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Early integrated palliative care in chronic heart failure and chronic obstructive pulmonary disease: a feasibility before-after intervention study

Submission date
17/08/2018

Recruitment status
No longer recruiting

Registration date
30/08/2018

Overall study status
Completed

Last Edited
26/10/2020

Condition category
Circulatory System

[_] 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
Palliative Care (PC) aims to improve the quality of life of patients with Chronic Heart Failure (CHF) and patients with Chronic Obstructive Pulmonary Disease (COPD) and their families. The effectiveness of early integration of PC services with standard care has been increasingly supported by research evidence, but access to PC services for CHF/COPD patients remains substantially limited. The aim of this study is to explore whether an “Early Integrated PC” intervention can be performed in an acute setting (cardiology and pulmonology wards) and whether it will have an effect on satisfaction of care, quality of life and level of symptom control of CHF/COPD patients and their informal caregivers.

Who can participate?
Adult patients with CHF and COPD and their informal caregivers

What does the study involve?
The study has three phases: i) a phase where patients receive standard care, ii) a training phase where personnel are trained on the Early Integrated PC intervention and iii) a phase where the intervention is applied in cardiology and pulmonology wards in University Hospital Leuven for patients with advanced CHF/COPD and their informal caregivers. Patients and their informal caregivers are asked to complete questionnaires at the start of the study and three months after hospital discharge. The study assesses the feasibility of carrying out PC-focused studies in acute wards for CHF/COPD patients and draws lessons for the further integration of PC alongside standard treatment. Further, it measures quality of life and quality of care of patients and thus sheds light on the care needs of this population. Finally, it evaluates the effectiveness of Early Integrated Palliative Care by comparing against existing practices.

What are the possible benefits and risks of participating?
The advantage of this study is that both patients and their informal caregivers have the chance to share their opinion of their chronic illness and to express their preferences for their care.

Even though the patients and their informal caregivers might not be directly affected from the study, providing their feedback can have a significant impact for the improvement of the quality of care of such patients in the future. The process of filling in the questionnaires could be potentially stressful for the patients and their informal caregivers. In order to the minimize the risk of emotional distress, questionnaires have been chosen that are quick to complete (about 7 to 10 minutes). The overall risk of the study is low.

Where is the study run from?
University Hospital Leuven (Belgium)

When is the study starting and how long is it expected to run for?
February 2015 to July 2018

Who is funding the study?
University Hospital Leuven (Belgium)

Who is the main contact?
Mrs Naouma Siouta

Contact information

Type(s)
Scientific

Contact name
Mrs Naouma Siouta

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Contact details
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Additional identifiers

Protocol serial number
This trial was registered prospectively in the Clinical trial center UZ Leuven in Belgium (registration number s58652; date of registration 05/11/2015)

Study information

Scientific Title
Early integrated palliative care in chronic heart failure and chronic obstructive pulmonary disease: a feasibility before-after intervention study

Study objectives

The aim of this study is to explore the feasibility of carrying an “Early Integrated Palliative Care” intervention in acute cardiology/pulmonology wards and evaluate the effect on: i) the satisfaction of care and ii) the quality of life and the level of symptom control of CHF/COPD patients and their informal caregivers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of UZ KU Leuven/ Research, Belg Regnr: B322201627749

Study design
Single-centre before-after intervention study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Chronic heart failure and chronic obstructive pulmonary disease

Interventions
This is a before-after intervention study consisting of 3 sequential phases: baseline phase, training phase and intervention phase. During the baseline phase the control group will receive standard care. During the training period the personnel will be trained on how to use apply the “early palliative care integration” intervention. Finally during the intervention phase, the intervention group will receive the updated care.

After the completion of the baseline phase of the study (patients receiving standard care), the appointed intervention team for each ward will receive a training on how to apply the intervention in a 3-month period. The psychologist of UZ Leuven’s Palliative Support Care Team will train the personnel on how to apply the intervention to the experimental group. In cardiology, the assistant physicians will provide an introductory flyer for the intervention to the patient and after the completion of this flyer, two psychologists and one psychology trainee will proceed with the implementation of the intervention. The same process will follow for pulmonology, where after the introductory flyer by the assistants physicians, a specialist nurse, two ward nurses and the spiritual counselor will proceed with the intervention.

The intervention will be based on the implementation of the Early Integrated Palliative Care Planning Intervention (“MIJN WENSEN voor mijn Gezondheidszorg”), a content validated communication tool for advance care planning in chronic disease developed by the Palliative Support Team in UZ Leuven.

This tool addresses the wishes and needs of the patients concerning the delivery of care. It considers how the patient’s needs may be translated into treatment agreements for the present and the future taking into account the medical possibilities and limitations. MIJN WENSEN will be used as an invitation to communication; as a guide for conversations with the caregivers and for matching the current and future care with the treatment specialists. MIJN WENSEN can be

also used as an informal declaration of intent, to register the patient's indicated representative who will advocate the wishes of the patient in case she/he ever becomes unable of taking any decisions on their medical care. It can even be used as a formal declaration of intent, not only for indicating a representative, but also the content of the treatment wishes for every type of mental incompetence.

In both groups (control and intervention), patients and their most important informal caregiver will be asked to complete the Canadian Health Care Evaluation Project Questionnaire (CANHELP Lite) Questionnaire and the Palliative Outcome Scale Questionnaire and an ad-hoc questionnaire developed by the Palliative Support Team (at the University Hospital Leuven) to measure the current level of integrated PC in the following two timings: i) inclusion moment after signing the informed consent and ii) 3 months after inclusion (for both baseline and intervention groups). This is a single-centre study that will take place in the cardiology and pulmonology wards.

Intervention Type
Mixed

Primary outcome(s)
Measured at baseline and 3 months follow-up:
1. Quality of life and the level of symptom control measured using the Palliative Outcome Scale questionnaire
2. Quality of care measured using the Canhelp Lite questionnaire

Key secondary outcome(s))
Different elements of advance care planning and overall quality of care measured using a self-developed ad-hoc questionnaire at baseline and 3 months follow-up

Completion date
31/07/2018

Eligibility

Key inclusion criteria
Patients:
Adult patients that have been re-admitted at least once within a year with a New York Heart Association classification (NYHA) classification of III/IV for CHF (table 1) and with Global Initiative for Chronic Obstructive Lung Disease (GOLD) stages C/D for COPD. These patients should have an assessed life expectancy of at least 6 months.

Informal caregivers:
Informal caregiver is defined as that proxy person who takes care and supports the patient for most of the time. This caregiver may not necessarily be a family member. They should be aged 18 or above, should be able to communicate in Dutch and should be cognitively able to complete questionnaires.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Under the age of 18
2. Unable to communicate in Dutch
3. People who lack mental capacity to complete questionnaires,
4. If the Surprise question “Would you be surprised if the patient died within 1 year?” is answered “Yes”

Date of first enrolment
01/05/2015

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
Belgium

Study participating centre
University Hospital Leuven (UZ Leuven)
Herestraat 49
Leuven
Belgium
3000

Sponsor information

Organisation
UZ Leuven/KU Leuven

ROR
https://ror.org/0424bsv16

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitaire Ziekenhuizen Leuven, KU Leuven

Alternative Name(s)
University Hospital Leuven, KU Leuven, UZ Leuven

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Belgium

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 Prof. Menten (johan.menten@uzleuven.be) who is the leading investigator of this study. However, due to protection of the privacy of the identity of the participants, the trialists will be able to provide only anonymous responses of the participants in the form of Excel sheets until 31/01/2030. Access will be granted for research purposes only e.g. meta-analysis or comparison studies on the field of palliative care.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/02/2019	26/10/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes