 2 **If no skip to Q10**	18
7	How many days or hours did you take **altogether** in that time? Days/hours……..	19
8	Did you lose any pay while off work in that time? Yes 1 No 2 If no, skip to Q10	20
9	Can you tell me the amount of earnings that you lost? **£**……..	21
10	In the past 8 weeks has your work situation been affected in any way because of your role as a carer (including changes due to an improvement in their condition)? *(please ring all that apply)* No, no effect on my work at all 1 **Skip to Q15** I took some time off work but no other effect 2 Yes, I have not been able to work at all 3 Yes, I stopped working and haven't started again 4 Yes, I was not working but I am now 5 Yes, I changed the type of job or tasks I do 6 Yes, I changed my place of work 7 Yes, I changed the number of hours I work 8 Yes, I retired early from work 9 Paid as carer for patient 10 Other *(please write in what)* 0 ……	22
11	In the past 8 weeks has there been any change in your earnings from paid or self-employment because of your role as a carer? Yes, earnings have changed 1	23

	No, no change 2 **If no, skip to Q13**	
12	If your earnings have changed:	
a)	What were your earnings before the change? *(please give the amount before tax)* **£……** ***Per (please circle) week /month /year***	Work out and record total for year 24
b)	b)What are your earnings now? *(please give the amount before tax)* **£……** Per (please circle) week /month /year	Work out and record total for year 25
c)	Was the change in your earnings due to: A change in the number of hours you work 1 An increase in your wage 2 A decrease in your wage 3 Loss of a job 4	26
13	In the past 8 weeks, has there been any change in the number of hours you work because of your role as a carer? Yes 1 No 2 *If no, skip to Q14*	27
a)	How many hours per week were you working before the change? ……	28
b)	How many hours per week are you working now? ……	29

14	In the past 8 weeks have you been unemployed at any time because of your role as carer? *Please include all times when you were not working even if you were not eligible for unemployment benefits.* Yes 1 No 2 **If no, skip to Q15**	30
a)	**If yes,** altogether, how many days were you unemployed in that time? ……	31
b)	**And** what were your earnings before you lost or gave up work? £ Was that per … *(please circle the one that applies)* week 1 month 2 year 3 (Work out and record per year)	32

15	How many hours per week do you usually assist Mr/Mrs…… **……**	33
a)	What would you have otherwise been doing normally if you were not assisting Mr/Mrs……? Housework…… 1 Caring for children……2 Caring for an adult friend/relative……3 Voluntary Work……..4 Leisure Activities……5 Attending school/college/university…….6 On sick leave……..7 Working…….. 8 Other……9 Don't know……10	34
16	Are you: Married or living with a partner 1 Divorced or separated 2 Widowed 3 Single 4 17. What is your date of birth? ☐☐ ☐☐ ☐☐ ..... **day** **month** **year** ..... 18. Is there anything else you would like to tell me about the condition of the person you are assisting, any related costs you have had to meet, or this interview?	

TOMS

Therapy Outcome Measures Data Collection Sheet

Therapist identity/code:
Patient Identity:
(Name or Code Number)
N.B. This information is for local use and will be removed before the Data Sheet leaves the Trust

Employing Authority:_____Enter Authority_____

Locality:___Enter place/s treated___

Profession: Speech and Language Therapy, Physiotherapy, Occupational Therapy

Patient/Client Details

Age at Entry
Date of Birth : ____/____/_____ **Carer :**_____(person rated)
dd mm yyyy

Aetiology Code 1: _____ _____ **Disorder Code 1 :** _____ _____
number letter number letter
Aetiology Code 2: _____ _____
number letter **Disorder Code 2 :** _____ _____
number letter

Ratings

Code*	Impairment Code 1	Impairment Code 2	Activity	Social Participation	Well-being Patient	Well-being Carer	Date Rated
A-							
I-							

* A = Admission to therapy, First rating: I = Intermediate ratings (when placed at the first entry it denotes previous interventions from therapy) F= Final rating.

Number of Contacts :_____ **Total time:** _____hrs_____mins **Discharge Code** _____
Use R0 not if analysing rating but case is not discharged

Comments:_____
_____
_____
_____
_____
Please send this form to your key worker for checking and data entry.

Tom Core Scale

Use 0.5 to indicate if patient is slightly better or worse than a descriptor.

Impairment

0 The most severe presentation of this impairment.
1 Severe presentation of this impairment.
2 Severe/moderate presentation
3 Moderate presentation
4 Just below normal/mild impairment
5 No impairment

Activity

0 Totally dependent/unable to function
1 Assists/co-operates but burden of task/achievement falls on professional or caregiver.
2 Can undertake some part of task but needs a high level of support to complete
3 Can undertake task/function in familiar situation but requires some verbal/physical assistance
4 Requires some minor assistance occasionally or extra time to complete task
5 Independent/able to function

Participation

0 No autonomy, isolated, no social/family life
1 Very limited choices, contact mainly with professionals, no social or family role, little control over life
2 Some integration, value and autonomy in one setting.
3 Integrated, valued and autonomous in limited number of settings.
4 Occasionally some restriction in autonomy, integration or role.
5 Integrated, valued, occupies appropriate role

Wellbeing/Distress

0 **Moderate frequent**: upset/frustration/anger/distress/embarrassment/concern/withdrawal.
Controls emotions with assistance, emotionally dependant on some occasions, vulnerable to change in routine etc, spontaneously uses methods to assist emotional control.

4 **Mild occasional**: upset/frustration/anger/distress/embarrassment/concern/withdrawal.
Able to control feelings in most situations, generally well adjusted/stable (most of the time/most situations), occasional emotional support/encouragement needed.

5 **No inappropriate**: upset/frustration/anger/distress/embarrassment/concern/withdrawal.
Well adjusted, stable and able to cope with most situations, opportunity to self-analyse, accepts and understands own limitations.

1 **Severe constant**: upset/frustration/anger/distress/embarrassment/concern/withdrawal.
High and constant levels of concern/anger/severe depression or apathy, unable to express or control emotions appropriately

2 **Frequently severe**: upset/frustration/anger/distress/embarrassment/concern/withdrawal.
Moderate concern, becomes concerned easily, requires constant re-assurance/support, needs clear/tight limits and structure, loses emotional control easily.

3 **Moderate consistent**: upset/frustration/anger/distress/embarrassment/concern/withdrawal.
Concern in unfamiliar situation, frequent emotional encouragement and support required.