

CIRACT

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The University of
Nottingham



The CIRACT (Community In- Reach And Care Transition) Clinical and Cost- effectiveness study

The CIRACT Trial

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Transition (CIRACT) Study

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This protocol describes the **Community In-Reach And Care Transition (CIRACT) Study** and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the trial. Problems relating to this trial should be referred, in the first instance, to the Chief Investigator.

This trial will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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Amendment History

Amendment No.			
Page	Section	Previous wording	New wording

Glossary of Abbreviations

CEACs	Cost-Effectiveness Acceptability Curves
CIRACT	Community In-Reach And Care Transition
CRF	Case Record Form
CSRI	Modified Client Service Receipt Inventory
DMC	Data Monitoring Committee
ICER	Incremental Cost-Effectiveness Ratio
LOS	Length of Stay
GCP	Good Clinical Practice
MAS	Mechanism and Action Study
NC	Nominated Consultee
NCTU	Nottingham Clinical Trials Unit
NHS	National Health Service
PCT	Primary Care Trust
PC	Personal Consultee
PPI	Patient and Public Involvement
PSS	Personal and Social Services
RA	Research Assistant
RCT	Randomised Controlled Trial
R&D	Research and Development Department
SAE	Serious Adverse Event
SSA	Site Specific Assessment
THB-rehab	Traditional Hospital Based rehabilitation
TMG	Trial Management Group
TMS	Time and Motion Study
TSC	Trial Steering Committee
QALYs	Quality Adjusted Life Years

Keywords

Rehabilitation, In-reach, Community, In-patients

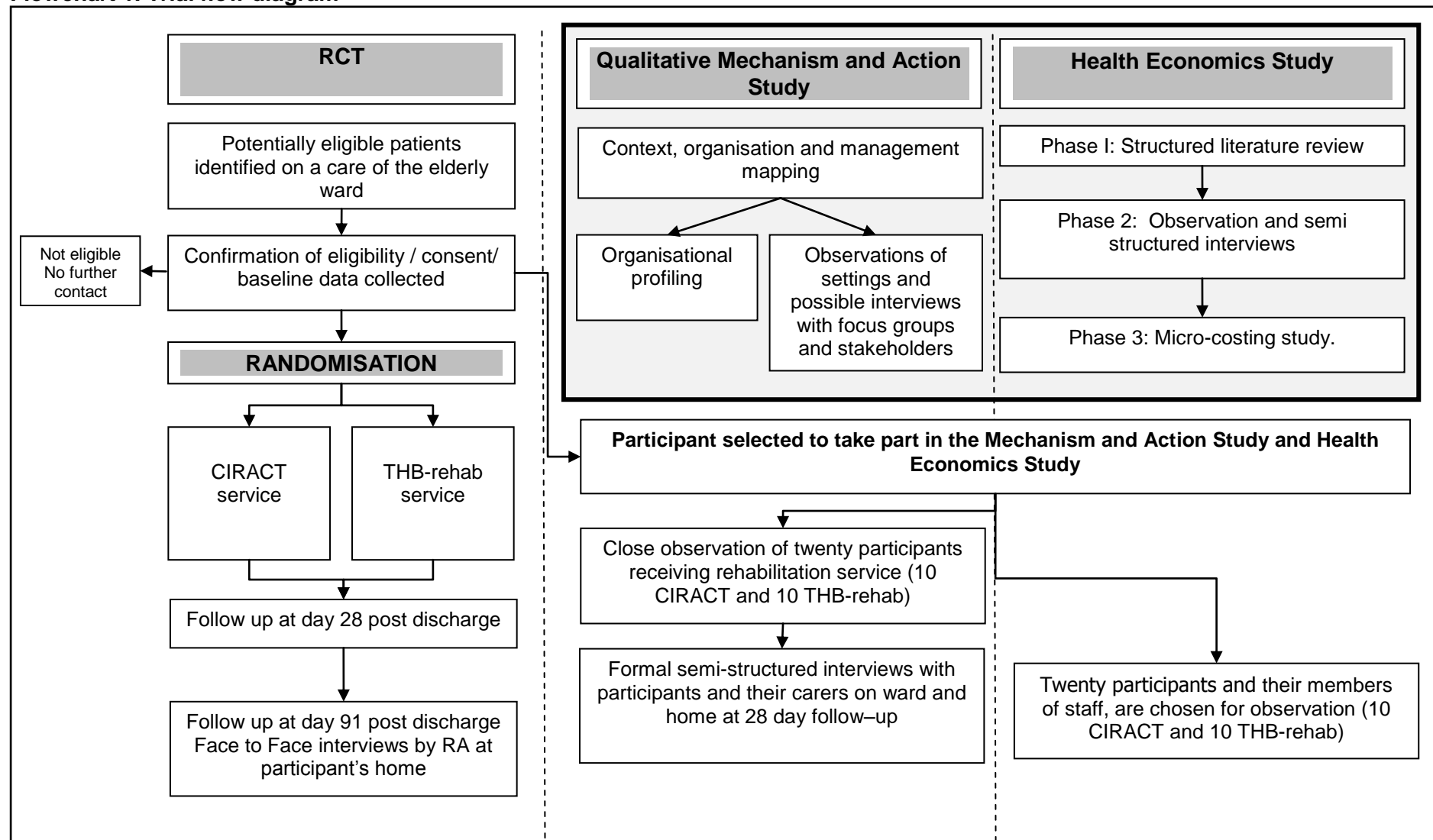
Trial Summary

TITLE	The CIRACT (Community In-Reach And Care Transition) Clinical and Cost-effectiveness study
DESIGN	Pragmatic, parallel randomised controlled trial including an integral qualitative action and mechanism and health economic study
AIMS	The healthcare aim is the reduce length of hospital stay, re-admission and improvement of health-related quality of life for unplanned hospital admission of older people (>70 years). The research aim is to determine whether CIRACT achieves this by comparing the clinical effectiveness, overall cost and cost-effectiveness of a community in-reach rehabilitation and care transition (CIRACT) service with the usual hospital ward based rehabilitation (THB-rehab) service.
OBJECTIVES	<p>Objectives of the RCT</p> <p>Primary objective To assess whether the CIRACT service reduces the length of hospital stay compared to the THB-rehab service for unplanned hospital admission of people 70 years or older.</p> <p>Secondary objectives The secondary objectives are to assess whether the CIRACT service:</p> <ol style="list-style-type: none"> 1. Reduces the re-admission rate within 28 days of discharge 2. Reduces super spell bed days (total time in NHS care (hospital care + community care/ intermediate care) 3. Improves patient function (Barthel ADL Index) 4. Improves patient health related quality of life (EQ-5D-3L) <p>Objectives of the Qualitative Mechanism and Action Study The objectives of the qualitative mechanism and action study are to:</p> <ol style="list-style-type: none"> 1. Investigate the design and delivery of the CIRACT intervention in terms of workforce configuration, including the barriers and drivers to sustain inter-occupational and inter-organisational working. 2. Assess service user experiences of the CIRACT intervention to understand the qualitative changes in service delivery to develop recommendations on future implementation. 3. Describe and explain how the CIRACT service is implemented at Nottingham University Hospitals NHS Trust to develop evidence for future roll-out 4. Describe and explain how the CIRACT service interacts with other care processes and systems, to develop knowledge on its strategic alignment with existing care models 5. Describe and explain how the CIRACT service impacts on established roles and relationships, to understand barriers drivers to change manifest in distinct professional knowledge, practice and cultural domains 6. Describe and explain how the CIRACT service is experienced by clinicians, patients and families, to develop recommendations for improvement

	<p>Objectives of the Health Economics Study</p> <p>The objectives of the health economics study are to:</p> <ol style="list-style-type: none"> 1. Define the methods of data recording and observation criteria used in time and motion research. 2. Determine the cost of the CIRACT service compared to the THB-rehab service using bottom up costing approach. 3. Compare bottomup costing results against cost estimates based on standard methods of collecting resource use information. 4. Compare social care cost of the CIRACT service compared to the THB-rehab service 5. Evaluate the cost effectiveness of the CIRACT service compared to the THB-rehab service from an NHS and PSS perspective
POPULATION	Patients aged 70 years and over having unplanned hospital admissions
ELIGIBILITY	<p>Eligible participants are patients:</p> <ol style="list-style-type: none"> 1. Aged 70 years and over 2. Admitted to hospital on the general medical elderly care ward as an unplanned medical admission 3. Admitted to hospital from their own home or residential care 4. GP registered within the Nottingham City PCT catchment area 5. Admitted Sunday to Friday <p>Potential participants will be excluded if they</p> <ul style="list-style-type: none"> • Previously bed bound • Receiving palliative care • Moribund on admission • Previously included in the trial on an earlier admission • Admitted from a nursing home
DURATION	Recruitment is for 13 months. Follow up is for 91 days post discharge. The trial takes place in total for 17 months

Reference diagrams

Flowchart 1. Trial flow diagram



The shaded area represents parts of the trial which does not have participant involvement

Flowchart 2. Guidance for consent

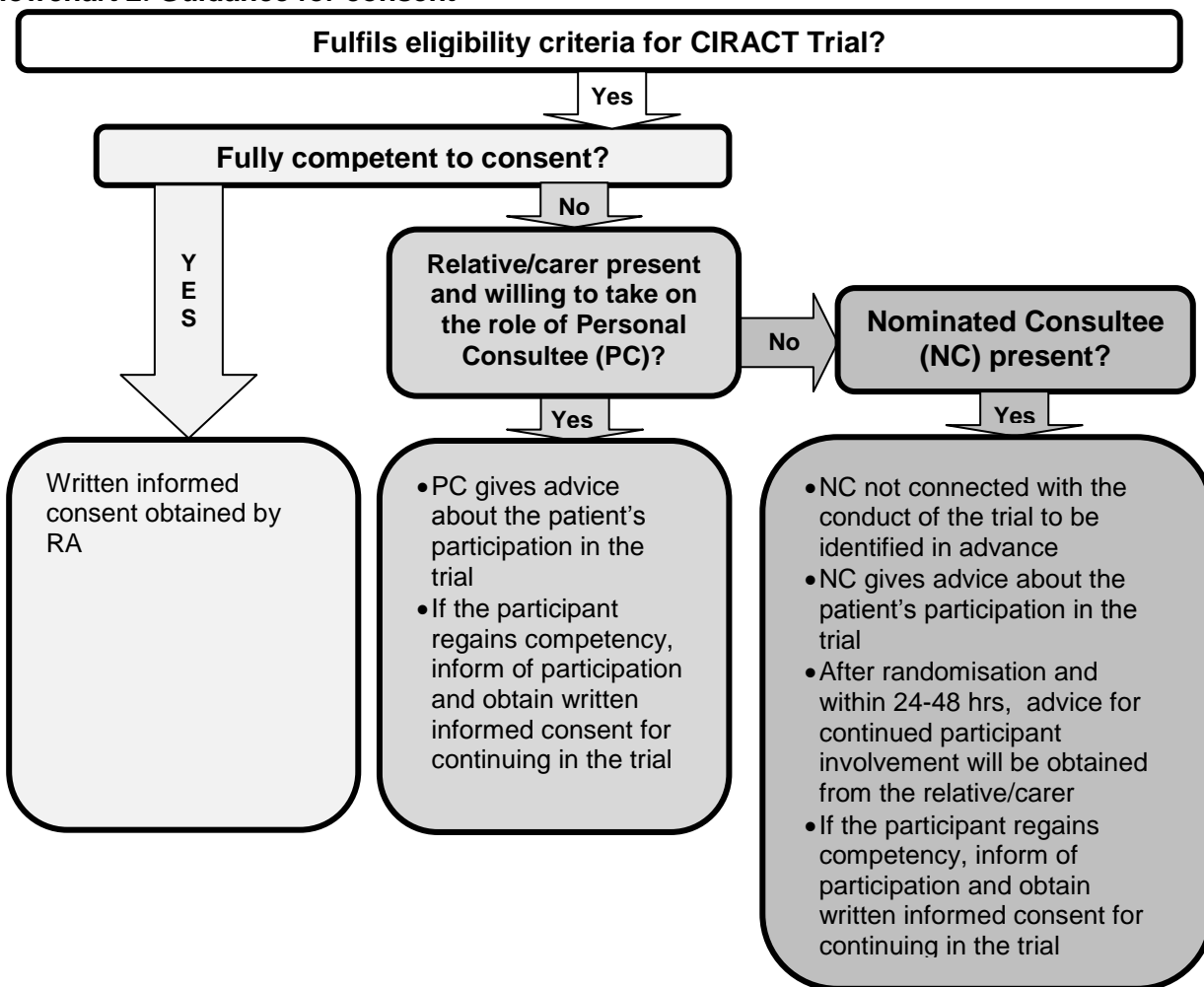


Table 1. Trial assessments

Patient assessments	Baseline	Time in hospital	DISCHARGE	Follow-up day 91(+/- 3 days) post discharge
Consent	X			
Demographics	X			X
Cognitive Assessment (MMSE)	X			
Co-morbidity scale and index (Chalson)	X			X
Barthel ADL Index	X			X
Health-related Quality of Life (EQ-5D-3L)	X			X
Randomisation	X			
CIRACT or THB rehab service		X		
Record review	X			X
Modified Client Service Receipt Inventory (CSRI) questionnaire	X			X
Face to face interview	X		X	

A selection of participants will also take part in	While in hospital	Follow-up after discharge
Participant observations (for CIRACT service)	X	
Participant interviews	X	X
A selection of Staff will take part in		
Staff observations (for CIRACT service also at home after discharge)	X	
Staff interviews	X	X

Summary

Older people represent a significant proportion of patients admitted to hospital as an emergency. Their care, compared to younger patients is much more challenging, their stay in hospital much longer, the risk of hospital acquired problems much higher, and the risk of being re-admitted within 28 days much greater. NHS Nottingham City Clinical Commissioning Group (Nottingham City CCG) currently delivers two rehabilitation services for older people admitted to hospital. One service is the traditional hospital based rehabilitation (THB-rehab) service. In the THB-rehab service patients are assessed and managed by the hospital based multidisciplinary team for the duration of their hospital stay and on hospital discharge they are referred to the community rehabilitation service and social service for personal care. The other service is a community in-reach rehabilitation and care transition (CIRACT) service. This is delivered by an occupational therapist, a junior physiotherapist and two assistant practitioners. They provide more intensive hospital rehabilitation, work closely with the patient and their carers while in hospitals and allow a more seamless, integrated discharge back to the home where they follow up the patient. A pilot comparing the two services showed that the CIRACT service resulted in a reduction in the length of stay in hospital and re-admission rates when analysed over the 4 month period.

This trial will evaluate the clinical and cost-effectiveness of the CIRACT service. This will be conducted as a randomised controlled trial (RCT) with an integral i) qualitative mechanism and action study designed to provide the explanatory and theoretical components on how the CIRACT service compares to current practice and ii) Health Economic Study to provide a detailed cost-analysis of the service.

1 INTRODUCTION

1.1 Background

The number of people aged 70 years and over in the UK is expected to double by 2025, compared to a 12% growth in the overall population ([Statistics. 2010](#)). The proportion of unplanned medical admissions contributed to by this age group has seen a significant rise in the last 5 years from 9.5% to 14% ([Blunt, Bardsley et al. 2010](#)). With ageing trends this is expected to increase significantly over the next 10 years. Many of these patients have multiple co-morbidities, such as polypharmacy, cognitive impairment and physical impairment making their care, management and timely discharge from hospital challenging. A trial comparing hospital admission of older patients with younger patients showed that hospital length-of-stay in older patients is much longer and the risk of hospital acquired complications is much higher. Furthermore the discharge planning is more complex and 28 day re-admission rates are much greater in older patients ([Sager, Franke et al. 1996](#)).

The Department of Health has allocated £150 million this financial year (2012), as part of the 'funding for re-ablement linked to the hospital discharge' funding stream ([Department of Health 2010](#)), which will be increased to £300 million by 2012/13. Primary Care Trust (PCT) organisations will be allocated the additional funding via increased revenue resource and cash limit allocations. They will be expected to develop local plans in conjunction with the Local Authority, Foundation Trusts / NHS Trusts and Community Health services, on the best way of using this money to facilitate seamless care for patients on discharge from hospital, and to prevent avoidable hospital readmissions. Some PCTs have invested in 'early supported discharge at home' schemes, some into 'community based rehabilitation' schemes and some very little investment at all. A recent review however of community and intermediate care services in the UK concluded that there were no clear patterns to the structure and organisation of community/intermediate care services in relation to their purpose, it remained unclear how different staffing configurations impact on service costs and patient outcomes, and that further evidence was required to determine the effectiveness and efficiency of these services before they should be funded ([Nancarrow, Moran et al. 2009](#)). In the Cochrane review by Bachmann et al ([Bachmann, Finger et al. 2010](#)), which examined 17 trials, comparing the effects of general or orthopaedic rehabilitation programmes with traditional hospital based rehabilitation (THB-rehab) services, concluded that inpatient rehabilitation designed specifically for elderly inpatients improved outcomes related to function, admission to nursing homes and mortality, although insufficient data were available for defining characteristics and cost effectiveness of successful programmes. Similarly in the Cochrane review by Shepperd et al ([Shepperd, McClaran et al. 2010](#)), 'Discharge planning from hospital to home' which reviewed 21 RCTs, concluded that a structured discharge plan tailored to the individual patient probably brings about small reductions in hospital length-of-stay and readmission rates for older people admitted to hospital with a medical condition, however the impact of discharge planning on mortality, health outcomes and cost remains uncertain.

In some hospitals in the UK there have been significant reductions in hospital length-of-stay, but an increase in 28 day readmission rates. Nationally over the last 6 years 28 day re-admission rates have increased from 11% to 14% ([Department of Health 2008](#)) More locally, in Nottingham, mean length-of-stay across the medical, elderly care wards over the last three years (5 wards, 6924 patients) has decreased from 14 to 9 days, but 28 day re-admission rate has increased from 14% to 19% (local unpublished audit data). Financially, re-admissions will have greater implications as the Government plans to impose penalties to hospitals if patients are re-admitted as an emergency within 28 days of being discharged ([Lansley 2010](#)) and healthcare organisation will have to return the proportion of people aged 65 years and over still at home at 91 days, following discharge from hospital into rehabilitation services as part of the NHS Operating Framework 2012/13 standards, with numbers expected to increase. The reasons for these readmissions are multi-factorial. An expanding evidence base demonstrates that serious deficiencies in quality exist for elderly patients undergoing transitions across sites of care. Patients are often unprepared for their self-management role in the next care setting ([Coleman, Parry et al. 2006](#)) receive conflicting advice regarding chronic

illness management([Grimmer, Moss et al. 2000](#); [Harrison and Verhoef 2002](#)) and are often unable to reach an appropriate health care practitioner who has access to their discharge summary when problems arise([Levine 1998](#); [Weaver, Perloff et al. 1998](#); [vom Eigen, Walker et al. 1999](#)). Furthermore, patient safety is also compromised during this vulnerable period, with high rates of medication errors([Beers, Sliwowski et al. 1992](#); [Moore, Wisnivesky et al. 2003](#); [Coleman, Smith et al. 2005](#); [Cornish, Knowles et al. 2005](#)), incomplete or inaccurate information on transfer([van Walraven, Seth et al. 2002](#)), and lack of appropriate follow-up care([Dudas, Bookwalter et al. 2001](#)). Collectively, these problems conspire to increase rates of recidivism to high intensity care settings when patients' care needs are not met, leading to greater health care costs([Boockvar, Fishman et al. 2004](#); [Services. 2006](#)).

New models of care are required which promote integration but also encourage carer and patient self management. The 'care transition model' has been proposed as a model to address potential threats to patient quality and safety during care transition([Parry, Coleman et al. 2003](#)) and has been shown to reduce early hospital re-admission rates([Coleman, Parry et al. 2006](#)). Care transition is defined as a set of actions designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location. Representative locations include hospitals, sub-acute and post-acute rehabilitation facilities, the patient's home, and long-term care facilities. Care transition is based on a comprehensive plan of care and the availability of health care practitioners who are well-trained in chronic care and have current information about the patient's goals, preferences, and clinical status. It includes logistical arrangements, education of the patient and family, and coordination among the health professionals involved in the transition. Care transition which encompasses both the sending and the receiving aspects of the transfer, is essential for persons with complex care needs. Key to this model, is a designated allied healthcare professional a 'transition coach', who is able to meet with the patient and their carers in hospital and then arrange a home visit, ideally within 48 to 72 hours after hospital discharge. The aim of the home visit is to ensure the patient has received appropriate services and equipment, co-ordinate communication between primary and secondary care, and review the patient's goals established on discharge from hospital. This is then followed up by a telephone call over the next 28 days to reinforce the importance of maintaining and supporting the patient's role in chronic illness and self management.

NHS Nottingham City Clinical Commissioning Group (Nottingham City CCG) have commissioned a pilot 'community in-reach rehabilitation and care transition' (CIRACT) service for elderly, general medical in-patients. The novel aspect of the CIRACT intervention compared to other models of care is that although the team will be based on the hospital ward, they will be employed by a community NHS provider, therefore able to bring their community knowledge into the hospital care setting, in addition to providing more intensive rehabilitation, working closer with the patient and their relatives and able to facilitate and access a wider range of care and services in the community and provide a community follow-up service. Most early /supported discharge models involve receiving patients back into the community from hospital, with little or no direct involvement in hospital based rehabilitation. In contract standard 'usual' rehabilitation, care is provided by the hospital ward based therapists, employed by the hospital, who may not have the knowledge and direct / rapid accessibility of care and services in the community.

Early pilot data has shown a reduction in hospital length-of-stay and 28 day readmission rate.

Nottingham City CCG have agreed to fund the excess treatment costs to allow a more formal randomised controlled clinical-effectiveness and detailed cost and cost-effectiveness evaluation of this project.

The outcome of the trial will have a significant influence in guiding clinical decision making with respect to allocation of re-ablement funding linked to hospital discharge planning and re-admissions in a very resource intensive and growing group of patients.

1.2 Rationale for the current trial

The specific health needs of the 70 year olds and over presents a significant and growing demand for unplanned hospital care. Service delivery needs not only to reduce unplanned care but for those

where admission to hospital is required, timely and supported re-settlement back home and avoidable re-admission is also necessary. Nottingham provides two forms of service delivery for elderly medical inpatients. One consists of the traditional hospital based multidisciplinary rehabilitation (THB-rehab) service, referring onto community rehabilitation and social services. The other, is a pilot community in-reach rehabilitation and home transition (CIRACT) service, consisting of a senior occupational therapist, junior physiotherapist and an assistant practitioner, working more closely across multiple boundaries, patients and their carers. Compared to the THB-rehab service, the CIRACT service has reduced median length of stay by 3 days and 28 day re-admission, over a 4 month period. We now propose a more formal clinical randomised evaluation of this service, including collaboration amongst clinicians, academics, service users and service providers, therefore building the research capability amongst those who manage, organise and deliver the service.

An integral qualitative action and mechanism study will inform the explanatory and theoretically evidence of how the CIRACT intervention is implemented and experienced in relation to prevailing modes of service organisation and delivery.

This study follows in the ethnographic tradition of describing and explaining social activities, including social change, through attention to the situated, naturally occurring and holistic experiences individuals and groups within their social, cultural and organisational context. In particular, it will focus on the qualitative experiences of those involved with a view to explain what works and why in relation to prevailing occupation and organisational structures and norms.

From a financial and cost point of view, we know that NHS managers are facing unprecedented financial challenges over the next few years. Therefore any new service requires both clinical and cost effectiveness evidence to support decision making. However, many research studies lack good quality costing or cost effectiveness data, and where studies have been published, average cost of events are often assigned using national and centre-specific price weights, which may not reflect true costs. Micro-costing studies involve direct enumeration and detailed costing of each input consumed ([Suh, Powers et al. 2010](#)), although are infrequently undertaken in complex interventional studies. Therefore in addition to the clinical evaluation of the CIRACT service, we propose to undertake a cost and cost-effectiveness evaluation of this service delivery, compared to the traditional hospital based rehabilitation service. The detailed costing will be undertaken by a health economic study, consisting of a 3 phases, which will run in parallel to the formal clinical randomised controlled trial evaluation, tracking the patient across the whole care pathway. This will also produce costings and methodology that may be transferable to other patient groups and service providers.

2 OBJECTIVES AND PURPOSE

2.1 Primary objective of the RCT

To assess whether the CIRACT service reduces the length of hospital stay compared to the THB-rehab service for unplanned hospital admission of people 70 years or older.

2.2 Secondary objectives of the RCT

The secondary objectives are to assess whether the CIRACT service:

1. Reduces the re-admission rate within 28 days of discharge
2. Reduces super spell bed days (total time in NHS care (hospital care + community care/ intermediate care))
3. Improves patient function (Barthel ADL Index)
4. Improves patient health related quality of life (EQ-5D-3L)

2.3 Objectives of the Qualitative Mechanism and Action Study

The objectives of the qualitative mechanism and action study are to:

1. Investigate the design and delivery of the CIRACT intervention in terms of workforce configuration, including the barriers and drivers to sustain inter-occupational and inter-organisational working.
2. Assess service user experiences of the CIRACT intervention to understand the qualitative changes in service delivery to develop recommendations on future implementation.
3. Describe and explain how the CIRACT service is implemented at Nottingham University Hospitals NHS Trust to develop evidence for future roll-out
4. Describe and explain how the CIRACT service interacts with other care processes and systems, to develop knowledge on its strategic alignment with existing care models
5. Describe and explain how the CIRACT service impacts on established roles and relationships, to understand barriers drivers to change manifest in distinct professional knowledge, practice and cultural domains
6. Describe and explain how the CIRACT service is experienced by clinicians, patients and families, to develop recommendations for improvement

2.4 Objectives of the Health Economics Study

The objectives of the health economics study are to:

1. Define the methods of data recording and observation criteria used in time and motion research.
2. Determine the cost of the CIRACT service compared to the THB-rehab service using bottom up costing approach.
3. Compare bottom –up costing results against cost estimates based on standard methods of collecting resource use information.
4. Compare social care cost of the CIRACT service compared to the THB-rehab service
5. Evaluate the cost effectiveness of the CIRACT service compared to the THB-rehab service from a NHS and PSS perspective

3 STUDY DESIGN

3.1 Primary outcomes of the RCT

The primary outcome will be hospital length of stay from admission to, to discharge from the general medical elderly care ward.

3.2 Secondary outcomes of the RCT

Secondary outcomes include:

1. Super spell bed days (total time in NHS care (all hospital care+ community care / intermediate care) at 28 and 91 days post discharge
2. Unplanned hospital re-admission at 28 and 91 days post discharge
3. Disability (Barthel ADL Index) at 91 days post discharge
4. Health related quality of life (EQ-5D-3L) at 91 days post discharge

3.3 Mechanism and Action study outcomes

The main outcome of the Mechanism and Action study will be the in-depth analysis and understanding of how and why CIRACT and THB-rehab rehabilitation services are organised and function as they do, in line with the objectives stated in Section 2,3.

3.4 Health economics outcomes

Bottom –up costing will be used to cost the CIRACT service and the THB rehab service. Time and Motion study will be a part of this methodology.

The main outcome for the cost utility analysis will be Quality Adjusted Life Years (QALYs) calculated from EQ-5D-3L using linear interpolation and area under the curve methods. Incremental cost

effectiveness ratio (ICER) will be presented with decision uncertainty represented via Cost-Effectiveness Acceptability Curves (CEACs) based on non-parametric bootstrapping of cost and effect pairs to help inform decision makers about whether the NHS should provide the CIRACT service or not compared to THB-rehab service.

3.5 Trial description

A single-centre pragmatic parallel randomised controlled trial with an integral qualitative mechanism and action and health economic study. Participants will be randomised to receive CIRACT service or THB-rehab service and will be followed-up for 91 days post discharge.

The trial will be conducted at Nottingham University Hospitals NHS Trust. The enrolment period will last for 13 months.

3.6 Randomisation

Participants will be randomly allocated in a 1:1 ratio to the two intervention groups. Sequence generation will be using computer generated random permuted balanced blocks of randomly varying size, created by the Nottingham Clinical Trials Unit in accordance with their standard operating procedure and held on a secure server. Randomisation will be done via a web-based system by a member of the research team.

3.7 Minimisation of bias

Allocation to the rehabilitation group will be concealed until after the participant baseline enrolment data set has been irreversibly entered into the trial randomisation system. This will minimise selection bias. The RA will not be aware of the rehabilitation allocation and the lead therapist will be informed by email.

The participants and CIRACT service team will not be blind to the allocated rehabilitation arm. It will be ensured that the Research Associate (RA) collecting the 28 day and 91 day data and performing the Activities of Daily Living (Barthel ADL Index) remains blind to rehabilitation allocation. At follow-up at day 91 post discharge the RA may require face-to-face contact. To prevent unblinding, the RA will request participants not to discuss any aspect of being involved with the trial.

3.8 Trial interventions

CIRACT service

The CIRACT team will jointly conduct an assessment of the participant's ability to perform certain tasks. Following the assessment a rehabilitation plan will be formulated which will be followed daily. The plan will focus on particular activities which are important to the participant. While in hospital the participants are treated every day (7 days a week) by the CIRACT team and the time of rehabilitation they receive will be dependent on their needs.

During the participant's hospital stay the CIRACT team will liaise with the participant and their carer(s) to visit the participant's home to carry out a home assessment in order to provide recommendations for equipment; make adaptations and/or modifications if required. In more complex cases the CIRACT team will take the participant out of the hospital for a home visit allowing assessment in the participants own home environment, if required.

Following hospital discharge, the CIRACT team will visit the participant at home within 48 hours of discharge. During this visit the level of rehabilitation required at home will be assessed and the CIRACT team will be able to undertake further follow-up visits as deemed necessary. .

THB-rehab service

The THB-rehab service, is provided by the hospital occupational therapy and physiotherapy services on weekdays only. Members of these teams jointly conduct an assessment of the participant's ability to perform certain tasks. Following this assessment the team will provide recommendation for rehabilitation. Depending on this advice, the rehabilitation care starts in the hospital, for instance when physiotherapy exercises need to be learned and these are practices with

the participant if time allows. Other rehabilitation care may only require some adaptation in the participant's home and for these the ward team will be asked to refer the participant to the appropriate community based services for provision of equipment at home, personal care and on-going rehabilitation where appropriate at the point of hospital discharge. Once discharged from hospital, the patient has no contact with the ward rehabilitation staff.

3.9 Duration of participation

Recruitment to the trial will be for 13 months. Follow-up will be for 91 days post discharge.

3.10 Qualitative Mechanism and Action and Health Economics Studies

An integral Mechanism and Action and Health Economic study will be conducted.

3.10.1 Qualitative Mechanism and Action Study

The Qualitative Mechanism and Action study aims to understand the situated activities and interactions that constitute the CIRACT service in comparison to THB-rehab service and to understand how these mechanics of care interact with other organisational and occupational factors located in the wider care system. The Qualitative Mechanism and Action study will involve a systematic programme of organisational profiling, observations of work processes, interviews with key informants and care providers and tracking of participants.

a. Organisational profiling

This involves acquiring factual information with regards to each ward/service, i.e. staffing levels, resources, patient throughput, commissioning arrangements and performance levels. This will be obtained through a standard profiling tool and interviews with service leaders (n=4-6). No patients will be involved in this part of the work.

b. Observations of work processes

This involves describing the general organisation and delivery of care within the two ward areas. This will involve being provided tours of the facilities, shadowing of representatives of key individuals (nurses, care assistants, therapists), observing management meetings, rest areas and clinical interactions to understand how care is organised. This will contribute to the detailed mapping of the care pathway, whilst also placing it in context, and will therefore inform parallel time-and-motion economic analysis. The process map, developed through systematic analysis of sequential work action, interaction and stages, will be used as a starting tool to identifying and tracking activities. Alongside these observations interviews with staff representatives, or focus groups where more convenient, will further specify how work is organised. These interview questions will be specified following the systematic review to reflect the theoretical models of change assumed in the CIRACT service. These observations will NOT focus directly on individual patients or their care, but it is likely that patients will see the researcher as they are in the general care setting. In line with previous ethnographic studies undertaken in the NHS posters will be displayed in ward areas raising awareness of the study. The patient information sheet informs participants about the qualitative studies and the consent form gives an option to consent to being observed.

Where any observations do involve observing direct clinical care delivery or an individual patients in anyway, this will only be done on participants who have consented to being observed. Where the research does involve shadowing clinicians in the vicinity of patients, the researcher will ensure the specific member of staff informs the patient about the research and directs their attention to the posters. The staff member or researcher will also assure the patient that the patient is not being observed, only the work of the clinician and if they would prefer the researcher can leave the local area to maintain privacy and dignity of the patient. Again, the patient and their individual care is not the focus of these observation, rather it is how services are organised.

c. **Participant tracking**

This part of the study involves close direct observations of patient care processes and interactions with different clinicians. It also involves small conversation type interviews with participants and their carers. The observations are to describe and explain how the service is organised, managed and delivered. Therefore the participants and their service providers are observed while receiving and delivering the CIRACT or THB-rehab service for the period the rehabilitation is provided to the participant from randomisation. The observations of the CIRACT service will also include the visit to the home where rehabilitation is being received.

The conversation interviews will be in a formal private setting and are recorded using a digital recorder to obtain the participant's or their carer's opinion of the CIRACT or THB-rehab service. The information given is confidential and some direct quotes may be used to help with the interpretation of the results.

3.10.2 Health Economic Study

The Health Economic study will undertake a within-trial cost utility analysis of the CIRACT service compared to the THB-rehab service from a NHS and PSS perspective. The cost of the two services to the NHS will be considered from a detailed time and motion study (phase 3) and compared against cost estimates based on standard methods of collecting resource use information. The Health Economics Study will be done in three phases:

1. A detailed structured literature review (phase 1)

The review will provide information on how to conduct the Time and Motion study (phase 3)

2. Observation and semi structured interviews (Phase 2)

The observations and interviews will provide information on how to conduct the Time and Motion study (phase 3)

3. Micro-costing study (phase 3)

Using the information from phase 1 and 2 a Time and Motion study will be conducted in 10 patients in each arm, recruited through purposive sampling, over a 6 month period. The precise time spent on each patient related activity will be recorded in detail.

3.11 Compliance with intervention

To ensure the fidelity and replicability of the intervention the member of the CIRACT team will produce an intervention manual detailing the aims of the service, treatment goals, record keeping and outcome assessments. They will also provide regular training and ensure that intervention records are kept, which will be regularly reviewed by the research team to make sure the interventions are delivered as specified. There will be random observation of the CIRACT service by the Research Team.

3.12 Maintenance of randomisation codes and procedures for breaking code

Neither the participants nor the CIRACT team will be blind to which treatment the participants will be receiving. The Research Assistant (RA) collecting the trial data at days 28 and 91 post discharge will be blind to the treatment received but there is no requirement for them to know the treatment allocation at any stage. As a result a procedure for breaking the code is not necessary.

3.13 Source data

The source data are medical notes, questionnaires, case record form (CRF) worksheets, audio recordings and interview transcripts. Demographic data, including a minimal amount of information that is required for randomisation, will be collected from each participant.

4 SELECTION AND WITHDRAWAL OF TRIAL PARTICIPANTS

4.1 Inclusion criteria

Eligible participants are patients:

1. Aged 70 years and over
2. Have been admitted to hospital on the general medical elderly care ward as an unplanned medical admission
3. Have been admitted to hospital from their own home or residential care home
4. Have their GP registered within the Nottingham City PCT catchment area
5. Admitted on Sunday -Friday

4.2 Exclusion criteria

Potential participant will be excluded if they

- Were previously bed bound
- Receiving palliative care
- Moribund on admission
- Previously included in the trial on an earlier admission
- Admitted from a nursing home

4.3 Participants who withdraw

Participants are free to withdraw from the trial at any time. The reasons for leaving the trial will be recorded, but participants are not obliged to give reasons. Participants will be assured that withdrawal will not affect the care they receive. They will be informed at the start of the trial that data collected up to the point of withdrawal will be retained and may be used in the final analysis. Participants who become moribund or have been placed on the end of life pathway will be withdrawn. Participants may be withdrawn from the trial if they fail to adhere to protocol requirements

All reasonable attempts will be made to contact any participant lost to follow-up during the course of the trial in order to complete assessments.

4.4 Managing and replacing participants who withdraw from the study early

Participants who withdraw from the study, will be referred back to their consultant for further treatment. Participants who withdraw after randomisation will not be replaced.

5 STUDY PROCEDURES

5.1 Study entry and recruitment

Patients aged 70 years having an unplanned admission to one of the two general medical elderly care wards participating in the research at Nottingham University Hospitals NUH Trust from the Nottingham City PCT catchment area will be informed about the trial by ward clinical staff as soon as possible after admission. Patients who indicate that they are interested in hearing more about the trial will be visited by the Research Assistant (RA).

The RA will explain the trial and provide the information sheet.

Patients will have the opportunity to discuss this with their family and to ask any questions they might have. Whenever possible, they will have at least 24 hours to consider participation. If the patient is willing to participate the RA will check the eligibility criteria and if still eligible they will be asked to provide written informed consent.

If the patient does not wish to participate, they will not be required to give a reason. Clinical care for the patient will not be influenced by whether or not they agree to participate. An anonymised log will

be kept of potentially eligible patients not recruited, patients who decline participation, and any other reasons for non-participation (if available).

In the Participant Information Sheet the qualitative part of the study is also explained and participants are asked to consent or opt-out of this part of the study.

While most potential participants will have capacity to consent, some may not due to cognitive impairment such as delirium or dementia. Delirium is often a symptom of an underlying condition and disappears when that condition has been treated. Patients with dementia may benefit as their hospital stay is often longer than other patients and this group of patients also experience a higher rate of re-admission.

For patients who lack capacity, the ward clinical staff would approach and inform the accompanying relative or carer about the trial. Relatives or carers who indicate that they are interested in hearing more about the trial can meet with the Research Assistant (RA). The relative or carer will be asked to act as the potential participants personal consultee, who will be able to advise the RA on the potential participant's wishes or feelings about taking part in the trial.

If an accompanying relative or carer cannot be found, the role of consultee can be fulfilled by a 'nominated consultee'. A nominated consultee will be someone unconnected with the trial, appointed by the researcher to advise him/her about the person's wishes and feelings in relation to the trial. This can be another health-care worker.

The consultee willing, to give advice will complete and sign a Declaration Form to document this advice. It will be made clear that the consultee can withdraw the advice at any stage. The patient can then be randomised.

If a nominated consultee has given advice, the researcher will speak with the participant's relative/carer to obtain advice on continued participation within 24-48 hrs after randomisation.

5.2 Treatment of participants

Once in the trial the RA will collect baseline data from the medical and nursing notes and where appropriate from the patient and/ or carer.

The baseline assessments are:

- i) socio-economic demographics (age, sex, deprivation) details
- ii) Mini Mental State Examination (MMSE) for cognitive assessment conducted by a 30-item instrument ([Folstein, Folstein et al. 1975](#)) that includes tests of orientation, memory, and concentration
- iii) The Charlson co-morbidity index ([Charlson, Pompei et al. 1987](#)) assesses co-morbidity by coding a range of co-morbid conditions such as heart disease, AIDS, cancer (a total of 22 conditions) into a single score.
- iv) The Barthel ADL index ([Mahoney and Barthel 1965](#)) assesses activities of daily living (ADL) and mobility to measure functional abilities.
- v) The ED-5Q-3L health-related quality of life measure ([1990](#)) is a standardized measure of quality of life looking at mobility, self-care, usual activities, pain/discomfort and anxiety /depression.
- vi) The modified Client Service Receipt Inventory (CSRI) questionnaire ([Beecham and Knapp 1999](#)) is a cost questionnaire to measure service cost.

Participants will then be randomised to either the CIRACT service or THB-rehab service (traditional hospital based rehabilitation service). Depending on the randomisation arm they are either seen daily and followed after discharge (CIRACT service) or for the initial assessment and then as required while in hospital (THB-rehab service).

Qualitative Mechanism and Action and Health Economic Study

The participant tracking part of the Qualitative Mechanism and Action study involves close direct observations of patient care processes and interactions with different clinicians. It also involves small conversation type interviews with patients and their carers. A total of 20 participants will be selected, from those who consented to participating in this part of the trial. Before any observations or interviews are done the RA will check that the participant is still happy to take part. Conversation interviews will be conducted with participants who consented to participation for this part of the trial. In this formal interview, which is recorded in private, using a digital recorder, the participant is asked to give their opinion of the rehabilitation service received. The information given is confidential and some direct quotes may be used to help with the interpretation of the results. In cases where the participant is incapacitated their relative will be asked to give their opinion of the rehabilitation service received.

The Time and Motion study will observe the delivery of the service and follow 20 participants (who have indicated in their consent that they would be willing to take part in the time and motion study) 10 in each intervention arm, through purposive sampling, over a 6 month period, from those who consented to participating in this part of the trial. Within each group, we will aim to include half of the participants with baseline admission Barthel ADL ≤ 14 and the other half with a Barthel ADL > 14 . The delivery of the service is being observed.

5.3 Participant follow-up

Participants will be followed up at day 91 post discharge and data collected by the RA who is blind to intervention allocation. Follow-up assessments include:

Follow up assessments at day 91 post discharge include:

- Participant is still living (established by the hospital's NHS spine portal enquiry).
- Hospital length-of-stay (ascertained by the hospital electronic database - supplemented by review of medical notes by a different member of staff to maintain blinding, if necessary)
- Unplanned hospital re-admission within 28 and 91 days post discharge (ascertained by the hospital electronic database, supplemented by review of medical notes if necessary).
- Face to face interview to collect information about the participant's:
 - place of residence
 - number of days at home following discharge
 - Barthel ADL assessment
 - EQ-5D-3L assessment
 - Modified client services receipt inventory

Qualitative Study follow-up

Semi-structured interviews will be conducted up to 91 days after discharge with some participants, to ask further information.

6 ADVERSE EVENTS

The adverse event risks of taking part in the trial is minimal as the CIRACT service is not a different type of rehabilitation but a change in delivery of the THB-rehab service (traditional hospital based rehabilitation service) the patients would receive as part of their usual care. The CIRACT service has been assessed in a pilot and no adverse events occurred..

As a result no adverse events (or serious adverse events) will be recorded or reported for this study.

In order to provide some formal reassurance that the trial is indeed of extremely low-risk, the DMC will be provided with a report detailing information, captured during the qualitative study during the observations and interviews, regarding comments about the intervention.

7 STATISTICS AND DATA ANALYSIS

7.1 Estimated sample size

The primary statistical analysis will be to test for a reduction in the length of hospital stay (length-of-stay). The four month pilot data showed the log transformed length-of-stay to be normally distributed with standard deviation 0.9. Therefore, 111 patients per arm will be required to detect a clinically important effect size of 3 days (ratio of means 0.7) with alpha 5% and 80% power. Allowing for 5% dropout rate at discharge, 240 patients in total will be required. Further allowing for 20% exclusions and a 10% refusal rate, we will need to screen 350 patients over 12 months. There are five health care of older people's (HCOP) general medical wards currently admitting 410450 patients per ward each year and the current CIRACT service is able to manage 30 patients per month. We propose to conduct the trial at two wards which will give the required numbers within our proposed timetable for the study.

7.2 Outcomes assessment

Baseline assessments will be conducted by the RA and include:

Socio-economic demographics details (age, sex, deprivation)

- Cognitive assessment ([Folstein, Folstein et al. 1975](#)), 30-item instrument that includes tests of orientation, memory, and concentration)
- Charlson Comorbidity Index. The Charlson co-morbidity index allows a range of co-morbid conditions such as heart disease, AIDS, cancer (a total of 22 conditions) to be coded into a single score. Each condition is assigned with a score and then the scores are summed up and given a total score.
- Barthel Activities of Daily Living Index. This is an ordinal scale used to measure performance in basic Activities of Daily Living. Each performance item is rated on this ordinal scale with a given number of points assigned to each level or ranking. It uses ten variables describing activities of daily living (ADL) and mobility. A higher number is associated with a greater degree of independence ADL Function).
- EQ-5D health-related quality of life measure (EuroQol Group 5-Dimension 3 level Self-Report Questionnaire. This is a standardized measure of health utility (quality of life) comprising five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety /depression. Each dimension has three levels: no problems, some problems, severe problems. The scores for each of the five dimensions are combined in a five digit number representing health status that can be converted into a summary index.

Primary Outcome of RCT

The primary outcome will be hospital length of stay from admission to, to discharge from, the general medical elderly care ward. This will be calculated from the date of randomisation to the date of discharge from the general medical elderly care ward.

Secondary outcomes of RCT

- Super spell bed days (total time in NHS care (all hospital care+ community care / intermediate care)
- Unplanned re-admission rates at day 28 and day 91
- Barthel ADL at 91 days post discharge from the acute hospital.
- EQ-5D-3L at 91 days post discharge from the acute hospital.

Barthel ADL and EQ-5D will be undertaken by the RA (face to face interviews, blind to allocation)

7.3 Analysis plan

We will compare the baseline differences between the CIRACT service and the THB-rehab service (in terms of the baseline assessment tests and assesses differences in any other potential confounding variables (age, sex, co-morbidity index, cognition and baseline ADL). All outcome measures will be summarised and 95% confidence intervals constructed for the difference in outcomes between standard care and intervention group. Independent t-tests or non-parametric

tests will be used for continuous outcomes as appropriate to the distribution, and a further multi-variable regression analysis will be used to adjust for confounding baseline variables. Readmission rates will be reported with 95% confidence intervals and a Fisher's exact test used to detect significant differences between groups. Logistic regression will be used to adjust for confounding baseline variables. Both adjusted and unadjusted values will be reported.

Patients excluded at discharge will be excluded from the length of stay (LOS) analysis but a sensitivity analysis using proxy LOS models will be used to check the robustness of the exclusion. The final intention-to-treat analysis will include all randomised participants for whom the follow-up assessment of the primary outcome measure is available. The per-protocol analysis will include all randomised participants who are deemed to have no protocol violations.

Further details of the analysis will be supplied in a Statistical Analysis Plan to be finalised before database lock.

7.4 Criteria for terminating the study

The study may be stopped as a whole because of a change in opinion of the REC or safety concerns or issues with trial conduct at the discretion of the sponsor.

7.5 Procedures for accounting for missing, unused and spurious data

The data entered into the database will be validated prior to analysis to correct spurious and missing data, if possible, by referring to the original data source.

In the case of missing outcome data, we will inspect the pattern of the missing data and use appropriate multiple imputation such as mixed models for repeated measurements (accounting for dropout bias using mixed-effects models ([Mallinckrodt, Clark et al. 2001](#))). If there is evidence for the data being Missing Not at Random, such as significant difference in drop-out rate between arms, then a sensitivity analysis will be performed.

8 MECHANISMS AND ACTION ANALYSIS

The qualitative data will be analysed following the principles of interpretative thematic analysis, informed by the principles and stages of grounded theory. This will involve close reading of all data and systematic coding using specialised computer software. This will be undertaken by members of the research team who will work together to develop a shared coding frame and through the principles of constant comparison will develop a robust thematic analysis of the data to address the stated research questions in line with the objectives in Section 2.3.

9 HEALTH ECONOMICS ANALYSIS

The cost of the two services to the NHS will be considered from a detailed time and motion study (see below) and compared against cost estimates based on standard methods of collecting resource use information (e.g. staff clinical logs of activity) valued using published sources (e.g. PSSRU and NHS Reference Cost Schedules). The wider resource use to the patient's personal and social service use (for example home help, meals on wheels) will be collected 91 days post discharge by administering a modified client service receipt inventory (CSRI) patient questionnaire ([Beecham and Knapp 1999](#)). This will increase the external validity and generalizability of the cost data.

Studies in the past have used a wide variety of costing methodologies ([Mogyorosy and Smith 2005](#)) but there has been no study showing a step-by-step practical analysis of costs for delivering rehabilitation services for elderly in-patients ([Melin, Hakansson et al. 1993](#)). Direct measurement of costs in complex interventions are reported to be time consuming to implement ([Shepard, Hodgkin et al. 2000](#)), expensive and not always a practical technique to run ([Muennig 2002](#)). We propose a formal micro-costing Time and Motion study (TMS), which will be undertaken in parallel to the RCT.

By using TMS as a technique of cost estimation, we will be able to obtain accurate information on the resources used, which will enable researchers and commissioners to estimate the precise costs of the intervention for its component parts rather than just the total cost of the intervention overall. We will also estimate the trade off between the cost and practicality of data collection against accuracy in a TMS and establish the most appropriate costing techniques.

Phase 1: Detailed Structured Literature review

We will carry out a structured literature review rather than a systematic review which will enable a review of a larger range of information without imposing inclusion/exclusion criteria. The exact topic of review will be broad and we will aim to examine the consistency of design, methodological quality, methods of data recording and observation criteria used in time and motion research. We will also identify the components of any intervention that are likely to be included in the costing, methods of direct observation of resource utilisation and monetary valuation of resources. These results will be used as an exemplar of how such criteria methods might be applied in our study. Search criteria will include:

'Time Studies', 'Studies,Time', 'Study, Time', 'Time Study', 'Time and motion study/methods', 'Micro costing', 'micro-costing', 'microcosting', 'Account classification', 'Activity logs', 'Manager surveys', 'Naturalistic studies', 'Work samples', 'Observer based'. The following electronic databases will be searched from inception: Medline (Ovid); Medline in Process; CINAHL; EMBASE; EconLit; the Cochrane Library including the Cochrane Database of Systematic Reviews, Cochrane Controlled Trials Register (CENTRAL), DARE, NHS EED and HTA databases; Science Citation Index (SCI). Current research registers (e.g. the NIHR CRN Portfolio, Current Controlled Trials, ClinicalTrials.gov) will also be searched.

Data extraction will be performed by two members of the research team independently, and a consensus meeting for the analysis of results will be performed using a subgroup of the study team (4 people). As well as extracting data, each included paper will be reviewed for methodological quality based on appraisal tools suited to the paper's design, which addresses the issue of assessment of quality (risk of bias). No studies/papers/documents will be excluded based on methodological quality and all studies pertaining to the research question will be included. The critical ingredients of care will be identified from thematic and narrative reporting. Vignettes of the methods and data recording procedures will be produced for phase 2 and 3 of the TMS.

Phase 2: Observation and Semi Structured Interviews

2a: The CIRACT and THB-rehab service will be mapped out into a flow chart to formulate top level activity codes for the RA to utilise in the observation phase. The RA will then observe the steps involved in delivering the two services and further map out all the associated activities into different subcategories to design a process map. The process map will be used as a starting tool in identifying and tracking activities. One of the limitations of an observational study is the potential for observer induced bias, however studies have shown that one to one observer bias diminishes over time as the participants becomes less aware of the observation for extended periods of time. Thus this phase of observation is designed to inform the RA about the process and reduce observer bias rather than collect research data.

2b: A qualitative researcher will review the tasks captured in the observational and mapping process in order to conduct Semi Structured Interviews. Three members of CIRACT and 3 of the THB-rehab team will be interviewed. The interviews will be audio taped and transcribed. Thematic analysis will be undertaken, supported by NVivo8 software to identify themes

emerging inductively from data, to complete the process mapping. The findings from this phase and phase 1, will then be used to produce the final mapped process that accurately defines and quantifies the activities and resources used and an activity list and location codes that will then be used in phase 3 (below). This will eliminate the bias of inappropriate data recording by detailing appropriate assumptions that will be made about the beginning and end point of each activity and increase the quality and reliability of the micro-costing data recording.

Phase 3: Micro-costing study

A micro-costing analysis will be conducted in 10 patients in each arm, recruited through purposive sampling, over a 6 month period. Within each group, we will aim to recruit half of the participants with baseline admission Barthel ≤ 14 and the other half with a Barthel ADL >14 . We will observe the variability of resource use and cost amongst the two groups and if we observe a significant resource use / cost changes amongst participants, we will increase our sample size to observe more patients. We are interested in detailed recording of the precise time spent on each patient related activity, therefore each activity will be monitored to estimate the number of observations needed to establish the mean cost for the intervention. Activities will be listed with location codes for the researcher to record the code as they observe and observation measured using a digital stopwatch. Data collected will be coded and entered into the database.

10 DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

Direct access will be granted to authorised representatives from the sponsor as requested for study-related monitoring and audit.

11 QUALITY CONTROL AND QUALITY ASSURANCE PROCEDURES

The study will be conducted in compliance with the current revision of the Declaration of Helsinki (last amendment October 2008), with relevant regulations, and with MRC Guidelines for Good Clinical Practice in Clinical Trials (1998) which is based on ICH guidelines for GCP (CPMP/ICH/135/95) July 1996.

Compliance with the trial protocol will be ensured by a number of procedures:

11.1 Data collection and processing

Data will be collected using specific CIRACT Trial data collections forms. Processing of trial data and monitoring for consistency, validity and quality will be done as data accumulate by the Nottingham Clinical Trials Unit. Screening will include computerised checks for out-of range data, and cross-checks for conflicting data within and between data collections forms. Missing data and data queries will be referred promptly back to the recruiting site for clarification.

11.2 Monitoring

Regular monitoring will be performed according MRC Guidelines for Good Clinical Practice in Clinical Trials. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents. Following written standard operating procedures, the Trial Manager or where required, a nominated designee of the Sponsor, will verify that the clinical study is conducted and data are generated, documented and reported in compliance with the protocol GCP and the applicable regulatory requirements.

11.3 Archiving

Data and all appropriate trial documentation will be stored for a minimum of 10 years after completion of the trial, including the follow-up period. The trial master file and trial documents held by the Chief Investigator on behalf of the sponsor will be archived in secure archive facilities at Nottingham University Hospitals NHS Trust. This archive will include all trial databases and associated meta-data encryption codes.

12 STUDY MANAGEMENT

Prior to the commencement of the trial, the research team and NCTU Trial Manager will meet to discuss implementation and training issues to ensure that all members are familiar with all aspects of the trial. The Research Assistant will have direct contact with the NCTU Trial Manager, who will keep track of recruitment and data collection.

Day-to-day management of the study will be the responsibility of the Trial Management Group. The Trial Management Group will report to the independent Trial Steering Committee. An independent Data Monitoring Committee will monitor safety of participants, and will report to the Trial Steering Committee. Trial co-ordination will be through the Nottingham Clinical Trials Unit (NCTU).

12.1 Trial Management Group

The Trial Management Group (TMG) will include the Chief Investigator (chair), members of the PPI advisory group, NCTU Research Manager and/or Senior Trial Manager, Trial Manager, Trial Statistician, and other project staff. This group, based at the NCTU, will meet regularly.

12.2 Trial Steering Committee

The independent Trial Steering Committee (TSC) will provide oversight of the trial. It will meet (in person or by telephone conference) prior to commencement of the trial, and then at regular intervals until completion (at least annually). A service user representative will also be invited to join this group. It will advise on recruitment strategies, monitor progress with recruitment, and check adherence to the trial protocol. Observers from NIHR Health Services and Delivery Research Programme (the funder) will be invited to TSC meetings.

Specific tasks of the TSC are:

- to approve the trial protocol
- to approve necessary changes to the protocol based on considerations of feasibility and practicability
- to receive reports from the Data Monitoring Committee
- to resolve problems brought to it by the co-ordinating centre and TMG
- to ensure publication of the study results

12.3 Data Monitoring Committee

An independent Data Monitoring Committee (DMC) will be established. The DMC will meet as agreed and will monitor the trial conduct and receive unblinded data in accordance with the pre-agreed terms of reference. Only the DMC will have access to unblinded data until the final assessment has been completed. The DMC will establish stopping rules and may recommend discontinuation of the study if significant ethical or safety concerns arise prior to trial completion.

13 ETHICS

13.1 Approvals

The Chief Investigator will obtain approval from the Research Ethics Committee, which will be submitted for Site Specific Approval (SSA) at each participating NHS Trust. The Chief Investigator will require a copy of the SSA approval letter before accepting participants into the trial.

All subsequent amendments to the protocol and associated documents will be submitted for approval prior to their implementation. The trial manager will provide reports to the ethics committee on behalf of the chief investigator at the intervals stipulated in the ethics committee guidelines.

Source documents shall be filed and may include but are not limited to consent forms, current medical records and CRFs. Only trial staff listed on the delegation log shall have access to the trial documentation other than the regulatory requirements listed above.

The study will be registered on the ISRCTN website (<http://isrctn.org/>).

13.2 Participant confidentiality

Confidentiality of all participant information will be maintained throughout the trial. Each participant will be assigned a unique trial identification number, allocated at randomisation. This number will be used for data collection forms, other trial documents, and the trial database. Trial documents and the trial database will also use participant's initials (of first and last names separated by a hyphen or a middle name initial when available). The date of birth (dd/mmm/yyyy) is entered into the database once for the use of data verification and is not visible when entering study data.

Data collection forms will be treated as confidential documents, and held securely. Participant identifiable data will only be accessed by the participant's member of the clinical care team and with the consent of the participant by the research team. Participants have the right to revoke their consent for the use of personal information.

The Chief Investigator is the custodian of the data. Participants will not be identified in any future publication.

14 DATA HANDLING AND RECORD KEEPING

All trial data will be entered on a trial specific database with participants identified only by the unique trial number, date of birth, and initials. The database will be developed and maintained by the trial coordinating centre at the NCTU. Access to the database will be restricted and secure. Data quality and compliance with the protocol will be assessed throughout the trial by verification of trial data against clinical records, and by data checking for accuracy and internal consistency.

For the follow up phase, identifiable information about participants will be held in a separate database to the trial anonymised data. Access to this information will be restricted to those involved in the follow up phase, as authorised by the Chief Investigator.

15 FINANCING AND INDEMNITY

NIHR Health Services and Delivery Research Programme is funding this trial. Nottingham University hospitals NHS Trust will act as the main sponsor for this trial.

Standard NHS Indemnity applies.

Participant visits in their own home or at community centres will be done in accordance to the sponsor's lone working policy.

16 PUBLICATION POLICY

16.1 Reporting, dissemination and notification of the results

The trial has been designed and will be reported according to the CONSORT guidelines.

The findings from this trial will contribute to knowledge on the delivery of change across organisational systems, linkages between different care agencies and sectors and detailed resource use and costing associated with complex interventions.

Findings will be published in relevant periodicals and updates sent to relevant websites e.g. Health Service Journal, NHS Primary Care Commissioning website. Methodology papers including those describing the development of methodology and the protocol are likely to be targeted at major online free to access journal, such as Trials. Major papers will include very high impact journals (e.g. Lancet), and other papers in the appropriate high impact general or specialist journals. We will also undertake high impact conference presentations.

Participants who requested a copy of the report will be sent a lay summary of the study.

16.2 Policy for publication and authorship

A publication policy will be agreed with co-applicants and a systematic plan, including authorship, for the peer reviewed publications.

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