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Community-based short-term integrated palliative and supportive care reduces symptom distress for older people with chronic noncancer conditions compared with usual care: a randomised controlled single-blind mixed method trial

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Abstract

**Background:** Globally, a rising number of people live into advanced age and die with multimorbidity and frailty. Palliative care is advocated as a person-centred approach to reduce health-related suffering and promote quality of life. However, no evidence-based interventions exist to deliver community-based palliative care for this population.

**Aim:** To evaluate the impact of the short-term integrated palliative and supportive care intervention for older people living with chronic noncancer conditions and frailty on clinical and economic outcomes and perceptions of care.
**Design:** Single-blind trial with random block assignment to usual care or the intervention and usual care. The intervention comprised integrated person-centred palliative care delivered by multidisciplinary palliative care teams working with general practitioners and community nurses. Main outcome was change in five key palliative care symptoms from baseline to 12-weeks. Data analysis used intention to treat and complete cases to examine the mean difference in change scores and effect size between the trial arms. Economic evaluation used cost-effectiveness planes and qualitative interviews explored perceptions of the intervention.

**Setting/participants:** Four National Health Service general practices in England with recruitment of patients aged $\geq 75$ years, with moderate to severe frailty, chronic noncancer condition(s) and $\geq 2$ symptoms or concerns, and family caregivers when available.

**Results:** 50 patients were randomly assigned to receive usual care ($n=26$, mean age 86.0 years) or the intervention and usual care ($n=24$, mean age 85.3 years), and 26 caregivers (control $n=16$, mean age 77.0 years; intervention $n=10$, mean age 77.3 years). Participants lived at home ($n=48$) or care home ($n=2$). Complete case analysis ($n=48$) on the main outcome showed reduced symptom distress between the intervention compared with usual care (mean difference -1.20, 95% confidence interval -2.37 to -0.027) and medium effect size ($\omega^2 = 0.071$). Symptom distress reduced with decreased costs from the intervention compared with usual care, demonstrating cost-effectiveness. Patient ($n=19$) and caregiver ($n=9$) interviews generated themes about the intervention of 'Little things make a big difference' with optimal management of symptoms and 'Care beyond medicines' of psychosocial support to accommodate decline and maintain independence.

**Conclusions:** This palliative and supportive care intervention is an effective and cost-effective approach to reduce symptom distress for older people severely affected by chronic noncancer conditions. It is a clinically effective way to integrate specialist palliative care with primary and community care for older people with chronic conditions. Further research is indicated to examine its implementation more widely for people at home and in care homes.
**Trial registration**: Controlled-Trials.com ISRCTN 45837097

**Tweetable abstract**: Specialist palliative care integrated with district nurses and GPs is cost-effective to reduce symptom distress for older people severely affected by chronic conditions.
Contribution of the Paper

What is already known

- Older people increasingly live and die with multiple chronic conditions that cause escalating distress and suffering as conditions progress and with nearness of end-of-life
- Palliative care is person-centred care for people with chronic and life-limiting conditions to reduce suffering and improve quality of life as the main goal of care
- Palliative care is advocated with integrated care between specialists in palliative care at points of escalating ill-health working with existing generalist healthcare providers, like district and community nurses and GPs.

What this paper adds

- Demonstrates effectiveness and cost-effectiveness of a community-based intervention of short-term integrated palliative and supportive care to reduce distress on five key palliative care symptoms for older people severely affected by chronic noncancer conditions and frailty living at home
- Patients’ and caregivers’ perceived the intervention as beneficial with themes of ‘Little things make a big difference’ of optimal management of unstable symptoms like breathlessness, coupled with ‘Care beyond medicines’ of psychosocial support to accommodate decline and maintain independence
- A unique examination of an intervention of integrated care between specialists in palliative care and primary and community care to deliver palliative care at points of increasing health-related suffering for older people living with chronic noncancer conditions.

Keywords: Aged; Palliative care; Community Health Nursing; General Practice; Randomized Controlled Trial; Costs and Cost Analysis; Qualitative interviews
Introduction

Globally, people increasingly live into advanced age and die with frailty and multimorbidity. The largest increases are in the oldest old with proportion of people aged 85 years and over projected to nearly double by 2043 in England and Wales. The trajectory of living and dying is often one of increasing frailty and for many, complex multimorbidity with four or more conditions and diminishing capacity, notably from dementia. Frailty is conceptualised here as a state of increased susceptibility to marked functional decline and poor outcomes, like unplanned hospitalization and institutionalisation when exposed to a minor stressor. As conditions progress, symptom burden and concerns escalate causing considerable distress for the person, reduced quality of life and increased risk of dying. Death is often unpredictable, and uncertainty as to nearness of end-of-life is inherent.

Palliative care is comprehensive person-centred care to prevent and reduce health-related suffering and improve quality of life for people with serious illness and their family caregivers. Main actions are multidimensional assessment of physical, psychological, social and spiritual symptoms and/or concerns, followed by the identification of preferences and priorities and agreed goals of care, then advance care planning processes, with regular review and careful management. Older people experience inequitable access to high-quality palliative care with disproportionately lower provision compared to younger adults.

In part, this is because older people often have progressive diseases other than cancer, which has traditionally been the focus of palliative care services internationally. Palliative care in chronic noncancer conditions is often delivered late in the disease trajectory, started reactively in a crisis or when dying is imminent for people with conditions like dementia and heart-failure. Palliative care is shown for people with chronic noncancer conditions as beneficial by reducing concerns, like symptom burden and unplanned hospitalization. However, the evidence is limited to specific conditions, notably heart failure and chronic obstructive pulmonary disease and hospital-based palliative care (inpatient and/or...
outpatient). No trials have reported a community-based palliative care intervention for older people with chronic noncancer conditions and frailty.

New models of community-based palliative care are demanded to reduce health-related suffering for older people with chronic noncancer conditions where they reside (at home and in care homes). In 2014, the World Health Assembly advocated the integration of palliative care into health services to strengthen provision for all people living with chronic and life-limiting conditions. Palliative care can be delivered by all generalist healthcare providers, like a community nurse, where this is part of their role, with support from specialists in palliative care to manage complex patient or caregiver needs, such as difficult symptoms like breathlessness. To integrate palliative care in services for older people with noncancer conditions requires pathways that encompass the often prolonged and fluctuating illness trajectory, with care provision based on individual needs, preferences and agreed goals of care. While models of palliative care in cancer are well defined and pathways to specialist palliative care evident, for older people with noncancer conditions the pathway is less clear. The main providers of care are typically their primary care team such as General Practitioners (GP), district and community nurses, with specialist palliative care advocated at points of escalating health-related suffering from serious illness, such as advanced disease stage.

Health systems emphasise integrated care for older people to meet their multiple health and social care needs associated with multimorbid chronic conditions, and older people and their family caregivers stress the need for effective integrated care at points of escalating ill health or crisis. The intention is to meet changing and rising health and social care needs with disease progression and promote continuity and coordination of care between care providers and services. We proposed a model of community-based short-term integrated palliative and supportive care for older people severely affected by chronic noncancer conditions and frailty living at home or in a care home. Our model built on a feasibility trial of short-term integrated palliative care for people severely affected by Multiple Sclerosis.
This earlier trial demonstrated the intervention processes, acceptability for patients, caregivers and practitioners and the benefit for patients and caregivers to improve symptoms, as well as cost-effectiveness. We modified the model for an older population with chronic conditions and frailty with findings from two development studies. These involved consulting with older people, caregivers, health and social care practitioners about a model of short-term integrated palliative care including the potential benefit, timing and process of integrated care, and a regional mortality follow-back survey to inform the components, processes and key symptoms for adults aged 75 years and over in the last months of life.

The primary aim of the Optimising Palliative care for Older People (OPTcare Elderly) trial was to evaluate the impact of a community-based short-term integrated palliative and supportive care intervention (SIPScare) on change in symptoms between baseline and 12-weeks for older people severely affected by chronic noncancer conditions compared to usual care. The secondary aims were to examine symptoms at six-weeks, and other palliative care concerns for the patient and caregiver at six- and 12-weeks, to evaluate cost-effectiveness and perceptions of SIPScare. Mortality was assessed at six-months as a safety outcome.

Methods

Study design

A randomised single-blind trial to examine the clinical outcomes of SIPScare compared to usual care and cost-effectiveness, with a nested qualitative study to explore perceptions of the intervention. The design was informed by the Methods Of Researching End of life Care statements to evaluate complex interventions in palliative care. Reporting followed the Consolidated Standards of Reporting Trials and Consolidated Health Economic Evaluation Reporting Standards (Supplementary material Tables A1 and A2). Trial registration number ISRCTN45837097.

Setting

Four general family practice centres across two geographical areas in South England encompassing rural and city geographical localities. The centres covered a total catchment
of over 45,000 registered patients with on average 10% (range 8-13%) aged ≥75 years. Three centres were in areas of low deprivation (decile of 9) and one moderate deprivation (decile of 6) (10 least deprived) (Supplementary Table C1. Profile of GP Centres).

**Participants and consent**

**Eligibility.** Adults registered with a participating General Practice (GP), aged ≥75, with a Clinical Frailty Scale score of ≥4 (vulnerable to severely frail/terminally ill)\(^3\), and severely affected by non-malignant chronic conditions were included. Severely affected encompassed ≥2 symptoms or concerns, including end-of-life issues, like advance care planning, progressive illness/frailty, complex needs (i.e. multiple psychosocial or physical symptoms or concerns), caregiver concerns and/or increasing health service use. People with or without mental capacity to give informed consent and living at home or in a care home were eligible. Their family caregivers (included family and close friends) were eligible to participate when identified. Patients receiving specialist palliative care were ineligible. Each general practice site screened their patient lists for eligibility and then approached eligible patients as part of their usual clinical care. Each site maintained a screening log detailing the number of patients screened, eligible patients identified and approached, and outcome of enrolment or decline and reason for decline if known. Non-identifiable demographic data (e.g. sex, age) from the screening logs were descriptively analysed to examine differences between non-participants and participants.

**Process of consent.** Consent was obtained from all participants for all study procedures. Each general practice invited eligible patients to participate using a letter of invitation and information leaflet. Those interested in the study, were followed-up by a research nurse to discuss the study and complete the informed consent process. Capacity to consent was assessed using Mental Capacity Act criteria\(^3\). Processes of consent were tailored to individual level of capacity to enable participation\(^2\) (Supplementary Figure B1: Process of consent). When a person could give informed consent, but might not recall consent overtime, we used a method of process consent asking individuals to re-confirm consent
verbally at each study timepoint. If a person lacked mental capacity, a personal consultee who knew the person well (i.e. a family member) advised on participation (or not) informed by understanding of the person’s likely preference had they had capacity to indicate.

Randomisation and masking
After baseline assessment, participants were randomly assigned at the individual level, using an independent web-based randomisation system within the UK Clinical Research Collaboration-registered King’s Clinical Trials Unit (London, UK). Block randomisation was employed with randomly varying block sizes and stratified by site (rural or city). The data collectors (research nurses, and A.B.) and the statistical and health economic analysis team (G.W. A.B., and D.Y.) were masked to the arm allocation during the main data analyses. It was not possible to mask the patients and caregivers, but they were asked not to disclose if received the palliative care intervention to the data collectors.

Intervention
The intervention and control arms received usual primary and community care as clinically indicated from the participating General Practice sites and community healthcare services. The intervention arm received usual care and the SIPScare intervention. Table 1 reports the intervention and usual care components using the Template for Intervention Description and Replication (TIDIER guide). The intervention comprised comprehensive, integrated person-centred palliative care delivered by community-based specialist multidisciplinary palliative care teams. Integration was with the general practitioners and community healthcare services, including district and community nurses, involved in the patient’s care. Integration built on established relationships. The specialist palliative care teams identified general practices they considered fostered the provision of end of life care through integrated working with specialists in palliative care and community healthcare, notably the community nurses. The additional support of specialists in palliative care intended to occur at points of escalating health-related suffering from serious illness for the patient and/or caregiver. The palliative care team were anticipated to deliver care for up to 12-weeks from the initial
baseline assessment. After 12-weeks, care would continue with the GP and community services and patients could re-access the palliative care team if symptoms or concerns developed. If symptoms or concerns persisted after 12-weeks, patients continued to receive care from the palliative care team if clinically indicated.

The intervention fidelity of palliative care delivery was monitored from baseline to 12-weeks. With participant consent/assent, data were extracted from participants’ specialist palliative care health record on: (1) Short-term delivery between baseline and 12-weeks reporting number of contacts, mode (e.g. face-to-face), time to deliver and discipline; (2) Integrated care with detail on the service/practitioner (e.g. GP), mode (e.g. telephone), time to deliver, purpose (e.g. advise, request medication change); (3) Palliative care team activities including multidisciplinary review of patient assessment and plan of care, advance care planning and phase of illness reported at first and last contact; (4) Length of time of palliative care team involvement was reviewed at 12-weeks and six months with data extracted on date of discharge (or not) and date(s) of re-access.
Table 1. Intervention description using the template for intervention description and replication (TIDieR) checklist

<table>
<thead>
<tr>
<th>Item</th>
<th>Intervention arm</th>
<th>Control arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>SIPScare – Short-term integrated palliative and supportive care (and usual primary and community healthcare)</td>
<td>Usual primary and community health care</td>
</tr>
<tr>
<td>Why</td>
<td>SIPScare has the potential to improve outcomes for older people with chronic noncancer conditions in primary care and community settings while also being cost-effective. The intervention intended to provide specialist palliative care at points of escalating illness to assess and manage care working with primary and community healthcare services.</td>
<td>Randomly allocated control arm to examine the possible effectiveness of SIPScare</td>
</tr>
<tr>
<td>What</td>
<td>Multidimensional person centred palliative care assessment, then multidisciplinary review and management, with coordination of care usually by a nurse specialist in palliative care. Delivered over 12 weeks with up to three visits/contacts. Integrated care between the palliative care team, GP and community nursing services through the multidisciplinary team review, information sharing on assessments and care and treatment plans.</td>
<td>Usual care from primary and community healthcare, and social care providers informed by individual assessment, priorities and preferences and agreed goals of care.</td>
</tr>
<tr>
<td>Who provided</td>
<td>Community-based Specialist Palliative Care Team, care coordination and management, usually by an identified practitioner, usually a nurse specialist in palliative care and review by the multidisciplinary team of the multidimensional assessment, individual priorities and preferences and agreed goals of care with regular review.</td>
<td>Usual primary and community healthcare, and social care providers.</td>
</tr>
<tr>
<td>How</td>
<td>Face-to-face assessments with phone or face-to-face follow-ups for regular review.</td>
<td>Face-to-face or phone contacts, as per usual clinical practice.</td>
</tr>
<tr>
<td>Where</td>
<td>Older person’s usual residence, such as at home or care home.</td>
<td>Primary care or community setting (including the older person’s usual residence).</td>
</tr>
<tr>
<td>When and how much</td>
<td>General practitioner identified people aged ≥75 years, frail or vulnerable to frailty (≥4 Clinical Frailty Scale) and severely affected by noncancerous conditions (i.e. ≥2 unresolved symptoms or concerns, increasing caregiver suffering, rising healthcare use). GP referral to the palliative care team.</td>
<td>Patients in the control arm were offered SIPScare after 12-weeks.</td>
</tr>
<tr>
<td></td>
<td>- the palliative care team telephone the older person’s family caregiver within 48 hours to arrange the first visit within five working days.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Palliative care team first visit to assess multidimensional symptoms and concerns for the patient and caregiver, identify priorities, agree goals of care and care and treatment plan, including advance care planning.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Palliative care team multidisciplinary review of assessment and plan for care and treatment.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Two follow-up visits/contacts to review and update care as clinically indicated over 12-weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Review discharge from the palliative care team with care continued by the GP (and community healthcare services) with detailed plan from the palliative care team to maintain continuity of care.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Patient and family advised how to access the palliative care service if symptoms and concerns develop.</td>
<td></td>
</tr>
<tr>
<td>Tailoring</td>
<td>Comprehensive assessment ensured tailoring of care based on individual priorities and needs</td>
<td>Determined by GP or community nurses.</td>
</tr>
<tr>
<td>Modified</td>
<td>Included patients considered clinically likely to benefit from palliative care aged &lt; 75 years with chronic conditions who presented as biologically older than chronological years (n=2, aged 72 and 74 years)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Trial fidelity</td>
<td>Fidelity of the intervention ensured by extracting data from the palliative care team health records for intervention patients over the period of study, and GP health records for both arms.</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
Outcome measures

Outcomes were measured at baseline, 6-weeks and 12-weeks. Data collection at baseline and 12-weeks was face-to-face, with the shorter questionnaire at 6-weeks administered by phone or face-to-face if preferred. Supplementary Table B1 graphically depicts the trial procedures and timepoints.  

Primary outcome. The primary outcome was five key symptoms (pain, breathlessness, patient anxiety, drowsiness and constipation) measured using the Integrate Palliative care Outcome Scale (IPOS), 3-day version, as a short, easy to use measure for palliative care with self-report and proxy-report versions. Each symptom is measured on a scale from 0 to 4 with the person (or proxy) reporting how affected by the symptom from ‘not at all’ (score 0) to ‘overwhelming’ (score 4). The selection of the five primary symptoms was informed by the trial development studies consulting with patients, caregivers and practitioners, the mortality follow-back survey, and evidence on symptom prevalence towards the end-of-life for people with advanced conditions. The Trial Steering Group of experts spanning multiple disciplines (e.g. General Practice, Specialist Palliative Care, Geriatrics, epidemiology and statistics) reviewed the key symptoms of pain, breathlessness, patient anxiety, drowsiness and constipation and considered these prevalent in the population and amenable to change through the intervention.  

Secondary outcomes. Secondary outcomes were palliative care concerns and symptoms (beyond the five key symptoms) across the multidimensional needs measured using the IPOS, including other physical (6 items scoring 0-4) and other psychosocial symptoms or concerns (6 items scoring 0-4), Barthel Activities of Daily Living Index, and caregiver burden using the self-assessed short form Carer Zarit Burden Interview (12 item short form). We extracted from GP health records participant primary diagnosis, comorbidities, prescribed medication and advance care planning, and survival from baseline to six-months as a safety measure.
Baseline data included demographic data (e.g. age, sex) and clinical circumstances, (e.g. diagnoses), Modified Fried’s Frailty criteria\textsuperscript{41} and Australia-modified Karnofsky Performance Status\textsuperscript{42}.

Sample size and data analysis

A priori sample size calculation was undertaken. The parameters for sample size estimation were informed by symptom prevalence for older people with dementia towards the end of life\textsuperscript{38}. The sample size assumed 20% attrition between baseline and 12-weeks. With the 20% attrition, the trial required 26 patients in each arm (52 in total) to detect differences of >2 (with a standard deviation [SD] of 2.25) on the IPOS symptom component with a two-tailed, two-sample t-test at alpha = 0.05, power= 80% at 12-weeks post-randomisation.

We used intention to treat analysis and complete cases in the primary analysis. We calculated the mean difference in change scores for the primary and secondary outcomes between each treatment arm, and the corresponding 95% confidence intervals. We modelled this using linear regression to calculate effect size, adjusting for baseline scores for each outcome examined. We calculated the omega squared effect size as an appropriate measure of effect size for regression analyses and preferable to eta-squared for small samples sizes as it corrects for bias\textsuperscript{43}. We conducted sensitivity analysis on the primary outcome to examine the effect of imputing values using 1) last observation carried forward, and 2) simple mean imputation. We explored the potential clinical benefit of SIPScare by identifying the primary outcome symptoms with low reported burden (not all/slightly) at baseline and replaced with symptoms with high reported burden (moderate and above) and amenable to improvement from the intervention.

Economic evaluation

Informal and formal services received were measured using the Client Service Receipt Inventory (CSRI)\textsuperscript{44} reported at baseline for the 12-weeks pre-baseline and 12-weeks post-randomisation. Reporting was by a family caregiver when available, or the patient. We also extracted data on service use from GP records to reduce reporting burden for participants.
We calculated service costs by combining the Client Service Receipt Inventory\textsuperscript{45,46} unit costs from usual sources such as UK 2013-2014 unit costs\textsuperscript{47}. Services included acute care and community care (including the palliative care team, community healthcare and primary care, and social care), equipment and informal care. Costs of care were described by randomisation and category (acute, community, informal) at baseline and 12 weeks.

Economic evaluation in palliative care trials is an emergent area of research\textsuperscript{48}. To examine cost-effectiveness we explored the Client Service Receipt Inventory cost data in two regression models using:

1) the EQ-5D\textsuperscript{49} as a generic quality of life measure typically used for cost-effectiveness analysis. We used the EQ-5D-5L Crosswalk Index value to derive the EQ-5D index score\textsuperscript{50}, following the NICE guidance\textsuperscript{51}. The EQ-5D index score was derived from five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) with range from 0 (death) to 1 (full health).

2) the trial primary outcome of the five key symptoms measured using IPOS (total mean score for the five key symptoms of pain, breathlessness, patient anxiety, drowsiness and constipation). Total score ranges from 0 to 20. Negative IPOS score indicates decrease in the mean symptom score and distress.

The level of missing for the economic and respective outcome data were less than 3-5%, and we used the complete cases only for analysis. As cost data are usually skewed, we used generalized linear model approach. Bootstrapping with 1,000 replications was used to understand the uncertainty. In each replication we controlled for baseline information for costs and outcomes and plotted the replications to inform the cost-effectiveness plane. Cost-effectiveness planes represent visually the differences in costs between baseline and follow-up and between treatment and control arms. Sensitivity analysis was undertaken with three different costs, including: Cost 1, cost of the health and social care service use; Cost II, cost of the health and social care service use and the cost of equipment (e.g. walking stick); and
Cost III, cost of the health and social care service use, cost of equipment and cost of informal care provided by family/friends. All data were analysed using Stata SE15.

**Nested qualitative study**

The nested qualitative study involved individual interviews with patients and caregivers and focus groups with health care professionals involved in the intervention delivery. We report here the patient and caregiver interviews. The focus groups are reported in a separate publication on the process to deliver the intervention of integrated palliative care.

Patients who received the intervention with capacity to undertake an individual interview were invited to participate, and their caregivers when available. The qualitative interviews explored patients’ and caregivers’ perceptions of the intervention to identify and strengthen key components to inform wider implementation if warranted. The interviews explored linkages between perceptions of benefit with intervention mechanisms to deliver change, and potential adverse events. The topic guide was reviewed by the Independent Project Advisory Group comprising eight public members who focused on issues of delivery, such as use of accessible sensitive language. Supplementary file part B details the guide. This was informed by the aims and objectives of the trial and refined drawing on the underpinning development studies, research involving older people and specifically on end of life care. The guide explored experiences of receiving care from the palliative care team, such as management of symptoms; timing of the referral; communication across and within services; and future involvement of the palliative care team.

The interviews were undertaken by an experienced qualitative researcher (C.J.E.) in participants’ usual residence, like at home. Pictograms of the respective palliative care team members, community nurses and research nurses were used to differentiate between the practitioners involved in the study and to prompt recall about the palliative care team’s involvement. The interviews were digitally recorded and transcribed and imported into NVivo version 8. The data were analysed thematically using the Coffey and Atkinson iterative approach. Detailed coding of transcripts was undertaken by two researchers (C.J.E. and
followed by identifying themes and underpinning categories. Matrices were then
developed to display and analyse underpinning categories to explore patterns and
relationships. Emergent themes were discussed and reviewed with the Trial Steering
Group and Independent Project Advisory Group. We triangulated data between patient
and/or caregiver perceptions of the intervention and quantitative clinical outcomes to
understand benefit and linkages with intervention component(s) and opportunities to
strengthen.

Ethical approval: The study was approved by the London- Queen Square NHS Research
Ethics Committee (REC reference 13/LO/1304).

Results
Participant flow and recruitment
179 patients were assessed for eligibility. Overall, 43.5% (n=50) enrolled in the trial assigned
to the two arms (intervention n=24; control n=26), and available caregivers (intervention
n=10; control n=16). Figure 1 details the CONSORT flow of participants through enrolment,
allocation, follow-up, and analysis. Enrolment stopped at 50 patients with attrition and loss
to follow-up low (6%, n=3) and at random. The low attrition allowed the minimum sample
size to be exceeded in both arms. Patient recruitment commenced 17/09/2014, ended
16/09/2015, with final 12-week data collection 12/11/2015 and 6-month survival 16/03/2016.
The proportion of eligible patients approached to randomization varied by GP practice (range
30.2% to 75.0%) (Supplementary Table C4). Of the 65 (51.2%) eligible patients who
declined, 86% gave reason for decline (Supplementary Table C2). No significant
differences were detected between participants and non-participants (Supplementary Table
C3).

Baseline demographics and clinical characteristics
Baseline data for the patient by allocated arm are presented in table 2, and caregivers (see
supplementary Table C5). The patients’ mean age was control 86.0 years (SD 5.7) and
intervention 85.3 years (SD 5.4) and with similar proportions of men and women. All were
White British. Two patients aged 72 and 74 years were included as considered biologically older with compromised function and symptom burden from chronic conditions. Symptom distress (moderate or above) was common for the IPOS-5 key symptoms (sum score, control mean 6.1 SD 2.8; intervention mean 6.5 SD 3.6), and other psychosocial symptoms or concerns (control mean 9.7 SD 4.53; intervention mean 9.3 SD 3.39) (see supplementary Figure CI). Circulatory diseases (control 84.6%; intervention 79.2%) and respiratory diseases (control 34.6%; intervention 20.8%) were prominent conditions reported as a main diagnosis or comorbidity. All patients had multimorbidity (control mean 3.5 SD 1.5; intervention mean 3.6 SD 2.14) and frailty (control 80.8%; intervention 91.2%).

Polypharmacy was common (prescribed medication control mean 8.4 SD 4.16; intervention mean 9.3 SD 2.45). Carer burden was indicated as high in the intervention (mean 14.0, SD 6.5) and control (mean 11.6, SD 8.7).
Figure 1: Consort flow diagram of recruitment

Assessed for eligibility (n=179)

Excluded (n=129)
- Ineligible (n=35) e.g. malignancy/receiving SPC (n=9)
- Declined to participate (n=65) e.g. too unwell (n=8), not interested (n=13)
- Hospitalised or died prior to consent (n=12)
- Unable to contact (n=17)

Enrolment

Randomized (n=50 patients, 8 lacked capacity and 26 carers)

Control arm (n=26 patients, n=16 carers)
Lost to follow-up (n=2 patients)
1 deceased
1 cancer new diagnosis
Follow-up and analysed (n=24 patients)

Intervention arm (n=24 patients, n=10 carers)
Lost to follow-up (n=1 patient)
(consultee hospitalised and patient unwell)
Follow-up and analysed (n=23 patients)
Qualitative interviews with patients (n=19) and carers (n=9)

Allocation

Follow-up T1

Follow-up and analysed T2
Table 2. Baseline characteristics of the participating patients

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=26</td>
<td>N=24</td>
</tr>
<tr>
<td>Age (years)</td>
<td>Mean (SD)</td>
<td>86.0 (5.7)</td>
</tr>
<tr>
<td></td>
<td>Median (min, max)</td>
<td>86 (72,98)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>14 (53.9%)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>12 (46.2%)</td>
</tr>
<tr>
<td>Education (age)</td>
<td>Ended ≤ 15 years</td>
<td>14 (53.9%)</td>
</tr>
<tr>
<td></td>
<td>Over ≥ 16 years</td>
<td>11 (42.3%)</td>
</tr>
<tr>
<td></td>
<td>Don't know</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>1 (3.9%)</td>
</tr>
<tr>
<td>Area</td>
<td>Rural</td>
<td>14 (53.8%)</td>
</tr>
<tr>
<td></td>
<td>City</td>
<td>12 (46.2%)</td>
</tr>
<tr>
<td>Usual place of care</td>
<td>Home</td>
<td>24 (92.3%)</td>
</tr>
<tr>
<td></td>
<td>Care Home</td>
<td>1 (3.9%)</td>
</tr>
<tr>
<td></td>
<td>Supported housing</td>
<td>1 (3.9%)</td>
</tr>
<tr>
<td>Perception of household's present income</td>
<td>Lives comfortably</td>
<td>17 (65.4%)</td>
</tr>
<tr>
<td></td>
<td>Coping</td>
<td>6 (23.1%)</td>
</tr>
<tr>
<td></td>
<td>Difficult</td>
<td>2 (7.7%)</td>
</tr>
<tr>
<td></td>
<td>Don't know</td>
<td>1 (3.9%)</td>
</tr>
<tr>
<td>Living Status</td>
<td>Alone</td>
<td>9 (34.6%)</td>
</tr>
<tr>
<td></td>
<td>Not alone (e.g.)</td>
<td>17 (65.4%)</td>
</tr>
<tr>
<td>Marital Status</td>
<td>Widowed/single</td>
<td>10 (38.5%)</td>
</tr>
<tr>
<td></td>
<td>Married/civil partner</td>
<td>16 (61.5%)</td>
</tr>
<tr>
<td>An identified primary caregiver</td>
<td>Yes</td>
<td>21 (80.8%)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>5 (19.2%)</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Primary diagnosis (at screening)</td>
<td>Circulatory disease</td>
<td>15 (57.0%)</td>
</tr>
<tr>
<td></td>
<td>Respiratory disease</td>
<td>6 (23.1%)</td>
</tr>
<tr>
<td></td>
<td>Dementia</td>
<td>2 (7.7%)</td>
</tr>
<tr>
<td></td>
<td>Endocrine diseases</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Neurological disease</td>
<td>2 (7.7%)</td>
</tr>
<tr>
<td></td>
<td>Genitourinary</td>
<td>1 (3.9%)</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>Circulatory diagnosis</td>
<td>22 (84.6%)</td>
</tr>
<tr>
<td></td>
<td>Respiratory</td>
<td>9 (34.6%)</td>
</tr>
<tr>
<td></td>
<td>Circularity &amp; respiratory</td>
<td>7 (26.9%)</td>
</tr>
<tr>
<td>Number of conditions</td>
<td>Mean (SD)</td>
<td>3.5 (1.50)</td>
</tr>
<tr>
<td></td>
<td>Median (min, max)</td>
<td>3 (1,7)</td>
</tr>
<tr>
<td>Number of prescribed drugs</td>
<td>Mean (SD)</td>
<td>8.4 (4.16)</td>
</tr>
<tr>
<td></td>
<td>Median (min, max)</td>
<td>9 (1,18)</td>
</tr>
<tr>
<td>Clinical Frailty Scale</td>
<td>Mean (SD)</td>
<td>5.7 (0.84)</td>
</tr>
<tr>
<td></td>
<td>Median (min, max)</td>
<td>6 (4,7)</td>
</tr>
<tr>
<td>Fried’s frailty scale</td>
<td>Frail</td>
<td>21 (80.8%)</td>
</tr>
<tr>
<td></td>
<td>Pre-frail</td>
<td>3 (11.5%)</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>2 (7.7%)</td>
</tr>
</tbody>
</table>
Primary outcome of five key symptoms

The complete case analysis (n=48) showed a reduction in symptom distress on the 5 key symptoms as the primary outcome with medium effect size (0.071) and difference between the control and intervention mean (-1.20 [95% CI -2.37 to -0.027]). Table 3 details the primary outcome complete case and imputation analyses at the primary endpoint (12-weeks) adjusting for baseline. The imputation analysis 1 showed consistent medium effect (effect size 0.087). Sensitivity analysis using secondary method of imputation showed a lower effect size (0.058) (see Supplementary Table C6 Sensitivity analysis).
Table 3. Primary outcome five key symptoms and secondary outcomes measured baseline to 12-weeks, and primary outcome measured at 6 weeks, by trial arm

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Control mean change (SD)</th>
<th>Intervention mean change (SD)</th>
<th>Difference in change intervention - control (95% CI), adjusting for baseline</th>
<th>P value</th>
<th>Effect size (omega squared)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcome:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Five key symptoms (IPOS-5) at 12 weeks (main endpoint)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete case</td>
<td>45</td>
<td>0.36 (2.11)</td>
<td>-0.96 (1.94)</td>
<td>-1.20 (-2.37 to -0.027)</td>
<td>0.045</td>
<td>0.071</td>
</tr>
<tr>
<td>Imputation 1</td>
<td>50</td>
<td>0.54 (2.16)</td>
<td>-0.88 (1.94)</td>
<td>-1.32 (-2.45 to -0.19)</td>
<td>0.023</td>
<td>0.087</td>
</tr>
<tr>
<td><strong>Secondary outcomes:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Five key symptoms (IPOS-5) at 6 weeks (secondary endpoint)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete case</td>
<td>48</td>
<td>1.54 (2.72)</td>
<td>-0.75 (1.96)</td>
<td>-2.20 (-3.51 to -0.89)</td>
<td>0.002</td>
<td>0.18</td>
</tr>
<tr>
<td>Imputation 1</td>
<td>50</td>
<td>1.27 (2.78)</td>
<td>-0.75 (1.96)</td>
<td>-1.91 (-3.24 to -0.58)</td>
<td>0.006</td>
<td>0.13</td>
</tr>
<tr>
<td>Other physical symptoms (IPOS) at 12 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete case</td>
<td>47</td>
<td>0.83 (2.53)</td>
<td>-0.30 (2.38)</td>
<td>-1.00 (-2.32 to 0.33)</td>
<td>0.136</td>
<td>0.028</td>
</tr>
<tr>
<td>Imputation 1</td>
<td>50</td>
<td>0.77 (2.67)</td>
<td>-0.25 (2.35)</td>
<td>-1.00 (-2.32 to 0.33)</td>
<td>0.137</td>
<td>0.026</td>
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<tr>
<td>Other psychosocial concerns (IPOS) at 12 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete case</td>
<td>40</td>
<td>-0.30 (5.13)</td>
<td>-1.43 (3.49)</td>
<td>-1.63 (-4.15 to 0.89)</td>
<td>0.25</td>
<td>0.01</td>
</tr>
<tr>
<td>Imputation 1</td>
<td>43</td>
<td>-0.045 (5.03)</td>
<td>-1.43 (3.49)</td>
<td>-1.63 (-4.15 to 0.89)</td>
<td>0.20</td>
<td>0.017</td>
</tr>
<tr>
<td>Quality of life - EQ5D-5L Index at 12 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete case</td>
<td>45</td>
<td>-0.052 (0.22)</td>
<td>-0.019 (0.16)</td>
<td>-0.024 (-0.091 to 0.14)</td>
<td>0.671</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Imputation 1</td>
<td>48</td>
<td>-0.048 (0.21)</td>
<td>-0.018 (0.15)</td>
<td>-0.024 (-0.08 to 0.13)</td>
<td>0.66</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Carer burden – Zarit- 12 items at 12 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete case</td>
<td>22</td>
<td>2.23 (6.30)</td>
<td>3.56 (5.68)</td>
<td>-1.80 (-2.98 to 6.57)</td>
<td>0.44</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Imputation 1</td>
<td>25</td>
<td>2.47 (6.10)</td>
<td>3.6 (5.36)</td>
<td>-1.83 (-2.83 to 6.49)</td>
<td>0.42</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

*Omega squared effect size of $<0.01$ represents a small effect size; $>0.01$ and $<0.06$ medium effect size and $>0.14$ a large effect size $^{43,59}$. Imputation 1 method used last observation carried forward.

IPOS-5 includes pain, breathlessness, constipation, drowsiness and patient anxiety. Other physical symptoms include weakness, nausea, vomiting, poor appetite, sore or dry mouth, and mobility. Other psychosocial concerns include depression, feeling at peace, being able to share feelings with family and friends, family anxiety, information received, and practical matters addressed.
Secondary outcomes

The pre-specified five key symptoms complete case analysis at 6-weeks showed a higher effect size (0.18) than at 12-weeks, with effect size maintained in imputation 1 (0.13) and imputation 2 (0.15). No other significant differences were detected for the secondary outcomes at 12-weeks (see table 3).

Costs and cost-effectiveness

Costs at baseline were slightly higher in the control (mean £8732, SD £6823) compared with the intervention (mean £7491, SD £8247). The main difference was higher informal care costs in the control (mean £5564, SD £5679) compared with the intervention (mean £3467, SD £5763). At the 12-week follow-up, total costs were similar between the two arms (control mean £6334, SD £6392 versus intervention mean £6306, SD £6099), with informal care costs remaining higher in the control (mean £3317, SD £5290 versus intervention mean £2658, SD £5190). Supplementary Table C7 reports by trial arm the baseline and 12-week mean (SD) total costs including equipment, health and social care and informal care.

Figure 2 illustrates the cost-effectiveness planes for the two models using outcome of EQ-5D (left panel) or the primary outcome of the five key symptoms (right panel) and service use costs. Both models indicated cost-effectiveness. ‘A’, on the top left panel, (cost I, health and social care costs) shows quality of life increased from baseline for 12 weeks with the intervention compared, and cost of care decreased. Similarly, ‘B’ on the top right panel, shows reduction in symptom distress on the five key symptoms (negative values) in the intervention compared with control for 12 weeks with decreased costs (cost I). Sensitivity analysis with addition of equipment (cost II, Fig.2 second row) and informal care (cost III, Fig. 2 third row), showed spread of dots on the planes. This indicates uncertainty around the cost-effectiveness of SIPSCare with addition of equipment and informal care costs.
Figure 2: Cost-effectiveness planes of short-term integrated palliative and supportive care (SIPS)

Note: Bootstrapping with 1000 replications was conducted using regression analysis, controlling for baseline information. **Costs include:** Cost I health and social care service use; Cost II health and social care service use and equipment (e.g. walking stick); and Cost III health and social care service use, equipment and informal care provided by family/friends. Each dot represents the difference in EQ-5D index score or primary outcome of five key symptoms (IPOS-5) plotted against the difference in the costs between the intervention and control arms. A on the top left panel, indicates the SIPScare intervention was cost-effective: SIPSCare improved quality of life measured with EQ-5D index score compared to usual care and the cost of care was less than usual care. B on the top right panel, also shows that SIPScare was cost-effective: symptom distress measured with the primary outcome of five key symptoms (IPOS-5) improved and cost of care was less than the usual care. High IPOS-5 score indicates rising symptom distress.

**Intervention fidelity**

Overall, the intervention was delivered to protocol (Supplementary Table C6 intervention components and frequency). Patients received the intervention for a mean average of 58.4
days (SD 27.94, range 6-84) over 12-weeks (84 days). At the end of 12-weeks, most patients were temporarily discharged (n=18), meaning the person could re-access the respective palliative care team if symptoms or concerns developed. One patient remained on the active palliative care caseload after 12-weeks. Face-to-face contacts in the home mean 3.5 (SD 4.20, range 1-19), but this varied by geographical area (rural mean 9.6, SD 5.8 versus city 2.1, SD 2.8, p<0.0063). The total mean contacts, including face to face and telephone, were non-significantly higher in the rural area (rural mean 9.6, SD 5.8 versus city mean 6.7, SD 6.1, p<0.097). The palliative care team showed a high level of interprofessional working with practitioner contact mean 9.30 (SD 7.99, range 2-40) over 12-weeks. Multidisciplinary review by the palliative care team of patient assessment and plan of care was reported for most patients (n=20, 83.3%), but advance care planning was less common (n=13, 54.2%). One patient did not receive the allocated SIPS care after an administrative error in the referral to the palliative care team.

Adverse events
No known study-related adverse events were identified. Survival at six months was similar (Wilcoxon test p=0.08) with deaths in the control (n=3) and intervention (n=2) arms.

Linkages between perceptions of benefit with intervention mechanisms
Qualitative interviews were undertaken with patients (n=19) and caregivers (n=9) (treatment arm only) (supplementary Table C8. Participant characteristics). The patients’ and caregivers’ narratives about living with frailty and chronic conditions echoed a sense of living in transition between ‘what is’ and ‘what next’. It seemed a place of both waiting - of living each day, and adapting to changes in wellbeing and function, and unpredictable future with experiences of rapid decline from a stressor like a fall.

Well I suppose that's roughly what I have to do, I have appointment come for some medical things somewhere and I just go with it that day, and I have to forget about that one [other condition], because something else is taking over.... but um if
someone asked me how I was, I have to ask how long they have to spare to listen (Patient: P2-01108-F)

A thread of ‘no quick fixes’ wove through the narratives. This iterated the frequent longevity of the conditions and symptoms lived with and accommodating multiple conditions triggering uncertainty as to the cause of a decline and how best to manage. Important benefits for patients and caregivers centred around ‘Little things make a big difference’ with optimal management of unstable symptoms to reduce distress (e.g. breathlessness, pain). Coupled with these biomedical outcomes was a theme of ‘Care beyond medicines’. This concerned reducing anxiety and distress by supporting individuals’ psychosocial work to accommodate living with an often uncertain future of decline and changing and increasing needs to maintain their level of independence, and ability to continue to pursue goals important to them.

[the palliative care nurse] she’s due again tomorrow, she’s been super. … Yeah, you know that way you treat yourself um I have great difficulty when I um, not always, when I am on these water pills because I swell and it’s looking after the tick tock. But when I have used the toilet, I have great difficulty standing, breathing. She [the palliative care nurse] says ‘go lean over there, put your hands out and breathe’.…. It is bad at times [breathlessness]. So that is, to give you an example of where she [the palliative care nurse] comes from [in helping me] (Patient: P2-01201-M).

To deliver change and benefit two key intervention mechanisms were conceptualised as themes of ‘Asked about everything’ and a ‘Safety net’. ‘Asked about everything’ emphasised the importance of individual comprehensive assessment to understand priorities for the person and the family and agree the shared goals of care, conducted by a skilled practitioner (usually a nurse specialist in palliative care). A skilled comprehensive assessment enabled discussion about concerns and priorities, and to align care and treatment with the person’s goals and avoid ‘unwanted’ or previously tried approaches.
Well as I said she was very pleasant [the palliative care nurse], so made me feel quite contented you know…. The way she put it all everything, it gave you confidence to know you can get them and they’ll do something (Patient: P2-01110-M).

The theme of a ‘A safety net’ echoed requirement for ongoing access to services. Essential mechanisms to reduce distress were care and treatments that maintained symptoms and concerns as stable to enable the person to live each day as well as possible. However, at points of decline this required a timely skilled response to manage symptoms and concerns when unstable, described as ‘troublesome’ and compromising day to day life.

To me I feel that they’re in the background [the palliative care team] it gives me a safety net I feel that they were so caring and lovely that I could phone them if I felt I was worried or concerned more than I could his doctor, cause I don’t have a lot of faith in his doctor [Caregiver: C2-02303-F].

Of particular importance for patients and caregivers was the availability of ‘Someone to call upon who knows me, listens to what’s important to me and my family, and understands my concerns and how to manage in ways that works with what’s important to me’. Maintaining function and independence required supporting adaptation and problem solving (e.g. continence, mobility, falls prevention, eating and drinking), and responding to change. Crucial to this was care coordinated around shared goals of care and pursuit with access to a multidisciplinary team, notably occupational therapists to support function (e.g. handrails), and physiotherapists and complimentary therapies (e.g. acupuncture) to provide non-pharmacological interventions to manage pain, breathlessness and poor sleeping.

They [the physio, OT, paid carers, benefit advisor, nurses] all want the same thing… what I want…. to keep me on my feet [Patient: P2-02409-F]

However, engagement in planning future care for the end of life was marked by uncertainty for the person in ‘not knowing what’s going to take hold’ and fear of increasing disability and
loss of capacity. The intervention seemed the start of an important conversation about the future that required revisiting with the person across the illness trajectory.

Discussion

This is the first randomised controlled trial of specialist community palliative care integrated with district and community nursing and general practice for older people with chronic noncancer conditions and frailty living at home or in a care home. The short-term integrated palliative care and supportive care intervention (SIPScare) showed a moderate effect size on the primary outcome of five key symptoms at 12-weeks as the main timepoint compared with usual care. The effect size was even larger at the earlier secondary timepoint of 6-weeks. The qualitative data supported benefit for patients with detailed skilled comprehensive assessment and review by a nurse specialist within a multidisciplinary team enabling optimal management of often enduring symptoms and concerns and formed a ‘safety net’ to coordinate care at points of escalating ill-health. The health economic analysis demonstrated cost-effectiveness on both the primary outcome of the five key symptoms at lower cost compared with usual care, and on the quality of life outcome (EQ-5D) typically used in economic evaluation. The intervention recorded no harms and a similar level of survival between the two arms.

A community-based short-term integrated palliative care model for older people with chronic noncancer conditions is cost-effective and appropriate. The model relies primarily on reconfiguring existing health services with additional shared support for patients from specialist palliative care at points of escalating ill-health. The evidence for short-term integrated models is growing. A definitive trial for people with neurological conditions demonstrated benefit in the intervention arm\(^6\) and longitudinal qualitative studies with patients with frailty\(^6\) and chronic obstructive pulmonary disease\(^6\) showed requirements to integrate palliative care across the illness trajectory with flexible intermittent delivery according to needs and main goal of care. However, greatest improvement in symptom distress from SIPScare occurred at 6-weeks and showed a large effect size. This likely
reflects the time the specialist palliative care teams were directly involved in the patients’ care (mean 58.4 days). At 12-weeks, the effect size reduced to moderate compared with usual care.

To sustain benefit from the short-term intervention, a key component is to support continuity of care through integrated care between the palliative care team and the community nurses and GPs. The World Health Organisation, *Integrated Care for Older People* programme, identify effective integrated care as involving multiple levels including clinical-level (micro), service/ organisational-level (meso) and system-level e.g. policy (macro)\(^{22,63}\). The SIPScare model mainly operated at the clinical-level delivering comprehensive assessment, case management and care coordination by a specialist nurse in palliative care within the multidisciplinary team and with other healthcare services (mean 9.3 [SD 7.9] contacts over 12-weeks). Processes of comprehensive assessment, case management, care coordination and multidisciplinary team working are consistently identified in systematic reviews as effective components of integrated care\(^{20,22,63}\). The qualitative interviews echoed the value of these processes, particularly delivery by a skilled nurse with expertise, time, and multidisciplinary resource to understand individual priorities and agree and implement a plan of care. However, activities at the organisational level to support continuity of care were limited. The services had no system to share health records. Communication relied on telephone calls, emails, letters, and multidisciplinary team meetings. Systems to facilitate information exchange between services, like eHealth to share electronic health records, are an essential element for integrated care for older people\(^{64}\) and to facilitate effective working between specialists and generalists in palliative care\(^{19}\).

The trial eligibility criteria enabled identification of older people likely to benefit from palliative care. The provision of palliative care for older people with chronic noncancer conditions is advocated as based on needs and the intention that the main goal of care is quality of life\(^{19,20}\). The trial demonstrates that practitioners (e.g. GPs, nurses) can identify older people severely affected by noncancer conditions with two or more symptoms or concerns from
their knowledge of the person, GP health records and identify frailty using the Clinical Frailty Scale\textsuperscript{31}. This needs-based approach moves away from temporal indicators such as prognosis of the last year of life. Temporal indicators have limited use for older people with multimorbidity and frailty when their illness trajectory and nearness of end of life is typically unpredictable and uncertain with inherent susceptibility to sudden disproportionate decline and risk of death following a stressor like an infection\textsuperscript{5,6}.

To scaleup the integrated palliative care model would require identification of patients with palliative care needs at the meso level, such as a General Practice population\textsuperscript{64}. Using validated population screening instruments for frailty in primary care could identify individuals, such as with moderate/severe frailty and increased risk of unplanned hospital attendance and end of life\textsuperscript{5}. The Electronic Frailty Index is such a validated instrument for primary care to screen older people for frailty using GP electronic health records implemented nationally in England\textsuperscript{65,66}. The risk assessment derived from the index could identify older people for palliative care assessment and intervention if indicated. However, the index is validated at the population level for case identification\textsuperscript{65}, and there is no robust evidence to support frailty identification alone as a way to improve individual clinical care and outcomes\textsuperscript{5}. An individual assessment is required to identify individual needs and priorities.

Using a person-centred outcome measure in routine care is a way to screen for palliative care needs to identify patients’ and caregivers’ symptoms and concerns\textsuperscript{67}, like using the Integrated Palliative Care outcome Scale (IPOS)\textsuperscript{37}, or version for older people with dementia and/or multimorbidity (IPOS-Dem)\textsuperscript{68}.

The trial demonstrated that community-based specialist palliative care integrated with community nursing and primary care was clinically effective at reducing symptom distress for older people with chronic noncancer conditions and frailty. Key was the interface for integration between specialists in palliative care with the community nurses and GPs as the main generalist providers of palliative care. This interface intended to ensure continuity of care by the main care provider. This was vital given the short-term and intermittent
involvement of the palliative care team to advise at points of escalating ill-health to manage, for example difficult symptoms like breathlessness. The pre-trial development study consulting with practitioners, older people and caregivers supported identification and agreement of processes to optimise integration between the services\textsuperscript{52}. The international report on \textit{Building Integrated Palliative Care Programs and Services} identifies elements to jointly agree for effective working between specialists and generalists in palliative care\textsuperscript{12,19}. The trial incorporated many of these aspects with criteria for intervention with trial eligibility criteria and intervention components manualised to detail activities, like comprehensive palliative care assessment and multidisciplinary review, communication with community nurses and GPs, and short-term involvement of the palliative care team. However, this built on the development study and the existing practice of the palliative care teams and relationships with the generalist providers. Specialist palliative care have a remit to work with generalist healthcare providers by both directly providing care to patients and their families and indirectly through education and support to generalists\textsuperscript{69}. It is uncertain which approach, or combination, best constitutes integrated care, such as a combination of direct and indirect provision using shared guidance on care pathways\textsuperscript{70}. To scale up, SIPScare needs to incorporate knowledge of the local context and interface between specialists and generalists in palliative care, and jointly identify and agree key mechanisms of shared-decision making, coordination of care and integrated care, like joint review of patients and shared policies.

Our study has limitations. Although the sample size was powered on the primary outcome and minimum exceeded in both arms with low level of attrition (<5%), trial recruitment was confined to four GP centres in a region of England with a mainly White British population. This impeded recruitment of Black and Minority Ethnic groups and the generalisability of the findings for more diverse populations. Although patients and carers described psychosocial benefits of receiving the intervention in the interviews, quantitative measurement of these items as secondary outcomes using the IPOS were not detected at a level of statistical significance. This may be due to a lower completion rate on these items, reducing the power
to detect a difference. The study recruited caregivers when available. This limited recruitment and examination of potential benefit for caregivers. Carer burden at baseline was at a similar level reported for caregivers of people with Multiple Sclerosis\textsuperscript{23}, dementia and cancer\textsuperscript{40}. However, the study failed to detect effectiveness on carer burden as a secondary outcome (table 3), in contrast to the earlier trial of short-term integrated palliative care in Multiple Sclerosis\textsuperscript{23}. Examination of wider implementation needs to identify optimisation for caregivers. The study recruited only two people from care homes. This reflects that only 11 residents from care homes were identified and approached, and residents’ high rate of decline (82% versus 27% people at home). To use SIPScare in care homes needs to incorporate understanding on the interface between specialists in palliative care and generalist health and social care providers. District and community nurses are the main providers of end of life care in the community\textsuperscript{71}. Data extraction on palliative care activities included the health records for the palliative care teams and the GP health records, but not the community nursing health records. This limited understanding on activities of usual generalist palliative care delivered by the community nurses.

Conclusions
The SIPScare model is unique to establish the delivery of specialist palliative care for older people with multimorbidity and frailty early in the disease trajectory, in a planned way based on individual palliative care needs and integrated with healthcare services for the population. Short-term integrated palliative and supportive care is effective and cost-effective to reduce symptoms and concerns for older people with multimorbidity and frailty living at home. The model demonstrates a clinically effective way to deliver community-based integrated specialist palliative care with district and community nurses and GPs. Further trials are warranted to include ethnically diverse older people with multimorbidity and frailty and to examine its implementation more widely for people at home and in care homes.

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