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Managing care for people in community hospitals

Submission date
02/02/2021

Recruitment status
No longer recruiting

Registration date
26/02/2021

Overall study status
Completed

Last Edited
21/06/2022

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
This study focusses on the management of clinical uncertainty in community hospitals. Community hospitals support recovery and rehabilitation for mainly older people in transition between hospital and home. Older people admitted to community hospitals often live with multiple conditions and frailty. They have many care needs. Outcomes of care can be uncertain and unpredictable as to recovery or continued decline and risk of poor outcome, such as end of life.
Using standardised documents can improve how care is managed, but these documents are mainly used in acute hospitals. It is not known whether they can be used in community hospitals or how to evaluate if they may benefit patients. The aim of this study is to evaluate the feasibility, process and acceptability of a new tool (SPACE – Symptom and Psychosocial Assessment and Communication Evaluation) to manage care for people in community hospitals and during clinical uncertainty. SPACE uses standardised documents to support three areas of clinical care: (1) assessing potential for recovery and 'what matters to the person'; (2) communication with the person and family about what to expect; and (3) ensuring care continues as planned on discharge.

Who can participate?
Adults aged 65 or over admitted to a community hospital for one or more nights 24 hours during the study period.

What does the study involve?
The researchers will undertake the study in two community hospitals. They will recruit 40 to 60 patients to evaluate the process of staff using the documents in clinical care, and the feasibility and acceptability of the research methods to inform a large study. They will evaluate the acceptability of using the documents for staff by reviewing participants' health records to see if the documents are used, observe how staff use the documents with patients and families, and talking to staff about their experiences.
The researchers will ask patients (or a family member on the person's behalf) to complete three questionnaires, twice in the hospital and once after discharge. The questionnaires ask about the

participant's experiences of care, how using the documents may benefit patients and the services used. The findings will inform a large study examining the benefit for patients if feasibility is demonstrated.

What are the possible benefits and risks of participating?
Patients can benefit from knowing that their contributions can help to improve care in hospitals. Completing the questionnaires may take some time and some people may find the questions difficult to answer.

Where is the study run from?
The study is a joint project between King's College London and Sussex Community NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2015 to December 2021

Who is funding the study?
1. Health Education England (UK)
2. National Institute for Health Research (UK)

Who is the main contact?
Dr Catherine Evans
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

280195

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 46429, IRAS 280195

Study information

Scientific Title
Evaluating the feasibility of a new tool SPACE - Symptom and Psychosocial Assessment and Communication Evaluation to manage care for people in community hospitals and during clinical uncertainty

Study objectives
The study aims to evaluate the feasibility, process and acceptability of a new tool SPACE - Symptom and Psychosocial Assessment and Communication Evaluation to manage care for people in community hospitals and during clinical uncertainty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/10/2020, London – Queen Square Research Ethics Committee (HRA NRES Centre Bristol, 3rd floor, block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8061; queensquare.rec@hra.nhs.uk), REC ref: 20/LO/0981

Study design
Non-randomized; Both; Design type: Process of Care, Complex Intervention, Management of Care, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
People in community hospitals

Interventions
The study will use a before and after feasibility design with an embedded qualitative study. The before and after design will use two phases to evaluate the feasibility and acceptability of the research methods including patient recruitment, the candidate outcomes measures and the methods of data collection and economic evaluation. The two phases will include:
1. Before the incorporation of the SPACE documents in clinical care during the training phase, and
2. After the SPACE documents are used in routine clinical care during the assessment phase.

The embedded qualitative study will evaluate the process of how the documents are used in clinical practice, the acceptability of the documents and the training and support provided. The process evaluation will identify potential modifiers to improve use and the potential for patient benefit.

SPACE includes standardised evidence-based documents. The standardised documents intend to enhance the management of clinical uncertainty by supporting three key areas of clinical practice, namely:
1. Assessing potential for recovery and 'what matters to the person' and their family
2. Communication with the person and family about what to expect
3. Transferring information on discharge to ensure care continues as planned, and priorities for future care are documented to facilitate care at the end of life.

The findings from the training phase (before SPACE is embedded) will refine understanding of the feasibility and acceptability of the documents proposed and the processes of using in clinical care and requirements to support use, such as training. The findings will be incorporated in the assessment phase (after SPACE is embedded in clinical care) to enhance how the documents are used and identify potential modifiers to enhance use and patient benefit.

Intervention Type
Other

Primary outcome(s)
Main candidate outcome:
The feasibility and acceptability of using the 'Patient/family anxiety and communication subscale' of the Integrated Palliative Outcome Scale (I-POS) as the main candidate outcome to inform the methods for a full trial if progression is indicated

Measured at:
1. Baseline: 0 to 14 days from the admission date (as soon after the admission as possible)
2. T1: 15 to 28 days after admission (or longer if extended admission)
3. T2: After discharge (28-56 days after discharge) to explore continuity of care and service use to inform the economic evaluation

Key secondary outcome(s))
Secondary candidate outcomes:
The feasibility of secondary candidate outcomes. These will include:
1. Palliative concerns in the IPOS not included in the patient/family subscale
2. Patient Reported Experience Measure (PREM) from the NHS National Benchmarking of Community hospitals (2018), comprising:
2.1. I had confidence and trust in the staff treating or supporting me
2.2. Overall, I felt I was treated with respect and dignity from this service
3. Physical disability measured using the Modified Barthel Index
4. Frailty measured using Fried's Phenotype of Frailty
5. Function measured using Australian Karnofsky Index for palliative care
6. Survival at 6 months measured by review of NHS site electronic patient records

Economic evaluation:
1. Quality of life measured using EQ-5D as recommended in cost-effectiveness analyses and formal inpatient service use, medication and informal care recorded using the Client Service Receipt Inventory (CSRI)

2. Economic data reported using admission questionnaire at baseline reporting preceding 12 weeks and discharge questionnaire at T2 (28-42 days after discharge)

Process measures/service outcomes:
Completed from the patient record at discharge, including:
1. Community hospital length of stay
2. Completion of the SPACE documents and decision making e.g. staff involved, completed proxy /self-report, communication multi-disciplinary teams and with patients and families. Collect completed and de-identified copies of the SPACE documents, including IPOS-Dem for assessment, the adapted- PACE for communication with families, and the Anticipatory Care Plan used on discharge.

Measured at:
1. Baseline: 0 to 14 days from the admission date (as soon after the admission as possible)
2. T1: 15 to 28 days after admission (or longer if extended admission)
3. T2: After discharge (28-56 days after discharge) to explore continuity of care and service use to inform the economic evaluation

Completion date
03/12/2021

Eligibility

Key inclusion criteria
Patient inclusion criteria:
1. An inpatient in a participating community hospital for 24 hours or more.
2. Aged 65 years or over.
3. Mental capacity to give informed consent for themselves, or for an adult lacking capacity a personal consultee (e.g. a family member) or nominated consultee.

Clinical staff inclusion criteria:
Staff will be purposively selected to represent the different grades and disciplines of staff delivering care to patients and their families. This will comprise individuals providing care in the wards including those directly employed, and those providing services to the community hospitals, for example, geriatricians, mental health nurses, social worker, caregiver support worker.

Non-participant observations:
Non-participation observations of activities to evaluate the processes and requirements for using the SPACE documents, and the accessibility and feasibility to inform modifications and wider implementation if benefit is apparent. Non-participant observations will be of general clinical activities, for example, staff training, team meetings and specific clinical activities e.g. Welcome Meeting on admission, and Family Meeting for discharge planning. All non-participant observations are undertaken with individuals able to give informed consent.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
49

Key exclusion criteria
Adults for whom the clinical staff indicate inappropriate to approach for participation because discharge date within next 48 hours, or considered too unwell

Date of first enrolment
03/05/2021

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sussex Community NHS Foundation Trust
Brighton General Hospital
Elm Grove
Brighton
United Kingdom
BN2 3EW

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: ICA-SCL-2015-01-001

Funder Name
Health Education England

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Catherine Evans (catherine.evans@kcl.ac.uk). Data will be collected, managed and analysed according to the principles of GCP and participants are fully informed of all plans for data sharing within the study. Participants are asked to consent to the sharing of data (link anonymised) for future prospective research purposes. Archiving is for at least 15 years. Analysis is conducted according to a pre-agreed analysis plan. Data are not released prior to analyses for purposes that might detrimentally affect the study integrity. Any request approved is covered by a written Data Transfer Agreement, detailing limitations of use, transfer to 3rd parties, data storage and acknowledgements. Safety/adverse events data are released to relevant bodies where appropriate to improve patient care. The results of the study are notified to participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			21/06/2022	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V1	07/09/2020	26/02/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V2.2	15/12/2020	26/02/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes