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Optimising palliative care for older people in community settings

Submission date
16/01/2014

Recruitment status
No longer recruiting

Registration date
16/01/2014

Overall study status
Completed

Last Edited
21/06/2021

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
People are living longer and more often die following a period of increasing illness and difficulties with their health. Palliative care is recommended for elderly people living with frailty and non-cancerous conditions to improve their quality of life and that of their carers, but how to achieve this is still uncertain. Palliative care is active holistic care that aims to relieve and avoid suffering for patients and their families, addressing physical, emotional, social and spiritual needs. Palliative care, unlike end of life or hospice care, is relevant at all stages of illness, including during curative treatment as well as at the end of life. This study aims to work with an NHS Community Trust to create and test a new service for frail elderly people with non-cancerous conditions living at home or in a care home. The new service is delivered by close working between specialists in palliative care such as Macmillan Nurses, and services provided by community workers such as community nurses and general practitioners (GPs).

Who can participate?
People aged 75 years or older and their carers can participate in this study.

What does the study involve?
The study has two parts:
Part one uses information gathered from a postal survey sent to 882 bereaved relatives or carers of people aged over 75 years to find out how health services could be better provided to support older people living with frailty and when nearing the end of life. We then ask older people and carers, professionals providing health and social care, and members of voluntary groups about what people told us in the survey and the best ways to create the new service. This takes place in group discussions in January and February 2014.
Part two looks at what is the best way to provide the proposed service and how the new service could benefit patients and carers. We ask 52 older people living with frailty and increasing health difficulties, and their carers, to receive either the new palliative care service or usual care provided by people like their GP. The new service is delivered by two palliative care teams working with four community nursing teams in a single Community NHS Trust. The new service involves up to three visits in the community by the specialist palliative care teams to provide an extra layer of support for frail older people and their carers at times of deterioration.
Participants who receive usual care in the study are offered the new service at the studys

completion. We will see how well the new service compares with usual care in improving symptom burden, carers support and any differences in the services used and how much they cost. This will tell us if this new service could benefit patients and carers.

What are the possible benefits and risks of participating?
This study will help to inform how we should continue our work to see if this is the best way to deliver palliative care to older people in the community. There are minimal risks to participating as the study is extending an existing service to a new population group.

Where is the study run from?
The study is run from Sussex Community NHS Foundation Trust and takes place in four GP practices (UK)

When is the study starting and how long is it expected to run for?
The study started in January 2014. Part 2 will run from May 2014 until May 2016.

Who is funding the study?
The National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Catherine Evans
catherine.evans@kcl.ac.uk
Tel: +44 (0)207 848 5579

Contact information

Type(s)
Scientific

Contact name
Dr Catherine Evans

ORCID ID
https://orcid.org/0000-0003-0034-7402

Contact details
Cicely Saunders Institute
Bessemer Road
Denmark Hill
London
United Kingdom
SE5 9PJ
+44 207 848 5579
catherine.evans@kcl.ac.uk

Additional identifiers

Protocol serial number
Phase 1b and 2: UKCRN ID - 15880; Phase 1a: UKCRN ID: 13275

Study information

Scientific Title
Optimising palliative care for older people in community settings: development and evaluation of a new short term integrated service (phases 1b and 2)

Acronym
OPTCare Elderly

Study objectives
Palliative care is advocated for frail older people with non-malignant conditions to improve assessment and treatment, but with little evidence of effectiveness. Short-term palliative care could be effective as it relies on existing services with additional support at times of actual or anticipated deterioration in wellbeing. This study intends to work with NHS staff in a community trust to develop a new short-term integrated palliative and supportive care (SIPS) service for frail older people living at home or in a care home and for their families. The new service will be evaluated in a community setting to test the impact on palliative symptoms, carer burden, formal and informal service use and to evaluate the cost.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Queen Square Research Ethics Committee, 17/10/2013, ref: 13/LO/1304

Study design
Randomised; Interventional and Observational; Design type: Treatment, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Generic Health Relevance and Cross Cutting Themes; Subtopic: Not Assigned, Generic Health Relevance (all Subtopics); Disease: All Diseases, Age and ageing

Interventions
Interventions as of 09/11/2016:
Participants are randomly allocated to intervention or control group following consent.

Intervention arm: This involves a service delivered by two palliative care teams working with four community nursing teams in a single Community NHS Trust. The new service involves up to three visits in the community by the specialist palliative care teams to provide an extra layer of support over a 12 week period.

Control arm: Participants receive their usual care provided by their GP or community nursing team. After 12 weeks, this group are offered the intervention however there is no research follow-up for this group beyond the 12 weeks from consent.

Both groups are given questionnaires to complete at baseline, 6 weeks and 12 weeks and the GP records are followed up for 6 months. The intervention group are also invited to take part in a qualitative interview after the 12 week study period.

Original interventions section:
SIPC: SIPC - short term integrated palliative. The SIPC intervention intends to provide an extra layer of support at points of actual or anticipated unstable/ deteriorating symptom presentation and wellbeing. The SIPC service is delivered by two community palliative care teams (CPCTs) through integrated professional working with community nursing teams (n=4) and general practices (n=4), and close working with geriatricians. The intervention involves referral to of the two CPCTs, comprehensive palliati; Follow Up Length: 3 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Phase I/II

Primary outcome(s)
5 key symptoms are measured using the integrated Palliative care Outcome Scale at baseline, 6 weeks and 12 weeks (primary end point).

Key secondary outcome(s))
1. Assistance with activities of daily living is measured using the Barthel Index at baseline and 12 weeks
2. Performance status is measured using the Australia Karnofsky Index at baseline and 12 weeks
3. Carer burden is measured using the Zarit carer burden at baseline and 12 weeks
4. Service use and cost is measured/calculated using the Client Service Receipt Inventory at baseline and 12 weeks
5. Survival is measured by reviewing GP medical records for mortality at 12 weks

Completion date
06/05/2016

Eligibility

Key inclusion criteria
1. Phase 1b: focus groups - Older adults living with frailty using one of the participating community groups or residing in the participating care home; or carers of older adults. Carers are either informal carers e.g. family member or a carer working as a volunteer for one of the participating charitable organisation supporting older people in community settings. Adults with capacity to give informed consent and communicate in English.
2. Stakeholder consultation participants comprise: service providers, commissioners and voluntary sector representatives from the study site. The purposive selection on the participants is based on:
The services providers are health or social care practitioners providing community based services

including: specialist palliative care, general practice, community nursing, end of life care facilitators, dementia services and social care.
3. The practitioners provide services in the locality of Sussex Community NHS Trust.
4. The commissioners are leads for end of life care services and are identified from the Care Commissioning Groups in the study site.
5. Voluntary sector representatives are local individuals representing local/national organisations supporting/advocating for older people.

Phase 2: Adults aged 75 years over residing in the study site at home or in a care home (with or without nursing) severely affected by non-malignant advanced illness and/ frailty with or without dementia and not using specialist palliative care. Severely affected encompasses one or more unresolved symptoms, psychosocial concerns, EoL issues, progressive illness, complex needs or Gold Standards Framework (GSF) prognostication index for frailty and dementia. Participants are registered with one of the four GP practices participating in the study. Participation will be offered to older people with or without carers. The inclusion criteria are broad as uncertainty surrounds when a frail older person may most benefit from palliative care. The findings from phases 1a and 1b will further develop and refine the inclusion criteria.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
50

Key exclusion criteria
Phase 2: Exclusion criteria
Older people with malignant disease receiving curative or palliative treatment .

Date of first enrolment
17/09/2014

Date of final enrolment
16/09/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sussex Community NHS Foundation Trust
Trust Headquarters
Brighton General Hospital
Elm Grove
Brighton
United Kingdom
BN2 3EW

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from catherine.evans@kcl.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2021	21/06/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version v1.7	11/11/2025	11/11/2025	No	Yes
Protocol file		19/11/2015	26/04/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes