ISRCTN92479122 https://doi.org/10.1186/ISRCTN92479122

Strengthening primary health care teams with palliative care leaders

Submission date	**Recruitment status**	[_] Prospectively registered
02/01/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/02/2017	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/10/2018	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Palliative care (PC), also known as end of life care, is the name given to terminally ill patients and their families in the last stages of life. According to the World Health Organization (WHO), patients with advanced cancer and other terminal diseases benefit from early identification and proactive PC. This study aims to evaluate the effectiveness of an program in which a PC leader is established in the primary health care center, and assess the effect of this on the early identification of patients in need of PC, the efficient use of health care services, and direct health care costs.

Who can participate?

GPs and nurses from the South Health District and the East Health District of Majorca.

What does the study involve?

Participating health care centers are randomly allocated to one of two groups. In health care centers in the first group, staff continue as normal for the duration of the study. In health care centers in the second group, a nurse or GP is appointed as a palliative care (PC) leader and attend a 42 hour training course in palliative care. The role of the leader is to train other staff members and promote PC, and to act as a consultant and liaison between the PC home-based services and other health professionals. Participants then implement PC statagies, which include use of a questionnaire to identify patients in need of PC and a tool to determine the complexity of PC needed for 16 months. Between 18-24 months after the start of the study, patients who died within 90 days have their electronic medical records accessed to look at death rate and the standard of palliative care provided.

What are the possible benefits and risks of participating?

GPs and nurses may benefit from a specific training in palliative care symptom managment, early identification of patient in need of palliative care, updated information in home-based PC services, diagnostic tools, and regular meetings for discussion of clinical cases with PC experts. Patients may benefit from an early detection and better management their care. There are no known risks to participants taking part in this study.

Where is the study run from?
The study is run from Baleares Health Services-IbSalut and takes place in 30 health care centers in Majorca (Spain)

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

Who is funding the study?
Spanish Institute of Health Carlos III (Spain)

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
pi14/01336

Study information

Scientific Title
Effect of palliative care leaders on early identification of patients needing palliative care and resource utilization: a cluster randomized clinical trial

Study objectives
The aim of this study is to evaluate whether appointing a palliative care (PC) leader or expert to health care teams who provide early identification of patients needing PC, encourages the appropriate use of health care services according to the complexity of the case and can reduce direct health costs and identify patients in need of palliative care earlier.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mallorca Ethical Committee of Clinical Research, 04/04/2016, ref: IB 3170/16

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Palliative care

Interventions
Participating health centers are randomised to one of two groups. Randomization and concealment will be centralized, through a single coordinating center, using a computer-generated block randomization in blocks of six.

Control group: Health centers receive organisation and training as usual for the duration of the study.

Intervention group: In participating health centers, palliative care leaders are appointed (nurses or doctors) and attend a 42 hour training course in palliative care based on “White Book” of PC training. The role of the leader is to train and promote PC, and to act as a consultant and liaison between the PC home-based services and professionals in the primary health care services. Leaders will encourage health professional in their Health care centers to early identificate and assess case complexity of patients. Leaders in the early identification and assessment of case complexity of patients receiving referral to PC home-based services will train primary health care doctors. Professionals will use The NECPAL CCOMS-ICO© questionnaire, which identifies patients in need of palliative measures, especially non-specific PC services, and the e IDC-PAL

tool, which is used for determining the complexity of PC that is needed for patients with advanced-stage or terminal diseases. The intervention will be implemented 16 months from randomization.

Although the intervention is carried out in the care of patients, patients themselves are now followed up. Outcome measures are collected for the last 90 days or last months of a patient's life by reviewing anonymised electronic patient records.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 23/10/2018:
Early identification (≥90 days before death) rate is assessed through electronic record review from patients who died between 18 to 24 months from randomization

Previous primary outcome measure:
Early identification (90 days before death) rate is assessed through electronic record review from patients who died between 18 to 24 months from randomization

Secondary outcome measures
Current secondary outcome measures as of 23/10/2018:
1. Case complexity is assessed through electronic record review from patients who died between 18 to 24 months from randomization
2. Number of patients who die at home is assessed by review of the death certificates from patients who died between 18 to 24 months from randomization
3. Total number of hospital admissions during the final month of life is assessed through electronic record review from patients who died between 18 to 24 months from randomization
4. Total number of emergency room admissions during the final month of life is assessed through electronic record review from patients who died between 18 to 24 months from randomization
5. Percentage of patients with any of the following “determinants of aggressive end-of-life care” during the final month of life is assessed through electronic record review from patients who died between 18 to 24 months from randomization
5.1. Two or more admissions to the emergency room
5.2. Two or more admissions to the hospital
5.3. Two or more admissions to the ICU
5.4. More than 14 days in the hospital
6. Cost of resources during the final month of life (including emergency department visits, outpatient office visits, primary health care visits, inpatient hospital stays, and ICU admissions) will be calculated by standard cost-per-unit prices, obtained from the Balearic official regional bulletin from patients who died between 18 to 24 months from randomization

Previous secondary outcome measures:
1. Case complexity is assessed through electronic record review from patients who died between 18 to 24 months from randomization
2. Number of patients who die at home is assessed by review of the death certificates from patients who died between 18 to 24 months from randomization
3. Total number of hospital admissions during the final month of life is assessed through electronic record review from patients who died between 18 to 24 months from randomization
4. Total number of emergency room admissions during the final month of life is assessed

through electronic record review from patients who died between 18 to 24 months from randomization
5. Percentage of patients with any of the following “determinants of aggressive end-of-life care” during the final month of life is assessed through electronic record review from patients who died between 18 to 24 months from randomization
5.1. One or more admission to the emergency room
5.2. One or more admission to the hospital
5.3. One or more admission to the ICU
5.4. More than 14 days in the hospital
6. Cost of resources during the final month of life (including emergency department visits, outpatient office visits, primary health care visits, inpatient hospital stays, and ICU admissions) will be calculated by standard cost-per-unit prices, obtained from the Balearic official regional bulletin from patients who died between 18 to 24 months from randomization

Overall study start date
01/01/2015

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. GPs and nurses
2. Working at primary health care centers located in the South Health District and the East Health District of Majorca

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
30 health care centers

Key exclusion criteria
Unwillingness to participate

Date of first enrolment
01/02/2015

Date of final enrolment
01/02/2016

Locations

Countries of recruitment
Spain

Study participating centre
Baleares Health Services-IbSalut
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Sponsor information

Organisation
Primary Care Management of Mallorca (Gerencia de Atención Primaria de Mallorca)

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Sponsor type
Government

ROR
https://ror.org/00d9y8h06

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCIII

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal between January and March 2018.

Intention to publish date
01/03/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Alfonso Leiva (aleiva@ibsalut.caib.es)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/07/2017		Yes	No