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Short-term specialized palliative care in primary care for frail older people and their family carers

Submission date
06/09/2019

Recruitment status
No longer recruiting

Registration date
10/09/2019

Overall study status
Completed

Last Edited
04/02/2025

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

There is recognition that older people with incurable diseases should have access to palliative care. Palliative care aims to improve the quality of life of patients with incurable diseases and their families through a holistic approach, by addressing their physical, emotional, social and spiritual needs. Palliative care could be divided into two complementary models: 1) generalist palliative care, which is provided by physicians and other health care professionals that are not specialized in palliative care, and 2) specialized palliative care, provided by a multidisciplinary service or clinician specifically trained in palliative care who support primary care professionals in caring for patients and family carers when needs become particularly complex. Involvement of these specialized services is proposed for periods in which the patient's and their family carers' palliative care needs become too complex to be handled by generalist palliative care providers alone. We have developed and modelled a short-term specialized palliative care intervention for frail older people and their family carers in primary care in Belgium (Frailty+ intervention). We aim to assess the feasibility and preliminary effectiveness of the Frailty+ intervention, a short-term specialized palliative care intervention in primary care for older people and their family carers in Belgium.

Who can participate?

Frail older people aged 70 years or older and their family carers.

What does the study involve?

The intervention will be provided alongside any standard care. At the core of the Frailty+ intervention is the provision of needs- and capacity-based, goal-oriented, person-centred, pro-active, and integrated palliative care, for older people and their family carers over a period of two months, facilitated by a specialist palliative home care service. This involves contacts with GPs and referring clinicians, home visits, advice, liaise and referring roles, and the organisation of at least one multidisciplinary meeting with involved primary care providers. Patients in the control group will receive standard best practice care from the primary care providers (e.g. general practitioner, district nurses).

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 specialized palliative care for frail older people and their family carers in primary care. There are minimal risks to participate.

Where is the study run from?
The study is run from Vrije Universiteit Brussels (VUB) and Ghent University (Belgium)

When is the study starting and how long is it expected to run for?
April 2019 to February 2021

Who is funding the study?
The Research Foundation - Flanders (Belgium) (Fonds Wetenschappelijk Onderzoek)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
30-08-2019

Study information

Scientific Title
Short-term specialized palliative care intervention in primary care for frail older people and their family carers

Acronym
Frailty+

Study objectives
This study is a pilot randomized controlled trial (RCT) to pilot and assess the feasibility and preliminary effectiveness of the Frailty+ intervention, a short-term specialized palliative care intervention in primary care for older people and their family carers in Belgium

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 21/01/2020, Ethics Committee of Ghent University Hospital and Ghent University (C. Heymanslaan 10, 9000 Ghent, Belgium; +32 93326855; ethisch.comite@uzgent.be), ref: EC UZG 2019/1586

Study design
Pilot randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Frailty, life-limiting diseases, old age

Interventions
The intervention group will receive the Frailty+ intervention in addition to standard care. The control group will receive standard care. Patients who gave their consent will be randomly assigned to one of the groups after baseline assessment has been done.

The intervention will be provided alongside any standard care. At the core of the Frailty+ intervention is the provision of needs- and capacity-based, goal-oriented, person-centred, pro-active, and integrated palliative care, for older people and their family carers over a period of two months, facilitated by a specialist palliative home care service. This involves contacts with GPs and referring clinicians, home visits, advice/liaison/referral, and the organisation of at least one multidisciplinary meeting among relevant primary care providers.

Standard care (control) group: Patients in the control group will receive standard best practice care.

Intervention Type
Other

Primary outcome measure
Five key symptoms that are amenable to change (i.e. breathlessness, pain, anxiety, constipation, fatigue), measured using the integrated Palliative care Outcome Scale at baseline (before randomisation) i.e. T0, and 8 weeks after the baseline measurement, i.e. T1

Secondary outcome measures

1. Well-being of the patient is measured using the ICECAP-SCM
2. Sense of security of the patient is measured using the SEC-P
3. Continuity of care is measured using the NCQ
4. Views on care of the patient is measured using the IPOS-VoC
5. Coping strategies used by the patient is measured using the brief COPE
6. Sense of security of main family carer is measured using the SEC-R
7. Carer support needs is measured using the CSNAT

All measures will be administered at baseline and 8 weeks after baseline

Overall study start date
01/04/2019

Completion date
28/02/2021

Eligibility

Key inclusion criteria
1. Aged 70 years or over
2. Clinical Frailty Scale (CFS) score > 5 (mild to severe)
3. One or more unresolved or complex* symptoms or problems (as judged by clinicians)
4. In a hospital and referred to return to their home in the region Gent-Eeklo or Dendermonde-Aalst-Ninove
5. Speak and understand Dutch, and provide informed consent to participate in the study OR when a person lacks capacity to consent for themselves the procedures detailed in the Belgian law for patient rights are adhered to
6. Have a family carer who is eligible and willing to participate (see below for inclusion criteria for family carers) OR does not have a family member corresponding to the inclusion criteria

*one or more unresolved or complex symptoms or problems can include a multitude of different situations such as:
3.1 Complex patients' needs on the physical, psychological, social and/or spiritual domain
3.2 Complex end-of-life issues such as being 'tired of living', highly conflicted decision-making, consideration of palliative sedation, requests for assisted dying or euthanasia
3.3 Difficulties with advance care planning
3.4 Complex patient characteristics such as multimorbidity, or complexity due to cumulation of problems
3.5 Cre-existing complexity, for example, long-standing difficulties with finances/housing, mental health needs
3.6 Difficult interactions between the patient, family and healthcare professionals (for example, dissonance or conflicts, older patients who do not seek help etc)

7. To pilot the trial and evaluate the intervention specifically in the population of frail older people with cancer, we will oversample people with a cancer diagnosis into the study sample. To do so, we will apply the following inclusion critierion, in addition to the ones specified above:
7.1 Advanced-stage solid tumor or hematologic malignancy

8. Inclusion criteria for family carers:
8.1 Patient (or health care provider if patient does not have capacity) indicated that they are the patients' main family carer or representative

8.2 This person lives with the patient or has in-person contact with him or her at least twice a week

Participant type(s)
Patient

Age group
Senior

Lower age limit
70 Years

Sex
Both

Target number of participants
Planned sample size: 76 patients (38 in each study arm). Of these, 52 patients (26 in each study arm) will have a cancer diagnosis.

Total final enrolment
37

Key exclusion criteria
1. One or more palliative care consultations (i.e. specialized palliative home care team and/or palliative care unit) in the 6 months prior to inclusion in the study
2. Taken/are taking part in another research study that is evaluating palliative care services
3. Urgent palliative care needs (and should be referred to specialized palliative care) and/or deteriorate rapidly
4. Do not speak and/or understand Dutch

5. Exclusion criteria for family carers:
5.1 Have taken/are taking part in another research study that is evaluating palliative care services
5.2 Do not speak and/or understand Dutch

Date of first enrolment
01/11/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Belgium

Study participating centre
University Hospital Ghent
Corneel Heymanslaan 10
Ghent

Belgium
9000

Study participating centre
AZ Sint-Blasius Dendermonde
Kroonveldlaan 50
Dendermonde
Belgium
9200

Study participating centre
Sint-Vincentiusziekenhuis
Schutterijstraat 34
Deinze
Belgium
9800

Study participating centre
Vrije Universiteit Brussel
Laarbeeklaan 103
Brussels
Belgium
1090

Study participating centre
Netwerk Palliatieve Zorg Gent-Eeklo
Bilksken 36
Lovendegem
Belgium
9920

Study participating centre
Netwerk Palliatieve Zorg Aalst - Dendermonde - Ninove
Gentsesteenweg 355
Aalst
Belgium
9300

Sponsor information

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Sponsor type
University/education

Website
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ROR
https://ror.org/006e5kg04

Funder(s)

Funder type
Research council

Funder Name
Fonds Wetenschappelijk Onderzoek

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/08/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request from lara.pivodic@vub.be. Data will be available after the main paper of the pilot RCT has been published. They will remain available for at least 25 years. Data will be shared with members of universities, scientific research institutions, or

clearly separate and independent research departments of public institutions or non-profit organisations. Data may be used for scientific research only (commercial use of data will not be permitted).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/01/2021	22/01/2021	Yes	No
Results article		03/02/2025	04/02/2025	Yes	No