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# 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

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| **Submission date**<br>25/08/2009 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol |
| **Registration date**<br>18/09/2009 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>21/12/2016 | **Condition category**<br>Other | [_] Individual participant data |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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

### Secondary study design
Non randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Quality of life

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

### 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 measure
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.

## Secondary outcome measures
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.

### Overall study start date
01/10/2008

### Completion date
30/06/2010

## Eligibility

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

### Participant type(s)
Patient

### Age group
Other

### Sex
Both

### Target number of participants

1080

### 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
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40225

## Sponsor information

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

### Sponsor details
c/o Projektträger im DLR, Versorgungsnahe Forschung
Heinrich-Konen-Str. 1
Bonn
Germany
53227

### Sponsor type
Government

### Website
http://www.gesundheitsforschung-bmbf.de/de/167.php

### 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

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 24/01/2011 | | Yes | No |
| Results article | results | 24/01/2014 | | Yes | No |