The HOME Study: A study comparing two different ways of looking after older people in hospitals to see if we can improve how quickly they go home

Submission date 03/01/2018	Recruitment status No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 12/01/2018	Overall study status Completed	[X] Statistical analysis plan [X] Results
Last Edited 12/08/2024	Condition category Other	Individual participant data

Plain English summary of protocol

Background and study aims

NHS general hospitals have more than two million unplanned admissions of people aged 65 and older every year. These patients typically spend more time in hospital than those aged under 65. Long hospital stays are bad for older patients: they can get new illnesses like infections and lose their independence. They are also bad for the NHS which has a shortage of hospital beds. Psychological problems, like dementia, confusion, depression and anxiety, are common in older patients and these are an important cause of long hospital stays. These problems are often not identified in busy hospital wards where the focus is on patients' physical illnesses. The aim of this study is to find out whether adding a new approach (sometimes called Proactive Liaison Psychiatry) to the identification and management of psychological problems reduces the time that older people spend in acute general hospital wards.

Who can participate?

Patients aged 65 and older who have been admitted to acute wards in hospitals in Oxfordshire, Cambridgeshire and Devon

What does the study involve?

Participants are randomly allocated to receive either usual care, or usual care plus the new approach (which involves seeing a doctor, nurse or occupational therapist who specialises in psychological problems in the medically ill). The study looks at whether the new approach reduces the time that patients spend in the hospital and whether it improves their quality of life and independence. Patients, carers and healthcare professionals are also interviewed to learn about their experiences with the new approach.

What are the possible benefits and risks of participating?

Taking part involves participants talking with the research team and allowing them access to their information. They may see an additional doctor or nurse who specialises in psychological problems. However, it is not known whether this will help them get home more quickly; that is

why this study is happening. The aim of the study is to find out how best to care for patients in the future.

Where is the study run from? 1. John Radcliffe Hospital (UK) 2. Horton Hospital (UK) 3. Royal Devon and Exeter Hospital (UK)

4. Addenbrooke's Hospital (UK)

When is the study starting and how long is it expected to run for? April 2017 to October 2022

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

Who is the main contact? Dr Jane Walker, jane.walker@psych.ox.ac.uk (UK)

Study website https://oxfordpsychologicalmedicine.org/research/thehomestudy/

Contact information

Type(s) Scientific

Contact name Dr Jane Walker

ORCID ID http://orcid.org/0000-0003-1938-1141

Contact details Psychological Medicine Research Group University of Oxford Department of Psychiatry Oxford United Kingdom OX3 7JX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 36034

Study information

Scientific Title

The HOME Study: a study comparing two different ways of looking after older people in hospitals to see if we can improve how quickly they go home

Acronym

The HOME Study

Study objectives

NHS general hospitals have more than two million unplanned admissions of people aged 65 and older every year. These patients typically spend more time in hospital than those aged under 65. Long hospital stays are bad for older patients: they can get new illnesses like infections and lose their independence. They are also bad for the NHS which has a shortage of hospital beds. Psychological problems, like dementia, confusion, depression and anxiety, are common in older patients and these are an important cause of long hospital stays. These problems are often not identified in busy hospital wards where the focus is on patients' physical illnesses.

In this study, the trialists will research whether adding a new approach (sometimes called Proactive Liaison Psychiatry) to the identification and management of psychological problems reduces the time that older people spend in acute general hospital wards.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 02/11/2017, Oxford C REC (Health Research Authority (Bristol), Ground Floor, Temple Quay House, 2 The Square, BS1 6PN, Bristol, UK; +44 (0)207 1048144, (0)207 1048241, (0)207 1048289; oxfordc.rec@hra.nhs.uk), ref: 17/SC/0497

Study design

Randomized complex intervention with qualitative component study

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet See trial outputs table

Health condition(s) or problem(s) studied Older people admitted to hospital

Interventions

The trialists will recruit approximately 3,588 patients aged 65 and older, who have been admitted to acute wards in hospitals in Oxfordshire, Cambridgeshire and Devon. Half of the study participants will get usual NHS care. This means that they will be looked after by doctors, nurses and other staff in the usual way during their hospital stay. The other half will get usual NHS care and they will also see a doctor or nurse who specialises in psychological problems – they will talk to them to find out if they have problems such as worries or confusion that might delay their discharge from hospital and will make a plan to help them with these. The trialists will study whether the new approach reduces the time that patients spend in hospital and whether it improves their quality of life and independence. They will also interview patients, carers and healthcare professionals to learn about their experiences of the new approach.

Intervention Type

Other

Primary outcome measure

Number of days spent as an inpatient in a general hospital in the month (30 days) postrandomisation; Timepoint(s): 30 days

Secondary outcome measures

Current secondary outcome measures as of 17/10/2022:

1. Cognitive function, measured using MOCA-T at 1 and 3 months

2. Independent functioning, measured using Barthel Index of Activities of Daily Living at 1 and 3 months

3. Health-related quality of life, measured using EQ-5D-5L at 1 and 3 months

4. Symptoms of anxiety and depression, measured using PHQ-4 at 1 and 3 months

5. Overall quality of life, measured using study-specific item at 1 and 3 months

6. Patient's experience of hospital stay, measured using study-specific item at 1 month

7. Patient's view on the length of their hospital stay, measured using study-specific item at 1 month

8. Discharge destination

9. Secondary healthcare use (including total length of index admission, length of index admission truncated at 30 days, number of readmissions, number of days in hospital) in the year post-randomisation

10. Death in the year post-randomisation

Previous secondary outcome measures as of 15/02/2018:

1. Cognitive function, measured using MOCA-T at 1 and 3 months

2. Independent functioning, measured using Barthel Index of Activities of Daily Living at 1 and 3 months

3. Health-related quality of life, measured using EQ-5D-5L at 1 and 3 months

4. Symptoms of anxiety and depression, measured using PHQ-4 at 1 and 3 months

5. Overall quality of life, measured using study-specific item at 1 and 3 months

6. Patient's experience of hospital stay, measured using study-specific item at 1 month

7. Patient's view on the length of their hospital stay, measured using study-specific item at 1 month

8. Discharge destination

9. Secondary healthcare use (including total length of index admission, number of readmissions, number of days in hospital) in the year post-randomisation

10. Death in the year post-randomisation

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7. Patient's view on the length of their hospital stay, measured using study-specific item at 1 and 3 months

8. Discharge destination

9. Secondary healthcare use (including total length of index admission, number of readmissions, number of days in hospital) in the year post-randomisation

10. Death in the year post-randomisation

Overall study start date

01/04/2017

Completion date

31/10/2022

Eligibility

Key inclusion criteria

To be included in the study patients must:

- 1. Be an inpatient in an acute ward
- 2. Have been admitted non-electively
- 3. Be aged 65 or older

4. Be expected (by their clinical team) to remain an inpatient for at least 2 days from the time of baseline assessment

5. Be able to give informed consent or if unable to give consent, a consultee advises that study participation is appropriate

Participant type(s)

Patient

Age group

Adult

Sex Both

Target number of participants Planned Sample Size: 3588; UK Sample Size: 3588

Total final enrolment 2744

Key exclusion criteria

Patients will be excluded if:

1. They are moribund (defined as when the clinicians caring for a patient estimate that they are likely to die before discharge from hospital)

2. Their participation in the study is judged to be clinically or practically inappropriate (e.g. patient visiting from overseas)

3. They have already been enrolled in the study

4. They have already been referred to the usual liaison psychiatry team.

5. They have been a general hospital inpatient continuously for 1 week at the time of the baseline assessment

6. They do not read or speak English

Date of first enrolment 12/02/2018

Date of final enrolment 05/03/2020

Locations

Countries of recruitment England

United Kingdom

Study participating centre John Radcliffe Hospital Oxford United Kingdom OX3 9DU

Study participating centre Horton Hospital Banbury United Kingdom OX16 9AL

Study participating centre Royal Devon and Exeter Hospital Exeter United Kingdom EX2 5DW **Study participating centre Addenbrooke's Hospital** Cambridge United Kingdom CB2 0QQ

Sponsor information

Organisation University of Oxford

Sponsor details University of Oxford Research Services

Clinical Trials and Research Governance Joint Research Office, Block 60, Churchill Hospital Oxford England United Kingdom OX3 7LE

Sponsor type University/education

ROR https://ror.org/052gg0110

Funder(s)

Funder type Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 15/11/16

Results and Publications

Publication and dissemination plan

Protocol will be published on the NIHR website and in a journal. Planned publication of study results in a high-impact peer reviewed journal.

Intention to publish date 31/12/2024

Individual participant data (IPD) sharing plan

Current IPD sharing statement as of 30/03/2023:

The datasets generated during and/or analysed during the current study are not expected to be made available because these include identifiable information and, under the terms of our agreement with NHS Digital, the use of these data is restricted to The HOME Study researchers and for the purposes of HOME Study analyses.

Previous IPD sharing statement:

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
<u>Participant information</u> <u>sheet</u>	version V2.0	17/10/2017	12/01 /2018	No	Yes
Protocol article	protocol	07/08/2019	27/08 /2019	Yes	No
<u>Statistical Analysis Plan</u>	statistical and economic analysis plan	04/05/2020	06/05 /2020	No	No
HRA research summary			28/06 /2023	No	No
<u>Results article</u>		10/08/2024	12/08 /2024	Yes	No