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Informed decision-making with and for people with dementia – evaluation of an education program for legal representatives

Submission date
31/05/2017

Recruitment status
No longer recruiting

Registration date
01/06/2017

Overall study status
Completed

Last Edited
19/07/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
In Germany, the guardianship system provides adults who are no longer able to handle their own affairs a court-appointed legal representative. These representatives only rarely are qualified in healthcare; they nevertheless play decisive roles in the decision-making processes for people with dementia. An education program (PRODECIDE) was developed to improve the qualification of legal representatives in healthcare decision-making. The subject areas covered were typical autonomy-restricting decisions in the care of people with dementia - namely, using gastric feeding tubes, physical restraints, and antipsychotic drugs. The aim of this study is to find out whether participation in the PRODECIDE program results in better understanding of decision-making processes in healthcare affairs, and in setting realistic expectations about the benefits and harms of gastric feeding tubes, physical restraints, and antipsychotic drugs in people with dementia.

Who can participate?
Legal representatives in Germany, both professional and volunteer, who represent at least one person with dementia

What does the study involve?
Legal representatives are randomly allocated to the intervention group or to the control group. The intervention group attends a ten-hour education program over two days about the decision-making process and the harms and benefits of the use of gastric feeding tubes, physical restraints, and antipsychotic drugs in people with dementia. The control groups receive standard care (no intervention). To assess their understanding and expectations, both groups complete a questionnaire at the start of the study, up to 2 weeks later and at 6-months follow-up. At the 3-month and 6-month follow-up, participants are contacted by phone to ask if they have made a decision regarding gastric feeding tubes, physical restraints, and antipsychotic drugs. If they have made a decision, they are either reminded to fill out and return the documentation or are directly interviewed by phone to fill out the sheet.

What are the possible benefits and risks of participating?
The results of this study will show whether participation in the PRODECIDE program results in better understanding of decision-making processes in healthcare affairs and in setting realistic expectations about benefits and harms of gastric feeding tubes, physical restraints, and antipsychotic drugs in people with dementia. Understanding the decision-making processes and setting realistic expectations are prerequisites for informed decision-making. Informed and evidence-based decisions may improve the quality of care of people with dementia and reduce both the overuse and the misuse of autonomy-restricting interventions. No negative effects for the participants are expected.

Where is the study run from?
University of Hamburg (Germany)

When is the study starting and how long is it expected to run for?
July 2017 to December 2018

Who is funding the study?
Deutsche Forschungsgemeinschaft (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2017.1

Study information

Scientific Title
Informed decision-making with and for people with dementia – efficacy of the PRODECIDE education program for legal representatives in a randomized controlled trial

Acronym
PRODECIDE-RCT

Study objectives
Legal representatives who take part in the PRODECIDE education program will achieve a better understanding of decision-making processes and higher levels of realistic expectations regarding probabilities of benefits and harms of percutaneous endoscopic gastrostomy, physical restraints and antipsychotics to people with dementia compared to legal representatives obtaining standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the German Society of Nursing Science (Deutsche Gesellschaft für Pflegewissenschaft), 01/10/2015, ref: 15-010

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Proxy decision-making for people with dementia

Interventions
The PRODECIDE-RCT is a randomized controlled superiority trial with two parallel groups, a 1:1 randomization and a six-month follow-up. Legal representatives will be allocated to the

intervention group or to the control group, stratified by professionals and volunteers. To ensure a close balance of entities in each group, randomization will be performed by randomly selected block sizes of four and six.

The intervention comprises a ten-hour education program of four modules that is given over two days. Module A addresses the decision-making process and introduces the assessment of harms and benefits. The modules B, C and D transmit evidence-based knowledge about percutaneous endoscopic gastrostomy, physical restraints and antipsychotics in people with dementia. As no equivalent intervention is available, the control group will receive standard care.

To assess understanding and realistic expectations, a novel questionnaire was developed. The questionnaire comprises 13 multiple choice questions, each with four choices and only one correct answer.

Participants receive a documentation sheet for each intervention at the beginning of follow-up to assess the starting point of the decision-making process, presence of the intervention before and after the decision, reason or trigger for decision-making and changes regarding the intervention. Participants will be contacted by phone to ask if they had made a decision regarding percutaneous endoscopic gastrostomy, physical restraints and antipsychotics. If they had made a decision, they will either be reminded to fill out and return the documentation or directly interviewed by telephone to fill out the sheet. The first decision of each intervention will be recorded.

Intervention Type
Other

Primary outcome measure
Knowledge (understanding of decision-making processes in healthcare affairs and realistic expectations regarding probabilities of benefits and harms of percutaneous endoscopic gastrostomy, physical restraints and antipsychotics to people with dementia), assessed using a novel questionnaire at T1 (up to 2 weeks after intervention)

Secondary outcome measures
1. Sufficient knowledge, measured with the same knowledge test as the primary outcome using a cut-off of 70% correct answers, at T1 (up to 2 weeks after intervention)
2. Sustainable knowledge, assessed with the same knowledge test at T3 (6-month follow-up)
3. The use of percutaneous endoscopic gastrostomies, physical restraints and antipsychotics, using data extracted from routine documentation and standardized documentation sheets at baseline and T3 (6-month follow-up)
4. Result of the first decision after intervention regarding percutaneous endoscopic gastrostomy, physical restraints and antipsychotics, assessed using documentation sheets and telephone interviews at T2 (3-month follow-up) and T3 (6-month follow-up)

Overall study start date
01/07/2017

Completion date
31/01/2020

Eligibility

Key inclusion criteria
1. Legal representatives in Germany, both professional and volunteer
2. Represent at least one person with dementia (assessed by the legal representative and/or medical diagnosis)

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
216

Key exclusion criteria
Participation in the PRODECIDE education program (either the whole program or a single module)

Date of first enrolment
01/07/2017

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
Germany

Study participating centre
University of Hamburg
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Sponsor information

Organisation
Deutsche Forschungsgemeinschaft

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Sponsor type
Research organisation

Website
http://www.dfg.de/en/dfg_profile/index.html

ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
All results of the study (including negative ones) will be published in international and open-access journals and presented at meetings and congresses. All participants will receive an abbreviated version of the final report written for laypersons.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
After study completion, adjusted data will be stored and made publicly accessible via a specialized database. Data will be published and maintained in the “datorium,” a service of the GESIS – Leibniz- Institute for the Social Sciences [http://www.gesis.org/en/services/archiving-and-registering/]. Participants will be informed that data will be published, but that this does not allow the identification of information concerning the individual person.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/09/2017	06/01/2021	Yes	No
Results article		09/05/2024	19/07/2024	Yes	No