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Implementation effectiveness of supporting ICUs

Submission date	Recruitment status	[ ] Prospectively registered
08/11/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/11/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/11/2016	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Approximately 8% of all intensive care unit (ICU) patients die in the ICU, and 80% of these deaths occur after withholding or withdrawing the life sustaining treatment. The care given before, during and after ending the life sustaining treatment is called end-of-life care. End-of-life care (EOLC) is s complex care pathway, which involves many different professionals. This includes ICU nurses, however it is not yet clear what the role and responsibilities of ICU nurses are during EOLC. Therefore, a Dutch guideline was developed called 'End-of-life care in the ICU, nursing care'. This guideline could help ICU nurses in their care during EOLC. Before this guideline can be followed, it needs to be implemented (put in place). This can be a difficult process, and so a possible way to support the implementation is to train those who are going to use it. The aim of this study is to find out whether supporting the implementation of this guideline can better help nurses to follow it.

Who can participate?
ICU nurses working at participating medical centres who are experienced with EOLC and family members of patients who died 4-5 weeks ago.

What does the study involve?
Participating ICUs are randomly allocated to one of two groups. ICU nurses in the first group take part in a four day training programme in which they are trained to implement the guildeline. This consists of a combination of lectures and workshops. ICUs in the second group are left to implement the guideline by themselves. At the start of the study and then after six and nine months, two ICU nurses from each ICU are interviewed about how well they are able to follow the guideline. In addition, family members of patients who died 4-5 weeks ago are also interviewed and complete a number of questionnaires about their experiences of end of life care in the ICU.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved for those participating.

Where is the study run from?
The study is run from HAN University of Applied Sciences and takes place in 13 medical centres (Netherlands)

When is the study starting and how long is it expected to run for?
June 2014 to December 2015

Who is funding the study?
Foundation Innovation Alliance, Regional Attention and Action for Knowledge circulation (Netherlands)

Who is the main contact?
Dr Lilian Vloet
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2013-15-16p

Study information

Scientific Title
Effectiveness of supporting intensive care units on implementing the guideline 'End-of-life care in the intensive care unit, nursing care': a cluster randomised controlled trial

Study objectives
Supporting ICUs leads to better adherence of the guidelines for end-of-life care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
CMO Radboudumc Nijmegen, 19/02/20195, ref: 2014-1363

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Nursing guidelines

Interventions
Participating ICUs are randomly allocated to two groups (manual generated randomization with random allocation concealment), without stratification of ICU size.

Both the intervention and control groups made their own implementation plan and implemented the guideline on their own ICU, with a project team.

Intervention group: ICUs are supported by a training program focusing on implementation processes and strategies and sharing experiences and best practices from other intervention sites. Training takes place over 4 days and consists of a combination of lectures and workshops which cover:
Day 1: Development of specific implementation plan and context analysis
Day 2: Context analysis and Implementation strategies
Day 3: Implementation strategies and Implementation plan
Day 4: Implementation plan and Embedding and monitoring

Control group: ICUs receive no support during the implementation and have to implement the guideline by themselves without supervision from the research group.

Follow up for all ICUs involves interviewing two ICU nurses from each participating ICU after 6 and 9 months and interviewing relatives of patients who have died 4-5 weeks previously at 9 months.

Intervention Type
Other

Primary outcome measure
Adherence to guidelines for end-of-life care is measured by a questionnaire for ICU nurses applying 25 recommendations of the guideline at baseline, and after 6 and 9 months.

Secondary outcome measures
Experiences of ICU nurses and family of deceased patients are measured the Quality of Death and Dying (QDD) and Consumer Quality Index (CQI-R), relatives in the ICU (LAIZ 2016) questionnaires at 9 months.

Overall study start date
01/06/2014

Completion date
01/12/2015

Eligibility

Key inclusion criteria
Nurses:
1. Working in the ICU
2. Graduated as a ICU nurse
3. Dutch speaking
4. Experience with EOLC in the ICU

Family of deceased ICU patients:
1. Dutch speaking
2. Aged 18 years and over
3. 4-5 weeks after death of the patient
3. Contact person of the deceased patient

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
11 clusters, 1500 ICU nurses, 60 family members

Key exclusion criteria
Nurses:
No experience with End-of-life care.

Family:
Family of patients who were organ donors.

Date of first enrolment
01/10/2014

Date of final enrolment
30/11/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
HAN University of Applied Sciences
Research department Emergency and Critical Care
Kapittelweg 33
Nijmegen
Netherlands
6525 EN

Study participating centre
Radboud University Nijmegen Medical Centre
Geert Grooteplein Zuid 10
Nijmegen
Netherlands
6525 GA

Study participating centre
Medisch Spectrum Twente
Koningsplein 1
Enschede
Netherlands
7512 KZ

Study participating centre
Slingeland Ziekenhuis
Kruisbergseweg 25
Doetinchem
Netherlands
7009 BL

Study participating centre
Ommelander Ziekenhuis Groep
Netherlands
9930 RA

Study participating centre
Treant Zorggroep
Dr. G.H. Amshoffweg 1
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7909 AA

Study participating centre
Nij Smellinghe
Compagnonsplein 1
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9202 NN

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Antonius Ziekenhuis
Bolswarderbaan 1
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Study participating centre
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Maelsonstraat 3
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1624 NP

Study participating centre
Antoni van Leeuwenhoek
Plesmanlaan 121
Amsterdam
Netherlands
1066 CX

Study participating centre
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Amersfoort
Netherlands
3813 TZ

Study participating centre
Alrijne Ziekenhuis Leiderdorp
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Netherlands
2353 GA

Study participating centre
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Dordrecht
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3318 AT

Study participating centre
Amphia Ziekenhuis
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4819 EV

Sponsor information

Organisation
HAN University of Applied Sciences

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Sponsor type
University/education

Website
www.laiz.nl

ROR
https://ror.org/0500gea42

Funder(s)

Funder type
Research organisation

Funder Name
Foundation Innovation Alliance, Regional Attention and Action for Knowledge circulation

Results and Publications

Publication and dissemination plan
Planned publication of study results in a peer-reviewed international journal, focusing on nursing sciences (journal of advanced nursing).

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Lilian Vloet (lilian.vloet@han.nl)

IPD sharing plan summary
Available on request