

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

<b>Submission date</b> 31/05/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/06/2017	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 19/07/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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?

Ms Julia Lühnen

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## Contact information

**Type(s)**

Scientific

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## Additional identifiers

**Protocol serial number**

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

## **Study type(s)**

Other

## **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(s)**

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)

### **Key secondary outcome(s)**

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)

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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**

Unit of Health Sciences and Education, MIN-Faculty

Martin-Luther-King Platz 6

Hamburg

Germany

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## **Sponsor information**

**Organisation**

Deutsche Forschungsgemeinschaft

**ROR**

<https://ror.org/018mejw64>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Deutsche Forschungsgemeinschaft

**Alternative Name(s)**

German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

Germany

# Results and Publications

## 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

### Study outputs

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