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

Short-title: Managing care for people in community hospitals

Protocol for Workstream 4 of the programme SPACE 'Development and feasibility evaluation of a new tool SPACE - Symptom and Psychosocial Assessment and Communication Evaluation to manage care for people in community hospitals and during clinical uncertainty'

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Chief investigator: Catherine J Evans[1, 3]
Researchers: Clare Ellis-Smith[1], Marsha Dawkins[1] and India Tunnard[1]
Co-applicants: Deokhee Yi[1], Wei Gao[1], Christine Norton[2], Susan Marshall[3], Sube Banerjee[4], Clare Goodman[5] and Irene Higginson[1]
Advisory members: Matt Maddocks[1] and Lucy Scragg[3]

Affiliations: [1]King's College London, Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation; [2] King's College London Florence, Nightingale Faculty of Nursing, Midwifery and Palliative Care; Sussex Community NHS Foundation Trust[3]; University of Sussex, Brighton and Sussex Medical School[4]; University of Hertfordshire, Centre for Research in Public Health and Community Care[5];

Correspondence: Catherine.evans@kcl.ac.uk

Sponsor	**NHS site contact**
Prof Reza Razavi Vice President & Vice Principal (Research) King's College London Room 5.31, James Clerk Maxwell Building 57 Waterloo Road London SE1 8WA Tel: +44 (0)207 8483224 Email: reza.razavi@kcl.ac.uk	Ms. Helen Vaughan Research and Innovation Manager Sussex Community NHS Foundation Trust Brighton General Hospital Bramber House Elm Grove Brighton Tel: 0273 696 011 ext. 3710/3795 e-mail: helenvaughan@nhs.net

STUDY SUMMARY

Identifiers	
IRAS Number:	280195
REC Reference No:	20/LO/0981
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Other research reference number(s) (if applicable)	Funder reference: ICA-SCL-2015-01-001
Full (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
Health condition(s) or problem(s) studied	Multimorbidity, frailty
Study Type i.e. Cohort etc	Before and after feasibility study
Target sample size	Patients n=40 for feasibility evaluation Process evaluation includes non-participant observations involving staff, patients and informal caregivers; and focus groups with staff
STUDY TIMELINES	
Study Duration/length	6 months
Expected Start Date	October 2020 (COVID-19 disruption until March 2021)
End of Study definition and anticipated date	Main study publication, December 2021
Key Study milestones	Budget and contract finalised: 01/05/2016 Programme commenced: 01/06/2016 **Workstream 4** study submission for HRA approval: 20/07/2020 Approval to commence recruitment: 01/10/2020 First patient recruited: paused, Covid-19 disruption until March 2021
FUNDING & Other	
Funding	HEE/NIHR Senior Clinical Lectureship
Other support	Cicely Saunders International is contributing to funding for India Tunnard, project coordinator and research assistant.
KEY STUDY CONTACTS	Full contact details including phone and email
Chief Investigator	Dr Catherine Evans King's College London, Cicely Saunders Institute Bessemer Road London SE5 9PJ Email: catherine.evans@kcl.ac.uk, Phone: 0207 848 5579
Project coordinator and research assistant	India Tunnard King's College London Cicely Saunders Institute Bessemer Road, London SE5 9PJ India.tunnard@kcl.ac.uk Tel: 0207 848 5520

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Plain English summary

Why does this research matter?

We focus on the management of clinical uncertainty. Clinical uncertainty is a complex area of clinical practice. A person's care needs are often multiple, changeable and unpredictable. Good communication with patients and their families is essential to reduce distress. Clinical uncertainty often happens at points of decline in a person's wellbeing. Older people living with several ongoing illness are vulnerable to a marked decline in wellbeing from an often seemingly minor health event, like an infection. Clinical uncertainty as to recovery or continued decline leading eventually to end of life is common. This means the care and treatment can be more complicated. It may take a person longer to recover and care must support both recovery and anticipate and plan for continued decline. Community hospitals are important in providing care to older people. Their central ethos of recovery and rehabilitation means they can support both recovery and anticipate and plan for continued decline and nearness of end of life. Community hospital are typically led by a nurse, with medical review by for example a GP. There are around 300 community hospitals in England. Together they admit over 100,000 people each year.

What are we trying to do?

Older people admitted to a community hospital often have complex care needs because of the many conditions they live with and uncertainty as to how well they will recover. It is vital staff can undertake good assessments to understand 'what's matters to the person', talk with the person and their family about what to expect, and ensure care and treatment continues as planned on discharge. We know that using standardised documents can improve how care is provided and the outcomes of care. But these documents have been developed and evaluated mainly in acute hospitals. We don't know how they could work in a community hospital, or what are the best methods to evaluate if using the documents benefits patients and their families. We want to evaluate the processes of using a set of standardised documents to manage care in community hospitals and during clinical uncertainty. We also want to evaluate the feasibility of the methods to understand if working in this way could benefit patients.

What will we do?

We will conduct a research study to evaluate the processes for staff to use a set of standardised documents with patients and their families in community hospitals, and the feasibility and acceptability of the research methods to examine benefit. The standardised documents form a tool called SPACE - Symptom and Psychosocial Assessment and Communication Evaluation. SPACE includes standardised documents to support 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; and (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. To achieve this, we will undertake the study in two community hospitals. We will recruit 40 patients to evaluate the processes of staff using the documents in routine care, and the feasibility and acceptability of the research methods to inform a large study. We will evaluate if it is acceptable for staff to use the documents by reviewing participants' health records to see if the documents are completed, observe how staff use the documents with patients and families, and talking to staff about their experiences. We 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 and explores possible ways using the documents may benefit patients. The findings will inform if and how the SPACE documents could be used in community hospitals and a large study evaluating the benefit for patients if feasibility is demonstrated.

Background and rationale

People are living longer and increasingly die with frailty and multimorbidities [1-4]. Over 40% of deaths by 2020 will be people aged 80 years or over. Older people with frailty are vulnerable to functional decline and poor health outcomes often from a seemingly minor health problem [1,3]. These points of decline are frequently associated with clinical uncertainty as to treatment outcomes, prognosis and recovery. A complex background of frailty, multi-morbidities and psychosocial conditions mean people admitted to community hospitals often present with diffuse symptoms and concerns, and uncertain outcomes of recovery or continued decline leading eventually to end of life [3, 5 6]. Community hospitals' central ethos of recovery and rehabilitation positions them as a vital resource in the healthcare system to manage the care of older people in supporting recovery and anticipating and planning for end-of-life [7 8]. In England they provide care for over 100,000 admissions per year [9]. These settings are typically small non-acute hospitals that are nurse-led with limited medical cover [10]. Patients are older with an average age of 84 years [8]. Around 40% have cognitive impairment [11]. Older people and their families often prefer these care settings to an acute hospital, providing care nearer to home [12 8].

We focus on the optimal management of care during clinical uncertainty. Clinical uncertainty is understood from the clinical construct of frailty.[3] Individuals living with frailty are considered vulnerable to marked decline from an often seemingly minor health event, and increased risk of poor outcomes of, for example, end of life. The increased risk of poor outcome means there is often uncertainty as to recovery or continued decline. To manage clinical uncertainty requires care and treatment to support a person's capabilities (function to enable independence however small), reduce distressing symptoms and concerns and provide opportunities to plan and discuss future care [13]. Poor management leads to worse psychological outcomes for patients and families, notably anxiety and distress [14, 15]. Mishel was one of the first to develop an overarching theory of uncertainty in illness [16-18]. The theory aimed to explain the underlying processes governing patients' experiences of uncertainty. Specifically, uncertainty in illness comprises four key concepts: 1) complexity; 2) unpredictability; 3) ambiguity; and 4) lack of information. Clinical uncertainty occurs when a clinician perceives an illness – including treatment, prognosis or recovery - as inconsistent, complex or unpredictable [19]. McCormick developed these concepts to describe situations of uncertainty in terms of the probability of events occurring, the temporality of events, and an individual's perception of their situation [20]. Goodman et al progressed this work specifically for older people in care homes and conceptualized uncertainty as something that is not always resolvable, but needs to be "held" when it is unclear if a person is actively dying and what the preferred outcome may be [21].

Managing clinical uncertainty is challenging [22-24]. This is because clinicians' focus on the acute presenting problem(s) with often limited consideration of the person's illness trajectory, and poor communication both within and between clinical teams about risk of poor outcomes and plans for escalation of clinical care [22]. Communication with patients and families about what to expect is critical [25]. But, this is often hindered by clinicians' limited openness about the goals of care or acknowledgement that the anticipated outcomes of care may be uncertain and changeable [26]. Collaborative decision-making is possible when uncertainty is acknowledged and managed alongside high quality care [27]. This can empower patients and their families[28-30], and in turn lead to improved outcomes and increased satisfaction with care [31, 32]. Palliative care is important in managing clinical uncertainty both in supporting patients who may recover and those who deteriorate [33]. Palliative care is relevant for older people with multi-morbidities and uncertain recovery across the illness trajectory. Palliative care emphasises improved quality of life for patients and families through comprehensive assessment, and relief and prevention of symptoms and concerns (e.g. physical, spiritual psychosocial) [34].

To improve the management of clinical uncertainty in community hospitals requires wider policies and resources that can improve person-centred care, communication and palliative care provision (e.g. symptom control).[35] We believe that this represents the area of greatest need. Nursing staff may struggle to assess care needs adequately, particularly for patients with dementia[36] and for those at the end of life.[35] Moreover, there is limited recognition that many patients are in the last year of life and could benefit from the provision of palliative care.[11] This also responds to national research priorities for patients and families on improving access to palliative care for all, training for staff to deliver, and the assessment and treatment of discomfort [37, 38]. Standardised documents are used increasingly by staff with patients in acute hospitals to improve communication and palliative care, e.g. the AmberCare Bundle.[39] Using standardised documents like a patient-centred outcome measures (PCOMs) in routine care can improve care by informing assessment, directing for example the need for palliative care and measuring outcomes of care from the perspectives of patients and families, promoting quality and equity [40]. But, most standardised documents are developed and evaluated in acute hospitals [33 41] or focus on a component of care (e.g. contingency plans) [42].

This feasibility study is workstream four of a programme of work. The preceding workstreams developed the SPACE intervention. The development workstreams included identifying the standardised documents that form the SPACE intervention [43], consulting with staff about the proposed documents and the acceptability and requirements for use in clinical care, and with patients about priorities and preferences in the management of care in community hospitals [44].

Aim and objectives

This 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.

Objectives

1. To evaluate the process of how healthcare practitioners, use the SPACE documents in clinical care and the acceptability of the documents and requirements for use
2. To identify potential modifiers to enhance use and the potential for patient benefit.
3. To assess the feasibility of recruiting patients to the study against the criteria of consenting three in every ten eligible patients approached to participate in the study.
4. To evaluate the feasibility of the methods of data collection, outcome measurement and economic evaluation in terms of level of missing data and patient acceptability to inform a protocol for a pilot and definitive trial if feasibility and acceptability is apparent.

Research methods

Feasibility study design

The study will use a before and after design to evaluate the process of using the SPACE documents in clinical care and the feasibility of the research methods. Evaluating the feasibility of the research methods will use observation time points:

1) Before the incorporation of the SPACE documents in clinical care during the training phase

2) After the SPACE documents are used in routine clinical care during the assessment phase.

The design incorporates a process evaluation to explore how the documents are used in clinical practice, the acceptability of the documents and the training and support provided, and identify potential modifiers to improve use and patient benefit [45]. The study design incorporates the MRC guidance for developing and evaluating complex interventions[46] and the MORECare Statement for application in palliative care.[47] In keeping with the MRC guidance[47], the study uses sequential development and feasibility workstreams to identify, adapt and evaluate the SPACE intervention. This protocol pertains to workstream 4, evaluating the process and acceptability of using SPACE in clinical care and evaluate the feasibility of the research methods to inform a pilot and definitive trial if feasibility and acceptability is demonstrated.

Study setting

The feasibility study will be undertaken in two community hospitals in Sussex Community NHS Foundation Trust. The trust has 13 community hospitals (inpatient community units) located in West Sussex and East Sussex with approximately 300 inpatient beds. The study is undertaken in West Sussex. This is the locality with the highest proportion of people aged 85 years and over, with the highest corresponding provision of community hospitals. The two hospitals participated in the development workstreams involving consultations with staff and patients. The hospitals will be purposively selected from the four community hospitals involved in the staff consultation workstream three. Purposive selection for the feasibility evaluation is based on the criteria:

- Large facilities to capture a breadth of patients
- Geographical catchment areas of mixed levels of deprivation and ethnicity
- Patients with comparatively high levels of dependency
- Engagement and participation in the preceding development workstream

Study procedures

Selection and withdrawal of patient participants

Eligibility criteria for patients

- An inpatient in the community hospital for 24 hours or more during the study period.
- Aged 65 years or over
- Mental capacity to give informed consent, or for adults lacking capacity availability of an individual who knows them well to complete the research questionnaires

Selection of patient participants

The direct care team will identify potentially eligible patients and approach those meeting eligibility criteria, or for adults lacking capacity approach the nearest caregiver, family member or close friend to act as the personal consultee and/or complete the research questionnaires. The direct care team comprises the clinical teams and/or the clinical research nurses. They will provide patients/consultees with the respective information sheet or post/email to consultees as appropriate. Consultees will receive a follow-up invitation by telephone and/or email. Patients/consultees can decline or indicate interest in participating/advising participation by informing a member of the direct care team. Consultees may also reply via email, telephone or return the reply slip in the Freepost envelope. If no personal consultee is identified, or does not

respond to requests for advice, a nominated consultee will be asked to advise about the person's participation (or not).

The clinical research nurses/clinical team will maintain a screening log of patients approached as eligible, including consultee approach when required. Table 1 details the clinical information recorded on the screening log. Anonymous data in the screening log is shared with the lead site via NHS email on a monthly basis pending resource and recruitment rate. This is to enable the clinical research nurses and the lead site to review the number of eligible participants screened and approached, and outcome of recruitment or decline and reason when given.

Table 1 Screening log

Clinical information
1. Age
2. Gender
3. Admitted from e.g. hospital or home
4. Main reason for admission
5. Medical diagnoses e.g. frailty, dementia.
6. Adult lacking capacity to consent (Y/N). a. Y – personal consultee identified and approached (Y/N) b. No personal consultee, nominated consultee approached
7. Reason for declining participation (if applicable, patient or consultee when advice is sought)

The Mental Capacity Act 2005

We apply the principles of the Mental Capacity Act (MCA) 2005 to include patients who might lack capacity to consent for themselves. The commonality of cognitive impairment in advanced age requires the inclusion of people with impaired mental capacity in the study. Approximately 40% of patients in community hospitals in the study site have dementia or cognitive impairment. Exclusion of people with cognitive impairment would likely exclude those with the highest disease burden, cause bias in the sampling and preclude assessment on the feasibility of recruiting adults lacking capacity.

Advice will be sought from a personal consultee (usually close caregivers/family members) who know the patient sufficiently well to give an opinion as to if the individual would have wanted to participate. If no personal consultee can be identified to advise, a nominated consultee will be approached for advice for example, NIHR Clinical Research Network staff supporting research studies in dementia, the Dementia Lead in the trust, or social worker for community hospitals. Individuals who show distress (verbally or non-verbally) or voice any objection to the study will be withdrawn at any stage and that withdrawal will not affect their usual care.

Raise awareness

The processes of raising awareness is informed by our experiences of consulting staff and patients about the study. We will raise awareness by:

- Some weeks prior to the study opening we will commence a programme of raising awareness sessions in the participating hospitals and the study site (e.g. lunchtime seminars, reporting in professional and senior management team meetings). These will continue throughout recruitment. The sessions will include information about the study,

why it is being conducted, processes of using the SPACE documents and training, how to identify and refer patients, and general information on managing clinical uncertainty for people with frailty and multimorbidity. These steps to raise awareness will be completed by the research lead (Evans) in her joint clinical academic post in the NHS site, supported by the research team, and the leads for the study in the respective community hospital.

- Displaying posters in appropriate places and flyers detailing the study, the research personnel and how to participate.
- Sign-posting to the study website https://www.kcl.ac.uk/cicelysaunders/research/studies/spacetoolkit.
- We will also discuss with staff in the hospitals our eligibility criteria and feedback on study recruitment to thank staff and enhance motivation.[48]

Consent

The process of consent and consultee advice for adults lacking capacity is shown in Figure 1. The MCA informs the process of consent and recent studies involving adults lacking capacity [49-51]. All participants are considered to have capacity unless established otherwise and all practicable steps will be taken to enable individuals to decide for themselves if they wish to participate. A potential participant's level of capacity is discussed with the referring clinician to identify participants with possible impaired capacity and to anticipate the likely recruitment procedure. Capacity is established when meeting the individual using the MCA four step process: 1) the individual is able to understand the information about the study; 2) retain the information (even for a short time); 3) use or weigh up that information and 4) communicate their decision.[52]

Potential participants' mental capacity is anticipated as ranging from able to give informed consent to lacking capacity to give informed consent. Incorporating different consent procedures is used in research studies on end of life care [49-51]. We will use consent procedures that are aligned to an individual's level of capacity, incorporating varying levels of capacity and anticipating that some participants may lose capacity during the study. This intends to enable individuals with varying levels of capacity to decide for themselves if they wish to participate, and to enable participation by adults lacking capacity. A witnessed consent will be included in the informed consent, and in the personal consultee declaration.

Consent in the moment for participants with impaired capacity

For adults with impaired capacity, who are able to understand, retain and weigh-up information in the moment, a procedure of consent in the moment is used with ongoing consent whereby informed consent to participate is verbally reaffirmed prior to each data collection point [53]. The approach of consent in the moment was developed and used in studies involving adults with dementia and/or cognitive impairment [53, 54]. If a participant's capacity declines and they are no longer able to give informed consent in the moment, the researchers follow the procedure for adults lacking capacity detailed below.

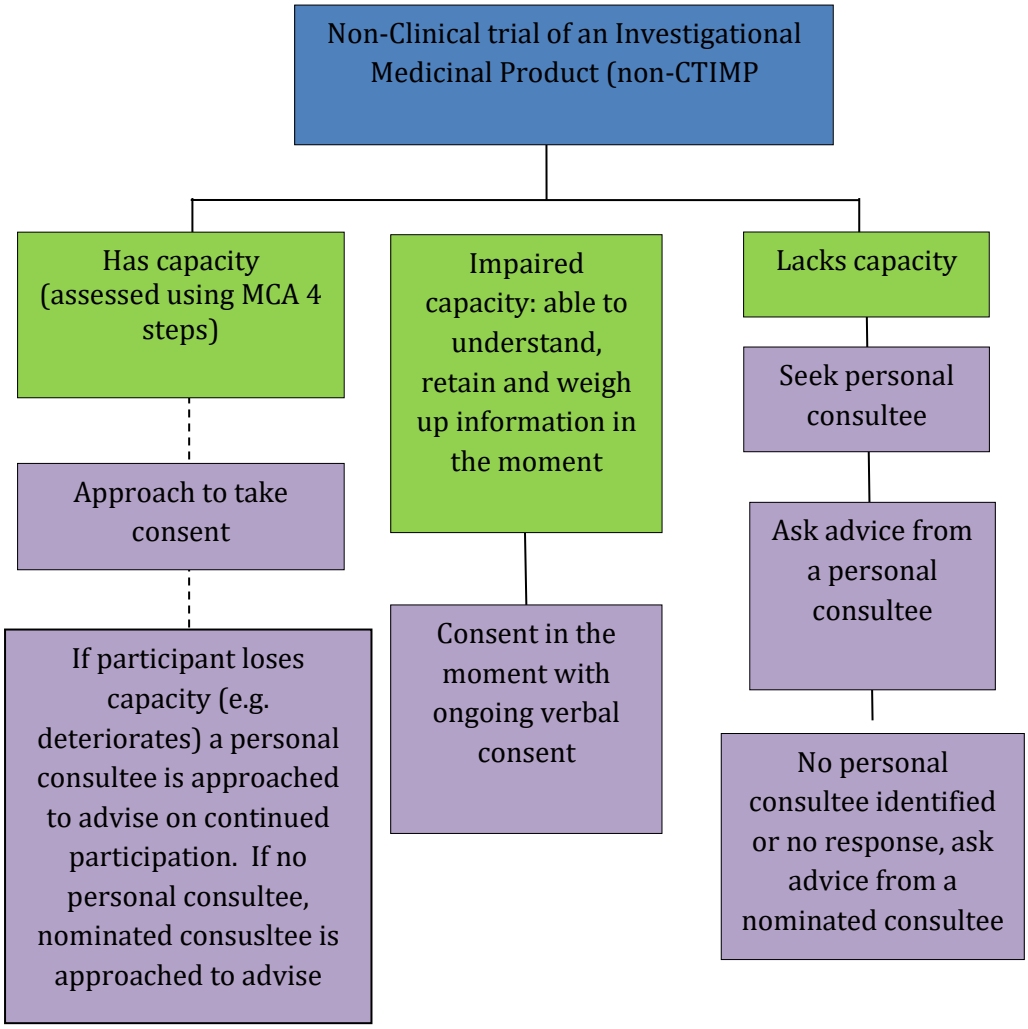
Adults lacking capacity

When an adult lacks capacity advice will be sought from a personal consultee about the person's participation in the study. If no personal consultee is identified, or does not respond to requests for advice, a nominated consultee will be asked to review and advise about participation. Participation is low risk. It will involve accessing the person's patient health records in the community hospital, the consultee (or other family member, close friend or staff when no family/friend) completing the study questionnaires on the person's behalf, and non-participant observation of clinical meetings about the person e.g. the Welcome meeting on admission with the informed consent of those participating in the meeting i.e. the family member, clinical staff.

Advice will be sought from the personal consultee about if in his/her knowledge of the person they would have wanted to participate in the study had they had capacity to indicate this, and that participation would not cause undue distress [49, 52]. A personal consultee will include for example next of kin, immediate caregiver, close friend or family member. The consultee documents are informed by research with older people [49], the MCA [52] and MCA guidance [55]. Identified consultees will be given (or emailed) the Consultee information leaflet about the study, a letter detailing why they have been approached and their responsibilities and the research questionnaire (admission questionnaire) for them to see the information requesting. The direct care team/research nurse will give the information to the potential consultee on the ward, or the information will be posted or emailed depending the information held. The request will be followed up 3-4 days after giving the information by telephone or email pending the information held (or letter if unable to reach by telephone). If a consultee agrees to participate, a time will be organized with the research team to complete the Consultee Declaration form by telephone or video call during the COVID-19 pandemic, and after the pandemic by telephone, video call or face-to-face pending preference. The researcher will read aloud the declaration form to the consultee and indicate on the form that each point has been agreed (or not) by the consultee. The researcher will email the completed declaration form to the consultee. The consultee will reply via email to confirm agreement with the consultee declaration. If no email is available, the declaration form will be posted to the consultee with a cover letter stating the study name, the declaration form is enclosed for the person [state name to participate in the study] following telephone/video call with [researcher name] on [state date and time]. The person will be asked to review and complete reply slip indicating agreement with the declaration form and return in the Freepost envelope.

If no personal consultee is identified, or gives no response after 7 days from the initial request, a nominated consultee will be approached for advice. The nominated consultee will not be involved in the patient's direct care or be supporting the study.

Figure 1 Processes of consent across the capacity trajectory



Documentation of study participation

All participants who give written consent to participate will be given a copy of the information sheet to retain and keep. Participants are offered a copy of their signed consent form to keep if they wish, and consultees a copy of the Consultee Declaration Form. A copy of the signed consent/declaration form will be filed in the participant's medical notes. The NHS site research and delivery team will retain the original signed consent and declaration forms.

Withdrawal of subjects

Participants are informed that they are free to withdraw from the study at any time. They will not need to provide any reason for withdrawing. If they decide to withdraw from the study for any reason, data will be anonymised and included in the study. Participant withdrawal is reported to the Chief Investigator to review, consider actions required and record withdrawal and actions in a site file note. If the participant gives a reason, this will also be reported.

Expected duration of the study

The feasibility study will run for nine months. This includes study setup, recruitment, data analysis and preliminary findings. Patients will receive the SPACE documents embedded in clinical care from admission to discharge and will be followed up for 28-42 weeks after discharge. End of the study recruitment is defined as the final participant data collection completed (by phone or visit), and study end date as publication of the main study paper.

Data collection

Data collection timepoints

We will use data collection timepoints for the two samples: 'before' SPACE is embedded in clinical care during the training phase on using the SPACE documents in the community hospitals; and 'after' SPACE is embedded in clinical care in the community hospitals. The timepoints are informed by understanding on the average length of stay is 25 days (range 16-42) for complex older patients with co-morbidities in community hospitals [56-58].

The data collection times points will include:

Sample 1: before SPACE is implemented during the training phase

Data collection will take place over 2-3 months during the training phase in each community hospital. Timepoints are:

1. 0 to 14 days from the admission date (as soon after the admission as possible)
2. 15 to 28 days after admission (or longer if extended admission), and
3. After discharge (28-56 days after discharge).

Sample 2: after SPACE is implemented during the assessment phase

Data collection will take place over two months after embedding the SPACE documents in clinical care in each community hospital. Timepoints will be informed by data completeness in sample 1, and modified if needed, e.g. removing an admission timepoint. Timepoints are planned as:

1. 0 to 14 days from the admission date (as soon after the admission as possible)
2. 15 to 28 days after admission (or longer if extended admission), and
3. After discharge (28-56 days after discharge).

Data collection methods

The methods of data collection will be 'tested' with sample 1 and refined with sample 2 if indicated to enable participation and enhance data reporting quality. The research nurses/researchers will support completion of the research questionnaires with patients during admission. The questionnaire administered on discharge will be posted with a cover letter, reply slip and Free post envelope to return the questionnaire to the research team at King's College London. The research team or the research nurses will assist completion if required by telephone during the COVID-19 pandemic and with face-to face offered after the pandemic (e.g. the person's own home). The research team will follow-up posted questionnaires with two reminders. Reminders will include a telephone call two weeks after postage of the questionnaire (or email, or letter if no phone number is available or calls are unanswered). We will ask the person if we can complete the questionnaire with them over the telephone, or if they prefer to self-complete and return by post. After 4 weeks a reminder letter will be posted with a further questionnaire booklet, reply slip and Free post envelope. The questionnaires will be checked for completeness by the researchers/research nurse, and a follow-up telephone call made to the participant to check accuracy if data is missing or clarify a response when unclear. Prior to posting the final questionnaire, we will check in the community health record if the person has died since discharged.

For adults lacking capacity the questionnaires will be completed by a proxy informant. The proxy informant will be the personal consultee, or another family member (for example the patient's son or daughter) or a close friend. If no family/friend are available the research questionnaire will be completed by a member of the community hospital staff who knows the person, and the post-discharge questionnaire completed by, for example, care home staff.
The proxy informant will self-complete the questionnaires on hard-copies either in the hospital or completed at home. Questionnaires will be returned by post to the project team at King's College London. We will make available an online questionnaire if this format is preferred. The proxy informant will be assisted to complete the questionnaires by telephone video call, during the COVID-19 pandemic or face-to-face after the pandemic as required by the research team or research nurses. Only remote interviews will be conducted with consultees during the pandemic. The research team will use two reminders with informants to complete the respective questionnaire. This will include a telephone call two weeks after giving or posting the respective questionnaire (or email or letter will be used if no phone number is available or calls are unanswered). If no response after 4 weeks we will post or email a reminder letter and enclose the respective questionnaire booklet, reply slip and Free post envelope. The questionnaires will be checked for completeness by the researchers/ research nurse, and a follow-up telephone call made to the participant to check accuracy if data is missing or to clarify a response when unclear.

Each patient or proxy informant (e.g. the personal consultee or other family member) will receive a thank you card and £5 voucher after completing the data collection during the admission. The card and voucher will be given to the person or posted to their address. The card will thank the person for participating in the study, state that their views are important and that we will ask them to complete a further questionnaire after they (or the person cared for) is discharged. We will post a further thank you card once data collection is completed, thanking the person for participating. The thank you cards will include the research team's contact details and indicate for the person to contact the team if they have any queries or questions about the study.

Distress protocol

There may be some distress and burden in completing the questionnaires and taking part in the study. It is important to note that patients and families often value taking part in research and welcome the opportunity to give their view. We have incorporated the opportunity for open comments, finding that this gives rich supplementary research data and is highly valued by patients and families in being 'heard' by researchers[59-62]. The research team will have completed Good Clinical Practice training, and specific training on addressing distress. The research nurses and researchers are experienced in recruiting and enabling older people to participate in research studies. We will ensure training and support on approaching patients, assessing capacity and collecting and managing data.

The research nurses and researchers will follow a distress protocol if patients or families become upset during the interviews or are found to be upset or in distress on arrival. Should this be the case they will first offer to pause, postpone or stop the interview and advise again that participation is voluntary. In the case of severe distress, the patient will be encouraged to share his or her feelings with a member of their healthcare team and/or the nurse offers to speak with ward staff with the person's agreement. We anticipate distress caused by the research will be infrequent. Given the general nature of the questions within the measures used, if distress occurs this will likely reflect the individual's concerns about their condition or situation. If participants disclose any ideation of self-harm or other risk to themselves or others, this will be managed as an urgent matter and clinical help will be sought. This will be in agreement with the participant. However, if the researcher/research nurse considers the participant is at imminent risk and refuses to allow voluntary disclosure, the research team will breach confidentiality. Based on prior experience, we anticipate this will be a very rare occurrence. Provision will be made to ensure the researchers have CI or senior back up available by phone whenever they are undertaking data collection. We make it clear that patients and families can omit any questions they don't want to answer and can withdraw at any time from the study with no effect on their usual care. We have ensured that we do not include terms that might be distressing, such as "prognosis", in the information leaflets and questionnaires.

Feasibility of the research methods

Sample size

The patient total sample size is 40 patients across the two community hospitals, with sample 1 comprising 20 patients and sample 2 comprising 20 patients. We will review the recruitment rate for sample 1, if recruitment is feasible within the timeframe, we will increase the sample 2 size to n=30. The sample size is informed by understanding that feasibility studies should include a minimum of 30 patients, and account for attrition. Attrition is calculated at ~30% as a typical rate for a study in palliative care.[47] A sample of 40 is considered sufficient for a feasibility study to explore the feasibility of recruitment to the study and the parameters to inform the sample size calculation in a future pilot trial.[63] We will recruit a maximum of 12 patients lacking capacity to assess the feasibility of the consultee process to advise on participation, and proxy reporting of research data. Patients lacking capacity will be recruited in sample 1 (pre-SPACE) and sample 2 (after-SPACE embedded). We will review our consultee process in the sample 1 recruitment to identify potential modifiers to enable participation.

Main candidate outcome

We will explore the feasibility and acceptability of a proposed candidate main outcome comprising '*Patient/family anxiety and communication subscale*' of the Integrated Palliative Outcome Scale (I-POS)[64-66 67 49]. Anxiety and communication are common distressing concerns for patients on admission to hospital and their families. These concerns are often exacerbated when clinical presentation is uncertain. The *Patient/Family anxiety and communication subscale* comprises 7 items of the I-POS[66]. The items concern information, practical matters, shared feelings, at peace, patient anxiety, family anxiety, and patient depression. Items are scored from 0 (best) to 4 (worst) and can be completed by the patient or a proxy (e.g. staff or family member) for adults lacking capacity. The I-POS is the latest refinement and improvement of the well validated and widely used Palliative care Outcome Scale (POS) developed and tested in palliative care[66]. The POS has been used in community and hospital settings, including in nursing homes (UK and the Netherlands), and in many different conditions including dementia,[67] heart failure[68], COPD,[69] cancer, neurological conditions,[70] and multiple co-morbidity[67].

Secondary candidate outcomes

- Palliative concerns not included in the patient/family subscale (I-POS)[66]
- Patient Reported Experience Measure (PREM) from the NHS National Benchmarking of Community hospitals (2018) https://members.nhsbenchmarking.nhs.uk/dashboard/2
    - *I had confidence and trust in the staff treating or supporting me*
    - *Overall, I felt I was treated with respect and dignity from this service*
- Physical disability (Modified Barthel Index)[71] (during admission timepoints)
- Function (Australian Karnofsky Index for palliative care)[72] (during admission timepoints)
- Frailty (Fried's Phenotype of Frailty[1]) (during admission timepoints). We will review the suitability of Fried's frailty scale for adults lacking capacity in our initially piloting of the questionnaires. The Fried measure includes physical assessment of hand strength, and for people able to walk, a timed 4 meter walk speed. We will review level of missing and feedback from the data collectors. If unsuitable we will remove Fried and replace with *FRAIL* [73]. FRAIL score is similar to Fried. FRAIL is very brief (2 minutes) measure of frailty comprising 5 items assessing fatigue, resistance, ambulation, illness and loss of weight. Each item is assessed using a different response option, but no physical measure of sarcopenia
- Survival at 6 months by review of NHS site electronic patient records

Process outcomes

- Community hospital length of stay
- Review and audit of patient records using a data sheet to record completion of the SPACE documents and decision-making[33] 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, the adapted-PACE and the Anticipatory Care Plan.

Economic evaluation

Comprises EQ-5D[74] as a quality of life measure recommended in cost-effectiveness analyses and the Client Service Receipt Inventory (CSRI) to record formal inpatient service use, medication and informal care.[75, 76] The economic data will be recorded in the admission questionnaire reporting the preceding 12 weeks, and repeated in the discharge questionnaire (28-42 days after discharge).

Embedded qualitative study

The embedded qualitative study intends to evaluate the process of using the SPACE documents in clinical practice, the acceptability and feasibility for clinical practice, and identify potential modifiers to enhance use and the potential for benefit, for example, improved communication and holistic assessment. The qualitative study will involve clinical staff in the participating community hospitals. The findings will inform refinements to the documents used in SPACE, solutions and challenges to enhancing and sustaining use in clinical care, potential benefit for patients and families, and methods of evaluation. The embedded qualitative study takes a generic approach that emphasizes common methodological practices across qualitative research methodologies[77] commonly used in qualitative studies in mixed method feasibility trials.[78]

Data collection

Data collection will involve non-participant observations, focus groups with staff and data from fieldnotes.

Non-participant observations will be of general clinical activity, and specific activities with clinical staff, caregivers and patients. The non-participant observations will be undertaken in both the before and after phases of the study. We estimate 30 observations of clinical practice across the two hospitals. Non-participant observations will include ward rounds and case meetings, staff training, and general activity, and specific observations of for example family meetings (with those present having given informed consent). Observations will be recorded on a A4 sheet with prompts of key areas including: communication (with patients and families, clinical teams); processes of assessment and goals of care; transition in care on discharge; and modifications to enhance document use (e.g. challenges and facilitators). The sheets will detail the date, time, hospital ID number and describe the nature of the observation e.g. case meeting. Observations will be accompanied by informal discussions with staff to clarify issues when indicated.

Focus groups with staff will be undertaken during the before and after phases of the study in each of the community hospitals. We will plan to conduct four focus groups involving 8-10 participants per group. The focus groups will be conducted with staff from the wards to explore the training and procedures for using the SPACE documents (before phase), views on using the SPACE documents and the outcomes (after phase). Additional focus groups will be offered if needed to accommodate staff availability, and individual interviews (or small groups of 2-3 people) to enable all grades and disciplines of staff to participate in the study. The topic guide will explore the processes of using the documents, training and potential to enhance clinical practice and outcomes for patients. The topic areas will include: enhancing key areas of clinical practice (communication with patients/families, comprehensive assessment, and continuity of care on discharge); managing clinical uncertainty; team working and communication; and facilitators and challenges to inform wider use. The topic guide is adapted from our evaluation of the PACE tool.[24]

Fieldnotes will be taken during staff training in groups or one to one on the use of the SPACE documents in clinical practice, and discussions with them about training and use across the study. The fieldnote data will record a summary of comments and discussions with staff. Fieldnotes will include the date, time, number of people, respective discipline(s) and ID code for the community hospital. No personally identifiable data will be recorded.

Sample size, participants and consent

Non-participant observations will involve caregivers, patients and clinical staff. The caregiver sample will include an estimated 12 caregivers (family member, or close friend) who participate in the non-participation observations of clinical activities, for example, Welcome Meeting on admission, and Family Meeting for discharge planning. The patient sample will comprise individuals recruited to the study with capacity to give informed consent, and patients in the community hospital able to give informed consent to take part in the non-participant observation of for example, the Welcome meeting (total patient observations n=12). The caregiver and patient sample sizes are considered enough to inform understanding on the processes and accessibility of clinical staff using the SPACE documents in clinical practice. The clinical staff will be the staff members involved in the respective clinical activity (e.g. the Welcome meeting, multi-disciplinary team meeting) who give informed consent for the observation. Prior to an observation the researcher (e.g Evans, clinical-academic and CI) will re-introduce her/himself, the study and ask if able to observe. If verbally agreed, each person is given an information sheet and the informed consent procedure is completed. At the end of the observation the researcher offers to show the information written down, check again that the person(s) has understood the observation is for a research study, clarify if further questions and offer for the individuals to contact the research team if they have questions about the study.

The focus groups will include 32-40 clinical staff from across the two community hospitals. 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. Staff will be identified by the senior nurses (e.g. ward matron) from each community hospital. They will be approached by the CI/research team by giving them the letter of invitation and information sheet or emailing via NHS email. Two reminder emails will be sent. Informed consent will be completed prior to commencing the focus group (or individual interviews). Some staff may choose to attend on the day of the focus group. They will be given the study information sheet if not received, and the informed consent procedure undertaken.

SPACE intervention

Theoretical underpinning

The SPACE intervention is underpinned by a Theory of Change[79]. This details a conceptual model depicting how the SPACE documents may work in clinical practice, the requirements to support use and linkages with the intended benefits for patients and their caregivers to improve communication and holistic care. The Theory of Change is underpinned by the Uncertainty of Illness theory[16-18] and its application in clinical practice[20] in general and specifically for older people[21], and the earlier stages of the study developing the SPACE intervention for clinical practice.

These earlier stages included:

- Systematic reviews to identify the documents used in SPACE to manage clinical uncertainty for older people with serious illness[43], and models of service delivery for older people towards the end of life[13] (workstream one).
- Stakeholder consultations with staff in four community hospitals exploring the acceptability of using the standardised documents in clinical care, the processes and

requirements to support use and the potential benefit for patients and families (workstream three)[44].

- Individual interview administered questionnaires with patients (n=30) in community hospitals on priorities to manage clinical uncertainty focusing on assessment, communication about what to expect, and information transferred on discharge (workstream three)[44].
- National cohort study (n=76, 704) in England using linked national databases on the need for palliative care in community hospitals examining the proportion of patients in the last year of life admitted to a community hospital (workstream two)[80].

SPACE components

SPACE will comprise usual care and the standardised evidence-based documents with training and support to incorporate in clinical care. Table 2 details the key clinical areas in the management of clinical uncertainty, and the respective standardised documents proposed in the SPACE intervention. The documents will be used in routine clinical care to enhance Symptom and Psychosocial Assessment and Communication Evaluation (SPACE). The findings from the training phase will refine understanding on the feasibility and acceptability of the documents proposed and the processes of using in clinical care and requirements to support use, e.g. training. The findings will be incorporated in the assessment phase to enhance how the documents are used and identify potential modifiers to enhance use and patient benefit.

The intention of SPACE is to use standardised evidence-based documents in clinical care to enhance key areas of practice in community hospitals and during clinical uncertainty. SPACE focuses on enhancing four key areas of clinical practice from admission to discharge, comprising:

1) comprehensive assessment and understanding on 'what matters to the person' and potential for rehabilitation
2) communication with the patient/family about expectations of care and treatment
3) review and evaluation of the care and treatment, and attainment of planned goals
4) Transition in care from hospital to home (including care home) for care and treatment to continue as planned and communication about the patient (and family) preferences and priorities for care in the future.

Table 2 Key clinical areas and the SPACE evidence-based documents to enhance practice

Clinical uncertainty	
Key clinical areas	**SPACE evidence-based tools for practice**
1. Comprehensive assessment including patient priorities, potential for rehabilitation, and symptom, information, and psychosocial needs. And review of outcomes of care and changing goals	**Integrated Patient care Outcome Scale for Dementia** (IPOS-Dem)[81, 82] a measure of symptoms and concerns for people with dementia and/or multi-morbidity promoting person-centred care asking how affected by a symptom and patient priorities. Validated for clinical practice and part of the established POS family of measure used in practice and research.[83, 84] **Clinical Frailty Scale**[85] (CFS) for clinical settings to measure frailty from 1 (robust health) to 7 (complete functional dependence on others) underpinned by theoretical model on fitness and frailty, and importance of function. Predictive for risk of mortality and institutional care. **Phase of Illness** (PoI) clinical assessment of illness presentation, validated and used in palliative care research and practice.[86, 87]
2. Arrangements to discuss and agree care and/or proposed changes with a patient/family	**Psychosocial Assessment and Communication Evaluation** (PACE) validated in ITU as improving staff communication and family understanding of symptom management.[33] Adapted for community hospitals with removal items relevant to adults <65 years, and addition of items from 'Welcome meeting' template.
3. Effective communication between hospital and home to maintain continuity of care on rehabilitation goals, anticipatory care, and patient priorities and preferences. Information shared with e.g. care home manager, GP, family	**Proactive Elderly Advance Care** (PEACE) for communication between hospital and care homes. Evaluation limited to pilots.[88,42, 89] Implemented in the local Anticipatory Care Plan (ACP) document developed from pilot work on PEACE.[89] Addition of ReSPECT to state recommendations for clinical care in a future emergency when person unable to express needs. Part of ACP process, particularly for individuals at risk of sudden deterioration, or nearness to end of life. ReSPECT used locally in regional and national implementation. Research evaluation pending. https://www.respectprocess.org.uk/

Frequency and duration of SPACE

The SPACE documents will be completed by staff in the respective community hospital (nurses, allied health professionals, medical doctors and health care assistants in a supportive role). The documents are intended to be incorporated in the individual patient document (IPD) (paper or electronic) used in clinical practice in the study site. How well (or not) the SPACE documents are used will be assessed in the study training phase (before SPACE embedded in clinical care) by auditing patient records in the community hospital, and non-participant observation of specific clinical activities, e.g. multi-disciplinary team meetings (see table 3). The findings will inform modifications to support use in the assessment phase (After SPACE embedded in clinical care).

Using the documents in clinical care will be supported by a manual on the SPACE documents detailing how to use, nursing/clinical leads (e.g. Modern Matron, ward manager and ward sister) and a designated champion(s) for SPACE in each participating community hospital. These individuals will provide ongoing support e.g. peer teaching, role modelling. They will draw on the expertise from the ward based Advanced Nurse Practitioner and Geriatrician/ Specialist doctor, and trust wide specialty leads for end of life care and dementia care. The process of using the SPACE documents is from admission to discharge for all patients in the participating community hospitals. The process of using the documents will consist of four key elements:

1. Ensure a comprehensive assessment on admission to identify priorities for the patient/family including physical, psychosocial and spiritual concerns; and potential for rehabilitation. Identify and agree:
    a. the goals of care, including rehabilitation goals and patient priorities
    b. planned treatment and care, including discharge date and place of discharge
    c. manner and timing of monitoring and evaluation
2. Arrangements to discuss and agree care and/or proposed changes with the patient/family
3. Review prior to discharge by repeating the assessment tools (IPOS-Dem and CFS) to give information on discharge on performance status (function), patient priorities and symptoms and concerns (deficits).
4. Effective communication between the community hospital and community services e.g. a care home manager. This intends to enhance the continuity of care between settings and enable a patient to remain in their chosen place of care, feeling safe and secure, with their autonomy preserved. Communication to maintain continuity of care will include, for example:
    a. Baseline at discharge including e.g. performance status (CFS score), deficits (IPOS-Dem – including symptoms and concerns, continence, skin integrity)
    b. Medical history including relevant PMH, falls, dementia screening, medications
    c. Goals of care including rehabilitation goals and patient priorities and preferences for care now and in the future
    d. Treatments e.g. medication and care e.g. to prevent pressure damage.
    e. Contingency plans detailing proposed care and treatment if the patient declines following, for example, a chest infection, and ResPECT document, for those at risk of sudden deterioration or nearness to end of life.

Supporting staff to use the SPACE documents

To support staff's use of the SPACE documents in clinical care we use processes of face-to-face training and nominated champions to model using the documents in routine care and coach staff. This will be undertaken in two phases: training phase (before SPACE documents fully embedded); and assessment phase (after SPACE documents embedded in clinical care). Table 3 overviews the phases and the respective processes. We have worked with the clinical teams and senior managers in the community hospitals and NHS site to refine these processes to support staff in using the SPACE documents in the community hospitals.

The incorporation of tools and measures in clinical practice are often impeded by clinicians' limited expertise and familiarity[84]. Our development work informed the processes of using the SPACE documents (workstreams 1 and 3). We also drew on national and international work on embedding the use of outcome measures in clinical practice in palliative care. This included studies undertaken in the Cicely Saunders Institute (CSI), on the knowledge mobilisation of outcome measures in palliative care in the UK (http://www.csi.kcl.ac.uk/oacc.html) and in Australia[86], systematic reviews on implementation in clinical practice,[90, 91] and resources on using outcome measures in clinical practice[82, 92] and specifically the POS family of measures, for example the Clinical Decision Support tool[93], and web resources http://pos-pal.org/.

Table 3 The phases and activities to use the SPACE documents

Activity	Actions required
Training phase (before): focusing on the processes and feasibility of using in clinic practice, auditing clinical records and amending processes accordingly.	
Setup SPACE in two hospitals. Sequential design implement, audit, learn and refine hospital 1, inform hospital 2	Sequential working with hospitals. Commence 1st hospital setup, auditing, learning and refining. Then commence 2nd hospitals. 1st hospital setup period over a month working with staff to refine processes of embedding in routine care practices. 2nd hospital commence implementation process refined from hospital 1. Work with staff in hospital 2 over a month to embed processes in routine practice.
Face-to-face training (conducted over a month in each site)	Face-to-face training approx. 2 hours in each site led by Catherine Evans (project lead), and site lead/champion working with the education lead. A training manual details specific documentation and processes for use. Training repeated if needed to enable participation of all clinical ward staff (e.g. nurses, AHPs, HCA, social worker, doctor). The training will focus on the introduction of SPACE, the specific documentation and incorporation in the individual patient-centred plan. The training is developed from the review of the evidence on managing clinical uncertainty (WS1) and consultation with clinical staff and patients/families on priorities on key processes (assessment, communication and continuity of care) (WS3).
Beginning to use the SPACE documents support to the ward staff (one month)	The ward staff are closely supported (coaching, telephone and direct guidance, discussion of clinical cases) by the nominated champions in each hospital, and Catherine Evans as project lead and Nurse Consultant in Palliative Care. The intention is to provide 'by the bedside' training by observing, doing and reflecting on processes.
Semi-intensive support to the ward staff (2-4 weeks)	The ward staff, the champions and project lead/Nurse Consultant, oversee the implementation processes, learning and refining how to use the SPACE documents in routine care. The champions and project lead conduct clinical audits of difficult cases, and review number of documents completed versus number of patients admitted to the hospital. This will seek to identify any training or implementation issues, what has worked well in the local context that could/should be included in the training manual.
Review and further training	Review and further training. The champions, project lead and education leads review the outcome of the initial steps. The aim is to refine the training strategy and processes for the ward staff.
Assessment phase (after)	
Evaluating the feasibility of using the SPACE documents in clinical practice and sustaining consolidating learning and training.	SPACE is embedded in the wards as an indicator of optimal care and management of clinical uncertainty from admission to discharge. The champions and project lead are responsible for the use of SPACE on the wards. They achieve this by ensuring incorporated in admission packs, care processes during inpatient stay and discharge checklists. Information about the SPACE documents are included in new starter induction packs, where documents are stored (e.g. electronic/ hard copies), with sign-posting for rolling training programme and support from the champions and education leads.

Data analysis

Quantitative analysis

The analysis will use the CONSORT guidelines for feasibility and pilot trials, supported by the Clinical Trials Unit, King's College London, and Dr Gao Wei, senior statistician and Dr Deokhee Yi, health economist, King's College London. The data analysis focuses on the feasibility of the research methods including patient recruitment and level of missing data, and frequency and completeness of using the documents in clinical care.

The data analysis plan will include:

1. Descriptive analysis on the number of patients screened for eligibility and the proportion of eligible patients recruited and reasons for decline, and differences between participants and non-participants e.g. age, gender
2. Descriptive analysis on completion of the SPACE documents from the patient record data extraction on when completed, proportion of missing data, and use over time e.g. IPOS-Dem to review and evaluate outcomes of care.
3. Examining the candidate main outcome of *patient/family anxiety and communication subscale* and secondary outcomes. We will examine missing data and evaluate the impact on results. We will explore the before (sample 1) and after (sample 2) measures and degree of change in the candidate main and secondary outcomes using non-parametric test for categorical data (e.g. Chi-Square) or parametric tests for continuous variables (e.g. T-Test).
4. Examine reasonable mean and variance estimates of the main outcome to inform the sample size calculation in a future pilot/full trial and estimates of inter-correlation co-efficient by examining variation between hospitals e.g. age, length of stay.
5. The data analysis in the economic evaluation will explore procedures to inform the economic evaluation in a pilot/full RCT. Economic evaluation is an emergent area in studies with patients with advanced progressive conditions and uncertainty surrounds best practice [76].

Qualitative analysis

We will undertake a full coding of focus group and interview transcripts, non-participant observations and fieldnotes to identify themes using constant comparative approach[94] in NViVo[95]. Data analysis will explore the range of experiences of staff using the documents in clinical care exploring feasibility and acceptability, solutions and barriers to enhance use, and potential benefit for patients and families. Quality appraisal will use procedures to ensure systematic attention to analysis and reporting e.g. analysis review meetings.

Ethics and regulatory approvals

The study will be conducted in compliance with the principles of the Declaration of Helsinki (1996), the principles of GCP and in accordance with all applicable regulatory requirements including but not limited to the UK Policy Framework for Health and Social Care Research and the Mental Capacity Act 2005. The protocol and related documents will be submitted to the Health Research Authority using IRAS and considered by NHS Research Ethics Committee (REC) that can consider vulnerable

adults. The Chief Investigator will submit a final report at conclusion of the trial to the funder, the REC and the Sponsor.

Data handling

The Chief Investigator will act as custodian for the study data. Patient data will be anonymised and stored in line with the General Data Protection Regulations 2018; the data will be archived in line with Sponsor requirements. Researchers will act to preserve patient confidentiality and will not disclose or reproduce any information by which participants could be identified or traced. Quantitative data will be entered into a pre-designed SPSS database created in collaboration with the study statisticians and the CI. Data entry is continuously monitored through supervision meetings where data entry rules are reviewed and agreed, and exceptions discussed. Ten percent of the data will be double-entered and cross-checked to identify the percentage of items with discordances, missing data and systematic errors (percentage of double-checked data will be adjusted according to outcome of cross-checks). Qualitative data transcripts, observations and fieldnotes are uploaded and analyzed using NVIVo.

Data management

Database passwords:
Database access will be restricted through passwords to the authorised research team.

Data Handling & Confidentiality/Format of Records:
Data will be accessed, handled, computerised and stored in accordance with the General Data Protection Regulations 2018. Participants will be identified on the study database using a unique code and initials. The researchers will maintain accurate patient records/results detailing observations on each patient enrolled. At the end of the study, study documentation will be archived in accordance with sponsor and local requirements. The retention of study data will be the responsibility of the Chief Investigator. The eCase Report From (eCRF) will become the formal record of the study dataset and will be retained for 20 years by the study team as part of the Study Master File. SAE data will be collected on paper. SAE report forms will be scanned and sent via NHS email to the Chief Investigator. Summary details of SAEs will be entered on the adverse event section of the eCRF.

Identifiable Data:
All participant contact information data will be stored on spreadsheets within the recruiting site, and at the lead site to complete follow-up data collection. The spreadsheets will have restricted access to the direct research team and research delivery team in the NHS site, and will be stored on password protected computers and kept separately from the data collected. The accrual data entered onto the UKCRN portfolio database will be anonymized, collated by the site and verified by the research team.

Data check:
The research team will monitor the validity of the data collected by the research nurses/researchers. Data entry will be completed at King's College London. On data entry

all data will also be checked for missing data and feedback will be given to the research nurses/researchers (including an attempt to try to still collect this data). We will send 1-3 monthly feedback pending recruitment rate to the research nurses on the quality of the data.

Assessments/Data Collection:
Written informed consent/consultee advice must be obtained prior to the baseline questionnaire (T0) and any other study specific procedures taking place.

Data sharing:
Anonymous research data will be stored securely and kept for future analysis. The data will be kept anonymous on secure access computers, and access will be via written confidentiality and use agreement with Dr Evans (or her appointed nominee), supervised by or with the involvement of Dr Evans, or members of the research team. A data sharing plan will be developed. The NHS site will also be able to request the data for analysis, signing the use agreement, providing it is kept on secure locked computers, and they provide verified details of this in advance. The person applying for use of the data will be scrutinized for appropriate eligibility by members of the research team. We will develop a data sharing policy, under guidance of the Study Steering Committee.

Envisaged data sharing policy:
• The study is registered prior to recruitment on the NIHR UKCRN Portfolio database.
• 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 sharing of the 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.
• Our dissemination plan includes publication in high quality peer reviewed journals, presentation at clinical and research conferences, and production of executive summaries for commissioners, clinicians, policy makers and patients and their caregivers.
• 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.

Publication Policy

It is intended that the results of the study will be reported and disseminated at national and international conferences, and in peer-reviewed scientific journals. The main publication and subsequent publications should include the chief investigator and all co-investigators. All authors (including these but also others) should fulfil the criteria as set out by the ICMJE (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html).

We will publish the main study paper reporting the results in a (peer-reviewed) journal and to make it available in accordance with NIHR guidance. Efforts will be made to send a summary of results to participants once they become available. Wider public dissemination will be facilitated by patient and service user representatives, who are part of the Study Steering Committee and a separate PPI committee. Feedback to the local participating community hospital teams and site with a presentation at appropriate research meetings. We will send the funding body progress reports every 12 months in accordance with their guidelines.

Insurance / Indemnity

The study will be sponsored by King's College London, who has taken out an insurance policy to provide indemnity in the event of a successful litigious claim for proven non-negligent harm. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

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