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PACE: cluster randomised controlled trial on ‘PACE Steps to Success' palliative care programme in Long Term Care Facilities in Europe

Submission date
08/07/2015

Recruitment status
No longer recruiting

Registration date
30/07/2015

Overall study status
Completed

Last Edited
05/08/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Aging populations, rising costs and sustainable delivery of high-quality care are increasingly common concerns in all European Union countries. While a growing number of older people will require palliative care in institutions, palliative care has only recently begun to be developed in Long Term Care Facilities (LTCFs) and there is very little research on the topic.
PACE is the name of the study that will be comparing the effectiveness of a palliative care intervention for elderly people in LTCFs in Europe with traditional care. PACE will implement a slightly adapted version of the successfully tested complex health service intervention called ‘The Route to Success in long term care facilities’, originally developed in the UK. The programme aims to enhance palliative care through facilitating organisational change and supporting staff in LTCFs to develop their roles around palliative care with the aim to ensure all residents receive high-quality palliative care. PACE will assess the effect of the intervention on resident and family outcomes, quality of dying, quality of palliative care, cost-effectiveness, and staff knowledge and attitudes. It will also assess the implementation process and identify facilitators/barriers across countries and in specific countries.

Who can participate?
LTCFs with specific resources available in line with eligibility criteria.

What does the study involve?
LTCFs will be randomly allocated to one of two groups: intervention group or usual care group
At month 1, the researchers will perform a retrospective study of all deceased residents over the past four months using structured after-death questionnaires to be filled in by nurses, GPs and relatives, in both groups. This is to serve as the pre-intervention measurement.
At month 13 and 17, all homes will again register all deaths of residents in and outside facilities over the previous four months. This will be the post-intervention measurement.
There will also be a process evaluation, using structured diaries, attendance lists, individual and group interviews.

What are the possible benefits and risks of participating?
Participating in the study might be beneficial to LTCF staff, residents and relatives, as the intervention ('PACE Steps to Success' palliative care program) is aimed to provide high-quality palliative care to LTCF residents, and could as such improve residents' quality of dying and quality of end-of-life care. A potential risk might lie in the participation of bereaved family members. Receiving the invitation letter and completing a questionnaire on a deceased family member may lead to a reawakening of bereavement and associated distress. However, by taking several measures (i.e., committing a legal/ethics expert, appointing an Ethical and Data Monitoring Review Board, providing relatives with information flyers/posters, and putting in place a series of procedures to identify and handle any signal of distress) we intend to minimize the risk of participating for this vulnerable group.

Where is the study run from?
LTCFs in seven European countries (Belgium, FinIand, Italy, Poland, The Netherlands, Switzerland, UK).

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

Who is funding the study?
The European Commission and Swiss Academy for Medical Sciences.

Who is the main contact?
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Study website
https://www.endoflifecare.be/pace-eu-fp7

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FP7-HEALTH-2013-INNOVATION-1 603111

Study information

Scientific Title
Comparative Effectiveness Research in long term care facilities in Europe - randomised controlled cluster trial on ‘PACE Steps to Success' palliative care programme

Acronym
PACE - PAlliative Care for Elderly

Study objectives
The primary trial hypothesis is that the introduction of the ‘PACE Steps to Success' palliative care programme in Long-Term Care Facilities (LTCFs) has positive effects on the quality of dying of residents, the quality of end-of-life care and on staff knowledge and attitudes.
More specific hypotheses are:
1. Resident outcomes are better in facilities using the ‘PACE Steps to Success’ palliative care programme than facilities which provide care as usual.
2. Resident outcomes improve over time in facilities using the ‘PACE Steps to Success’ palliative care programme as a result of the implementation of the programme.
3. Staff knowledge about and attitudes towards palliative care are better in facilities using the ‘PACE Steps to Success’ palliatieve care programme than facilities which provide care as usual.
4. Staff knowledge about and attitudes toward palliative care improve over time in facilities using the ‘PACE Steps to Success’ palliative care programme as a result of the implementation of the programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Netherlands: Medical Ethics Review Committee of VU University Medical Center, 02/07/2015, ref: 2015.253
2. Belgium: Medical Ethics Committee of Brussels University Hospital (Vrije Universiteit Brussel), 27/05/2015, ref: 143201524752
3. Finland: Research Ethics Committee of the National Institute for Health and Welfare, 30/06

/2015, ref: THL/850/6.02.01/2015
4. Poland: Bioethics committee of the Jagiellonian University Cracow, 25/06/2015, ref: 122.6120.113.2015.
5. UK: North East - Newcastle & North Tyneside 1 Research Ethics Committee, 10/09/2015, ref: 15/NE/0261
6. Italy: Il Comitato Etico, Universita Cattolica del Sacro Cuore,15/10/2015, ref: 0010736/15
7. Switzerland: Commission cantonale d'éthique de la recherche (CCER), 06/08/2015, ref: 15-165

Study design
A randomized controlled cluster trial using pre- and post-measurement of relevant outcome variables, process evaluation and economic evaluation to determine the intervention effects. It will use a sample of LTCFs fitting a number of inclusion criteria from a predetermined geographical region in each of the 7 participating countries.

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Older people living in long term care facilities

Interventions
In each country, six of 12 LTCFs will be randomized to the intervention group, in which they will receive the support of a Country Trainer and with the aid of a self-appointed PACE coordinator in the facility, will implement the 'PACE Steps to Success' palliative care programme. The other six LTCF will be randomized to the control group, in which care will be provided as usual.

The intervention 'PACE Steps to Success' palliative care programme aims to integrate palliative care in day-to-day routines of staff working in LTCFs, to ensure behavioural sustainability. At the core of the intervention is the nomination of a Representative for palliative care from the LTCF (named PACE coordinator in a facility). These coordinators are supported to develop their knowledge and skills and encouraged to empower staff within their organisation to deliver palliative care. All staff in the LTCF are supported by a Country Trainer who delivers workshops and provides support and education to all staff.

The timing of the intervention is as follows (total duration of 12 months):
- A two-month pre-implementation phase. During this phase PACE coordinators will get a "pre-intervention training" given by the Country trainer.
- A six month implementation of the intervention, with one step of the intervention being

delivered every month. The implementation phase consists of six 90 minute workshops for nursing staff given by the Country trainer. Each workshop covers one of the six steps to deliver quality care for people dying in the facility. Each of the six steps of the intervention is related to a key element of the intervention. Within the workshops, the materials and tools that LTCFs can use are introduced.
- A four-month consolidation phase of the trial intervention and accompanying facilitation of the Country Trainers to ensure the training is fully delivered before evaluating its effects. In the consolidation phase the tools and actions introduced in the workshops are further implemented and monthly meetings are held led by the PACE coordinator (and supported by the Country trainer).

Steps and key elements of the intervention

Step 1: Discussions about current and future care: Advance care planning discussions with residents and/or families to elicit wishes and preferences around end-of-life care. This communication process usually takes place in the context of an anticipated deterioration in the individual's condition in the future, with attendant loss of capacity to make decisions and/or ability to communicate wishes to others.

Step 2: Assessment and review: Completion of a prognostic register to prompt appropriate advance care planning discussions, and 'do not attempt cardio-pulmonary resuscitation'-orders alongside regular symptoms assessments for pain and depression.

Step 3: Co-ordination of care: Monthly multidisciplinary review meetings in which residents identified as having less than six months to live are discussed in detail, with specific invitations sent to GPs.

Step 4: Delivery of high quality palliative care: symptom management: General staff education concerning principles of palliative care for frail older people, including those with dementia, symptom control, and complex communication skills.

Step 5: Care in the last days of life: Use of an integrated care plan for the last days of life to empower staff to provide high quality care to the dying resident and their family.

Step 6: Care after death: Monthly reflective de-briefings groups to support staff following a death and encourage experiential learning.

Intervention Type
Other

Primary outcome measure
1. Quality of dying of the residents is measured using structured after-death questionnaires including validated instruments like EOLD-CAD (End-Of-Life in Dementia - Comfort Assessment in Dying) and QOD-LTC (Quality of Dying in Long-Term Care) at baseline, month 13 and month 17 after the start of the trial period
2. Staff knowledge and attitudes is measured using structured questionnaires including validated instrument like the ECPS (End-of-Life Professional Caregiver Survey), PCS (Palliative Care Survey) and S-EOLC (Self-Efficacy in End-of-Life Care Survey) at baseline and month 13 after the start of the trial period

Secondary outcome measures

Quality of palliative care is measured using structured after-death questionnaires including validated instruments like EOLD-SWC (End-Of-Life in Dementia - Satisfaction With Care) and FPPFC (Family Perception of Physician-Family Communication) at baseline, month 13 and month 17 after the start of the trial period.

Overall study start date
01/02/2014

Completion date
31/07/2018

Eligibility

Key inclusion criteria
To enhance comparability between countries, LTCFs are eligible to be recruited when they fulfil all of the following inclusion criteria:
1. An off-site family physician or GP is responsible for the resident's medical care.
2. Social and nursing care is provided onsite .
3. Number of beds per facility is at least 30 but does not exceed 100.
4. We strive to include facilities with at least 15 deceased residents in or outside the facility over the last year. If it is not possible to find enough LTCFs that fit this inclusion criterion, facilities should be selected in which the number of deceased residents in the past year is closest to 15.
5. LTCFs from a predefined geographical location (to be determined by the researchers).
6. Each partner lists all LTCFs fitting these inclusion criteria. From this list, only those LTCFs where the Board of Directors (1) expresses explicit motivation to participate in the study and (2) agrees to free time for one PACE coordinator for e.g. 0.5 days per working week, depending on setting, will be included in the study.

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
Per country, 6 LTCFs in which the PACE Steps to Success palliative care programme will be implemented + 6 control LTCFs in which residents receive care as usual. In Switzerland 4 intervention + 4 control LTCFs will participate.

Key exclusion criteria
Researchers exclude facilities already using a palliative care planning tool e.g. (accredited users of) the Gold Standards Framework, Route to Success, Six Steps to Success, interRAI-PC version or end of life care integrated pathways such as Liverpool Care Pathway; or those facilities where they judge explicit and detailed palliative care guidelines to be available and corresponding high-quality practices to be implemented.

Date of first enrolment
01/06/2015

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
Belgium

England

Finland

Italy

Netherlands

Poland

Switzerland

United Kingdom

Study participating centre
VU University Medical Center
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
European Commission

Sponsor details
Square Frère Orban, 8
Brussels
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Sponsor type
Government

Website
http://ec.europa.eu/research/index.cfm

ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type
Government

Funder Name
European Commission (7th Framework Programme, Health 2013 Innovation, and Grant Agreement No: 603111)

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Swiss Academy for Medical Sciences

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 29/01/2019:
Articles in international peer-reviewed journals:
The dates indicate when the articles will be submitted for publication.

First half of 2019:
1. Cross-national analyses of the effect of the intervention on primary outcomes
2. Economic evaluation

Second half of 2019
1. Cross-national analyses of the effect of the intervention on secondary outcomes.
2. National (single-country) and cross-national subgroup analyses in each of the participating countries.

Regarding subgroup analyses, each partner will create their own analysis plan relevant to their research questions and hypotheses.

Previous publication and dissemination plan:
Articles in international peer-reviewed journals:
The dates indicate when the articles will be submitted for publication.

First half of 2018:
1. Cross-national analyses of the effect of the intervention on primary outcomes
2. Economic evaluation

Second half of 2018
1. Cross-national analyses of the effect of the intervention on secondary outcomes.
2. National (single-country) and cross-national subgroup analyses in each of the participating countries.

Regarding subgroup analyses, each partner will create their own analysis plan relevant to their research questions and hypotheses.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/03/2018		Yes	No
Results article	results	01/02/2020	13/11/2019	Yes	No
Other publications	feasibility of implementation evaluation	19/12/2019	23/12/2019	Yes	No
Results article	results	22/09/2020	23/09/2020	Yes	No
Results article	subgroup analysis results	07/03/2021	09/03/2021	Yes	No
Protocol article		12/03/2018	18/10/2022	Yes	No
HRA research summary			26/07/2023	No	No
Other publications		24/10/2019	05/08/2024	Yes	No
Other publications	Secondary analysis	06/07/2020	05/08/2024	Yes	No