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The impact of social action services on end of life experience

Submission date
20/05/2015

Recruitment status
No longer recruiting

Registration date
20/05/2015

Overall study status
Completed

Last Edited
14/06/2023

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
End of life care is support given to people who are considered likely to die within the next 12 months. The aim of end of life care is to improve the quality of life of the patient, and also to provide support to their family or carers. End of life care also includes palliative care given to patients with an incurable illness. There is a need to provide services which use the Social Action Model to support end of life care in community settings. The goal of the Social Action Model is to enable everybody to have access to community resources, and also to engage members of the community to help give back to society (e.g. by volunteering). Such services could work to reduce patient isolation, help meet emotional needs and maintain a sense of connectedness to the community. It is also important to robustly evaluate these models to see if they have a positive influence on the patient experience of end of life care. The UK Cabinet Office's Centre for Social Action proposed, and launched, The Social Action End of Life Support Fund which aims to support a range of social action initiatives, including befriending (e.g. companionship, emotional and peer support), practical support (e.g. house/garden work, walking pets, picking up prescriptions) and provision of information/navigation towards relevant services. The aim of this study is to see what impact access to projects associated with the The Social Action End of Life Support Fund has on the quality of life of people in the last year of life.

Who can participate?
Adults in the last year of life.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are given access to volunteer-provided Social Action services straight away following any service related administrative procedures. Those in group 2 (control group) are put on a 4 week waitlist before being given access to volunteer-provided Social Action services. The impact of having access to the Social Action services intervention on end of life experience (i.e. quality of life, loneliness, social support and carer burden) is measured using a predetermined set of outcome measurement tools in the form of an A4 self-reporting questionnaire booklet. Repeated assessments are carried out at weeks 4 and 8 for the intervention group, and at weeks

4, 8 and 12 for the control group. A selection of participating end of life care sites are selected for case study evaluation. These sites have interviews, observation and documentary analyses to understand the mechanisms underpinning any found impact on patient quality of life.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
1. Saint Michael's Hospice (UK)
2. Aquarius (UK)
3. Peace Hospice (UK)
4. St Joseph's Hospice (UK)
5. Hampshire Hospitals NHS Foundation Trust (UK)
6. Six Sue Ryder hospices across the UK

When is the study starting and how long is it expected to run for?
April 2015 to June 2016

Who is funding the study?
Cabinet Office (UK)

Who is the main contact?
Dr C Walshe

Contact information

Type(s)
Public

Contact name
Dr Catherine Walshe

Contact details
Lancaster University
International Observatory on End of Life Care
Furness Building
Lancaster
United Kingdom
LA1 4YW

Additional identifiers

Protocol serial number
18742

Study information

Scientific Title

End-of-Life Social Action Study (ELSA): a randomised wait-list controlled trial and embedded qualitative case study evaluation assessing the causal impact of social action services on end-of-life experience

Acronym
ELSA

Study objectives
Receiving care from a social action volunteer service plus usual care significantly improves patient quality of life in the last year of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - South Yorkshire, 12/03/2015, ref: 15/YH/0206.

Study design
Randomised interventional process of care study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Health services and delivery research

Interventions
1. Intervention group: patients are given access to volunteer-provided social action services at the end of life tailored to individual needs of patients e.g. befriending, social support straight away.
2. Control group: patients are put on a 4 week waitlist before being given access to the volunteer-provided social action services.

Intervention Type
Other

Primary outcome(s)
The World Health Organization Quality of Life (WHOQOL)-BREF questionnaire will be used at baseline, 4 weeks and 8 weeks in the intervention group. For the control group, the WHOQOL-BREF will be used at baseline, 4 weeks, 8 weeks and 12 weeks.

Key secondary outcome(s))
Taken at baseline, 4 weeks and 8 weeks in the intervention group. For the control group, the measures are taken at baseline, 4 weeks, 8 weeks and 12 weeks:
1. Loneliness is measured using the De John Greiveld 6-item Loneliness Scale, a short, well-used, reliable and valid measurement instrument for overall, emotional, and social loneliness, chosen for brevity and relevance of the items when mapped onto anticipated outcomes

2. Social Support is measured using the 8-item modified Medical Outcomes Study Social Support Survey (mMOS-SS), a short validated scale covering two domains (emotional and instrumental social support) designed to identify potentially modifiable social support deficits, chosen for brevity and relevance of the items when mapped onto anticipated outcomes
3. Carer Burden is measured using the Caregiver Burden Scale-End of Life Care (CBS-EOLC), a reliable and valid measurement tool designed to specifically assess family caregivers' burden within the palliative care context, chosen for brevity and relevance of the items when mapped onto anticipated outcomes
Social network (network size, number of confidante, number and percentage of relatives in network and number and type of main helpers) will also be measured as mediator/moderator (not outcome) using an adapted Hirsch matrix.
Socio-demographic data (age, gender, disease diagnosis, education, marital status, living status, spirituality and ethnicity) in the form of a questionnaire will be collected from both patients and informal carers at baseline.

Completion date
01/06/2016

Eligibility

Key inclusion criteria
Sites participating in this study will be selected as part of a government Cabinet Office funded initiative to support social action at the end of life in England. Twelve sites that provide these services will be shortlisted for interview. Selection considerations at shortlisting and interview will include the sites' match to the tender, their capacity to deliver the proposed service, and their ability and willingness to contribute to the evaluation of these services. All sites will be made aware at interview that they are providing their services in the context of this study design (wait list RCT and case study evaluation).

Patient inclusion criteria:
1. Those eligible to be referred to an end of life care service determined by the referring organisation/individual. They should be able to answer 'no' to the 'surprise question': 'would you be surprised if the patient dies within a year?'
2. Able to give informed consent
Carer inclusion criteria
1. Those identified by participating patients as people who provide lay or unpaid support. These may be family, friends or other informal carers
2. Able to give informed consent

Volunteer/staff inclusion criteria (for interview):
1. Those volunteering for a participating befriending service, and providing support to a trial participant (who was allocated to either trial arm) OR those working for a participating befriending service who are involved in the provision or management of these services
2. Able to give informed consent

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patient exclusion criteria:
1. Age <18
2. Those who only who only understand or speak a language in which our main outcome measure (the WHOQOL BREF) is unavailable. This is anticipated to be a very small number of potential participants as the WHOQOL BREF is available in a wide range of languages, including the main languages spoken in the participating sites
3. Those with an anticipated prognosis of <4 weeks

Carer exclusion criteria:
1. Age <18 years
2. Those who only who only understand or speak a language in which our carer outcome measure is unavailable

Date of first enrolment
08/06/2015

Date of final enrolment
08/01/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Saint Michael's Hospice
Crimple House
Hornbeam Park Avenue
Harrogate
United Kingdom
HG2 8QL

Study participating centre
Aquarius
236 Bristol Road
Birmingham
United Kingdom
B5 7SL

Study participating centre
Peace Hospice
Peace Drive
Watford
United Kingdom
WD17 3PH

Study participating centre
St. Joseph's Hospice
Mare Street
London
United Kingdom
E8 4SA

Study participating centre
Hampshire Hospitals NHS Foundation Trust
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Leckhampton Court Hospice
Church Road
Leckhampton
Cheltenham
United Kingdom
GL53 0QJ

Study participating centre
Sue Ryder Manorlands Hospice
Hebden Road
Oxenhope
United Kingdom
BD22 9HJ

Study participating centre

Sue Ryder Nettlebed and Dutchess of Kent Hospice
Joyce Grove
Nettlebed
Henley on Thames
United Kingdom
RG9 5DF

Study participating centre
St John's Hospice
St John's Road
Moggarhanger
United Kingdom
MK44 3RJ

Study participating centre
Thorpe Hall
Longthorpe
Peterborough
United Kingdom
PE3 6LW

Study participating centre
Sue Ryder Wheatfields Hospice
Grove Road
Leeds
United Kingdom
LS6 2AE

Sponsor information

Organisation
Lancaster University

ROR
https://ror.org/04f2nsd36

Funder(s)

Funder type

Government

Funder Name
Cabinet Office (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Patient level data are stored in the ELSA database developed by the study authors on a secure server maintained by Lancaster University. Catherine Walshe may be contacted to forward requests for data sharing which may be possible for some of the trial datasets, but consent was not given by participants to share some data.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/12/2016		Yes	No
Results article		29/03/2018	14/06/2023	Yes	No
Protocol article	protocol	13/07/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes