Trial Description

Title

Advance directives as an example for shared decision making in the General Practitioner practice

Trial Acronym

PPP

URL of the trial

http://www.freiburger-patientenverfuegung.de

Brief Summary in Lay Language

In Germany, an increasing number of people want to take preemptive measures concerning end-of-life decisions including, among others, preparing advance directives. An advance directive helps to determine the patient`s health care wishes at a time when he is no longer capable due to illness. The present study, which is funded by the German Federal Ministry of Education and Research (BMBF) is supposed to examine and improve the consultation about the completion of advance directives.

Brief Summary in Scientific Language

Advance directives enable people to make medical decisions in case of future incoherence and as such constitute an important instrument for maintaining the patient`s autonomy. According to surveys, there are already 8 million completed advance directives in Germany. On September 1st, 2009, the first legal regulation regarding advance directives came into effect in Germany. Due to the implementation of said regulation and the complexity of the subject matter there is considerable public demand for further information. The goal of the present randomized controlled trial is to promote the patients` participation in medical decision making with regard to advance directives. This is to be achieved by training general practitioners in the field of shared decision making (SDM). SDM is a process of interaction between patient and doctor, which is aimed at reaching a mutually acceptable agreement based on shared information. Because of their experience in attending to chronically ill patients and their individual beliefs, expectations and concerns, general practitioners are specifically qualified to give advice on end-of-life decisions. The process is evaluated using three main factors:. "participation in medical decision making", "decisional conflicts" and "satisfaction with decision". They are measured using validated measuring instruments.

Organizational Data

- DRKS-ID: **DRKS00000191**
- Date of Registration in DRKS: **2009/10/30**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **22/08 , Ethik-Kommission der Albert-Ludwig-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1111-9476**

Health condition or Problem studied

- Free text: **Consultation for Advance Directive**

Interventions/Observational Groups

- Arm 1: **Consultation for completing an Advance Directive after training of General Practitioners in Shared Decision Making**
- Arm 2: **Control group, treatment as usual**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Single blind**
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Patient participation in medical decision making in context of completing Advance Directives.
Instrument: Shared Decision-Making Questionnaire
Measurement point: after consultation
Outcome measure: total score || Decisional conflicts in medical decision making
Instrument: Decisional Conflict Scale (DCS)
Measurement point: after consultation
Outcome measure: total score

Secondary Outcome

Patient satisfaction with a decision
Instrument: Satisfaction with Decision Scale
Measurement point: after consultation
Outcome measure: total score

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/11/01**
- Target Sample Size: **600**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Competent patients, sufficient knowledge of the German language.

Exclusion criteria

Incompetent patients, insufficient knowledge of the German language.

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  Bundesministerium für Bildung und Forschung

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Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*