ImproveCare - The management of clinical uncertainty in hospital settings

Submission date	Recruitment status	[X] Prospectively registered
16/01/2017	No longer recruiting	[X] Protocol
Registration date	Overall study status	Statistical analysis plan
18/01/2017	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
24/02/2023	Other	

Plain English summary of protocol

Background and study aims

Around 500,000 people die every year in the UK and around half of all these deaths occur in hospital. Most people prefer to die at home but this doesn't always happen because there is little discussion about what they want. It is made worse when it's difficult for health care professionals (HCP) to identify patients, whose situation is clinically uncertain, a care area many professionals do not have enough knowledge/skills in. Reports have highlighted what can go wrong when there is clinical uncertainty, and at the end of life it can be devastating for patients and families. The AMBER care bundle has been developed to care better for hospital patients whose situations are clinically uncertain and are at risk of dying during their hospital stay despite treatment. For these patients, staff develop a plan with patients and their family that documents what is important to them. The patient's health status and their wishes are revisited daily. A small study explored the AMBER care bundle, highlighting some benefits and concerns with the program. Before more hospitals use the AMBER care bundle, it's important to find out whether the it actually improves care, or not. The aim of this study is to find out if a study comparing the AMBER care bundle and usual care is feasible. In addition, open interviews with patients, caregivers and staff will help improve understanding about what they value about the AMBER care bundle and how it works.

Who can participate?

Patients in hospital whose situation is clinically uncertain and are at risk of dying during their hospital stay and their relatives and friends; healthcare professionals working on the study wards; and bereaved relatives/friends of who died at wards supported patients with the AMBER care bundle or up to 100 days post-discharge.

What does the study involve?

Patients who agree to take part are interviewed by a research nurse at the start of the study and then 3-5 and 10-15 days later about how they are feeling physically and emotionally and if they feel that they are receiving enough care and support while they are on the hospital ward. Willing relatives/friends of the patients are also interviewed by a researcher about their experiences of the quality of care the patient has received, their understanding of the patient's illness and of the treatment and care being given, and their views on being involved in important decisions about the patient's care with an interview. If the teams on the ward agree, a researcher also

observes multidisciplinary team meetings (where different professionals involved in patient's care discuss cases) on the ward to collect information on the structure of the meeting, processes, details of patients with clinically uncertain situations, where their condition is irreversible, and where there is a risk they will die during their stay despite treatment, and how decisions are made regarding their care, particularly at the end of life. Healthcare professionals are invited to take part in in a ward-based focus group to explore their views about caring for patients whose situations are clinically uncertain, views about whether a large scale trial would be possible.

What are the possible benefits and risks of participating?

People find it helpful to talk in confidence about what is happening to them or their relative. Many patients and relatives benefit from the knowledge that what they share during interviews contributes to improving care in hospitals and other settings. These interviews, will take some of their time. The interview can be a relief or a challenge. There is a small risk that the nature of the questionnaires might be distressing for some people. If the participant feels distressed, the highly trained researcher will be present to talk to the participant. If required, the participant will be referred to a colleague who can help more. For HCPs, taking part in the focus groups, could contribute to our findings and recommendations for the improvement of the care and support of patients whose situations are clinically uncertain, where their condition is irreversible, and where there is a risk they will die during their current episode of care despite receiving treatment. Partaking in the focus groups should not have any disadvantages, but the interview will take between 30-60 minutes. For relatives/friends engaging in follow-back surveys can evoke some distress. Many participants, nevertheless, report it to be a positive experience. Relatives will get a chance to express their views about the quality of care received by the patients and could potentially lead to improvements in care.

Where is the study run from?

- 1. Chesterfield Royal Hospital (UK)
- 2. East Surrey Hospital (UK)
- 3. Northwick Park Hospital (UK)
- 4. Tunbridge Wells Hospital (UK)

When is the study starting and how long is it expected to run for? February 2015 to April 2018

Who is funding the study? National Institute for Health Research (NIHR) Heath Technology Assessment (HTA) Programme (UK)

Who is the main contact?
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Additional identifiers

Protocol serial number

v2.0 07.12.16

Study information

Scientific Title

ImproveCare – The management of clinical uncertainty in end of life care – a feasibility cluster randomised controlled trial

Acronym

ImproveCare

Study objectives

The aim of this study is to determine the feasibility of a pragmatic, multi-centre, cluster randomised control trial to optimise the design, and to define the outcomes, for a fully powered definitive trial of the AMBER care bundle versus standard care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

London Camden & King's Cross Research Ethics Committee, 20/12/2016, ref: 16/LO/2010

Study design

Multi-centre feasibility cluster randomised controlled trial with embedded qualitative evaluation

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

End of life care

Interventions

Randomisation was at the level of the cluster (NHS Trusts) which was performed by King's College Clinical Trials Unit. The four clusters were randomised prior to collection of data at sites, but after all sites had agreed to participate. The four clusters were randomised at once by randomly sequencing the order of randomisation and then randomising the sites in this order into fixed blocks of two, to active or control arms. As a result of computerised randomisation, in the first wave of the study, East Surrey Hospital will be the active arm and Chesterfield Royal Hospital will be the control arm. In the second wave of the study, Maidstone and Tunbridge Wells NHS Trust will be the active arm and Northwick Park Hospital will be the control arm.

Active arm: The AMBER care bundle will be implemented on a selected general medical ward. The AMBER care bundle is an approach used in hospitals when clinicians are uncertain whether a patient may recover and are concerned that they may only have a few months left to live. The AMBER care bundle is intended to encourage staff to identify patients who fulfilled these criteria, for the clinical team responsible for those patients to then to develop and document, within a reasonable period of time, a clear medical plan in conjunction with the patient and their family, to consider anticipated outcomes, and resuscitation and escalation status. This involves communicating openly with the patient and their family about their wishes and preferences should the worst happen. The person's condition is then monitored closely on daily basis to record any changes, and address any concerns that they or their family may have. Staff working on the ward where the AMBER care bundle is being implemented (the intervention board) will be introduced to, and will be trained in the use of the AMBER care bundle, in March 2017. The intervention will continue until the end of data collection (Beginning of October 2017). The intervention ward staff in the second wave of the study will be introduced to and trained in the use of the AMBER care bundle in April 2017, and the AMBER care bundle will be used until the end of data collection (Beginning of October 2017). Patients who fulfil the criteria to be supported by the AMBER care (i. Patients who are deteriorating; ii. Patients whose situations are clinically uncertain, with limited reversibility; iii. Patients at risk of dying during their current episode of care, despite treatment), and who have provided their written informed consent for data to be shared with the research team, will complete a questionnaire at up to three time points. Relatives of patients who participated, and who died on the ward or 100 days after discharge, will be contacted for a follow-up post-bereavement survey, after waiting at least 3 months to pass after the death of the patient.

Control arm: Participants continue to receive usual care. Patients will be recruited for data collection and the questionnaires will be completed at the same three time points. Relatives of patients who participated, who died on the ward or 100 days after discharge will be contacted for a follow-up post-bereavement survey, after waiting at least 3 months to pass after the death of the patient.

Qualitative component of the study:

For the qualitative component of the study, interviews will be conducted with a purposefully selected sample of patients and relatives across both the intervention and which will include questions related to their illness, information and communication issues, their involvement in decision making, and their confidence in care provided. Focus groups with healthcare professionals on the intervention wards will explore their views on the AMBER care bundle and the study. Focus groups with healthcare professionals on the control wards will explore their views on caring for patients with advanced illness who are deteriorating, clinically unstable and likely to die during their episode of care, despite receiving treatment. Finally, a researcher will observe and take notes of consenting healthcare professionals in the multi-disciplinary meetings taking place on the wards.

Intervention Type

Other

Primary outcome(s)

- 1. The effect of the AMBER care bundle is measured using the Patient/family anxiety and communication subscale of the Integrated Palliative care Outcome Scale (I-POS) at baseline, 3-5 days, 10-15 days
- 2. Patients reported experiences of health care are measured using the howRwe questionnaire at baseline, 3-5 days, 10-15 days

Key secondary outcome(s))

- 1. Cost of care is measured with the EQ-5D at baseline, 3-5 days, 10-15 days
- 2. Other subscales of the Integrated Palliative Care Outcome Scale (I-POS) questionnaire at baseline, 3-5 days, 10-15 days
- 3. What patients and carers value most about AMBER care bundle and how it may be working is assessed through qualitative interviews, focus groups and non-participatory observation of multidisciplinary team meetings
- 4. Patients views on how they feel about taking part in this study are collected at 3-5 days and 10-15 days

Embedded qualitative study:

Preferred place of death and whether this is realized, along with satisfaction which will be collected from the relatives of patients who have lost their lives is measured using the QUALYCARE postal survey.

Completion date

31/10/2018

Eligibility

Key inclusion criteria

Patient inclusion criteria:

1. Participants must be 18 or over

- 2. Participants can be female or male
- 3. Patients who are deteriorating
- 4. Patients whose situations are clinically uncertain, with limited reversibility
- 5. Patients at risk of dying during their current episode of care, despite treatment

Relative inclusion criteria:

Relative or close friends of the patients who fulfil the criteria above.

Healthcare professional inclusion criteria:

Working on the study wards.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

65

Key exclusion criteria

Patient exclusion criteria:

- 1. Participants under 18 years old
- 2. Patients whose situations are clinically certain

Relative exclusion criteria:

Relatives or close friends of the patients who do not meet the inclusion criteria

Healthcare professional exclusion criteria:

Not working on the study wards

Date of first enrolment

01/05/2017

Date of final enrolment

01/10/2017

Locations

Countries of recruitment

United Kingdom

England

Study participating centre East Surrey Hospital

Canada Avenue Redhill United Kingdom RH1 5RH

Study participating centre Northwich Park Hospital

Watford Road Harrow United Kingdom HA1 3UJ

Study participating centre Tunbridge Wells Hospital

Tonbridge Road Tunbridge Wells United Kingdom TN2 4QJ

Study participating centre Chesterfield Royal Hospital

Calow Top Road Chesterfield United Kingdom S44 5BL

Sponsor information

Organisation

King's College London and King's College Hospital NHS Foundation Trust

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made 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	results	16/08/2019	21/08 /2019	Yes	No
Results article	results	01/10/2019	10/10 /2019	Yes	No
HRA research summary			28/06 /2023	No	No
Other publications		21/02/2020	24/02 /2023	Yes	No
Other publications	Multi-method process evaluation	16/09/2020	24/02 /2023	Yes	No
Participant information sheet	version V2	06/01/2017	18/01 /2017	No	Yes
Participant information sheet	version V1	19/12/2016	18/01 /2017	No	Yes
Participant information sheet	version V2	06/12/2016	18/01 /2017	No	Yes

Participant information sheet	version V3	03/01/2017	18/01 /2017	No	Yes
Participant information sheet	version V2	12/12/2016	18/01 /2017	No	Yes
Participant information sheet	version V1	19/12/2016	18/01 /2017	No	Yes
Participant information sheet	version V2	06/12/2016	18/01 /2017	No	Yes
Participant information sheet	version V2	06/12/2016	18/01 /2017	No	Yes
Participant information sheet	version V2	06/01/2017	18/01 /2017	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11 /2025	No	Yes
Protocol file	version v6.0	02/02/2018	17/10 /2018	No	No