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A feasibility trial of the partners at care transitions (PACT) intervention

Submission date
02/05/2019

Recruitment status
No longer recruiting

Registration date
16/07/2019

Overall study status
Completed

Last Edited
11/08/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Transitions of care from hospital to home can be risky, especially for older people with multiple health conditions. Previous research has suggested that the post-discharge period may be improved by better involving patients and families in their care. This study forms part of a programme of research which aims to develop an intervention to improve the safety and experience of transitions from hospital to home for people aged 75 years and over.

Who can participate?
Patients aged 75 and over who are community-dwelling at the time of admission and anticipated to be discharged to their own home or that of a relative.

What does the study involve?
A minimum of 200 patients will provide informed consent to complete a questionnaire at three-time points postdischarge and for routine data about their care to be collected from medical records. On intervention wards, a subset of 20-24 of these patients will also consent to a qualitative evaluation of the intervention (interviews and observation). Up to 28 staff will be interviewed to gain their views on the intervention.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in the study. However, it may help improve future services to support older people as they transition from hospital to home. As a small token of our appreciation for their support, participants will receive a £5 gift voucher with each questionnaire. We do not think that there are any disadvantages or risks to participating in the study.

Where is the study run from?
1. Mid Yorkshire Hospitals NHS Trust
2. Airedale NHS Foundation Trust
3. Leeds Teaching Hospitals NHS Trust

When is the study starting and how long is it expected to run for?
September 2019 to July 2020 (updated 10/01/2020, previously: April 2020)

Who is funding the study?
National Institute for Health Research (NIHR), UK

Who is the main contact?
1. Dr Ruth Baxter
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
42191

Study information

Scientific Title
Partners at Care Transitions (PACT): Improving patient experience and safety at transitions of care - Assessing the feasibility of using the PACT intervention to improve safety and experience of the transition process in a randomised controlled trial setting.

Acronym
PACT

Study objectives
This study explores the feasibility of the PACT intervention and trial methodology to refine the intervention and inform the decision whether or not to proceed to a full cluster randomised controlled trial. The following objectives will be addressed:
1. Explore the acceptability, usefulness and feasibility of intervention components to patients and carers
2. Explore the acceptability, usefulness and feasibility of intervention and implementation components to ward staff
3. Assess the feasibility of methods to identify, recruit and retain patients in the trial and determine the best way to follow-up patients in this population
4. To identify the required approach for obtaining hospital emergency readmission data:
a. To explore the most accurate and feasible way of obtaining these data for consented participants
b. To explore the most accurate and feasible way of obtaining non-identifiable readmission data for non-consented participants
c. To identify the optimal time period over which baseline readmission data should be collected
5. To identify the required approach for obtaining health economic data
6. To optimise the intervention and implementation & training package
7. To explore how we might measure fidelity of the intervention
8. To inform the development of a definitive protocol for the cRCT

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/06/2019, NHS HRA Wales REC 7 (ADDRESS; 01874 615949; Wales.REC7@wales.nhs.uk), ref: 19/WA/0162

Study design
Feasibility cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
No specific condition. Patients will have been admitted to hospital for care for conditions such as stroke, COPD, infection, or with injuries from falls. It is not possible to know in advance what conditions the patients will have because we are recruiting from a range of hospital specialties which are likely to include stroke, respiratory, cardiology, and elderly medical wards. Patients may have dementia and/or acute delirium alongside their presenting complaint.

Interventions
A feasibility cluster randomised controlled trial will be conducted across 10 wards clustered within three acute NHS trusts. Wards will be randomised in an unequal allocation ratio (3:2) with six randomised to the intervention and four to usual care. Blinding will not used due to this unequal allocation. Recruitment and follow up of patients within each ward will take place over a 7 month period.
Randomisation will be done using naïve minimisation with a base probability 1.0 (i.e. deterministic minimisation) will be conducted using the following key wards characteristics: ward type (speciality), the percentage of patients over 75 years, and NHS Trust.

Intervention wards will deliver the Partners At Care Transitions (PACT) intervention - a patient-facing intervention which seeks to improve the safety and experience of older people as they transition from hospital to home. Control wards will deliver usual care to their patients.

A minimum of 200 patients (approximately 20 patients per ward) will be recruited to participate in the trial. Participants will provide informed consent to: baseline data collection at the point of recruitment; follow-up questionnaires to assess patient reported outcomes at three points post discharge (up to 21 days post discharge, 30 days and 90 days post-discharge); and access to their medical records to gather routinely collected data (e.g. readmissions post discharge, and information about co-morbidities). Depending on their preferences, patients may be followed-up by post, telephone or email. At the 30 day follow-up, if patients received a copy of the PACT intervention while they were in hospital, patients will be asked to return it to the research team.

Within the sample of 200 patients, a nested sub-sample of between 20-24 patients will be recruited to participate in a qualitative assessment of feasibility. If relevant, the informal carers of these patients will also be recruited. In addition to completing the trial procedures outlined above, these participants will consent to the observation of their care while they are in hospital, and up to two interviews (post-discharge and 30 days post-discharge). Field notes will be taken during observations, and interviews lasting between 30 and 60 minutes and will be audio-recorded and transcribed. In addition, up to 28 staff members (24 from intervention wards and 4 from control wards) will be invited to participate in an interview lasting between 15 and 30 minutes. Ward level observations and informal conversations will also be conducted on participating wards.

In addition, this study seeks to identify an efficient and accurate way of accessing readmission data for patients who are discharged to their own homes rather than other usual places of

residence (e.g. nursing homes). Confidentiality Advisory Group advice will be gained to access the medical records of 100 patients without their consent to assess their actual discharge destinations (own home vs nursing/care home or other).

The findings from this study will be used to optimise the intervention, implementation package, and the trial methodology, and ultimately inform the decision about whether to proceed to a full trial.

Intervention Type
Behavioural

Primary outcome(s)
30-day emergency hospital readmission measured using patient records

Key secondary outcome(s))
1. Safety and experience of older people during transitions from hospital to home measured using the Patient At Care Transitions Measure (PACT – M); Timepoint(s): up to 21, 30 and 90 days post-discharge
2. Patient-centred quality of care transitions measured using the Care Transitions Measure 3 items (CTM-3); Timepoint(s): up to 21, 30 and 90 days post-discharge
3. Quality of life measured using the EuroQol 5-Dimension Health Questionnaire (5 levels) (EQ5D-5L) and Proxy EQ5D-5L; Timepoint(s): up to 21, 30 and 90 days post-discharge
4. Healthcare resource use measured using an adapted version of Client Service Receipt Inventory (CSRI); Timepoint(s): up to 21, 30 and 90 days post-discharge
5. Utility of the intervention measured using...

Completion date
31/07/2020

Eligibility

Key inclusion criteria
1. Aged 75 and over
2. Community-dwelling at the time of admission and anticipated to be discharged to their own home or that of a relative (this can include a period of rehabilitation after hospital discharge)
3. Staying for at least one night on a participating ward
4. Ability to read and understand English
5. Willing and able to give informed consent (or personal consultee if lacking in mental capacity)

For patients who lack capacity, eligible consultee/proxys (e.g. carers) will fulfil the following criteria:
1. A primary carer for the patient
2. Provides informal care to the patient (i.e. not paid / professional)
3. Willing to act as a consultee for the patient and/or willing and able to give informed consent to act as the patient’s proxy throughout the study.
4. Ability to read and understand English

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Senior

Sex
All

Key exclusion criteria
1. Out of area patients and/or patients who are to be transferred to another hospital
2. Admitted for psychiatric reasons (other than dementia/delirium)
3. Nursing/residential home resident or planning to be discharged to a nursing / residential home on a permanent basis
4. Less than one overnight stay (on the participating ward) at time of recruitment
5. Identified as being at the end of their life/subject to fast-track discharge to palliative care
6. Unable to read and understand English
7. Unable to give informed consent and where a suitable personal consultee cannot be identified, or if no one is prepared to act as a consultee for the patient

Date of first enrolment
02/09/2019

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Mid Yorkshire Hospitals NHS Trust
Rowan House
Aberford Road
Wakefield
United Kingdom
WF1 4EE

Study participating centre
Airedale NHS Foundation Trust
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Skipton Road
Steeton

Keighley
United Kingdom
BD20 6TD

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
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Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-1214-20017

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2022	03/10/2022	Yes	No
Results article		01/04/2025	11/08/2025	Yes	No

Protocol article	protocol	02/09/2020	11/09/2020	Yes	No
Basic results		11/08/2021	11/08/2021	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes