

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/08/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/10/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 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

Study website

<http://www.uzleuven.be/nl/clinical%20trial%20center>

Contact information

Type(s)

Scientific

Contact name

Mrs Naouma Siouta

ORCID ID

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Contact details

Herestraat 49

Leuven

Belgium

3000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Quality of life

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

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 measure

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

Secondary outcome measures

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

Overall study start date

25/02/2015

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

25 heart failure patients and 25 COPD patients for the baseline phase and 25 heart failure patients and 25 COPD for the intervention phase (in this an attrition number of 30% is included).

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

Sponsor details

Herestraat 49

Leuven

Belgium

3000

Sponsor type

Hospital/treatment centre

Website

<http://www.uzleuven-kuleuven.be/lki/nl/laboratory/experimental-radiotherapy-laboratory>

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

Results and Publications

Publication and dissemination plan

The trialists plan to submit the protocol of this study for publication in the following week. The data of the baseline have been analysed and will be submitted for publication in the following week and the challenges that faced/lessons learned in the intervention will be also communicated with a paper submitted in the following month in a palliative care journal.

Intention to publish date

20/08/2018

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