ISRCTN91308077 https://doi.org/10.1186/ISRCTN91308077

A follow-up study to evaluate the advance care planning program Beizeiten Begleiten (care in good time) in one regions nursing homes

Submission date
21/12/2011

Recruitment status
No longer recruiting

Registration date
18/01/2012

Overall study status
Completed

Last Edited
12/04/2012

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Advance directives (ADs, or living wills) have been encouraged in the Western world since the early 1970s. However, they have not become the standard of care in any country. Despite recommendations from health professionals and politicians, and despite specific legislation in the USA in 1993, ADs remain infrequent (about 1 to 2 in 10). They are often not at hand when needed, are vague so that they prove no help for the concrete treatment decisions to be made, are questionable with regard to their validity (i.e. it is not sure whether the text of the AD is identical to what the person had in mind when drawing up the AD, let alone whether the person is still of the same opinion), and they are not being followed by health professionals for various reasons. Therefore, many researchers have drawn the conclusion that the instrument AD itself is flawed and should therefore as such be abandoned.
Advance care planning (ACP), on the other hand, is a novel approach to enable people to make their personal end-of-life decisions. The idea behind ACP is that end-of-life decision making for future scenarios needs a complex response. Signing a form that contains standard sentences, which is often the case with traditional ADs, is not likely to have such a complex response.
ACP, in contrast, rests on two pillars:
1. Recognising that advance decision making for future hypothetical health crises can only be done on the basis a health professionals opinion, and that this opinion would need to be repeatedly offered over the time, to consider changes in health, chronic disease, and personal views towards life.
2. Recognising that all health professionals concerned with patients who did ACP need to be involved in a regional effort to ensure that advance care plans are understood and valued.
ACP is a regional initiative to establish structures that allow skilfully facilitated conversations for all members of a population group, and that warrant that the ACPs resulting from such conversations will be honoured.
In February 2009, we started an ACP program in the nursing homes of one town, comparing the outcomes with a number of nursing homes of two other towns where no intervention was offered. The aim of that study was to train selected social workers in the nursing homes to

facilitate ACP discussions with all residents, to train the family physicians to cooperate with the newly trained facilitators, and to contribute to supporting the residents making ACP. With this follow-up study, we want to measure the long-term effect of our earlier study.

Who can participate?
The study is carried out with two groups of residents of either sex, regardless of age. The first group is a random sample of all residents who live in the participating nursing homes at the time of data collection. The second group is a random sample of residents deceased in the second half of 2010. Residents who moved into the nursing homes less than 3 months earlier are excluded from the study.

What does the study involve?
The study only involves measuring the long-term effect of the main study described above. In the intervention region, social workers employed in the residential homes were trained to facilitate ADP conversations with all residents. In the control region, there was no intervention. We expect that many, if not all residents in the intervention regions nursing homes will receive the opportunity to draw up meaningful AD on the basis of skilfully facilitated, comprehensive conversations. This is not standard in German nursing homes yet.
What we want to find out is whether the residents living in the former intervention region are more likely to have AD in place that are relevant and valid than those living in the intervention region. We ask each residential home staff to look into their residents charts and to document whether it contains an AD or not, and if yes to answer certain questions in order to describe the quality of this AD.

What are the possible benefits and risks of participating?
Since this is a follow-up, there are no possible benefits or risks involved.

Where is the study run from?
The coordinating centre is the department of General Practice at the University Hospital of Düsseldorf (Germany). Three nursing homes of the original intervention region are compared with eight nursing homes in the original control region (both regions close to Düsseldorf).

When is the study starting and how long is it expected to run for?
Data collection started in April and lasted until May 2011. Data were electronically processed and recently sent to the statistician in December 2011.

Who is funding the study?
German Ministry of Education and Research who also funded the original intervention study.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
01GX0753

Study information

Scientific Title
Controlled, cross-sectional, follow-up study to evaluate the degree of implementation of the advance care planning program Beizeiten Begleiten (care in good time) in one regions nursing homes - RESPEKT

Acronym
RESPEKT

Study objectives
Approximately 2 years after launching the advance care planning (ACP) program "Beizeiten Begleiten" in February 2009, valid and emergency relevant advance directives are more common in the three participating nursing homes of the intervention region compared with the ten nursing homes in the control region

Follow up to RESPEKT study: www.controlled-trials.com/ISRCTN99887420/

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, University Hospital of Düsseldorf, Germany, 17 March 2011, ref: 3116

Study design
Controlled inter-regional cross-sectional non-randomised non-blinded follow-up study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Advance Care Planning (advance directives)

Interventions
The intervention was to implement an advance care planning program in the nursing homes of the intervention region. Follow up to RESPEKT study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Availability of advance directives (in the resident's charts) that are:
1. Valid (defined by a physician's or specifically qualified non-physician's signature)
2. Emergency-relevant (defined by clearly deciding the question of CPR in case of cardiac arrest on one page, possibly on a separate form, also validated by a physician's or qualified non-physician's signature)

Key secondary outcome(s))
1. Valid (defined by a physician's or specifically qualified non-physician's signature) - validity defined by the signature of ANY third person
2. Emergency-relevant (defined by clearly deciding the question of CPR in case of cardiac arrest on one page, possibly on a separate form, also validated by a physician's or qualified non-physician's signature) - only residents who moved in after 1 July 2010
3. Prevalence of just an emergency-relevant document with physician's signature
4. Designation of a proxy decision maker (durable power of attorney)
5. Number of months since advance directive was last updated

Completion date
31/05/2011

Eligibility

Key inclusion criteria
In order to examine the ACP programs effect comprehensively, we studied the prevalence and properties of advance directives in two samples of the enrolled nursing homes:
Sample 1: Residents currently living in the enrolled nursing homes at the date of data collection (adults of either sex)
Sample 2: Random sample of residents deceased between 1 July 2010 and 31 December 2010 (adults of either sex)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Key exclusion criteria
Residents who moved in during the last three months before data collection

Date of first enrolment
01/04/2011

Date of final enrolment
31/05/2011

Locations

Countries of recruitment
Germany

Study participating centre
Abteilung für Allgemeinmedizin
Düsseldorf
Germany
40225

Sponsor information

Organisation
German National Ministry of Education and Research (German)

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration