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PACT: cluster randomised controlled trial of the 'Your Care Needs You!' intervention

Submission date
03/02/2020

Recruitment status
No longer recruiting

Registration date
11/02/2020

Overall study status
Completed

Last Edited
05/08/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Going home from hospital can sometimes be a tricky period for people, particularly older people who may have more health problems. This can be made worse when people don't understand what needs to be done to manage their health. For example, they may not understand their medicines or they may have lost the confidence to move about in their homes because they didn' t move about much when in hospital. Sometimes this leads to unnecessary hospital readmissions. Patients who are more involved in their care in hospital do better when they get home. Researchers have designed an approach called 'Your Care Needs You!' which includes a patient booklet, a short film and an enhanced discharge letter. These aim to encourage patients to 'know more' and 'do more' in hospital so that they are better prepared to manage at home. The study aims to find out if the 'Your Care Needs You!' approach reduces hospital readmissions and improved the quality and safety of the transition from hospital to home for older people.

Who can participate?
Patients aged 75 and over who have stayed for at least one night on a participating ward and are going to be discharged to their own home or that of a relative's

What does the study involve?
The research will take place within 40 wards (across 8 acute NHS Trusts) over a 12-month period. In total, 20 wards are randomly allocated to deliver the 'Your Care Needs You'intervention and 20 wards deliver care as usual. On the wards that have been selected to use 'Your Care Needs You', all patients can have the booklet, see the film and have an enhanced discharge letter. The researchers compare outcomes (such as hospital readmissions or experience of transition to home) for people who receive 'Your Care Needs You!' with those who don't. The evaluation will involve taking informed consent from patients and then asking them to complete some questionnaires by post or with telephone support. There will be three questionnaires, one at around 7 days after discharge, one at 30 days and one at 90 days. The researchers will also ask some patients to take part in an interview to ask them about their experience of the approach.

What are the possible benefits and risks of participating?
There will be no direct benefits for participants because they will only be consenting to complete questionnaires. Patients on the wards selected to give out 'Your Care Needs You!' will

get the booklet and film etc regardless of whether they decide to take part in the research evaluation. The benefits to taking part in the evaluation might actually be for patients in the future because by taking part in the research the researchers will get data that will tell them if they have improved the patient experience. There are no known risks to taking part in the evaluation.

Where is the study run from?
The study will be run from the Yorkshire Quality and Safety Research Group based in Bradford. The team will be supported by the York Trials Unit. The study will include up to nine NHS Hospital Trusts from the Yorkshire region and between 40 and 50 wards within these Trusts.
1. Hull And East Yorkshire Hospitals NHS Trust
2. York Teaching Hospital NHS Foundation Trust
3. Calderdale and Huddersfield NHS Foundation Trust
4. Barnsley Hospital NHS Foundation Trust
5. Bradford Teaching Hospitals NHS Foundation Trust
6. Doncaster And Bassetlaw Teaching Hospitals NHS Foundation Trust
7. Harrogate And District NHS Foundation Trust
8. Leeds Teaching Hospitals NHS Trust

When is the study starting and how long is it expected to run for?
August 2019 to October 2023

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

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
277060

Central Portfolio Management System (CPMS)
44559

Study information

Scientific Title
A cluster randomised controlled trial to assess the effectiveness and cost-effectiveness of the 'Your Care Needs You!' intervention to improve safety and experience of care transitions

Acronym
PACT

Study objectives
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. In this study, a cluster Randomised Control Trial will be conducted to assess the effectiveness of, cost-effectiveness of, and fidelity to the Your Care Needs You! (YCNY) intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 07/08/2020:
Approved 31/01/2020, amendment 1 approved 27/04/20202, North East – Newcastle and North Tyneside 2 REC (NHSBT Newcastle Blood Donor Centre, Holland Dr, Newcastle upon Tyne NE2 4NQ, UK; Tel: +44 (0)207 1048091, +44 (0)207 104 8222; Email: nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net), REC ref: 20/NE/0020

Previous ethics approval:
Approved 31/01/2020, North East – Newcastle and North Tyneside 2 REC (NHSBT Newcastle Blood Donor Centre, Holland Dr, Newcastle upon Tyne NE2 4NQ, UK; Tel: +44 (0)207 1048091, +44 (0)207 104 8222; Email: nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net), REC ref: 20/NE/0020

Primary study design
Interventional

Study design
Randomized; Both; Design type: Process of Care, Complex Intervention, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Care transitions

Interventions
Current interventions as of 07/08/2020:
The research will take place within 40 wards (across 8 acute NHS Trusts) over a 12 month period. In total, 20 wards will deliver the intervention and 20 wards will deliver care as usual. A minimum of 1000 patients will provide informed consent to complete a questionnaire at three timepoints post-discharge and for routine data about their care to be collected from medical records. Data from the questionnaires will be used to measure the effectiveness of the YCNY intervention at improving quality and experience of transitions, quality of life, health care utilisation and 60/90 day unplanned readmission rates (secondary outcomes).

The researchers will also obtain anonymised ward level data for 5,440 patients discharged from participating wards during the period of recruitment to assess the effectiveness of YCNY in reducing 30-day unplanned readmission rates (primary outcome). A process evaluation assessing intervention fidelity and mechanisms of action/contextual factors influencing intervention delivery, will also be conducted. In eight intervention wards, a subset of 24-30 of these patients (with/without carers) will also consent to a qualitative evaluation of the intervention (interviews and observations). Up to 45 staff will be interviewed to gain their views on the intervention and explore contextual factors.

Previous interventions:
The research will take place within 40 wards (across 8 acute NHS Trusts) over a 12 month period. In total, 20 wards will deliver the intervention and 20 wards will deliver care as usual. A minimum of 782 patients will provide informed consent to complete a questionnaire at three timepoints post-discharge and for routine data about their care to be collected from medical records. Data

from the questionnaires will be used to measure the effectiveness of the YCNY intervention at improving quality and experience of transitions, quality of life, health care utilisation and 60/90 day unplanned readmission rates (secondary outcomes).

The researchers will also obtain anonymised ward level data for 7,000 patients discharged from participating wards during the period of recruitment to assess the effectiveness of YCNY in reducing 30-day unplanned readmission rates (primary outcome). A process evaluation assessing intervention fidelity and mechanisms of action/contextual factors influencing intervention delivery, will also be conducted. In eight intervention wards, a subset of 24-30 of these patients (with/without carers) will also consent to a qualitative evaluation of the intervention (interviews and observations). Up to 45 staff will be interviewed to gain their views on the intervention and explore contextual factors.

Intervention Type
Behavioural

Primary outcome(s)
30-day hospital emergency readmissions, measured using routinely collected data on 30 unplanned hospital readmissions

Key secondary outcome(s)
1. Quality and experience of care transition for patients, measured using Partners at Care Transitions Measure (PACT-M) at 7 days, 30 days and 90 days post discharge
2. Difficulties that patients experienced in hospital that could affect them after discharge, measured using Post Hospital Syndrome questionnaire at 7 days post discharge
3. Quality of life, measured using EuroQol 5-Dimension Health Questionnaire (5 levels) (EQ5D-5L) and Proxy EQ5D-5L at 7 days, 30 days and 90 days post discharge
4. Healthcare resource use measured using unvalidated questions about services used since discharge at 7 days, 30 days and 90 days post discharge
5. Utility of the intervention measured using unvalidated questions asking about the intervention at 7 days post discharge
6. Unplanned readmissions at 60 and 90 days, measured using routinely collected data

Completion date
31/10/2023

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
75 Years

Sex
All

Key exclusion criteria
Current participant exclusion criteria as of 07/08/2020:
1. Patients who have previously been recruited to the study (e.g. during a different admission or on a different ward)
2. Patients / Consultees who require an interpreter (e.g. because they are unable to read or understand English).
3. Patients who live out of the area included in the study
4. Patients who are expected to be transferred to another acute hospital/trust prior to discharge
5. Admitted for psychiatric reasons (other than dementia/delirium)
6. Nursing/residential home resident or planning to be discharged to a nursing / residential home on a permanent basis
7. Identified as being at the end of their life / subject to fast-track discharge to palliative care
8. 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

Previous participant 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)
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 and without a carer who can 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
8. On an acute medical admission unit and to be transferred to another ward within the hospital

Date of first enrolment
16/11/2020

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
-
United Kingdom
-

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

Funder(s)

Funder type
Government

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

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from The York Trials Unit

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/05/2025	05/08/2025	Yes	No
Protocol article		14/10/2023	16/10/2023	Yes	No
Basic results			12/11/2024	No	No
HRA research summary			28/06/2023	No	No
Other files			05/08/2025	No	No
Other publications	process evaluation results ran alongside the PACT trial	28/01/2025	05/08/2025	Yes	No
Participant information sheet	version v1	10/10/2019	11/02/2020	No	Yes
Protocol file	version v1	12/12/2019	11/02/2020	No	No
Statistical Analysis Plan	version 1	11/02/2020	12/08/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes