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INSPIRE study: INvestigating Social and PractIcal suppoRts at the End of life.

Submission date
17/11/2014

Recruitment status
No longer recruiting

Registration date
18/02/2015

Overall study status
Completed

Last Edited
30/05/2019

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Most people want to die at home. Formal services can help people with the needs they face at the end-of-life. However, most of the time, people living with an advanced life-limiting illness are at home, supported by a network of family and friends living within a community. Each of us has a network of personal support and depending on our circumstances, we can call on people to help us. Sometimes a person living at home, who is facing the end of life, may need help with things such as taking the dog for a walk, lighting the fire or doing some shopping. However, they may be worried that they might be a burden to others, or may have no-one in their immediate circle who can help. This study explores the relationship between a person's unmet instrumental activities of daily living (tasks needed for someone to live independently) and their quality of life at the end, together with their social network, to see how it can affect where a person dies, their use of health services and their overall well-being. It also considers how we can better organise those networks by means of a Good Neighbour Partnership, to help people living with life-limiting illness, potentially making a real difference to the person needing help and also those who provide it.

Who can participate?
Adults (aged over 18) living in the community with a life-limiting illness in Limerick. They must be considered to be in their last year of life and have unmet social and/or practical needs.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (control group) receive their usual care and services. They are given a diary to record any visits they make to doctors, health centres etc over an eight week period. Participants in this group meet with the researcher for approximately 30 minutes during week 4 and week 8 of their assignment to this group. They are given questionnaires to complete that ask about unmet social and psychological needs and psychosocial wellbeing. After eight weeks, participants are given an option to take advantage of the Good Neighbour Partnership. Those in group 2 (intervention group) are invited to take advantage of the Good Neighbour Partnership immediately. The Good Neighbour Partnership can help someone with advanced illness, and their family, to find the extra social and practical support that they may need from within their community. This happens by making links with those living close by who would like to offer help. A Compassionate Communities

Volunteer (CCV) meets with a person four times during the next eight weeks. The first visit takes approximately one hour and the CCV meets the person at home to identify their unmet social and practical needs and the type of support required. The CCV identifies with the person who, from within their local circle of community, the person would be happy for them to approach, to enable these needs to be met. A plan of action is agreed. A diary is given to the patient/family to record any visits they make to doctors, health centres etc during the eight week period. After the first meeting with the patient/family, the CCV makes contact with those Good Neighbours agreed in the action plan. Within seven days, the CCV visits the patient/family a second time to discuss the agreed plan. Four weeks after the initial visit the CCV visits again to determine if the system is working and if there are any further supports required. The researcher meets with the person. Eight weeks after the first visit the CCV makes a final visit and decide whether any further support is required. A final interview with the researcher is also conducted. During the meetings with the researcher, questionnaires are used to determine unmet social and psychological needs and psychosocial wellbeing.

What are the possible benefits and risks of participating?
There may be benefits to participants who take part in this study, particularly for those in the intervention group since they will be involved in testing a model that may reduce unmet social and practical needs immediately. During meetings with the researcher, participants will talk about their needs and support. This may result in people expressing emotions during the interviews. This is natural and the researcher will provide support as appropriate, In the event that a person requires additional support, the researcher will, with the participants permission, contact either the public health nurse or a member of Milford Care Centre's Hospice at Home team. All Compassionate Communities Volunteers have been recruited via interview, reference checked, Garda vetted, have attended training and are supervised to conduct their duties.

Where is the study run from?
1. Department of Psychology, Maynooth University (Ireland)
2. Milford Care Centre, Limerick (Ireland)

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

Who is funding the study?
1. All Ireland Institute of Hospice and Palliative Care (Ireland)
2. Irish Cancer Society Research Fellowship (Ireland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Exploratory delayed intervention randomised controlled trial to investigate the feasibility, acceptability and potential effectiveness of a volunteer-led model of social and practical support with community dwelling adults living with advanced life-limiting illness in Limerick, Ireland.

Acronym
INSPIRE

Study objectives
It is hypothesised that the intervention, in comparison to a control of usual care will: (1) reduce unmet need for instrumental activities of daily living; (2) reduce unplanned health service utilisation; (3) improve overall quality of life (including social connectedness and psychosocial wellbeing); (4) increase the size of, and shift dependencies, within social networks; and (5) reduce caregiver burden.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mid-West University Hospitals Group Regional Ethics Committee, Limerick Ireland, 22/11/2014.

Study design
The evaluation will be guided using the MRC Framework for the Evaluation of Complex Interventions.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
A patient information sheet has been developed and will be made available on the trial website.

Health condition(s) or problem(s) studied
Palliative and end of life care.

Interventions
The Good Neighbour Partnership (GNP).

The Good Neighbour Partnership can assist the person affected by advanced illness, and their family, to find the extra social and practical support required from within their community by making links with those living close-by who would like help. The Partnership can find additional help for activities such as walking the dog, doing the shopping, collecting a prescription, going to the library, filling a coal bucket, lighting the fire, mowing the lawn, making a snack, tidying up or sitting with a person who needs a break. It does not involve providing personal or physical care, heavy lifting of people/objects and nor does it provide help with medical or financial matters.

At least 15 Compassionate Communities volunteers will be recruited and trained to facilitate the Good Neighbour Partnership over an 8-week intervention period. The role of a Compassionate Community Volunteer with the Good Neighbour Partnership is to make the link between a person / family living with palliative care needs at home, and those in their circle of community who are able to offer support to seek out and enlist the Good Neighbour capacity within local communities.

All volunteers will be expected to demonstrate:
Maturity, common sense and the ability to be discrete and sensitive
A good understanding of ethical/confidentiality issues
The ability to confident and out-going, relate well to others and communicate effectively
A respectful and non-judgmental approach at all times
A good sense of humour
Good organisational skills and ability to complete paperwork
A good sense of personal boundaries and a clear understanding of purpose of the role

Volunteers will be nominated by a community organisation, or by a person of good standing. They will have Garda Clearance; references will be checked and selection will be by interview. They will be provided with initial training and on-going support by Milford Care Centre. As part of that training, they will be given a manual to help them understand their role, what is expected of them and what they can expect from Milford Care Centre. Insurance will be provided by Milford Care Centre and has already been agreed with the insurer. The volunteer recruitment and selection process has already commenced.

The Good Neighbour Partnership Co-ordinator will assign a Compassionate Communities Volunteer, taking into account the profile of the person requiring support, their age and gender, geographical location, personality and the volunteers availability and experience. It is anticipated that Compassionate Communities Volunteers will meet with the person up to four times during the 8 week cycle.

The new intervention will be offered in addition to the standard best practice services outlined above. This is aimed to complement existing services and not to duplicate or replace them. The intervention will be informed by Phase 0/1 of this study, but an outline of what is expected, is provided here.

Visit One: Within 72 hours of initial screening and allocation to the intervention, the assigned Compassionate Communities Volunteer visits the person at a mutually agreed time, in the person s own home, to identify their social and practical needs and the type of support required. They identify with the person, who in their circle of community they would be happy to approach, to enable these needs to be met. We refer to these people as Good Neighbours.

An agreement will be reached regarding a plan of action. This may involve the person requiring support directly approaching the identified Good Neighbours to enable their needs to be met, perhaps agreeing a formula of words to break the ice. Alternatively, it may also involve the Compassionate Communities Volunteer directly asking the agreed Good Neighbours to engage in the tasks identified. In the event that no-one has been identified in the persons circle of community, then an agreement will be reached to approach community organisations and/or Milford Care Centres bank of Compassionate Communities Good Neighbours to determine if they are in a position to enable the need to be met.

Visit Two / or Phone Call: Once agreement has been reached regarding who will complete the specific tasks, the Compassionate Communities Volunteer will report back to the person requiring support, to update them as to who will do what, and when. It is anticipated that this visit will take 20 minutes and in some cases, a phone call may suffice. Depending on the situation, it may be necessary for the Compassionate Communities Volunteer to accompany the Good Neighbours completing the task on their first visit, to introduce them to the person who requires support. Assistance is provided without an expectation or implication of payment or other reward or benefit.

Visit Three: Four weeks after the first visit, the Compassionate Communities Volunteer will visit again, to determine if the new arrangements/systems are working well, or if there needs to be any changes to the plan / modified supports. A mid-way interview will also be conducted two days later by the PI. It is anticipated that this visit will take 30 minutes.

Visit Four: Eight weeks after the first visit, the Compassionate Communities Volunteer will visit again to evaluate the process and determine if any additional support is required. It is anticipated that this visit will take 30 minutes and a final interview will be conducted two days later by the PI.

All visits will be agreed in advance and will be made by appointment only. Compassionate Communities Volunteers will be asked to keep a record of their visits on the Good Neighbour Partnership Report Form. This will be used to record include information on dates of visits, duration of visits, and type of activity undertaken. Volunteers will be asked to remind the Good Neighbours to keep a note of their visits on a separate similar form. At the end of the 8- week cycle, these forms will be returned to the Good Neighbour Partnership Co-ordinator.

Intervention Type
Behavioural

Primary outcome measure
Effect of the intervention on Instrumental Activities of Daily Living (IADLs) after eight weeks.

Secondary outcome measures
Effect of the intervention on quality of life, social connectedness, psychosocial wellbeing, unscheduled health service utilisation, caregiver burden, adverse impacts, and satisfaction with intervention after eight weeks.

Overall study start date
02/02/2015

Completion date
17/10/2016

Eligibility

Key inclusion criteria
Community dwelling adults (over 18 years) living with a life-limiting illness in Limerick, considered by a member of the primary care / hospice at home team to be in their last year of life and/or their carer are eligible to participate in this study. Those who meet the criteria on the brief screening tool as having unmet social / practical needs are eligible for inclusion in the RCT.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
In the event that a person with a life limiting illness is not able to engage in the study, as indicated by the nurse responsible for their care, due to their condition or a cognitive impairment, data will not be collected from them directly, but their carer will instead be given the option to engage and complete measures relevant to them.

Date of first enrolment
02/02/2015

Date of final enrolment

17/10/2016

Locations

Countries of recruitment
Ireland

Study participating centre
Maynooth University Dept of Psychology
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Sponsor type
Not defined

ROR
https://ror.org/048nfjm95

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
All Ireland Institute of Hospice (Ireland)

Funder Name
Palliative Care and Irish Cancer Society Research Fellowship (Ireland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/11/2015		Yes	No