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End-of-life communication in nursing homes – Patient preferences and participation

Submission date	**Recruitment status**	[_] Prospectively registered
23/02/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/03/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/06/2019	Other	

Plain English summary of protocol

Background and study aims
Approximately half of all Norwegians die in nursing homes. Many nursing home patients suffer from cognitive impairment (problems with memory and thinking skills). If these patients suddenly become very ill, then this combined with cognitive impairment issues may make it difficult for patients to play an active role in making end-of-life decisions. Next of kin and health personnel often do not know whether patients had previously expressed preferences about what kind of end-of-life treatment they would wish to receive. Advance care planning (ACP) is a voluntary process, in which patients can set on record choices about their care and treatment and, in particular, the end-of-life care they wish to receive. The aim of this study is to look at the effects of using ACP in nursing home patients, by getting to know patient preferences and wishes for the future before patients lose capacity to communicate.

Who can participate?
Nursing home patients aged 70 or over, their next of kin and the health personnel looking after them.

What does the study involve?
Participating nursing homes are randomly allocated to one of two groups. In the first group, staff receive training in advance care planning (ACP) conversations. Patients and/or their next of kin at these nursing homes are offered an opportunity to participate in these conversations. The conversations are concerned with patients' hopes and worries for the future, appointment of a proxy (someone to make decisions for them if they are no longer able to), their wishes for information, wishes for participation in decision-making, and wishes for life-prolonging treatment and hospitalization. Some patients, next of kin and health personnel are asked whether a researcher can observe this conversation and interview those participating directly after the conversation. In the second group, patients receive care as usual. At the start of the study and 12 months later, participants have their electronic patient records reviewed in order to make a note of any end-of-life decisions made and if these are in line with patient wishes (if known).

What are the possible benefits and risks of participating?
Advance care planning conversations may be beneficial to patients, next of kin and health

personnel caring for the patient. This process of conversations may help patients cope with end-of-life challenges, enable patient and next of kin to talk about wishes, values and preferences not previously expressed and help put the patient at the centre of attention when end-of-life decisions need to be made. Ultimately, the hope is that appropriate treatment is as much in line with what the patients wants as possible. There are no notable risks involved with participating.

Where is the study run from?
Centre for Medical Ethics at the University of Oslo (Norway)

When is study starting and how long is it expected to run for?
April 2010 to August 2018

Who is funding the study?
Research Council of Norway (Norway)

Who is the main contact?
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Additional identifiers

Protocol serial number
The Research Council of Norway project number: 222088

Study information

Scientific Title
Implementation of advance care planning in Norwegian nursing homes - a cluster randomized controlled trial

Study objectives
Current study hypothesis as of 15/02/2018:
Research questions:
1. What characterizes ACP in NHs, after implementation of ACP?
2. Does an ACP intervention increase the documentation of patients hope and worry for the future?
3. Does an ACP intervention influence the elicitation of patient preferences about end-of-life issues, such as life-prolonging treatment and hospitalization?
4. Does an ACP intervention increase patient involvement when decisions are made on life-prolonging treatment and hospitalization?
5. What is the significance of ACP for participating patients, NOK and health care personnel?
6. How did we implement the ACP guideline?
7. What are our experiences with implementation of a complex intervention, and what are the barriers and facilitators?

Previous study hypothesis:
Research questions:
1. Does an ACP intervention influence the documentation of patient preferences to end-of-life issues?
2. Does an ACP intervention increase documentation of patient involvement when decisions are made on life-prolonging treatment and hospitalization?
3.Does an ACP intervention increase the documentation of patients hope and worry for the future?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Regional Ethics Committee, 15/04/2015, ref: 2014/2210/REK sør-øst
2. Norwegian Social Science Data Services, 03/03/2015, ref: 41114

Study design
Multi-centre cluster randomised controlled trial

Primary study design

Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Care

Interventions
Eight nursing home wards from eight nursing homes are pair-matchedusing the following data from a national survey/KOSTRA/the nursing home's annual report: size of the municipality, size of the nursing home and ward (number of beds), number of hours with doctor present per week, and personnel position characteristics (educational backgrounds, percentage of professionals, ratio of part time/full time). One ward from each pair of wards is then randomized to be included in the intervention group and the other to the control group.

Intervention group: : The intervention consists of systematic implementation of Advance care planning (ACP) conversations. A guideline has been developed for these conversations which includes a definition of ACP, outlines aims and purposes of ACP, emphasizes voluntary participation and includes a suggested text on how to invite patients to the conversation, addresses competency to consent, notes the researchers aim of including patients with cognitive impairment in conversations, recommends setting and timing of conversation, recommends who should participate and how to prepare for and lead the conversation, recommends what questions to ask and suggests how the conversations should progress, and finally states recommendations on what to do after the conversation.
Patients at the ward, or next of kin when patients could not consent, are invited to an ACP conversation. The ACP conversation lasts no more than an hour. Each patient did not get invitation to more than one conversation during the 12 month intervention period.
A project group from each of the nursing home wards in the intervention group are educated in ACP, the guideline and how to conduct ACP conversations prior to the intervention. They also got a recommendation on how to assess competency to consent, and are told the importance of doing so. They are responsible for educating their own staff. However, the research group at the University of Oslo contributed at 3 of the 4 wards in educating staff from the wards on the project, the guideline and how to do ACP.
Each nursing home ward has one contact person from the research group they could contact if they have any queries. This researcher also contacts the local project coordinator regularly asking about development at the ward.
Local project groups are gathered three times during the 12 month intervention and then again afterwars. These gatherings consist of sharing experiences, obstacles with the implementation and how to move on.

Control group: Care as usual during the 12 month intervention. Wards in the control group do not receive education in ACP, the guideline and how to conduct ACP conversations prior to the intervention, but rather March 2nd 2017.

Added 15/02/2018:
The clinical intervention was a guideline for how to carry out systematic ACP.
The implementation strategies included:
Training, supervision, and follow-up of the project teams.

Written information to patients and relatives including project information, themes to be included in conversations, invitation to conversation and contact information.
Information meeting about the ACP project for NH staff.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measures as of 15/02/2018:
Number of patients with a documented conversation on end-of-life treatment assessed through electronic health record review at baseline and 12 months.

Previous primary outcome measures:
1. Number of patients with a documented conversation on end-of-life treatment is assessed through electronic health record review at baseline and 12 months
2. Number of patients with a documented wish regarding life-prolonging treatment and hospitalisation assessed through electronic health record review at baseline and 12 months
3. Concordance between patient wishes and treatment given will be measured based on documentation of events assessed through electronic health record review at baseline and 12 months

Key secondary outcome(s))
Current secondary outcome measures as of 15/02/2018:
Based on information in the patient's EHR the following secondary outcomes will be assessed (at baseline and at the end of the 12 month intervention period):
1. Patient's hopes and worries for the future
2. Patient’s wishes for a proxy, information to oneself and NOK, and patient wishes for participation in decision-making processes
3. Patient’s competence to consent assessed in relation to conversations on future life-prolonging treatment
4. Wishes regarding life-prolonging treatment and hospitalization
5. Patient’s own wishes regarding life-prolonging treatment and hospitalization are known
6. NOK's knowledge of the patients’ wishes regarding life-prolonging treatment and hospitalization
7. NOK's own opinion on life-prolonging treatment and hospitalization
8. Wishes regarding life-prolonging treatment and hospitalization being positive to treatment
9. Life-prolonging treatments and hospitalizations during the past 12 months
10. Life-prolonging treatments and hospitalizations decided not given during the past 12 months
11. Patient's competence to consent assessed during the past 12 months, when life-prolonging treatments and hospitalizations were given or decided not given
12. Concordance between patient wishes and treatment given will be measured based on documentation of events during the past 12 months.

Previous secondary outcome measures:
1. Documentation of: patient's hopes and worries for the future, wishes for information to oneself and next of kin, wishes for participation in end-of-life decision-making
2. Decisions on end-of-life treatment and hospitalisation
3. Concordance between patient's previously expressed wishes and actual treatment given

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Nursing home resident
2. Aged 70 years and over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Under the age of 70
2. Do not understand or speak Norwegian
3. Severe psychiatric condition

Date of first enrolment
21/04/2015

Date of final enrolment
29/06/2016

Locations

Countries of recruitment
Norway

Study participating centre
Centre for Medical Ethics, University of Oslo
Norway
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Sponsor information

Organisation
University of Oslo

ROR
https://ror.org/01xtthb56

Funder(s)

Funder type
Research council

Funder Name
The Research Council of Norway

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	17/06/2019	Yes	No
Protocol article	protocol	13/08/2018		Yes	No