ISRCTN99887420 https://doi.org/10.1186/ISRCTN99887420

RESPEKT: Study to implement advance care planning (ACP) in the nursing homes (n/h) of a model region by means of qualifying selected n /h staff to facilitate ACP discussions with residents or their proxies

Submission date
25/08/2009

Registration date
18/09/2009

Last Edited
21/12/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Other

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jürgen in der Schmitten

Contact details
Abteilung für Allgemeinmedizin (Dpt. of General Practice)
Universitätsklinik (University Hospital)
Moorenstr. 5
Düsseldorf
Germany
40225

Additional identifiers

Protocol serial number
01GX9753

Study information

Scientific Title
Controlled intervention study for the process- and system-oriented implementation of advance care planning in the nursing homes and further relevant care suppliers of a model region by means of qualifying n/h staff to facilitate ACP discussions, and a multi-faceted informational intervention (RESPEKT - Respekt für vorausverfügte Entscheidungen und Präferenzen für den Fall von Krankheit und Tod)

Acronym
RESPEKT

Study objectives
The prevalence of both meaningful and valid advance directives in nursing homes will increase significantly if nursing home staff trained as facilitators for advance care planning discussions provide thorough consultation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University Hospital of Düsseldorf (Germany) approved on the 17th November 2008 (ref. 3116)

Study design
Longitudinal non-randomised non-blinded controlled interventional study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Advance care planning process and results

Interventions
The core of the intervention is the training of altogether 16 nurses or social workers from the four nursing homes of a middle-sized town. The training consists of a week of intensive training (20 hours) and subsequently regular plenary sessions, and personal supervisions/coachings for at least one year, though with decreasing frequency. The training aims to teach the future facilitators to initiate discussion on advance care planning, to help residents or their proxies understand the choices to be made, and to develop, communicate, and document their personal preference. The training program is an adaptation of the US program Respecting Choices® (cf. http://www.respectingchoices.org/).

In the control group of 10 nursing homes in two other towns, there is no intervention (care as usual).

Recruitment for the controlled study was stopped on 30th June 2009 because the intervention began to strongly bias recruitment outcome in the intervention region. Follow up is ongoing.

Intervention Type

Other

Phase
Not Applicable

Primary outcome(s)
Prevalence of written advance directives (authored by the resident or, if incapacitated, the legal proxy), in a three-step approach:
1. Presence of an advance directive (yes or no). If an advance directive is present, then the following step is evaluated:
2. Meaningfulness of the advance directive, i.e. it addresses the following scenarios typically relevant for nursing homes in Germany: cardiopulmonary resuscitation; hospital admission for life-sustaining treatment; long-term artificial feeding in dementia, both for the state of current decision-making capacity (if still given), and a possible future decision-making incapacity. If an advance directive is meaningful in that sense, then the following step is evaluated:
3. Validity of the advance directive, defined by a physician's written testimony that the signer (resident or proxy):
3.1. Has currently decision making capacity, and
3.2. Has understood and appreciated the implications of his or her decision

Primary outcomes measured on 30/06/2010.

Key secondary outcome(s))
1. Process quality:
1.1. Presence of a physician's order for emergency situations directed at the nursing staff, clarifying the issue of cardiopulmonary resuscitation (yes or no), of hospital admission, and of any urgent procedures aiming to prolong life.
1.2. Accessibility of advance directives/physician's order from within the nursing ward:
1.2.1. Rate of easily noticeable references to a given advance care planning in the paper or electronic file
1.2.2. Copy of advance directive and/or physician's order is prepared for the case of a transferral to hospital
1.3. Management of advance directives or physician orders' during residents' hospital stays
1.3.1. Copy of AD or physician order is in the hospital file
1.3.2. Treatment limitations stated in physicians' orders brought from the n/h are translated into corresponding written orders by hospital doctors
1.3.3. AD or physician's order is mentioned in discharge letter

2. Outcome quality:
2.1. Treatment:
2.1.1. Incidence of feeding tube insertions, days of artificial feeding, days of parenteral fluid application, as far as congruent with the expressed residents' preferences
2.1.2. Incidence and days of hospital treatments
2.1.3. Incidence of decubital ulcers
2.2. Course before dying:
2.2.1. Location of dying
2.2.2. Number of transferrals to hospital in the 30 (90) days before death
2.2.3. In-hospital (in-ICU) days in the 30 (90) days before death
2.2.4. Rate of index-treatments in the 30 (90) days before death (i.e., CPR, feeding tube insertions, days of artificial feeding, artificial ventilation, pace maker insertions, incidence of general surgery)

2.2.5. Incidence of decubital ulcers in the 30 (90) days before dying
2.3. Perception of the dying process from the perspective of third parties:
2.3.1. Judgment of the dying process from the nursing perspective
2.3.2. Judgment of the dying process from the relative perspective (after-bereavement interview)

3. Analysis of possible confounders:
3.1. Sex
3.2. Age
3.3. Nursing home
3.4. Facilitator

Secondary outcomes measured on 31/07/2010.

Completion date
30/06/2010

Eligibility

Key inclusion criteria
All residents of the enrolled nursing homes (adults of either sex)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Life expectancy below four weeks according to medical or nursing judgment
2. Expected duration of stay in the nursing home below three months (short-term nursing care)
3. Unsurmountable language or communication barrier (resident and proxy)

Date of first enrolment
01/10/2008

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
Germany

Study participating centre
Abteilung für Allgemeinmedizin (Dpt. of General Practice)
Düsseldorf
Germany
40225

Sponsor information

Organisation
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany)

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany) (ref: 01 GX 0753)

Funder Name
B. Braun Foundation (Germany) - providing small additional funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/01/2014		Yes	No

Protocol article	protocol	24/01/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes