Study Protocol

OPTCare Elderly - Optimising palliative care for older people in community settings: a feasibility study developing and evaluating a new short term integrated service

(Phase 2)

Applicants

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Abstract

Background: People are living longer and dying increasingly with frailty and complex co-morbidities. Many suffer unnecessarily because of limited recognition of palliative care needs, aggressive management and under treatment. Palliative care is advocated for frail older people with non-malignant conditions to improve assessment and treatment, but with little evidence of effectiveness. This study intends to work with NHS staff in a community trust to develop and evaluate a new short-term integrated palliative and supportive care (SIPS) service for frail older people living at home or in a care home and their families. Short-term palliative care could be effective and cost-effective as it relies on existing services with additional support at times of actual or anticipated deterioration in wellbeing.
Aim: To develop and evaluate the feasibility of the new SIPS service for frail older people in community settings (including care homes) delivered through integrated working between specialist palliative care services and community nursing teams, and close working with GPs and geriatricians.

Methods: The research methods follow the Medical Research Council guidance for the development and evaluation of complex interventions. Phase 1a intervention development involves a post-bereavement survey to determine preferences for care and palliative care outcomes by place of death for older people (n=882); and phase 1b a stakeholder consultation with recipients of care and service providers/ commissioners, on the survey findings to develop the intervention and then, an on-line/postal survey on the proposed components and outcomes. Phase 2 is a feasibility trial to develop procedures for a full randomised controlled trial and refine a model of integrated professional working. Phase 2 involves 52 older people randomised to receive short-term palliative and supportive care (SIPS) or usual care. The primary outcome is symptom burden for five key palliative symptoms (*breathlessness, anxiety/depression, constipation, pain and fatigue)* from the Integrated -Palliative Outcome Scale symptom component (I-POS), secondary outcomes: palliative outcomes (I-POS), survival, attainment of preferred place of death, carer burden (Carer Zarit Burden Interview), and economic evaluation (Client Service Receipt Inventory). Nested qualitative studies examine recipients' experiences of the intervention (patients/carers n=12) and service providers/commissioners experiences of delivering (n=16).

Abstract in plain English

People are living longer and more often die following a period of increasing frailty and difficulties with their health. Palliative care is recommended for elderly people living with frailty and non-cancerous advanced illnesses to improve their quality of life and their carers, but uncertainty surrounds how to achieve this. This study aims to work with an NHS community trust to create and test a new service for frail elderly people living at home or in a care home. The new service is delivered by close working between specialists in palliative care such as a Macmillan Nurse, and services provided by community nurses like a district nurse and general practitioners (a GP). The study is in three parts. This application is for parts 1b and 2. Part 1b refines the salient components of the new service by asking older people and carers, professionals providing services and members of voluntary groups about the results of a carers' survey on care for older people at the end of life (part 1a underway). Part 2 examines if we are able to provide the new service in practice and if it benefits patients and carers. We will select 52 older people with deteriorating health, and their carers, to receive either the short-term palliative care service or usual care. The new service is delivered by two specialist community palliative care teams working with four community nursing teams and four GP practices. We will see how well the new service compares with usual care to improve older people's wellbeing, reduce carers' burden and differences in the services used and costs. The results tell us if this new service is likely to benefit patients and carers and if benefit is shown how we should carry out a larger study.

Scientific summary

Background: People are living longer and more often die following a period of increasing frailty and health difficulties associated with non-malignant advanced illnesses. Frailty is a state of vulnerability to resolve stressor events on one's health, notably infection, because of cumulative physiological decline over a lifespan.[2] It is a clinical expression that implies concern about an elderly person's vulnerability and outlook.[3] Palliative care is advocated for older people living with frailty and advanced non-malignant illness to improve the quality of life, but with little evidence of effectiveness.[4 5 6] This study intends to work with NHS staff in a community trust to develop and evaluate a new short-term integrated palliative and supportive care (SIPS) service for frail older people with complex needs living at home or in a care home. Short-term palliative care could be cost effective and appropriate because it relies on existing community services, but with additional shared support from specialist palliative care services at points of increasing vulnerability and uncertain outcome.

Aims: The study's primary aim is to develop and evaluate the SIPS service for frail elderly people living at home or in a care home. The service is delivered through integrated professional working between specialist palliative care services and community nursing teams, and GPs and geriatricians as main providers of care. This is a feasibility study to develop procedures for a full RCT. The secondary aims pertain to: developing the methodology for a full RCT and a model of integrated professional working between generalist and specialist nurses. The project comprises two phases: phases Ia and 1b developing the intervention (objectives 1-2); and phase 2 assess the feasibility of the intervention (objectives 3-5).

Objectives:

1. To identify and develop the active components of the new SIPS service a single community NHS trust using a post-bereavement postal survey to relatives/carers on preferences of care, palliative outcomes and cost-effectiveness for frail elderly people by place of death.
2. To consult with stakeholders (e.g. recipients and providers/commissioners of care) on the survey findings and identify the most salient SIPS components and outcomes.
3. To identify and strengthen the active components of the SIPS intervention for the full RCT and the model of integrated working, using nested qualitative studies to explore experiences of a) service receipt and b) barriers and facilitators to integrated working.
4. To test the impact of SIPS on the primary outcome of five palliative symptoms (I-POS symptom component), and secondary palliative outcomes (I-POS), carer burden (Carer Zarit Burden Interview), and economic evaluation including informal and formal service use (Client Service Receipt Inventory).
5. To develop the methodology for a future full RCT by testing procedures in order to calculate sample size, manage attrition and missing data, and to guide future assessment of cost-effectiveness.

Plan of investigation: The research methods follow the MRC guidance to develop and evaluate complex interventions.[7] The study comprises two phases: Phase 1a intervention development to identify active components of SIPS and gaps in service provision using a post-bereavement survey to model preferences for care, palliative care outcomes and service use by place of death; and phase 1b stakeholder consultations on the findings to refine the salient components of the SIPS intervention involving 1) elderly people and carers using focus groups, and 2) representatives from service providers, commissioners, and the voluntary sector using Transparent Expert Consultation (TEC) of nominal group to generate recommendations and identify divergence, and on-line/postal survey to prioritise the intervention components and outcomes[8]. Phase 2 tests the feasibility and procedures to develop the methodology for a full RCT with 52 participants randomly allocated to receive SIPS or usual care. The primary outcome is the impact on five key symptoms identified from earlier studies[9-11] and the phase 1a findings, and secondary outcomes on palliative outcomes, carer burden and service use assessed at baseline, 6 and 12 weeks. Nested qualitative studies at intervention completion to examine experiences of service receipt (n=12) and barriers and facilitators to deliver (n=16).

Potential impact: Improving elderly people' access to specialist palliative care could impact patients' and cares' quality of life and reduce NHS costs. This is a feasibility study that if found beneficial will develop

procedures for full RCT, and a refine model of integrated working, or if negative inform future interventions and service developments.

Background

People are living longer and increasingly die with frailty and multiple co-morbidities following a period of progressive illness and escalating symptoms. The proportion of people who die aged over 85 is expected in the UK to increase from 32% in 2003 to 44% in 2030.[12] The trajectory of dying is often one of increasing frailty and for many, complex co-morbidities, with diminishing capacity, notably from dementia, and increasing risk to poor health outcomes.[2, 3, 13, 14]Frailty is conceptualised as a diminishing capacity to accommodate threats to health and increasing risk of poor health outcomes, and presents as a myriad of clinical features, notably loss of strength and fatigue.[2] UK health and social care policy advocates palliative care for elderly people to support complex care needs at the end of life.[15] However, elderly people have disproportionately lower access to these services compared to younger adults[11, 15, 16] and there is little evidence of effectiveness.[4, 17] Moreover, elderly people predominantly have diseases other than cancer which traditionally palliative care services have focused on.

This study intends to work with NHS staff in a community trust to develop and evaluate the feasibility of a new short-term integrated palliative and supportive care (SIPS) service for elderly people living with frailty and advanced non-malignant illness and escalating health needs living at home or in a care homes (with or without nursing). A short term service may be cost effective and appropriate as it relies primarily on existing health services, but with additional shared support from SPC services at points of, for example, deterioration in health and uncertain outcomes. To develop and sustain a new service in palliative care requires firm integration into the existing health care system.

The short-term palliative care integrated service is informed by work led by applicant Higginson who developed and evaluated this approach with patients severely affected by Multiple Sclerosis (MS) and demonstrated patient and carer benefits and cost savings.[18] The new service targeted individuals severely affected by MS with, for example, unresolved symptoms, and offered direct assessment by a specialist in palliative care and one to three follow up contacts to plan and manage care, in close liaison with the primary health care team , and (re)-referral to community services for continued management when indicated. Research led by applicant Evans on experiences of health in advanced age and a systematic review on the effectiveness of specialist palliative care for elderly people (finalising paper), indicated potential patient benefit of a short-term integrated palliative care service for frail elderly people in community settings. In particular, at points of actual or anticipated deterioration in health, and the requirement for greater recognition of elderly people's palliative care needs. Palliative care is likely beneficial for elderly people dying with frailty and complex co-morbidities in the community by addressing in particular, the use of aggressive treatments in the dying phase,[10, 19] improving pain management , notably for people with dementia[4] and facilitating advanced discussions on, for example, allowing a natural death and preferred place of care in the last days of life. Overall, the evidence on the effectiveness of specialist palliative care for frail elderly people is equivocal, but the literature informs understanding on the potential processes to deliver specialist palliative care and areas of likely patient benefit.

This feasibility study intends to develop Higginson et al's work[18] to tailor to the population of frail elderly living with non-malignant advanced illnesses by emphasising service delivery through integrated professional working between specialist palliative care and community nurses, and general practitioners and geriatricians as the main providers of care. An integrated approach enables continuity of health service provision by the main care provider, development of generalists' provision of palliative care and support from specialists at points of, for example, increasing complexity in an elderly person's care. Specialist palliative care has a remit to work with generalists by both directly providing care to patients and their families and indirectly through education and support to generalists.[20] It is uncertain which approach, or combination, best constitutes

integrated professional working, for example, a combination of direct and indirect provision using shared guidance on care pathways. [21] The study involves elderly people living at home or in a care and their carers (informal carers, e.g. a family member). Elderly people with increasingly high levels of dependency associated with frailty and com-morbidities may continue to reside at home, but many move into a care home particularly in the last year of life.[22] Care home provision involves homes with or without nursing depending on the health and social care needs of the individual. This study aims to develop and evaluate the feasibility of the SIPS for frail elderly people living at home or in a care home. This is a feasibility study to support the development of the research methodology for a future full randomised controlled trial and develop and refine a model of integrated professional working between generalist and specialist nurses in the community.

Aims and objectives

The primary aim of the study is to develop and evaluate the feasibility of SIPS service for frail elderly people in community settings delivered by SPC teams working with community nursing teams, general practitioners and geriatricians. This is a feasibility study. The secondary aims pertain to: testing and developing procedures for a full RCT; and developing and refining a model of integrated working between generalist and specialist nurses. The study comprises two phases: phase 1a intervention development (objective 1); phase 1b intervention refinement (objective 2); and phase II comparative feasibility trial of the intervention (objectives 3-5). The objectives are:

1. To identify and develop the active components of the new SIPS service in a single community NHS trust using a post-bereavement postal survey to relatives/carers on preferences of care, palliative outcomes and cost-effectiveness for frail elderly people by place of death.
2. To consult with stakeholders (e.g. recipients and providers/commissioners of care) on the survey findings and identify the most salient components of SIPS and outcomes using: focus groups with older people and carers; and with service providers and commissioners a Transparent Expert Consultation (TEC)[8]of nominal group workshops to generate recommendations on the salient components, explore areas of consensus and divergence, and an on-line/postal consensus survey on the recommendations generated.
3. To identify and strengthen the active components of the SIPS intervention for the full RCT and the model of integrated working, using nested qualitative studies to explore experiences of a) service receipt and b) barriers and facilitators to integrated working.
4. To test the impact of SIPS on the primary outcome of five palliative symptoms (I-POS symptom component), and secondary palliative outcomes (I-POS), carer burden (Carer Zarit Burden Interview), and economic evaluation including informal and formal service use (Client Service Receipt Inventory).
5. To develop the methodology for a future full RCT by testing procedures (including patient recruitment methods, processes of consent, outcomes measurement, resource use measurement and time points) to calculate sample size, manage attrition and missing data, and to guide future assessment of the cost-effectiveness of the service.

This research protocol pertains to phase 2 and amendments following findings from phases 1a and 1b. Phase 1a recruitment opened October 2012 and closed May 2013, phase 1b opened December 2013 and closed February 2014. Data analysis is underway for both phases. Ethical approval was awarded for phase 1a (NRES Committee South East Coast - Brighton and Sussex (REC reference: 12/LO/13), and phases 1b and 2 (NRES Committee London- Queen Square, REC reference: 13/LO/1304). Sussex NHS Research Consortium awarded governance for all phases.

Phase 2: Comparative feasibility trial

(Objectives 3-5: timing 18 months – April 2014 to October 2015)

Study design

The study design follows the MRC Framework Developing and Evaluating Complex Interventions[7] that is widely used in evaluative studies of palliative care services and treatments.[18, 23] The study uses a phased design to develop and evaluate the feasibility of the SIPS service for elderly people with frailty and advanced non-malignant illness living at home or in a care home (nursing or residential). The study uses two phases: phase 1a intervention development; phase 1b intervention refinement; and phase 2 comparative feasibility trial to field test the procedures and develop the methodology for a full RCT (see appendix 1 study flow diagram). This protocol pertains to phase 2 only. Phase 1a intervention development using a post-bereavement survey is detailed in a separate protocol that received ethical and governance approvals in September 2012 (REC reference: 12/LO/13) and commenced October 2012.

Phase 2 uses a comparative feasibility trial of the SIPS intervention with a nested qualitative study. Phase 2 aims to test procedures to develop the methodology for a full RCT and refine a model of IPW between specialist and generalist nurses in community settings (objectives 3 & 4). Figure 1 uses a graphical method to depict the intervention, interviews and timings in the trial.[24, 25]

Study setting

The new service is based in the single study site of Sussex Community NHS Trust (SCT). The Trust serves a population of over 1 million and covers Brighton and Hove, and West Sussex. The area has a network of specialist palliative care services including in-patient hospices, hospice at home, and community specialist palliative care teams (SPCTs), two of which are directly managed by the NHS Trust (Brighton and Hove, and Midhurst Community SPCTs). Several of the co-applicants work clinically in the Trust locality including: Evans, Lindsay and Bruni as specialist palliative care clinicians in the Trust's SPCTs; Taherzadeh is a GP in West Sussex; and Wright is a senior lecturer in elderly medicine at BSMS and honorary consultant geriatrician at Brighton and Sussex University Hospitals.

Specialist, primary and community care practitioners

The service providers are identified through discussion with clinicians in the study site who are co-applicants or advisors to the study. The delivery of the SIPS intervention involves four general practices and their respective attached community nursing team working with a specialist palliative care team, Brighton and Hove or Midhurst, West Sussex. The general practices and community nursing teams identified for the phase 2 feasibility trial are invited to participate in the stakeholder consultation. General practices are identified in discussion with the participating specialist palliative care team using purposive sampling. General practice selection is based on:

- A practice size of ≥ 10,000 patients
- Participating in Direct Enhanced Services for:
    - End-of-life care requiring maintenance of a register of patients considered in the last year of life and holding regular multi-disciplinary meetings to review patients on the register, e.g. monthly Gold Standards Framework (GSF) meetings
    - Risk Profiling and Care Management Scheme[26] requiring GP practices to proactively profile patients registered with the practice who are predicted of becoming or are at significant risk of emergency hospital admission. This is the closest available register in GP practices for the frail elderly
- Close working with the specialist palliative care team and attached community nursing team. This is an ambitious study, incorporating existing collaborative relationships intends to enhance delivery of the study's objectives.

A letter of invitation for the stakeholder consultation and feasibility trial is sent to eligible practices signed by Evans as the project lead and Higginson as the joint lead, and the co-applicant palliative care consultant for the respective palliative care team (Lindsay, Brighton and Hove Community Palliative Care Team; and Bruni, Midhurst Macmillan Community Team). The palliative care consultants liaise with the practice regarding their interest in the study. If they express an interest the research team arrange to meet at a convenient time to discuss their involvement. A letter of invitation is sent to the respective community nursing teams for the stakeholder consultation and feasibility trial. Each team's manager is contacted by telephone to inform them of the community nursing teams' invitation to participate in the study. Practitioners wishing to participate in the consultation receive a personal email invitation with pre-consultation briefing packing. Potential participants are asked to confirm attendance by email.

The intervention is delivered by the two SPCTs directly employed by SCT and four general practices and their respective attached community nursing team. The general practices and the respective community nursing teams are identified and invited to participate in the stakeholder consultation (phase 1b) and the phase 2 feasibility trial (see stakeholder consultation recruitment).

Care home staff

The participating general practices identify local care homes with older people registered with the practice. The care home manager and the care home owner are sent a letter indicating the GP practice and community nursing team's involvement in the study and requesting the care home's participation. The researcher telephones the care home manager one week after the initial letter to ascertain their interest in supporting the study. A meeting is arranged with the care home manager and care staff to discuss the study. If a care home decides to support the study the researcher suggests displaying in the care home posters about the study with photos of the research staff to inform friends and families about the study. Information booklets about the study are left with care home to give to friends and relatives visiting the home.[27, 28] In instances where the GP practices are working with more than three care homes, the larger care home which the GPs identify as having a good working relationship with are approached first. Building on existing collaborative relationships intends to enhance delivery of the study's objectives.

Study participants

Older people

Eligibility criteria

The inclusion criteria are broad encompassing age, one or more unresolved symptom as uncertainty surrounds when a frail older person may most benefit from palliative care.[4] The findings from phases 1a and 1b have refined the inclusion criteria. The inclusion criteria comprises:

- Adults aged 75 years or over
- With or without an informal carer (e.g. a family member).
- Participants registered with one of the four GP practices participating in the study
- Residing at home or in a care home (with or without nursing)
- Severely affected by non-malignant advanced illness and/ frailty with or without dementia

- Severely affected encompasses two or more unresolved:
  - Symptoms
  - Psychosocial concerns
  - EoL issues e.g. advance care planning
  - Progressive illness/frailty
  - Complex needs (i.e. palliative care needs)
  - Increasing health service use
  - Carer burden
- CSHA Clinical Frailty Scale participant in one of the categories from 4 and above (4 to 9) [29]

This is a feasibility study and our intention is to explore measures for frailty to identify participants most likely to benefit from the intervention. There is curently no valid frailty index on severity to inform clinical decision making regarding treatments and interventions.[3] Living with frailty comprises clinical judgement on accumulative clinical deficits (identified by clinical history and clinical assessement i.e. signs, symptoms and test results). A person living with frailty is conceptualised as presenting with three or more clinical features of: weight loss, fatigue, reduced walking speed, loss of muscle strength or prefence for less physical activities.[2] Severity is incorporated in the participant eligibility criteria using the Clinical Frailty Scale based on clinical judgement and validated for clinical practice. In our baseline measures we use an objective measure of Fried's Phenotype of Frailty. Fried's measure is most commonly used in research studies to describe the sample, and frailty severity,[30] but not in clinical practice because of limited focus on sarcopenia deficit and no consideration, for example of cognitive impairement.

Exclusion criteria

Older people are excluded with malignant disease receiving curative or palliative treatment, or non-malignant disease using specialist palliative care.

Study procedures

Sample size

There is limited data to provide estimates for a sample size calculation. The study's findings will inform future sample size calculations. We estimate that a sample of 21 older people in each arm would allow a two-tailed, two-sample t-test detect differences of >2 (with a standard deviation [SD] of 2.25) on the I-POS symptom component at alpha = 0.05, power= 80% at 12 weeks.[19] Allowing for 20% attrition requires 26 participants in each arm.

Sampling

The elderly people meeting eligibility criteria recruited from the participating general practices, community nursing teams and care homes (with or without nursing) caring for elderly people registered with one of the participating general practices. Eligible participants who give consent to participate (or process of assent is completed for adults lacking capacity) are randomly assigned to receive the intervention of SIPS or best usual care. The nested qualitative study uses purposive sampling to identify participants in the intervention group whose primary outcome measure at the week six time point showed either: 1) improvement; 2) no change; or 3) three deterioration. The qualitative interviews are conducted at the 12 week time point (table 1).

Participant identification and recruitment over 10 months

An 'active' recruitment approach is used to identify eligible participants. This requires the research team to work with clinicians and care home managers to actively identify potential participants and follow-up. Reviews of trials of palliative care services[31] and trials involving elderly people[27] advocate an active recruitment approach because of frequent problems of poor recruitment contributing to trials failing and the diffuse nature of frailty.[3] Potential participants are identified and recruited using a staged approach

beginning with the GPs, then community nursing teams and finally the care homes. The approaches used comprise:

1) GP practices by:
    a. Practices identifying potential participants through national initiatives in primary care involving Risk Profiling and Care Management Scheme. Risk profiling requires GP practices to proactively profile patients registered with the practice who are predicted of becoming or are at significant risk of emergency hospital admission. Practices conduct a Risk Profile of all registered patients once every quarter and work with the multi-disciplinary team to manage individuals' care. This is the closet available register in GP practices for the frail elderly and is a way of integrating highly relevant developments in practice with the research study. Individuals identified through the practice's Risk Stratification/Proactive Care Profiling and Register are discussed with the lead practitioner for the study (e.g. a GP) and eligibility ascertained using the criteria detailed below. Characteristics for the Risk Profiling includes:[32]
        - Elderly patients with recent hospital admissions
        - On multiple medications
        - With multiple chronic diseases
        - Housebound
        - Patients who have had more than 5 courses of antibiotics in the last 12 months are over the age of 75
        - Patients over 80 who have not been seen in the last 12 months
        - Patients who do not have codes for having had an influenza vaccine, and have not declined

    a) The GP practices use an identification log (Excel sheet electronic or hard copy) to record patients considered eligible and code outcome e.g. eligible, or predefined code for ineligibility. This document is not shared with the researchers. On recruitment completion the GP practice completes the identification log summary document stating number patients identified, number eligible, non-eligible and number for each ineligibility category. This is a feasibility study and examination of application of eligibility criteria and proportion eligible on a GP caseload will inform the methods for a full trial. The GP practice enters eligible participants onto the screening log detailing recruitment stages and outcomes e.g. study information sent/given, GP follow-up telephone call and outcome. The screening log forms the sampling frame. The screening log states patient initial for the GP practice to track between the identification and screening log. The screen log details factors to enable comparative analysis of participants and non-participants. Factors include: age, gender, 1st and 2nd diagnosis, ethnicity, receipt of community nursing services, living status e.g. lives alone, Clinical Frailty Scale category. We use this data in the data analysis to explore the differences between participants and non-participants. No patient identifiable data is shared.
2) Community nurses by:
    a. The participating community nursing teams reviewing their caseload to identify potentially eligible individuals. Identified individuals are discussed with the lead for the team (e.g. case manager). Identification and eligibility outcome is recorded on the identification log (detailed above). No patient identifiable data is shared.
3) Care homes by meeting with care home managers of care homes (with or without nursing) caring for elderly people registered with one of the participating GP to identify eligible participants. The care home manager identifies potentially eligible participants. No patient identifiable data is shared with researchers.

The identifying clinician gives or sends the patient (or personal consultee for adults lacking capacity) the invitation letters (GP practice indicating support for the study; and researcher letter of invitation), participant information sheet (PIS), A4 PIS summary sheet with large text, 'palliative and supportive care' information sheet, reply slip and Freepost return envelope on behalf of the research team. The identifying clinician may discuss the study with a patient by telephone before sending study information if they consider this is required to facilitate understanding and allay anxiety. If the clinician gives a participant the study information, they ask for verbal consent for the research team to telephone the individual in a week to discuss the study, if they have not been in contact themselves. The clinician documents the verbal consent in the person's medical record (or nursing record when a participant is identified by a community nurse). When no verbal consent is in place, a week after sending/giving the information a member of the GP practice (e.g. GP) telephones the patient/consultee. The telephone call is to ascertain interest in the study and obtain verbal consent to give the individual's contact details to the research team, or to decline participation. Studies involving elderly people,[33, 34] including Davies et al's[28] work show that the method of direct contact by telephone following receipt of letter of invitation was preferred by elderly people and more successful in ascertaining their interest (or not) in the study, then requesting return of a reply slip to indicate participation. Potential participants can themselves decline participation or request further information from the research team. The study invitation letter asks a potential participant to call the researchers if they wish to participate or to decline, or to send a reply slip in a FREEPOST envelope to indicate participation or decline.

The invitation letter is from the research team with an accompanying letter of support from the respective GP practice or community nursing team, and a detailed information booklet. An extensive study by Davies and colleagues[28] in Newcastle involving over 800 elderly people aged 85+ years demonstrated elderly people's preference for a letter from the research team, with an accompanying letter from the respective clinician. This improved clarity on who was undertaking the work and who potential participants should contact for further information; the research team, rather than the clinician. The letter of invitation is sent promptly after identification of an eligible participant. This is to minimise sending letters of invitation to people who have died; the shorter the time between identification and invitation reduces the likelihood of causing distress to relatives by writing to a relative who has recently died.[28]

A different procedure is used with older people residing in a participating care home. If a GP is visiting a resident they may give the study information to the older person and ask for a verbal consent for the research team to contact the older person. Or the GP practice informs the care home manager of a resident eligible to participate in the study. The GP sends the study information to the care home manager to give to the eligible older person. The older person informs the care home manager if they are interested in the study and the care home manager asks for verbal consent to pass on his/her details to the research team. The care home manager contacts the research team to inform them of the participant's interest in the study, or the GP practice to decline participation on the older person's behalf. The research team liaise with the care home manager to arrange a date and time to visit the older person interested in the study. If there is no contact from the manager a week after sending the study information the GP practice calls the care home. The older person may also contact the research team directly themselves using the reply slip or by telephoning.

When a potential participant lacks capacity to give informed consent the GP or care home manager is asked to identify a personal consultee, for example the individual's next of kin. A letter of invitation is sent by the GP practice or care home manager on behalf of the research team requesting an assent for the older person to participate in the study (see figure 1). The letter requests telephone or email contact with the research team within one week. The letter is accompanied by a letter of support from the care home manager and an information sheet about the study. When no personal consultee can be identified (e.g. the person has no next of kin), or contact cannot be made with the personal consultee within a week of initial identification, a nominated consultee is contacted[35, 36] (see procedure below).

The respective GP practices maintain identification and screening logs. The identification log is not shared with the research team. The GP practice record on the identification log a patient's name identified from the Risk Profiling Register and outcome of the eligibility criteria e.g. eligible, or non-eligible inserting pre-defined code for reason e.g. cancer receiving curative or palliative treatment. On completion of recruitment the practice informs the researchers on the number of patients identified and outcome of application of eligibility criteria using numbers only. No patient identifiable data is shared. This is a feasibility study, examination of potentially eligible participants in a GP practice is important to inform the research methods for a definitive RCT. The GP practice enters an eligible patient onto the screening log using the patient's initials. The screening log details completion and outcome of the recruitment stages e.g. date study information sent, date of follow-up phone call and outcome. The screening log forms the sampling frame. Each GP practice records demographic details for each eligible participant including primary diagnosis, gender, age and living status using defined codes (e.g. lives alone, care home). We use this data in the data analysis to explore the differences between participants and non-participants. No patient identifiable data is shared.

It is anticipated that many eligible participants may have impaired capacity, but are able to understand, retain and weigh up information in the moment. An A4 information sheet accompanies the detailed study information leaflet and letters of invitation. The information sheet is a single A4 sheet with font size of at least 14, with a photo of the researcher. Using a single A4 information sheet enables older people with impaired capacity to decide for themselves if they wish to participate or not in the research.[37] A laminated version of the A4 sheet is used for participants requiring continuous consent process to consent in the moment[1](see figure 1). A participant is given both the A4 sheet and the detailed participant information sheet, in particularly for family members to review the full detail on the study and talk through with an eligible participant if they wish to be involved. All written information for the older participants are prepared using clear font, accessible language, short sentences and where possible at least size 14 font size. The information booklets are printed in colour with photos of the research team. This approach is advocated by studies involving elderly people.[27, 28] The information booklets have been reviewed by the Lay Project Advisory group and the clinicians working with us and suggestions/amendments incorporated. We use a pictorial diagram of the research team and the clinical team with participants at the first meeting to clarify who different individuals are and our respective contacts numbers. We include this at the request of our Lay Project Advisory Group to improve clarity on differentiation between the research team and clinical team.

Process of consent and assent for adults lacking capacity

The commonality of cognitive impairment in advanced age associated in particular, with dementia and end of life requires the inclusion of elderly people with impaired mental capacity in the study.[3] Elderly people with dementia and/or cognitive impairment are considered likely to benefit from the intervention of specialist palliative care. People with dementia in the last year of life experience symptoms and care needs comparable to people with cancer,[9] but have a high prevalence of poor symptom management, notably pain management and often experience aggressive treatment at the end of life.[4]

The Mental Capacity Act 2005[38] (MCA) informs the process of consent protocol and recent studies involving adults lacking capacity.[28, 35, 36] All participants are considered to have capacity unless established otherwise and all practicable steps are taken to enable individuals to decide for themselves if they wish to participate, for example, the Information Sheet uses accessible language. A potential participant's level of capacity is discussed with the referring clinician/care home manager to identify participants with possible impaired capacity and to anticipate the likely consent procedure. Capacity is established when meeting the individual using the MCA three step process: 1) the individual is able to understand the information about the study; 2) retain the information (even for a short time); and 3) use or weigh up that information.[38]

Potential participants' mental capacity is anticipated as ranging from able to give informed consent to lacking capacity to give informed consent. We have developed a processes of consent and assent that are

tailored to an individual's level of capacity that incorporates varying levels of capacity and anticipates that some participants may lose capacity during the study because, for example, of nearness to death (flow diagram 1).[39] Incorporating different processes of consent and assent is used in research studies on end of life care involving adults of advanced age.[28, 35, 36] This intends to enable individuals with varying levels of capacity to decide for themselves if they wish to participate, and incorporate a process of assent for adults lacking capacity.

Consent in the moment for participants with impaired capacity

For adults with impaired capacity, but able to understand, retain and weigh-up information in the moment a process of consent in the moment is used with ongoing consent whereby informed consent to participate is reaffirmed prior to each data collection point.[1] The approach of consent in the moment was developed and used in studies involving adults with dementia and/or cognitive impairment.[1, 37] If a participant's capacity declines that they are no longer able to give informed consent in the moment, the researchers follow the procedure for adults lacking capacity detailed below.

Advanced consent and assent for participants who lose capacity

An advanced consent is incorporated in anticipation that some participants may lose capacity and may no longer have capacity to indicate their right to withdraw from the study. The process of advanced consent is informed by previous studies with older people[28] and on end of life care.[40] Participants able to give informed consent are asked to indicate should they lose capacity in the future if they would wish to continue to be involved in the study, and if indicate yes then they are asked to nominate a personal consultee (e.g. next of kin), or if not available a nominated or professional consultee (e.g. social worker). The named consultee is approached if in the future the participant loses capacity to an extent they are no longer able to indicate their right to withdraw from the study and to complete patient reported outcome measures, requiring instead a proxy informant (e.g. informal or formal carer). The procedure for assent for adults lacking capacity is followed to ascertain the named consultee's opinion on the individual's continued participation (see below).

Assent for adults lacking capacity

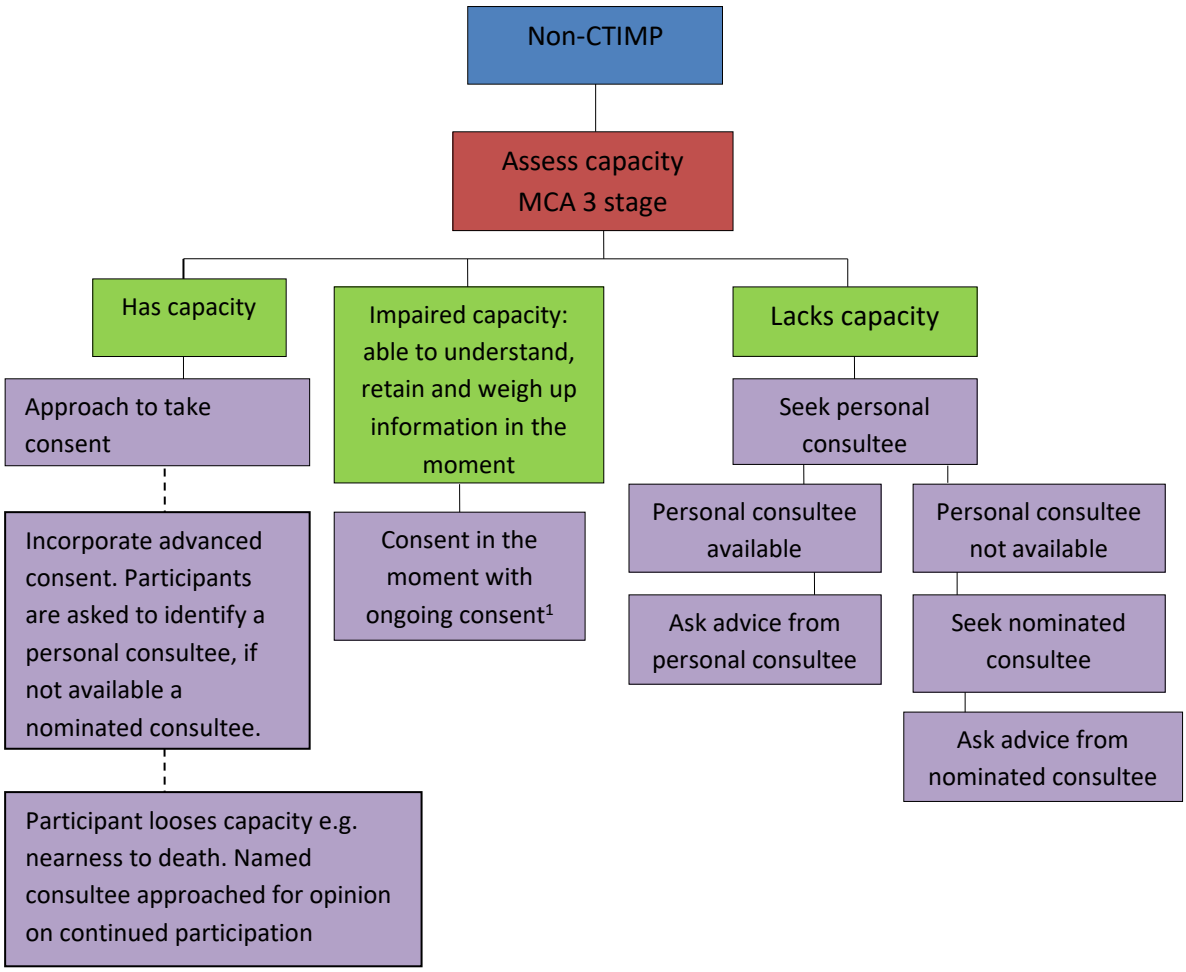
When an adult lacks capacity a personal consultee is sought to give an opinion as to whether in his/her knowledge of the potential participant they would have wanted to participate in the study had they had capacity to indicate this, and that participation would not cause undue distress.[28, 38] A personal consultee comprises next of kin, immediate carer or attorney with Lasting Power of Attorney. Identified consultees are given an information leaflet about the study, a letter detailing why they have been chosen as a consultee and their responsibilities as a consultee. The consultee documents are informed by research with elderly people,[28] the MCA[38] and MCA guidance.[41] If contact cannot be made with a personal consultee within one week of initial identification a nominated consultee is contacted.[35, 36] The nominated consultee has a professional relationship with the potential participant, but is not connected to study e.g. a geriatrician, social worker.[35] The nominated consultee is asked based on their knowledge of the individual to give an opinion on whether it is in the individual's best interest to participate in the study and that they would not be caused undue distress by participating. A participant's respective GP is informed by letter of their participation.

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, and all consultees giving written assent. Participants are offered a copy of their signed consent form to keep if they wish, and consultees a copy of their signed assent form. A copy of the signed consent/assent form will be filed in the participant's medical notes (either community nursing, palliative care team, care home or GP notes). The research team will retain the original signed consent form. For those people who give consent for their general practitioner (GP) to be informed about their participation in the

study (on the consent form), the GP will be sent a copy of the consent form using the contact details provided. All the participants are registered with one of the four participating GP practices. It is anticipated that GP practices will enter patients in the intervention arm on the practice's end-of-life care register and discuss at GSF multi-disciplinary meetings.

Figure 1: Process of consent[39]



Randomisation

Once individual consent/assent is given, the researcher/research nurse uses NHS e-mail to email relevant identifiable patient data to Evans as PI. Evans completes the randomisation using web-based facility from the Clinical Trials Unit, KCL who oversees the randomisation procedure. Randomisation uses block randomisation to keep the numbers in each group very close at all times.[42] We will use a mix of 2 and 4 blocks as multiples of 4 as the anticipated maximum number of intervention contacts with the specialist palliative care team (assessment and 1-3 follow-ups). Randomisation is stratified by geographical areas (Brighton and Hove, and West Sussex). Stratification by area is to ensure equal recruitment to support clinical teams' delivery of the intervention, and not for statistical analysis. Participants are randomised to receive:

- Intervention of SIPS service and usual care, or
- Best usual care (without provision of a specialist palliative care service) and provision of specialist palliative care after study completion.

The Principal Investigator Evans (or delegated colleague in absence) uses King's College London CTU web based randomisation facility set up for the study to complete randomisation. Evans (or delegate) telephones the elderly person/carer/care home manager to inform them of the outcome and the SPCTs, and sends a letter detailing the outcome and dates of follow-up timepoints. The SPCTs contact participants' randomised to the intervention arm within 48 hours.[18] The researcher (research nurse and research assistant) are blinded to the randomisation for data collection purposes at baseline, 6 and 12 weeks. Single-blinding in community studies with palliative care patients is feasible, but requires careful consideration of methods to reduce unblinding by carefully considering the content of interviews at the data collection measurement points.[43] Interview content that potentially threatens this is the 'views on care' questionnaire, which participants will likely reveal if received specialist palliative care. This questionnaire is administered at 12 weeks after completion of the primary and secondary outcome measures.

Intervention

Control group: best usual care

Participants randomised to usual care will continue to receive best usual care from their health and social care providers, and will continue to have the same access to specialist services as at pre study entry. At the end of the study elderly people in the control group will be offered access to the SIPS service. If during the study a participant requires palliative care in line with services' referral criteria e.g. new diagnosis of advanced cancer for palliative treatment, the individual is withdrawn from the study.

Intervention group: Short term integrated palliative care and supportive (SIPS) and usual care

The SIPS intervention is developed from studies on palliative care for elderly people[4, 25] and a model of short-term palliative care developed and evaluated for patients with multiple sclerosis. [18, 44] The SIPS intervention is further refined by the phase 1a and 1b findings. Appendix 5 details the SIPS intervention, box 1 the procedures to deliver and box 2 components of the training manual to support intervention delivery.

The SIPS intervention intends to provide an extra layer of support at points of actual or anticipated unstable/ deteriorating symptom presentation and wellbeing (appendix 5 SIPS intervention). A brief integrated intervention is anticipated as providing specialist palliative care at points of unstable/deteriorating condition to assess and manage care and prevent, for example, unplanned hospital attendance, and support primary and community staff's on-going provision of palliative care. The SIPS service is delivered by two SPCTs through integrated professional working with community nursing teams (n=4) and general practices (n=4), and close working with geriatricians.

Following referral to the SPCT a member of the team, often a nurse, contacts the patient within two working days to arrange a visit within the next five working days to undertake a comprehensive palliative care assessment and co-ordinate the care (appendix 5). The number of referrals is a key process measure to indicate identification of palliative need for elderly people and the acceptability for elderly people with non-malignant conditions of referral to the palliative care team. The SPCT member who undertakes the assessment visit is the patient's key worker. The detailed assessment is discussed at the SPCTs' multi-disciplinary meeting (MDM) who discuss ways to improve management of physical, social, emotional and other problems. The key worker records the nature of assessments, treatment plan and services provided. The key worker liaises with and acts as a catalyst with the community nursing team and GP and other relevant local health and social care services (see figure 1). There are up to three follow-up visits to action, review and evaluate the proposed treatment plan, undertaken in close liaison with the community nursing team and GP and drawing on expertise of the wider primary health care team and geriatrician as indicated (Box 1).[18] After three visits the patient is discharged from the SPCT. The GP continues to provide care and other services remain involved to support unmet/ ongoing needs e.g. community nursing service. The intervention incorporates a training manual (Box 2) and tools to support the provision of palliative and EoL care (e.g. SBAR [situation, background, assessment, recommendations] to support MDM discussion

http://www.institute.nhs.uk/quality_and_service_improvement_tools/). The procedures to deliver the intervention and training manual are refined by the findings from phases 1a and 1b.

Box 1. Procedures for care of elderly people receiving SIPS

1. The SPCT receive the referral with the details of the patient from the GP practice (who are informed by the trial manager, Evans of their patient's allocation). Evans also informs the SPCT to expect the referral, and informs the patient/family of allocation.
2. The SPCT allocate a key worker who telephones the patient to introduce themselves, explain about the service, confirm the referral and make first contact. This occurs within 2 working days of receipt of the information. On the telephone call the key worker e.g. clinical nurse specialist assesses the severity of problems and determines the urgency required for visit. They arrange the first contact. With the patient's permission the respective community nursing team are advised of the visit date and time and a joint visit is requested. Standard clinical tools are used to support practice.
3. The first face to face contact occurs within 5 working days of the telephone call (sooner in urgent cases), in the place of a patient's preference. The first contact comprises a specialist palliative care assessment lasting 1-2 hours. It includes: assessment of symptom control and management, continuity and coordination of care and access to services, psychosocial needs including responses to loss and change, information needs, in particular, gaps in information, wishes to participate in care, need for advanced care planning. There is assessment of the caregiver when possible.
4. As a result of this assessment the key worker generates a treatment plan with the patient and outlines a proposed action plan, agreed with the patient. This might involve a change in symptom management (e.g. medication change), referral to other services e.g. carer support and/or psychosocial support.
5. Liaison with the GP and community nurses and other relevant clinicians and social care staff on the proposed treatment plan to arrange, for example, changes in medication (for example, changes in medication are agreed with the GP, or the GP is requested to complete).
6. At the weekly multi-disciplinary meeting the SPCT review and revise the treatment plan to optimise the management of care provided to the patient and caregiver and plan future visits. Input from other members of the multidisciplinary team occurs at this point.
7. The GP, community nurses and social care staff are informed of any changes to the treatment plan. The GP is requested to include the patient on the practice's End-of-Life Care register and following local service protocols asked to complete a Palliative Care Handover form faxed to out–of- hours services (GP and community nursing) and ambulance control to advise, for example a palliative care patient and preferred place of care if known.
8. The key worker and other members of the team, if appropriate, implement the plan.
9. Patients and their carers are discussed at the End-of-Life register meeting e.g. GSF meeting held by the GPs weekly to monthly and involving the wider primary health and community teams. The treatment plan is reviewed and roles and responsibilities are identified and agreed.
10. The key worker phones the patient/carer to arrange the 2nd face to face contact. During the phone contact they key worker makes an initial assessment and may refine the treatment plan. In some instances another relevant member of the team becomes directly involved, as agreed at the multidisciplinary team meeting e.g. Occupational therapist, welfare benefit advisor.
11. The 2nd face to face contact normally occurs within 2 weeks of the first face to face contact.
12. At the 2nd contact, the key worker reviews outcomes from the actions already taken (e.g. changes in medication to control symptoms), reassesses using the same standardised assessment tools, reviews the treatment plan. If immediate issues are resolved, s/he explores the potential to move to more hidden issues, such as, advanced care planning or dealing with other information needs. At this visit there is development of a plan for discharge.
13. Following the 2nd contact there is re-discussion of the problem list and treatment plan in the multidisciplinary team meeting, liaison with the GP and community nurses, discussion at the End of Life register meeting and liaison with other relevant professionals as appropriate.
14. There is contact with the caregiver as required throughout.
15. Following these actions the key worker organises a 3rd visit to the patient normally within 3 to 4 weeks of the 2nd face to face contact – this is determined by patient need and other actions being undertaken.
16. At the 3rd visit there is a review of the outcomes from the actions taken and a reassessment using the standardised assessment tools, a review of the problem list future action plan and discharge.
17. Following the 3rd visit there is further discussion with the multidisciplinary team and liaison with GP

Box 2. Outline of contents of SIPS intervention manual

1. Background to the SIPS intervention and rationale
2. Mode of how the intervention is expected to work
3. Summary of the research importance
4. Screening instruments and inclusion and exclusion criteria for the research
5. Detailed protocol of assessment
6. Standardised assessment protocols and tools to use on each visit
7. Standardised clinical records to be collected by the team
8. Standardised sheet for the multidisciplinary team meetings e.g. SBAR (Situation-background-assessment-recommendations) NHS tool to aid communication http://www.institute.nhs.uk/quality_and_service_improvement_tools/
9. Process of communication, liaison and integrated working with the community nursing teams and GPs
10. Procedures for first, second and third face to face contacts
11. Procedures for telephone contacts
12. Discharge procedures
13. Education and training of other health professionals

Research interviews

Face-to-face interviews are conducted with both groups at baseline, six weeks (time point one) and 12 weeks (time point two) post randomisation (table 1) according to standardised schedules using trained interviewers with experiencing in interviewing patients requiring palliative care. Interviews are undertaken with participants who have capacity to give informed consent. For adults lacking capacity baseline and outcome measures are obtained from a proxy informant. The use of a proxy informant is common in research on palliative care associated with patients' advancing illness and deteriorating condition, and the importance of capturing data at points of deterioration when a patient may most benefit from palliative care, notably the last days of life.[45] A proxy informant is an individual who knows the elderly person well. This includes, for example, carers/family members, the community nurses, SPCT or GP. Research on proxy informants indicates higher agreement between patient and caregiver dyads than in patient and health care provider dyads,[46] but over time, similar reporting is seen as practitioners' knowledge of their patients increases.[47] To elicit a proxy-patient perspective, the proxy is instructed to *answer the questions as you believe the patient would*.[47]

The interviewer reads the baseline questionnaire and outcome measures to the patient using large print laminated cards of the possible response categories for the standard scales. In addition, at the 12 week time point individual qualitative interviews are conducted with purposively selected patients and their carers (n=12) from the intervention group. The interviewers include research nurses employed by Sussex Community NHS Trust allocated to the research study, the research assistant working on the study and Evans (PI).

Steps to prevent harm to participants

Participants will be advised they are under no obligation to take part. The purpose and intent of the work will be explained. Participants will be given the choice not to answer any particular question, whether in an interview or when completing a questionnaire. Participants are advised they may skip the question and move on, return to the question later, omit the question altogether, or stop the interview or questionnaire. Participants will be made aware that they can withdraw from the study at any time, with no adverse implications for their clinical care.

Table 1: Graphical depiction of SIPS intervention versus standard care [24, 44]

Timeline	SIPS intervention (intervention group)	Best standard care (control group)
Consent and baseline	(a)	
Randomisation		
48 hours	B	
1-6 weeks	C	
6 weeks	(d)	(d)
6-12 weeks	E	
12 weeks	(f)	(f)
12-18 weeks	H	I
6 months	J	J

(a)	Baseline research interview and consent on entry to the study before randomisation or for adults lacking capacity process of assent and baseline interview with carer who knows individual well (e.g. family member or care home staff)
B	Palliative assessment within 48 hours by member of the specialist palliative care team. Following standard team protocols for new referrals this comprises: case notes review of referral details, telephone call to the patient/carer to ascertain priority of the visit (e.g. urgent in 48 hours), the most appropriate person to visit e.g. nurse specialist, consultant in palliative medicine, arrange a convenient date and time to visit and to give contact details for the SPCT service.
C	Palliative team care, including assessment, treatment, referral and review
(d)	Research interview at 6 weeks post randomisation
E	Palliative care team care continues usually ending by 12 weeks. Close liaison with community nursing team and GP for elderly people requiring ongoing care and support, and referral to the wider primary health care team/social care if indicated.
(f)	Research interview at 12 weeks after randomisation including for purposively selected elderly people and/or carers in the intervention group a qualitative individual interview. Two focus groups held with service providers involved in delivering the SIPS intervention.
H	Elderly people receiving SIPS discharged from the specialist palliative care team in close liaison with the community nursing team and GP, e.g. discussion at the multi-disciplinary GSF meeting and identification of areas requiring ongoing treatment, monitoring and review.
I	Standard care group now offered SIPS, but no study data collection for this group
J	Data extraction from GP records on survival or mortality and place of death

Distress Protocol

It is possible that participants may become distressed or raise issues during interviews which raise concerns or warrant a change in their medical management. Should this be the case, then a member of the research team will gain consent from the participant to discuss matters with the relevant member(s) of the multidisciplinary palliative care team or the patient's general practitioner, as appropriate. We anticipate distress will be very infrequent, if at all, given the general nature of the questions within the measures used,

and is likely to reflect advanced disease and not the questionnaires themselves. All of the research team will have completed Good Clinical Practice training, and specific training on addressing distress in palliative care. All questionnaires will be screened immediately following completion to check their content for any areas of clinical concern. This screening will be done by the researcher. If participants disclose any ideation of self-harm or other risk to themselves or others, then this will be dealt with as an urgent matter on discussion with the PI and a senior member of the treating medical team. Provision will be made to ensure the researchers have PI or senior back up available by phone whenever they are undertaking data collection.

Baseline data and outcome measures

The baseline questionnaire captures demographic and clinical circumstances e.g. co-morbidities, prescribed medication (appendix 7). The selection of the outcome measures used is based on previous research[9, 44] and ongoing research developing and evaluating a patient-centred nationally applicable casemix classification for palliative care.[48] The outcome measures have versions both as a patient reported outcome measure (PROM) and a proxy version for carers/staff. Appendix 7 contains the baseline questionnaire and outcome measures.

Primary outcome measure

The primary outcome is symptom burden for five key palliative symptoms: *breathlessness, anxiety/depression, constipation, pain and fatigue*. Original symptoms were identified as *pain, low mood, constipation, poor appetite and fatigue* but were revised from the phase 1a findings, which established greatest symptom distress amenable to change.

Symptom burden is assessed by change in score on the Integrated Palliative care Outcome Scale symptom component (I-POS).[49, 50] The I-POS is an integration of the Palliative care Outcome Scale (POS) and POS-symptom scale (POS-S).[48] The POS and POS-S are widely used in palliative care studies for cancer and non-cancer populations including elderly people with dementia/cognitive impairment,[51] and have versions for self-administration (PROM) and by proxy. I-POS is short, easy to use and acceptable to patients and carers– an important consideration with frail elderly[28] – and is reliable but responsive to changes in symptoms and palliative concerns.[49] The selection of the five primary symptoms is informed by studies on symptom prevalence in the last months of life for elderly people with dementia[9, 19] and work on frailty.[3] The symptoms selected are amenable to change through palliation. Many prevalent symptoms experienced by elderly people associated frailty and advancing non-malignant illness are not amenable to change, for example, communication, incontinence for people with advanced dementia. Care management may be optimised to reduce symptom distress, but reversal of symptom severity is not amenable to change.

Secondary outcome measures

Secondary outcomes are:

- Patients' palliative needs and symptoms measure using I-POS (all symptoms beyond the five captured above)
- Carer burden using short form Carer Zarit Burden Interview (12 item short form) as self assessed by carers.[52]
- Satisfaction with health care service provision using FAMCARE scale widely used and validated for palliative care for patients (Modified FAMCARE P-16) and carers (FAMCARE 2). [53-57]
- Evidence of end of life/proactive care and advance care planning e.g. evidence in nursing/medical records of discussion and documentation on preferred place of care, allow a natural death (DNACPR), Palliative Care Handover Form. Data extracted from GP medical records (usual care group) and specialist palliative care records (intervention) at 12 weeks. Extraction from GP records of patients registered on End of Life Care register e.g. GSF and or Proactive/Risk profiling register and date commenced.

- Length of survival or mortality and attainment of preferred place of death at 6 months extracted from the GP records. Trials on palliative care services have shown increased longevity for cancer patients, compared to usual care.[58] Mortality and attainment of preferred place of death are important outcomes for palliative care services.

Economic evaluation

The health economic evaluation uses the EQ-5D[59] as a generic quality of life measure recommended in cost-effectiveness analyses and the Client Service Receipt Inventory (CSRI) to record formal service use, medication and informal care.[60, 61] Service use includes specialist palliative care, other primary and secondary health care, medication, social care and care by family members. Data is recorded at baseline and 12 weeks. Data on formal service use is extracted from the GP records and/or community nursing home records at baseline and 12 weeks when no carer is available (informal e.g. family member, or formal care home manager) and the older person is unable/partially able to provide this information because of, for example, cognitive impairment.

We also include the ICECAP-O as a secondary cost-effectiveness analysis. ICECAP-O is a new capability/well-being measure for use in economic evaluations. It consists of 5 items (*feeling settled and secure; love, friendship and support; being independent; achievement and progress; enjoyment and pleasure*) each scored 1-4.[62] The possible states derived from the ICECAP-O are being valued in a way appropriate for QALY calculations (this will be completed well before our analyses).

Monitoring and process measures

- Demographic survey at baseline with patient (and carer if available) date of birth, ethnicity, marital status, previous occupation, living status and primary diagnosis and co-morbidities. To minimise missing data, data extraction from GP records at 12 weeks and/or review of community nursing home records at baseline, in instances with missing data because of, for example, patient recall on diagnosis and co-morbidities.
- Level of frailty using Fried's Phenotype of Frailty[2] assessed at baseline
- Dependency using The Northwick Park Dependency Scale (this translates automatically into a Barthel Index) and provides (a) a measure that includes physical and cognitive disability and (b) an estimation of care hours and costs of care, regardless of who provides it[63] (completed at baseline and 12 weeks). However, this measure is longer than the originally proposed Barthel Index.[64] We will pilot the NPDS with the first 10 participants and assess problems of fatigue, length of time to complete and level of missing data to inform our decision of continuation with the NPDS or use the Barthel Index. The completed pilot indicated use of the Bartel Index retaining two question sets in the NWPD scale questions of communication and behaviour. The pilot indicated carers taking up to an hour to complete the NWPD scale and problems of clarity in the question language and applicatbility for the frail elderly, for example, specialist nursing procedures. The NWPD scale questions on communication and behaviour are retained. Findings from phase 1a indicated these as prominent areas of concern for carers, but are not captured in the Barthel Index. This is a feasibility study and a main purpose is the development the research methods for a definitive RCT.
- Function using Australian Karnofsky Performance Scale (AKPS) as an adapted version on the Karnofsky Index for palliative care performance status[65] (baseline and 12 weeks)
- Monitoring integrated working between specialist palliative care team and community and primary care services. Data extraction from specialist palliative care team record at 12 weeks on communication/liaison including: clinician (e.g. GP), mode (e.g. telephone, fax, face-to-face), date, purpose (e.g. update, request medication change, advise)

Phase of illness (PoI) characteristics encompassing stable, unstable, deteriorating and terminal[66] is recorded by the palliative care teams as part of their standard clinical assessment tools. Information on phase of illness is extracted from the respective palliative care team's electronic records. This is a feasibility study. PoI data informs understanding on use of this assessment tool for patients' with non-malignant conditions. The tool was developed with patients with cancer. PoI data is not captured for those in receipt of usual care. Use of this data is limited to describing intervention group.

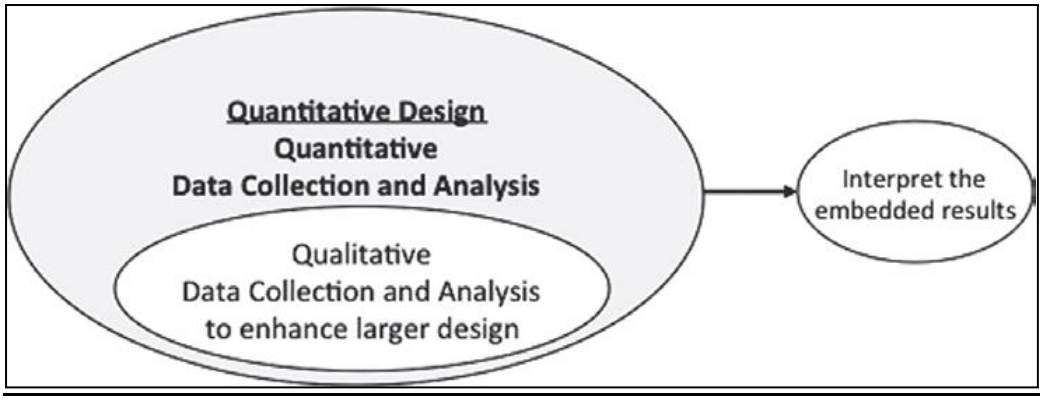
Statistical analysis

Parametric or non-parametric statistical methods (depending on the distribution of the data) is used to describe and compare changes in the I-POS symptom scores on the five defined symptoms (primary outcome), secondary outcomes of palliative outcomes and carer burden, and process and monitoring measures, between baseline and time points one and two. Time point two at 12 weeks is the primary analysis point.[19] If appropriate, bivariate analysis (and if necessary and sufficient power, multivariable regression analysis) is used to identify and explore the factors associated with the outcome variables. Missing data is explored, ascertaining cause(s) of missing data, testing missing mechanisms and the impact of missing data on results (last value carried forward, next value carried backward, and mean value).[44, 67] Differences between participants and non-participants are explored to ascertain potential sample bias. The data analysis in the economic evaluation examines resource implications and makes preliminary cost-effectiveness calculations (e.g. combining CSRI data on costs and EQ-5D score). Economic evaluation is an emergent area in palliative care and uncertainty surrouds best practice. [61] The feasibility study will test procedures to inform the economic evaluation in the full RCT protocol.

Nested qualitative study

Nested qualitative studies enhance the primary research by addressing questions of particular importance.[68, 69] They can examine the content, delivery and implementation of an intervention by: exploring the feasibility, acceptability and perceived value; identify active ingredients; and help explain findings. A nested qualitative study is conducted at the end of the intervention (12 weeks). It is embedded in the quantitative trial design, but the quantitative component is predominant (figure 1).[68] Qualitative and quantitative data collections are concurrent. The nested study intends to provide insights on the processes of implementing SIPS including the procedures for delivering (e.g. timing, integrated working), exploring if the intervention was delivered as envisaged and to generate understanding on how the effectiveness of SIPS was promoted or limited in practice. Two qualitative studies are conducted at intervention completion to examine experiences of receiving SIPS and barriers and facilitators to deliver. The studies comprise: study 1) individual semi-structured interviews with patients who received the SIPS intervention and their carers when available; and study 2) focus groups with health and social practitioners involved in delivering the SIPS intervention.

Figure 2: Qualitative study embedded in the quantitative design[68]



The nested qualitative study aims to:

- Explore recipients' and health care providers' experiences of receiving or delivering SIPS to provide insights on the processes of implementation including: the procedures for delivering SIPS and the intervention manual; the active ingredients and if delivered as envisaged; and how the effectiveness of SIPS was promoted or limited in practice.
- To identify and strengthen the active components of the SIPS intervention for the full RCT and the model of integrated working.

Study 1: Individual interviews with patients & Carers

Sample

Patients who received the intervention with capacity to participate in an individual interview are asked to participate in an interview after timepoint two (12 weeks). When carers of patients are available they will be asked to participate in a separate interview. We anticipate offering an individual interview to all participants who received the SIPS intervention with capacity to participate in an individual interview. We estimate approximately a third of participants will lack capacity (estimated as 8 patients). This gives a planned sample size of 18 patients who received the intervention with capacity to participate in an individual interview.

Timeline

For recipients of the intervention qualitative and quantitative data are collected on separate occasions. This intends to enable the research nurse to remain blinded to a patient's allocated group and minimise fatigue by undertaking two interviews each anticipated as around an hour in length. [28] The timing of the interview is agreed with individual patients/carers to minimise burden and fatigue. Participants are asked at the baseline data collection point to given informed consent to participate in an individual interview. This is reaffirmed at the time point two quantitative interview. If in agreement a further interview date is arranged for the following week. Interviews are undertaken after the quantitative data collection end point at 12 weeks (T_2). Completion (or not) of the intervention and discharge from the SPCTs' active caseloads, and amount of contact with the SPCT will vary by participant depending on their clinical requirements.

Semi-structured individual interviews

Individual qualitative interviews are conducted by researchers trained in qualitative research interview. The interviews are conducted in a patient's place of residence. The interviewers use a topic guide informed by the aims and objectives of the research study and refined by the phase 1a findings, the Lay Project Advisory Group, drawing on research involving in elderly people[28] and specifically on end of life care[37, 70]The guide explores: experiences of receiving care from the SPCT in general and specifically on management of symptoms/problems, psychological distress and advance care planning; timing of the referral; communication across and within services (integrated working); and future involvement of the SPCT. Interviews are digitally recorded and transcribed. If a participant declines digital recording, a request is made to take written notes during the interview. These are shown to the participant at the end of the interview to agree their accuracy.

Study 2: Focus groups with health and social care practitioners

Setting

The focus groups are held during two project workshops presenting the findings from the initial research work developing the SIPS intervention and preliminary findings from the feasibility trial. This intends to minimise participants' time away from practice and maximise opportunities to understand the integration of SIPS with practice and potential patient benefit. Individual interviews will be held with the lead GPs who are not able to attend the focus groups due to clinical commitments. This is to ensure the views of the leads of each participating GP practice are represented. The interviews will be held over the phone or face-to-face in the GP practice at the participants' convenience.

Service providers and commissioners

Focus groups are held with health and social practitioners involved in the delivering the SIPS intervention. This will include the SPCTs, community nurses, GPs, geriatricians and social care staff e.g. from participating care homes. The focus groups will explore the barriers and facilitators to delivering SIPS including: experiences of delivery SIPS probing for patient acceptability, timing and patient benefit; experiences of communication and service co-ordination (integrated working); and refinement of the SIPS intervention. Each workshop involves up to 20 people from the two geographical areas (Brighton and Hove, and West Sussex). The focus groups are undertaken as part of the workshop with participants divided into groups of 10 to form the focus. The groups are pre-assigned to encompass a mix of representative from SPC, community nursing, general practice, social care and elderly medicine. Participants are invited via NHS.net email to participate in the focus group and asked to reply to indicate interest in participation. Interested participants receive a further email with an attached PDF copy of the information sheet and details of the date, timing, venue and format of the workshop and focus group. Participants are asked to give an informed consent on arrival at the venue for the workshop and complete a brief demographic questionnaire detailing: gender, professional title, time in present post and time working in current field of practice e.g. as a GP, community nurse..etc.

Timeline

Completion of the main study.

Topic Guide

The topic guide is informed by the findings from phase 1a and 1b on the SIPS intervention (e.g. patient benefit, timing and integrated working) and from the phase 2 trial preliminary analysis of the primary outcome of symptom change and secondary outcomes of satisfaction with care. Patient quotes or vignettes based on phase 2 qualitative interviews are used to facilitate discussion. Each group is facilitated by a researcher experienced in qualitative research methods with an observer to document, for example, group processes and interactions. The groups are digitally recorded, transcribed and anonymised prior to analysis.[71]

Quality appraisal

Quality appraisal is addressed through procedures to ensure contribution of the findings to the evidence base, credibility of the findings in terms of defensibility and plausibility, and rigour in terms of documenting and reporting research processes and decisions.[72, 73] The data analysis approach of constant comparison intends to lead to theoretical generalization of the findings to ensure the relevance of the findings beyond

the participants to contribute to the evidence base.[74] The credibility of the work is enhanced through the presentation of the findings, for example, detailing the coding tree to show data categorization, matrixes to illustrate formation of themes, diagrams to illustrate constructs and inclusion of raw data using quotations. A process of triangulation is used in the data analysis to check the integrity of the emergent findings and inferences by exploring preliminary themes across the respective participant groups and in the quantitative data. Rigour is enhanced through attention to the audibility of the work. This comprises careful documenting and reporting of research decisions through use of a detailed protocol, maintaining fieldnotes and use of notation during data analysis to record decisions on, for example, coding initial thinking, notably on emergent relationships between categories and themes.[73]

Data analysis

A full coding of transcripts is undertaken to identify themes, with initial broad coding using *priori* codes based on the respective topic guides and top level areas of: patient/carer benefit of an 'extra layer of support of SPC; timing of the intervention; and integrated working (e.g. communication and co-ordination of services). The *priori* codes are followed by detailed codes to identify sub-categories and themes for the respective areas. Analysis of the focus groups pays particular attention to the views of different professionals on integrated professional working, the contextualisation of responses and areas of consensus or disagreement. [75]

Data analysis uses an approach of data mapping of emergent themes using matrices to display and analyse underpinning categories. An approach of constant comparison is used to identify and explore *negative* exceptions and *positive* patterns to identify the main themes and build conceptual coherence in the data.[74] [76] The intention is to form a construct that details how the SIPS intervention may provide patient/carer benefits, the optimal timing for provision, the acceptability of 'short-term' provision and the key ingredients and requirements to support integrated working between generalist and specialists in palliative care.

Synthesis of quantitative and qualitative data

The synthesis of quantitative and qualitative data focuses on the primary outcome of effect on five key symptoms to identify ways to enhance SIPS, the processes for wider implementation if beneficial, and a model of integrated working between generalist and specialist nurses. Qualitative and quantitative data is synthesised using a matrix to explore paradoxes within the data for each case (a participant) and across cases.[77] Each participant in the qualitative interviews forms a 'case' and a row in the matrix. The columns display for each case different data, for example change in IPOS-symptom score, experiences of receipt of palliative care, perceptions of value. The intention is to interpret the change in the primary quantitative outcome measure, the clinical significance, and the impact of SIPS at the three main levels of: people and context; processes and tasks; and underpinning theory.[78]

Data management and security

All personal data will be managed according to the principles established in the Data Protection Act 1998. All of the researchers will undertake and update GCP training, and current research governance processes will be followed. Completed demographic forms, questionnaires and interview transcripts will be anonymised using a unique study identification number and contain no patient identifiable data. The participant identification number and linkage with the participant's name only occurs on the consent form and code

book. The code book is held in a password protected Excel Spread sheet, stored on an encrypted memory stick at KCL in a locked filing cabinet, and backed up on an NHS computer in the Research and Development Service Sussex Community NHS Trust. Data is transferred via NHS email account. Questionnaires, demographics forms and transcripts will be stored separately to the consent forms, each in a separate locked cabinet.

Patient and Public Involvement

Patient and public involvement (PPI) is guided by the NIHR Involve programme [79] [80] at all stages of the project through consultation, collaboration and co-investigation.

Consultation

We have engaged local service users in Brighton and Hove, and West Sussex in the protocol development through presentations, discussions and correspondence with representatives from the Older People's Council (OPC), Pensioners Action, Pensioner Forum and Age Concern, and nationally through Age UK's Engagement Team. Consultation involved members discussing and reviewing the study focusing on the relevance of the topic area for elderly people and their families, the acceptability of the proposed research methods, PPI involvement in the study and dissemination. The comments received informed the protocol development. This included refining the plain English summary, adapting the post-bereavement survey for families/carers of elderly people, and engaging elderly people in the stakeholder consultation (e.g. involving older people attending a day centre and use of a postal survey, and advertising the research project through local voluntary organisations' newsletters). Members considered it important to use newsletters to inform older people and their families about the study, in particular prior to the distribution of the post-bereavement survey and to advertise membership of the Lay Project Advisory Group. We have invited people involved in the consultation to continue to support the study through membership of the Steering Group and/or Lay Project Advisory Group, or to join as a named co-applicant. Four individuals have indicated their continued commitment.

The lay members of the Research and Design Service South East (RDS SE) review panel commented on a full draft of the application. The lay members' detailed feedback further refined the protocol. This included confirmation of the relevance of the study for older people/carers, and requirement for greater detail on PPI (e.g. users' involvement in the research and training), the research methods (e.g. patient recruitment in phase II to approach people before the EoL to obtain consent and minimize encroaching on their lives at a difficult time) and dissemination (e.g. leaflets detailing the study, outcomes and service development available for older people in hospital and GP settings.

Collaboration

On-going collaboration with service users involves participation in the project's Lay Project Advisory Group and Steering Group, and a stakeholder consultation to develop and refine the intervention. The Lay Project Advisory Group comprises the lay PAG members and individuals recruited through, local organisations in the study site (e.g. Brighton and Hove Older People's Council (OPC), the Pensioners' Forum, Pensioners' Action and Age UK (local and national)). The Lay Project Advisory Group assist with aspects of the project, including developing and piloting Information Sheets and letters of invitation to older people, refining the post-bereavement survey, setting up the stakeholder consultations with older people and cares and consideration of study findings to develop and evaluate the new SIPS service. The lay members involved in the protocol development advised separate workshops in the consultations for older people and service providers, and to involve frail older people in the consultation, for example, working with an independent day centre for older people.

Co-investigation

Two lay co-investigators work with us on specific aspects of the study, notably supporting the organisation and co-ordination of the Lay Project Advisory Group, the involvement of older people and their families in the stakeholder consultation and the development of the intervention. The co-investigators are from the Brighton and Hove Older People's Council and the Midhurst Macmillan Community Team volunteer service (West Sussex).

We reimburse travel expenses for lay members working with us and pay an hourly fee in recognition of their time and contribution, in accordance with NIHR Involve guidance[80]. The Age UK engagement team advised on PPI costing and advised on ways to involve lay members identifying groups in West Sussex and facilitating contact. Training for our lay members is accessed through the Biomedical Research Unit at KCL, support through the Lay Project Advisory Group and by working with the voluntary groups involved in the study.

Ethical considerations

The main ethical issue is processes of consent and assent for adults with impaired capacity/ lacking capacity. Adults lacking capacity are likely to experience the most complex needs and greatest benefit from the intervention. The NRES toolkit on research involving adults lacking capacity guides the study. [81] A process of assent is used with adults lacking capacity following procedures in the Mental Capacity Act 2005, and research studies. [82] A process of on-going consent is used with adults with impaired capacity to enable them to consent in the moment with continual monitoring of verbal/non-verbal signs to stop. [1] A process of advanced consent is incorporated for older people able to give informed consent, but who may lose capacity over the course of the study e.g. nearness to death.[40] This ensures an individual's right to withdraw at any stage is upheld if they lose capacity to be able to indicate this. Applicants Evans and Hall are experienced in research involving adults lacking capacity.[82] [83] Evans leads a study on capacity and consent in research on palliative and end of life care, funded by Marie-Curie Cancer Care UK (http://www.csi.kcl.ac.uk/mcc.html).

Management and Governance

Expertise and experience

The project applicants form an expert panel who meet three –four monthly over the course of the study to oversee the project and contribute to: the project development; the execution and analysis of the post-bereavement survey; the intervention development and theoretical modelling; the feasibility of the intervention and testing procedures; and the final data synthesis to develop the methodology for a full RCT and inform a model of integrated working between specialists and generalist nurses.

The expert panel comprises individuals with the breadth and depth of expertises required to undertake the study. Expertise include: developing and evaluating complex interventions (Evans, Higginson, Morgan, McCrone, Hall and Pountney), palliative care service development and provision (Evans, Higginson, Hall, and Lindsay), managing large postal surveys (Gordon and Gomes), statistical analysis (Wei), qualitative analysis (Morgan and Evans) and care of the elderly (Wright and Evans).

The team has a strong track record in areas highly relevant to the proposed study. The team has expertise of running studies developing and evaluating health service interventions including palliative care for non-cancer groups (Higginson, Hall [18, 44] [84], older people(Hall, Evans, Wright [84] [83] [85] [86] [82]), community based services (Pountney[87]), economic evaluation (McCrone[61]) and mixed methods (Hall[88], Morgan).

The team has expertise in managing and analysing large quantitative surveys[89], using qualitative methodology in trial designs (Morgan) and measuring palliative outcomes (Higginson[52], McCrone[61], Gomes[90]).

We have particular expertise in enabling older people to participate in research studies, particularly at the end of life with advanced disease (Evans[82], Wright[86]). The team have major national collaborations e.g. with the Medical Research Council/National Institute of Health Research-funded MORECare project [91] appraising 'best practice' methods for evaluation of palliative care (Higginson, Evans), and Marie Curie developing methods guidance on processes of consent for adults lacking capacity (Evans and Higginson). We have invited co-applicants with supplementary areas of expertise for the study from the Office of National Statistics to oversee the management and support the analysis of the post-bereavement survey (Gordon), and within the study site for care of the elderly (Wright), palliative medicine (Lindsay, Bruni) and community nursing (Evans). We have two senior lay members working with us as co-applicants to support aspects of the study e.g. the Lay Project Advisory Group and development and piloting of data collection tools and the emergent intervention.

Research management arrangements

Management structure: The expert panel (the co applicants) have responsibility for progress and delivery of outputs, and oversee the research team on a day-to-day basis, with strategic programme direction from the Steering Group (through 6 monthly meetings, and advise between meetings, as required), and the Lay Project Advisory Group meeting 4-6 monthly on specific aspects of the study.

Steering Group: Comprises the expert panel and invited members with particularly expertise. Membership includes representatives from health and social care including academics, service providers, service commissioners, policy makers, the voluntary sector and lay users. The Steering Group guide all stages of the project, and specifically the analysis of the post-bereavement survey and development of the short-term palliative care intervention. Meetings: 4-6 monthly

Financial Management: Executive Director of Finance, Sussex Community NHS Trust; Financial Manager, Cicely Saunders Institute, KCL; project leads; and Research Grants and Contracts Team KCL

NIHR research networks

The phase 1a component of the study is an NIHR portfolio study adopted by the PCRN SE who indicated their continued support for the study phases 1b and 2. CLRN Surrey and Sussex and the Primary Care Research Network South East (PCRN SE) reviewed and approved the study's NHS Treatment Costs and Research Support Costs.

Success criteria and barriers to the proposed work

Measures of success

1. Maintaining the project's progress by achieving the specific milestones and deliverables
2. Development of a short-term palliative care intervention based on relevant literature, quantitative survey findings on service use and outcomes, and consultation with stakeholders on key components
3. A model of integrated working between specialist and generalist nurses
4. The methodology for a full RCT on the effectiveness of short-term palliative care for frail older people in community settings

Key risks and contingencies phases 1b and 2

1. *Limited integrated working between specialist palliative care services and community nurses.* We are working closely with the NHS Trust to ensure the proposed intervention is feasible within existing resource and will meet important service objectives (e.g. increase the provision of anticipatory care)
2. *Poor recruitment in phase 2 (feasibility) and /or higher attrition than anticipated.* We will monitor progress closely at the beginning of phase 2 and review our recruitment and consent processes. However, this is a feasibility study that intends to test procedures for a full RCT.

Expected outputs of the research

Palliative and EoL care services are in place, but older people dying with frailty and/or non-malignant disease generally have limited access to them. A short term palliative intervention is potentially a way of using existing resource more effectivelly to optimise care provision to older people at the EoL. The project's outputs present potentially a significant saving to the NHS if a short term service is found effective in increasing anticipatory care and reducing unplanned hospital admissions, and identifying and testing a model of integrated working between generalist and specialist nurses.

The expected outcomes are to develop the methodology for a full RCT to evaluate the effectiveness and cost-effectiveness of SIPS for frail older people, and a model of integrated working between specialist and generalist nurses. The relevance of this line of investigation is to identify whether the provision of SIPS for frail older people can:

- Improve palliative outcomes e.g. attain prefered place of care
- Reduce symptom distress (e.g. physical, psychosocial)
- Reduce carer burden
- Increase carer mastery
- Be cost-effective by developing existing services

Dissemination

Outputs for the phase 2 feasibility pertain to the methodology for a full RCT and a model of integrated professional working between specialists and generalists nurses in community settings. A negative feasibility trial will help redirect services. The outputs inform local service provision and national policy on EoLC for older people (e.g. out-of-hours services). The study acts as a springboard for research on palliative interventions for older people, for example, pain management, tools to deliver palliative care for non-cancer groups, and ways to measure requirements for palliative care.

Findings are disseminated through:

- International conference presentations on a model of SIPS, feasibility of implementing in practice and likely patient benefit; and a model of integrated working between specialist and generalist nurses in community settings.
- Peer-reviewed publications in high impact scientific journals on:
    - Preferences, cost-effectiveness and palliative outcomes for frail older people by place of death
    - Development of SIPS service for older people in community settings
    - The feasibility of integrated working between specialist and generalist community services to deliver a short-term model of palliative care for older people

- Publication through the voluntary sector in, for example, in Age UK and Pensioners Action newsletters and websites.

Intellectual Property and Innovation

King's College London, the lead co-sponsor of the study, has an established code of practice for intellectual property, commercial exploitation and financial benefits.[92] The King's College Technology transfer office acts as Intellectual Property advisor for this project, and King's Business manages all research development, knowledge exchange and commercialisation activity within King's College London. King's Business has a policy of actively identifying, protecting and commercialising intellectual property, including patents, copyright and related rights, trademarks, rights in design, rights in computer software, database rights, registered or unregistered, which it believes to be of value. To this end, it works with a variety of organisations to ensure that intellectual property is commercially exploited in such a way as to realise its maximum potential. A Technology Transfer Manager has been assigned to this project and will continue to provide support and advice as well as ensure that appropriate protection and exploitation of any intellectual property arising from this project is managed. Standard intellectual property acknowledgment forms, assignment agreements, and confidentiality and disclosure agreements will be used with non-college employees, where required, for the purpose of this project

Research timetable

The annexed Gantt chart details the research plan (appendix 7). Specific milestones for phases 1b and 2 are:

- Ethical and governance approval for phase 2, feasibility of the intervention (August –September 2013)
- Invited representatives from academia, policy, health and social care, voluntary sector and lay members from the Lay group to the Steering Group (April 2014)
- Stakeholder consultations focus groups and workshops (November 2013-February 2014): and then on-line/postal consensus survey (March 2014). Data analysis and confirmation of intervention (context, process and outcomes) (April 2014).
- Deliverables - publications on the study protocol (April 2014), survey findings (June 2014) and consultation (May 2014), and international and local presentations
- Commence phase 2, May 2014 recruitment opens, processes of consent, randomisation, intervention versus usual care data collection. Close March 2015
- Complete phase 2 data collection May 2015, data analysis complete August 2015
- Project end 6th November 2015
- Deliverables – publication feasibility trial findings and model of integrated working between specialist and generalist nurses in community settings.

Appendix 1: Applicant details

Name	Institution	Role and contribution
Dr Catherine Evans NIHR Clinical Lecturer in Palliative Care Honorary Clinical Nurse Specialist Palliative Care Sussex Community NHS Trust	Cicely Saunders Institute, King's College London Sussex Community NHS Trust	Joint lead applicant and lead clinician. Leads the study and the service development, co-ordinates all aspects, manages the research team, particular interest in promoting older people's quality of life, and leads the final synthesis and RCT protocol development.
Professor Irene Higginson Director, Cicely Saunders Institute, Professor of Palliative Care and Policy, and Honorary Consultant King's College Hospital NHS Trust	Cicely Saunders Institute, King's College London	Joint lead applicant and clinician. Provides expertise on palliative care both clinically and as an NIHR Senior Investigator, trial design and execution, oversees the scientific rigour of the study.
Professor Myfanwy Morgan Professor of Medical Sociology,	Department of Primary Care & Public Health Sciences, King's College London	Provides expertise in the use of qualitative research methods to understand interventions and integration/mixed method approaches and cultural aspects of measurement.
Dr Emma Gordon Head of Health Analysis Centre for Health Analysis and Life Events	Office for National Statistics	Provides expertise on administering, managing, and analysing national and local surveys and the application of findings to develop policy and health services.
Dr Barbara Gomes Research Fellow	Cicely Saunders Institute, King's College London	Provides expertise on health service research on palliative care, execution and management of large surveys, and analysis of large data sets, particular interest effectiveness and cost-effectiveness and influences of place of death
Dr Gao Wei Medical Statistician	Cicely Saunders Institute, King's College London	Provides expertise in outcome and quality of life measurement, and trial and longitudinal data analysis.
Prof Paul McCrone Professor of Health Economics	Department of Health Service and Population Research, King's College London	Provides expertise on economic evaluation in primary care and palliative care, and intervention cost-effectiveness.
Dr Sue Hall Herbert Dunhill Lecturer in Palliative Care	Cicely Saunders Institute, King's College London	Provides expertise on trial design in palliative care, mixed methods and undertaking research with older people.
Dr Terry Pountney Research & Development Director, Head of Research, Senior Research Fellow in Paediatrics	Sussex Community NHS Community Trust	Provides expertise on health service research in community settings, trial design and execution, research governance and ethical review, and implementing research into practice.
Dr Juliet Wright Senior Lecturer and Honorary Consultant in Elderly Medicine, Brighton and Sussex University Hospitals Trust	Brighton and Sussex University Hospitals Trust Brighton and Sussex Medical School	Expertise in elderly medicine in hospital and community settings, particularly management of co-morbidities, health services research on care of the elderly, and the provision of local health services for older people.
Dr Fiona Lindsay Consultant in Palliative Care, Brighton and Hove Community Palliative Care Team, research and development lead	Sussex Community NHS Trust	Provides expertise in palliative medicine in community settings for both cancer and non-cancer groups, health services research and the provision of local palliative care services.

Dr Carla Bruni, Consultant in Palliative Care, Midhurst Community Macmillan Team	Sussex Community NHS Trust	Provides expertise in palliative medicine in community settings for both cancer and non-cancer groups, health services research and the provision of local palliative care services.
Dr Shamim Taherzadeh, GP West Sussex, involvement transforming end-of–life care services for older people, particularly with dementia.	Northbourne Medical Centre, Shoreham-by-Sea, West Sussex	Contributes to the study execution, particularly recruitment, close working with specialist palliative care and adoption of findings if benefit is demonstrated
Two senior lay co-investigators	Brighton and Hove, and West Sussex (e.g. member Older People Council Member or Age UK)	Support co-ordination of the Lay Project Advisory Group, involvement of older people/carers in the consultation and developing aspects of the study e.g. post-bereavement survey and ensure user involvement is extensive and highly regarded by the researchers.

Appendix 2: Project research funding, timeline and flow chart

NIHR/CNO CAT Clinical Lectureship awarded to Evans (start March 2011- end March 2015)

NIHR RfPB grant contract June 2013 (start within three months) funding for 24 months

Pre clinical phase: protocol development

Systematic literature review on the effectiveness of palliative care for older people; establish research team, Steering Group, Lay Project Advisory Group and collaboration with NHS stakeholders in the study site

Phase 1a and 1b: Developing and refining SIPS service

Phase 1a: A post-bereavement postal survey (QUALYCare survey[1]) single wave administered October 2012 through the ONS to carers (n=882) who registered the death of a person aged 75+ who lived in the study site. Aim to examine preferences for care, palliative care outcomes and cost-effectiveness for older people by place of death. (April 2012-September 2013)

Phase 1b: Stakeholder consultation on the survey findings to refine the SIPS service forming a consensus on the key components and identify areas of contention/uncertainty. Stakeholders: older people and their families, service providers and service commissioners (health and social care) and voluntary sector representatives. Four workshops and on-line/postal consensus survey (October 2013-December 2013)

Phase 2: Feasibility trial on SIPS service

Intervention delivery two SPCTs with integrated working with four community nursing teams and close working GPs and geriatricians. Following referral SPCT key worker provides comprehensive palliative care assessment, 1-3 follow-up visits to review and evaluate care, and integrate care with community nurses, close working GPs and relevant health professionals
Sample 52 older people with advanced illness/frailty with/without dementia randomly assigned to one of two groups (intervention or standard care)
Outcome measures at baseline, 6 and 12 weeks primary outcome 5 key symptoms (I-POS symptom), secondary outcomes palliative outcomes (I-POS), carer burden (Carer Zaret Burden Interview), and economic effectiveness (Client Service Receipt Inventory & EQ-5D).
Process evaluation nested qualitative study to explore patient/carer (n=12) experiences and service providers/commissioners' experiences of integrated practitioner (n=16) (January 2014-September 2015)

Final synthesise and dissemination

- Policy and practice on palliative care services for frail older people
- Development and grant application for a full RCT protocol if evidence of patient benefit and cost-effectiveness (e.g. HTA)
- Publications in high impact journals of elderly medicine/palliative care

Appendix 3: What is frailty and palliative care?

What is frailty?

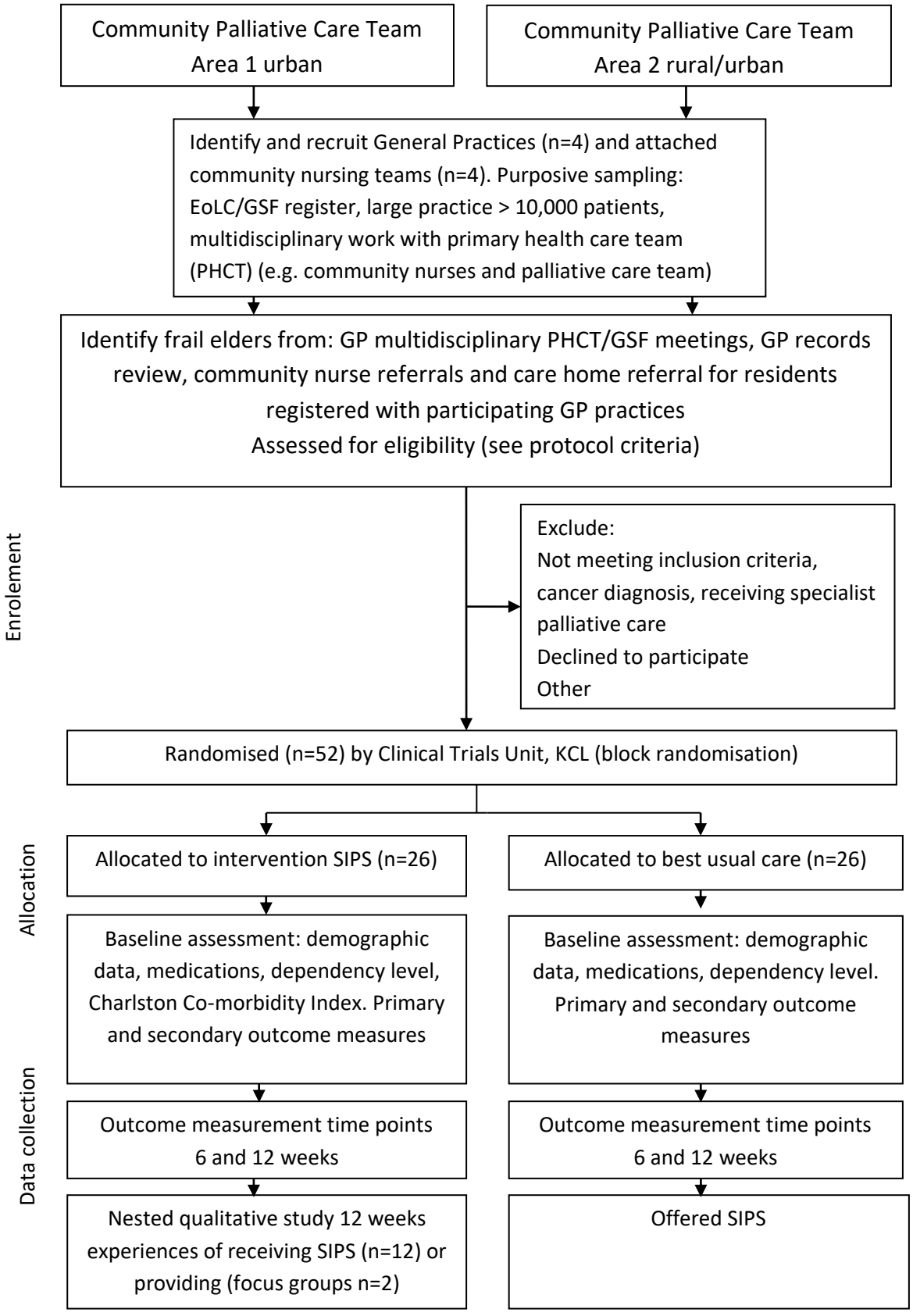
As we get older we may live with increasing frailty. This means we may feel more tired, find we need to walk more slowly and prefer activities that are less physically demanding. A seemingly small health problem, like a chest infection, can take a lot out of us. It takes time to recover and may lead to needing more help from others to continue to pursue things important to us.

What does supportive and palliative care mean?

Palliative care services provide an extra layer of support to people living with advanced illness (both cancer and non-cancer) and their families. Palliative care is offered at times when a person is experiencing increasing difficulties with their health because of advanced illness or increasing frailty. We talk about supportive and palliative care as the services aim to enable people to live well with increasing illness or frailty by providing the support needed for people to pursue things important to them and their families, and to plan future care particularly for when we are nearing the end of life.

Palliative care teams provide palliative care. They are sometimes called Macmillan Teams. The teams have many different people working with them - doctors, nurses, occupational therapists, social workers. This enables the service to assess and support many different needs; physical, social, emotional and mental health needs. Palliative care teams support both patients and their families, and provide care while someone is living with advanced illness and into bereavement. They work with GPs, community nurses and carers to provide specialist advice on how best to manage the care required by people with advanced illness to live well, plan future care and support their families.

Appendix 4: Phase 2 Feasibility Trial flow diagram



Appendix 5: Phase 2 Intervention - Short-term integrated palliative and supportive care (SIPS) frail elderly

Specialist Palliative Care

- Multi-professional teams trained to deal with complex interacting problems
- Holistic assessment
- Patients and their families/close friends

Short-term – three visits anticipated

Visit 1 *from key worker (e.g. nurse specialist PC)* ***(likely joint visit)***

- Comprehensive palliative care assessment
- Continuity and co-ordination of care, access to services and information needs
- Need for Advance Care Planning
- Symptom control and management, psychosocial needs
- Assessment of caregiver
- Agreed problem list and action plan

Review problem list/plan with SPCT & community nurses, GP, other practitioners

Visit 2 *from key worker or other relevant team member*

- Review outcomes from actions taken and reassessment.
- If immediate issues resolved e.g. advance care planning, plan for discharge

Re-review problem list/plan with SPCT & community nurses, GP and other practitioners

Visit 3 *from key worker or other relevant team member*

- Review outcomes from actions already taken
- Reassessment. Discharge (temporary – open re-referral by e.g. Patient/family

Final Review with SPCT & community nursing team, GP and other practitioners

Main outcome

Five key Palliative outcomes from the Integrated Palliative care Outcome Scale (IPOS): breathlessness, anxiety/depression, constipation, pain, and fatigue.

Secondary outcomes

- Additional Symptoms from IPOS beyond the 5 above
- Capability and wellbeing from ICECAP-O
- Level of frailty using Fried's Phenotype of frailty
- Level of Dependency using Northwick Park Dependency scale
- Functional status using adapted version of Australian Karnofsky Index
- Patient views of care
- Caregiver burden using short form Carer Zarit Burden Interview
- Hospital admissions and length of hospital stay
- Costs (informal and formal)
- Length of survival and place of death at 6 months

Appendix 6: Feasibility trial data collection tools and measures

(see separate supporting documents)

Baseline measures

- Demographic baseline questionnaire
- Fried's Phenotype of Frailty

Primary outcome

- I-POS symptom component

Secondary outcomes

- I-POS palliative outcomes and symptoms not included in the primary outcome
- Carer Zarit Burden Interview (short 12 question)

Process measures and monitoring

- Australian Karnofsky Performance Index
- Northwick Dependency Scale
- Views on Care
- Integrated working between specialist and generalist services using standardised data extraction sheet to record, e.g. contacts, timing, nature, format and intervention delivery e.g. timing from referral, number of contacts with patients/family, discharge from service, discharge to other services e.g. community nurses or continuation on SPCT caseload. Extracted at 12 weeks.
- Advance care planning reviewed at 12 weeks through data extraction of GP/community nursing records (usual care group) or SPCT records (intervention group) e.g. date of discussion and outcome i.e. preferred place of care recorded, DNACPR in place.
- Survival/mortality and place of death and attainment preferred place of care extracted GP records at 6 months.

Economic evaluation

- Client Service Receipt Inventory
- EQ-5D
- ICECAP-O

Appendix 7 Phase 2 nested qualitative study topic guides

Individual qualitative interview guide for elderly patients and their carers

The nested study aims to provide insights on the experiences of receiving the new palliative care services to support patients and their carers pursue goals important to them.

Individual interview guide

- What were your experiences of the specialist palliative care team visiting you at home [or in your care home]?
- What did you think might be helpful by receiving this service?
- How could the service support you to pursue things important to you?
- What ways do you think the service could be delivered differently?

Focus groups guide for practitioners delivering the new service and service commissioners

The focus groups aim to provide insights on the processes of implementing the short term integrated service including the procedures for delivering, the intervention manual , exploring if the intervention was delivered as envisaged and to generate understanding on how the benefit of SIPS for patients and families was promoted or limited in practice.

Focus group topic guide

- What were your experiences of delivering the short term palliative care service to patients living
    - at home
    - in a care home (with nursing or without)
- How did you think patients and families could benefit from receiving the service?
- What benefits to patients and families gain from receiving the service?
- How did integrated working between the specialist palliative care teams and the community nurses and GPs work? What facilitated this process, what were the barriers?

Reference List

1. Dewing J. Participatory research: A method for process consent with persons who have dementia. *Dementia* 2007; **6**(1): 11-25.
2. Fried LP, Tangen CM, Walston J, et al. Frailty in older adults: evidence for a phenotype. *J Gerontol A Biol Sci Med Sci* 2001; **56**(3): M146-56.
3. Clegg A, Young J, Iliffe S, Rikkert MO, Rockwood K. Frailty in elderly people. *Lancet* 2013; **381**(9868): 752-62.
4. Sampson EL, Ritchie CW, Lai R, Raven PW, Blanchard MR. A systematic review of the scientific evidence for the efficacy of a palliative care approach in advanced dementia. *Int Psychogeriatr* 2005; **17**(01): 31-40.
5. Zimmermann C, Riechelmann R, Krzyzanowska M, Rodin G, Tannock I. Effectiveness of specialized palliative care: a systematic review. *JAMA* 2008; **299**(14): 1698-709.
6. Lorenz KA, Lynn J, Dy SM, et al. Evidence for improving palliative care at the end of life: a systematic review. *AnnInternMed* 2008; **148**(2): 147-59.
7. MRC. Developing and evaluating complex interventions: new guidance. London: Medical Research Council, 2008.
8. Yardley L, Beyer N, Hauer K, McKee K, Ballinger C, Todd C. Recommendations for promoting the engagement of older people in activities to prevent falls. *Quality & safety in health care* 2007; **16**(3): 230-4.
9. McCarthy M, AddingtonHall J, Altmann D. The experience of dying with dementia: A retrospective study. *Int J Geriatr Psychiatry* 1997; **12**(3): 404-9.
10. Mitchell SL, Teno JM, Kiely DK, et al. The clinical course of advanced dementia. *N Engl J Med* 2009; **361**(16): 1529-38.
11. Burt J, Shipman C, Richardson A, Ream E, Addington-Hall J. The experiences of older adults in the community dying from cancer and non-cancer causes: a national survey of bereaved relatives. *Age Ageing* 2010; **39**(1): 86-91.
12. National End of Life Care Intelligence Network. Deaths in Older Adults in England. Bristol: South West Public Health Observatory, 2010.
13. Gill TM, Gahbauer EA, Han L, Allore HG. Trajectories of disability in the last year of life. *N Engl J Med* 2010; **362**(13): 1173-80.
14. Falaschetti E. The Health Survey for England 2000: the general health of older people and their use of health services. London, 2002.
15. Department of Health. End of Life Care Strategy - promoting high quality care for adults at the end of life. London: Crown, 2008.
16. Addington-Hall J, Fakhoury W, McCarthy M. Specialist palliative care in nonmalignant disease. *Palliat Med* 1998; **12**(6): 417-27.
17. Goodman C, Evans C, Wilcock J, et al. End of life care for community dwelling older people with dementia: an integrated review. *IntJGeriatrPsychiatry* 2009.
18. Higginson IJ, McCrone P, Hart SR, Burman R, Silber E, Edmonds PM. Is short-term palliative care cost-effective in multiple sclerosis? A randomized phase II trial. *J Pain SymptomManage* 2009; **38**(6): 816-26.
19. Mitchell SL, Kiely DK, Hamel MB. Dying with advanced dementia in the nursing home. *Arch Intern Med* 2004; **164**(3): 321-6.
20. Shipman C, Gysels M, White P, et al. Improving generalist end of life care: national consultation with practitioners, commissioners, academics, and service user groups. *BMJ* 2008; **337**: a1720.
21. Davies SL, Goodman C, Bunn F, et al. A systematic review of integrated working between care homes and health care services. *BMC Health Serv Res* 2011; **11**: 320.
22. Fleming J, Zhao J, Farquhar M, Brayne C, Barclay S. Place of death for the `oldest old': >/=85-year-olds in the CC75C population-based cohort. *Br J Gen Pract* 2010; **60**(573): 275-82.

23. Farquhar MC, Higginson IJ, Fagan P, Booth S. The feasibility of a single-blinded fast-track pragmatic randomised controlled trial of a complex intervention for breathlessness in advanced disease. *BMCPalliatCare* 2009; **8**: 9.
24. Perera R, Heneghan C, Yudkin P. Graphical method for depicting randomised trials of complex interventions. *BMJ* 2007; **334**(7585): 127-9.
25. Goodman C, Evans C, Wilcock J. End of life care for community dwelling older people with dementia: an integrated review. *Int J Geriatric Psychiatry* 2010; **25**(4).
26. NHS Commissioning Board. Enhanced Service Specification; Risk Profiling and Care Management Scheme. London, 2013.
27. McMurdo ME, Roberts H, Parker S, et al. Improving recruitment of older people to research through good practice. *Age Ageing* 2011; **40**(6): 659-65.
28. Davies K, Collerton JC, Jagger C, et al. Engaging the oldest old in research: lessons from the Newcastle 85+ study. *BMC Geriatr* 2010; **10**: 64.
29. Rockwood K, Song X, MacKnight C, et al. A global clinical measure of fitness and frailty in elderly people. *CMAJ* 2005; **173**(5): 489-95.
30. Bouillon K, Kivimaki M, Hamer M, et al. Measures of frailty in population-based studies: an overview. *BMC Geriatr* 2013; **13**: 64.
31. Evans CJ, Harding R, Higginson IJ, MORECare obo. 'Best practice' in developing and evaluating palliative and end-of-life care services: A meta-synthesis of research methods for the MORECare project. *Palliat Med* 2013; **10.1177/0269216312467489**.
32. Coastal West Sussex CCG. Guidance for completion of the Risk Profiling and Care Management DES Goring by Sea, West Sussex, 2013.
33. Fleming J, Zhao E, O'Connor DW, Pollitt PA, Brayne C. Cohort profile: the Cambridge City over-75s Cohort (CC75C). *Int J Epidemiol* 2007; **36**(1): 40-6.
34. Resnick B, Concha B, Burgess JG, et al. Recruitment of older women: lessons learned from the Baltimore Hip Studies. *Nurs Res* 2003; **52**(4): 270-3.
35. Scott S, Jones L, Blanchard MR, Sampson EL. Study protocol: the behaviour and pain in dementia study (BePAID). *BMC Geriatr* 2011; **11**: 61.
36. Jones L, Harrington J, Scott S, et al. CoMPASs: IOn programme (Care Of Memory Problems in Advanced Stages of dementia: Improving Our Knowledge): protocol for a mixed methods study. *BMJ open* 2012; **2**(6).
37. Mathie E, Goodman C, Crang C, et al. An uncertain future: the unchanging views of care home residents about living and dying. *Palliat Med* 2012; **26**(5): 734-43.
38. Department of Health. Mental Capacity Act. London: Department of Health, 2005.
39. University of Leicester, University of Bristol. Adults lacking capacity – on-line toolkit. NRES; 2010.
40. Rees E, Hardy J. Novel consent process for research in dying patients unable to give consent. *BMJ* 2003; **327**(7408): 198.
41. Division DSDaB. Guidance on nominating a consultee for research involving adults who lack capacity to consent, 2008.
42. Altman DG. Practical statistics for medical research. 1st ed. London ; New York: Chapman and Hall; 1991.
43. Farquhar M, Higginson IJ, Booth S. Fast-Track Trials in Palliative Care: An Alternative Randomized Controlled Trial Design. *Journal of Palliative Medicine* 2009; **12**(3): 213-.
44. Higginson IJ, Hart S, Burman R, Silber E, Saleem T, Edmonds P. Randomised controlled trial of a new palliative care service: Compliance, recruitment and completeness of follow-up. *BMCPalliatCare* 2008; **7**: 7.
45. Evans CJ, Benalia H, Preston NJ, et al. The Selection and Use of Outcome Measures in Palliative and End-of-Life Care Research: The MORECare International Consensus Workshop. *J Pain Symptom Manage* 2013; **10.1016/j.jpainsymman.2013.01.010**.
46. Kutner JS, Bryant LL, Beaty BL, Fairclough DL. Symptom Distress and Quality-of-Life Assessment at the End of Life: The Role of Proxy Response. *J Pain Symptom Manage* 2006; **32**(4): 300-10.

47. Jones JM, McPherson CJ, Zimmermann C, Rodin G, Le LW, Cohen SR. Assessing agreement between terminally ill cancer patients' reports of their quality of life and family caregiver and palliative care physician proxy ratings. *J Pain Symptom Manage* 2011; **42**(3): 354-65.
48. Murtagh F, Bausewein C, McCrone P, et al. The C-Change project - delivering high quality and cost-effective palliative care for patients in the last year of life and their families. London: Cicely Saunders Institute, King's College London; 2011.
49. Hearn J, Higginson IJ. Development and validation of a core outcome measure for palliative care: the palliative care outcome scale. Palliative Care Core Audit Project Advisory Group. *Qual Health Care* 1999; **8**(4): 219-27.
50. Siegert RJ, Gao W, Walkey FH, Higginson IJ. Psychological well-being and quality of care: a factor-analytic examination of the palliative care outcome scale. *J Pain Symptom Manage* 2010; **40**(1): 67-74.
51. Brandt HE, Deliens L, Steen JTvd, Ooms ME, Ribbe MW, Wal Gv. The last days of life of nursing home patients with and without dementia assessed with the Palliative care Outcome Scale. *Palliat Med* 2005; **19**(4): 334-42.
52. Higginson IJ, Gao W, Jackson D, Murray J, Harding R. Short-form Zarit Caregiver Burden Interviews were valid in advanced conditions. *J Clin Epidemiol* 2010; **63**(5): 535-42.
53. Lo C, Burman D, Hales S, Swami N, Rodin G, Zimmermann C. The FAMCARE-Patient scale: measuring satisfaction with care of outpatients with advanced cancer. *Eur J Cancer* 2009; **45**(18): 3182-8.
54. Lo C, Burman D, Rodin G, Zimmermann C. Measuring patient satisfaction in oncology palliative care: psychometric properties of the FAMCARE-patient scale. *Qual Life Res* 2009; **18**(6): 747-52.
55. Ringdal GI, Jordhoy MS, Kaasa S. Measuring quality of palliative care: psychometric properties of the FAMCARE Scale. *Qual Life Res* 2003; **12**(2): 167-76.
56. Kristjanson LJ. Validity and reliability testing of the FAMCARE Scale: measuring family satisfaction with advanced cancer care. *Soc Sci Med* 1993; **36**(5): 693-701.
57. Aoun S, Bird S, Kristjanson LJ, Currow D. Reliability testing of the FAMCARE-2 scale: measuring family carer satisfaction with palliative care. *Palliat Med* 2010; **24**(7): 674-81.
58. Temel JS, Greer, J.A., Muzikansky, A., Gallagher, E.R., Admane, S., Jackson, V., Dahlin, M. C., Blinderman, C.D., Jacobsen, J., Pirl, W.F., Billings, J. A., Lynch, T. J. Early Palliative Care for Patients with Metastatic Non–Small-Cell Lung Cancer. *N Engl J Med* 2010; **363**: 733-42.
59. Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med* 2001; **33**(5): 337-43.
60. Beecham J, Knapp M. Costing psychiatric interventions. In: Thornicroft GJ, ed. Measuring mental health needs. 2nd ed ed. London: Gaskell; 2001: 200-24.
61. McCrone P. Capturing the costs of end-of-life care: Comparisons of multiple sclerosis, Parkinson's disease, and dementia. *J Pain Symptom Manage* 2009; **38**(1): 62-7.
62. Al-Janabi H, Flynn T, Coast J. Development of a self-report measure of capability wellbeing for adults: the ICECAP-A. *Quality of Life Research* 2012; **21**(1): 167-76.
63. Turner-Stokes L, Williams H, Rose H, Harris S, Jackson D. Deriving a Barthel Index from the Northwick Park Dependency Scale and the Functional Independence Measure: are they equivalent? *Clin Rehabil* 2010; **24**(12): 1121-6.
64. Collin C, Wade DT, Davies S, Horne V. The Barthel ADL Index: a reliability study. *Int Disabil Stud* 1988; **10**(2): 61-3.
65. Abernethy AP, Shelby-James T, Fazekas BS, Woods D, Currow DC. The Australia-modified Karnofsky Performance Status (AKPS) scale: a revised scale for contemporary palliative care clinical practice [ISRCTN81117481]. *BMC Palliat Care* 2005; **4**: 7.
66. Eagar K, Watters P, Currow DC, Aoun SM, Yates P. The Australian Palliative Care Outcomes Collaboration (PCOC)--measuring the quality and outcomes of palliative care on a routine basis. *Aust Health Rev* 2010; **34**(2): 186-92.

67. Preston NJ, Fayers P, Walters SJ, et al. Recommendations for managing missing data, attrition and response shift in palliative and end-of-life care research: Part of the MORECare research method guidance on statistical issues. *Palliat Med*, 2013. http://www.ncbi.nlm.nih.gov/pubmed/23652842 (accessed May 7).
68. Curry LA, Krumholz HM, O'Cathain A, Clark VLP, Cherlin E, Bradley EH. Mixed Methods in Biomedical and Health Services Research. *Circ Cardiovasc Qual Outcomes* 2013; **6**(1): 119-23.
69. Bradley F, Wiles R, Kinmonth AL, Mant D, Gantley M. Development and evaluation of complex interventions in health services research: case study of the Southampton heart integrated care project (SHIP). The SHIP Collaborative Group. *BMJ* 1999; **318**(7185): 711-5.
70. Gott M, Seymour J, Bellamy G, Clark D, Ahmedzai S. Older people's views about home as a place of care at the end of life. *Palliat Med* 2004; **18**(5): 460-7.
71. Goodman C, Evans C. Focus Groups. In: Gerrish K, Lacey A, eds. The Research Process in Nursing 6th ed. Oxford: John Wiley and Sons; 2010: 358-68.
72. Spencer L, Ritchie J. In pursuit of quality. In: D. Harper, A.R. Thompson, eds. Qualitative Research Methods in Mental Health and Psychotherapy: a Guide for Students and Practitioners. London: John Wiley and Sons Ltd; 2012: 227-42.
73. Rolfe G. Validity, trustworthiness and rigour: quality and the idea of qualitative research. *J Adv Nurs* 2006; **53**(3): 304-10.
74. Coffey A, Atkinson P. Making sense of qualitative data : complementary research strategies Thousand Oaks, California.: Sage Publications; 1996.
75. Green J, Thorogood N. Qualitative methods for health research. London: Sage; 2004.
76. Denzin NK, Lincoln YS. The Sage handbook of qualitative research. 4th ed. Thousand Oaks: Sage; 2011.
77. O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. *BMJ* 2010; **341**: c4587.
78. Bradley N, Sweeney K, Waterfield M. The health of their nation: how would citizens develop England's health strategy? *BrJ GenPract* 1999; **49**(447): 801-5.
79. INVOLVE. Good practice in active public involvement in research. London: NIHR, Involve, 2009.
80. INVOLVE. Payment for involvement: A guide for making payments to members of the public actively involved in NHS, public health and social care research. Eastleigh: INVOLVE, 2010.
81. National Research Ethics Service. Adults lacking capacity – on-line toolkit 2009. https://connect.le.ac.uk/alctoolkit/ (accessed 18/09/2011 2011).
82. Goodman C, Baron NL, Machen I, et al. Culture, consent, costs and care homes: Enabling older people with dementia to participate in research. *Aging Ment Health* 2011; **15**(4): 475-81.
83. Hall S, Longhurst S, Higginson IJ. Challenges to conducting research with older people living in nursing homes. *BMC Geriatr* 2009; **9**: 38.
84. Hall S, Goddard C, Opio D, Speck P, Higginson IJ. Feasibility, acceptability and potential effectiveness of Dignity Therapy for older people in care homes: A phase II randomized controlled trial of a brief palliative care psychotherapy. *Palliat Med* 2011; **26**(5): 703-12.
85. Hall S, Opio D, Dodd RH, Higginson IJ. Assessing quality-of-life in older people in care homes. *Age Ageing* 2011.
86. Cashman J, Wright J, A. R. The treatment of co-morbidities in older patients with metastatic cancer *The Journal of Supportive Care in Cancer* 2010; **18**: 651-5.
87. Pountney TE, Mandy A, Green E, Gard PR. Hip subluxation and dislocation in cerebral palsy - a prospective study on the effectiveness of postural management programmes. *Physiother Res Int* 2009; **14**(2): 116-27.
88. Hall S, Chochinov H, Harding R, Murray S, Richardson A, Higginson IJ. A Phase II randomised controlled trial assessing the feasibility, acceptability and potential effectiveness of dignity therapy for older people in care homes: study protocol. *BMCGeriatr* 2009; **9**: 9.

89. Gomes B, McCrone P, Hall S, Koffman J, Higginson IJ. Variations in the quality and costs of end-of-life care, preferences and palliative outcomes for cancer patients by place of death: the QUALYCARE study. *BMC Cancer* 2010; **10**: 400.
90. Gomes B, Higginson Irene J, McCrone P. Effectiveness and cost-effectiveness of home palliative care services for adults with advanced illness and their caregivers. *Cochrane Database of Systematic Reviews*, 2010. http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD007760/frame.html (accessed.
91. Medical Research Council. Methods for evaluating service delivery models for end of life care (EoLC): development of best practice guidance. 2009. http://www.mrc.ac.uk/ResearchPortfolio/Grant/Record.htm?GrantRef=G0802654&CaseId=14304 (accessed 12th Sept 2011).
92. Committee KsCLF. Code of Practice for Intellectual Property, Commerical Exploitation and Financial Benefits. London: King's College London, 2008.