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ImproveCare - The management of clinical uncertainty in hospital settings

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

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

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 measure
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

Secondary outcome measures
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.

Overall study start date
01/02/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Across all sites incluing patients, relatives and healthcare professional the total number of participants is expected to be 185. In each arm 40-45 patients are expected to be recruited. There are 4 sites; 2 intervention, 2 control. Around 20 patients per site will be recruited. For qualitative interviews, 20 patients from those who already been recruited and consented will participate. Around 20 relatives will be recruited for qualitative interviews. Around 40

healthcare professionals will be recruited for the focus groups and the non-participatory observation of multidisciplinary team meetings. For the post-bereavement QUALYCARE survey, around 35 relatives are expected to be recruited.

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
England

United Kingdom

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
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United Kingdom
S44 5BL

Sponsor information

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

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Findings will disseminated through:
1. International conference presentations on the feasibility of implementing in practice and likely patient benefit; and the feasibility of conducting a cluster RCT of the AMBER care bundle in hospital settings
2. Publication of findings in open access high impact online journals, and preparation (with support from patient collaborators) user friendly summaries for patients and users to access, as well as on patient advice and support forums (e.g. patient.co.uk, BBC health), and well as to national patient and carer groups in 2018 -2019. For this, the researchers will also work with patient groups in individual centres, and national and international charities.
3. Development of web pages about the project on the researchers website - www.csi.kcl.ac.uk with links to other relevant organisations, encouraging those organisations to link. These will be updated regularly with information on study progress, newsletters etc. The project team will also take advantage of social media forums such as Twitter, blogs, podcasts, and other media sites to disseminate these findings further. Linking to other projects within the Cicely Saunders Institute at KCL we will explore opportunities to develop e-based education/training packages for clinicians and others, based on the findings of the research.

Intention to publish date
30/09/2019

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?
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
Protocol file	version v6.0	02/02/2018	17/10/2018	No	No
Results article	results	16/08/2019	21/08/2019	Yes	No
Results article	results	01/10/2019	10/10/2019	Yes	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
HRA research summary			28/06/2023	No	No