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# Advance research directives for dementia research

## What do affected people think? A German interview study

**Julia Perry, M.A. & Dr. Karin Jongsma**

Dept. of Medical Ethics and History of Medicine
University Medical Center Göttingen

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# Background

- Research with persons with dementia
  - Important to better understand causes of dementia and to develop more effective diagnostics, therapies, and risk reducing measures
  - Difficulties due to cognitive decline in the course of dementia and potential lack of (full) capacity
  - International legal standard including consent of legal representative has flaws (Kim et al. 2013; Wendler 2011; Livingston 2010)
- Advance research directives (ARDs) can give competent individuals opportunity to express preferences for research participation for later stage of incapacity (Andorno et al. 2016; Jongsma & van de Vathorst 2015)
  - Despite regulated use in some countries, uptake remains considerably low (Ries et al. 2020; Bravo 2016; Muthappan 2005)

# German (legal) context and need for empirical study

- Nov. 2016: Changes to the German Medicinal Products Act (MPA)
  - Research with “group benefit”
  - Condition: Drafting of ARD
- Little knowledge about perspectives of those affected
- Our study: Focus on how people with subjective or mild cognitive impairment assess the introduction of ARDs

# Methods

- Semi-structured interviews: 24 persons with cognitive impairment (SCI/MCI)
  (1) How do you assess the introduction of ARDs?
  (2) Should anyone besides you be involved in drafting an ARD?
  (3) What is a good time to draft an ARD?
  (4) What would assist you in drafting an ARD?

- Participants:
  – aged between 45 and 85 years
  – even distribution of gender
- Interviews lasted between 16 and 80 minutes; ⌀42 minutes
- Thematic content analysis assisted by the scientific software Atlas.ti™

# Results:
## a) General Attitudes

- Positive attitudes towards ARDs
  - Instrument for making own decisions regarding consenting to or vetoing research participation
  - Importance of helping others by participating in research / value of scientific research
- Negative or ambivalent attitudes due to difficulty of making anticipated decisions

# Results:

## b) Necessary Conditions

### Who should be involved?

- Ability to fill out ARD own their own
- Desire to discuss with a clinician
- Researchers conducting specific research
- Children/partners

### When is a good time?

- When one is still healthy
- Shortly after receiving diagnosis / at time of diagnosis
- Necessity to make information more widely available

### What preconditions should be fulfilled by health providers?

- Trust building / no conflict of interest
- Sufficient time and medical expertise
- Combination of template and safeguarding through representative

# Results:
## c) Remaining Worries

- Fear of not being able to withdraw from research
- Fear of abuse in research or of insufficient protection through ARDs
- Concern whether physicians and other staff will be trained sufficiently to deal with ARDs

# Practical recommendations

- Need for expertise and training of treating physicians concerning dementia research
- Need for time to talk about anticipated course of the disease and its implications
- Need for development of standardized template with space for individualized wishes and adaptations
- Need for additional safeguards to be in place
- Need for spread of information on ARDs and provision of practical support
- Need for studies testing motivational approaches taking cultural differences into account

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# Thank you!

Contact:
julia.perry@medizin.uni-goettingen.de




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# Participant demographics

| Characteristic | No. |
|---|---|
| Gender | |
| *Male* | 11 |
| *Female* | 13 |
| *Prefer not to say* | 0 |
| Age in years | |
| <60 | 10 |
| *60-74* | 9 |
| *>74* | 5 |
| Educational level | |
| *High school/practical education* | 18 |
| *College* | 2 |
| *Postgraduate education* | 4 |
| Diagnosis | |
| *MCI* | 8 |
| *SCI* | 11 |
| *Prefer not to share/not sure* | 5 |