# Cross-cultural acceptability of interventions that may increase control at the end of life in people with dementia

No registrations found.

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|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON26073

**Source**
Nationaal Trial Register

**Brief title**
CONT-END WP1

**Health condition**

Dementia

### Sponsors and support

**Primary sponsor:** Leiden University Medical Center, Leiden, The Netherlands
**Source(s) of monetary or material Support:** European Research Council (ERC), personal grant awarded to Jenny van der Steen, PhD (grant agreement number 771483).

### Intervention

### Outcome measures

#### Primary outcome

The main outcome is whether the participants want the interventions at the end of life (people with dementia for themselves, family caregivers for their loved one, and whether

physicians would use it at request). Do not know will be a valid response option.

### Secondary outcome

Differences in acceptability between types of interventions, group (role), countries will be investigated, and also, in an explorative manner, associations with other characteristics. Open-ended questions in the interviews will be used to examine, in a qualitative manner, possible ambiguity regarding being in control through the interventions, and as to why and in what situation the respondent feels the interventions are acceptable.

## Study description

### Background summary

Care for people with dementia is one of public health top priorities. Interventions should meet the needs of people with dementia and their caregivers across the course of the illness. In dementia at the end of life, cognitive and physical decline imply that control is typically lost. This work package is a part of the CONT-END project and will examine control in the context of three types of emerging interventions which contain a potentially controversial element of striving for control in the process of dying with dementia. In this work package we focus on acceptability of interventions in the context of end of life with dementia.

The interventions under study are two forms of advance care planning: (1a) detailed advance treatment orders versus (1b) goal setting and coping based advance care planning; (2) technology for symptom monitoring when unable to self-report; and (3) euthanasia. The main goal is to examine if and when people with dementia, their family caregivers, and physicians, find the interventions, explained with video vignettes, acceptable for people with dementia. Acceptability and factors associated with acceptability will be studied in six countries: the Netherlands, Germany, Switzerland, Israel, Japan and the United States.

A total sample size of 900 participants is needed to assess associations of outcome with country and respondent type in case of an unfavorable outcome distribution (if only 10% find an intervention (un)acceptable). The total number is achieved with 300 people with dementia participating, 300 family caregivers, and 300 physicians; 150 participants from each of the six countries, 50 per study group.

### Study objective

We purposefully selected four interventions, three groups with different roles and six countries because we expect acceptability to differ within these dimensions. There are specific hypotheses (H) for part of the possible contrasts. We will explore other contrasts, and also which demographics, variables indicating life view such as religion, and variables indicating personality are associated with acceptability of the interventions. In particular, we test the following hypotheses:

A. Types of interventions
H1. The two forms of advance care planning (which offer limited control over future care and treatment) will be most often acceptable among the four interventions under study.
H2. Euthanasia (which strongly controls the end-of-life timing and context) will be least often acceptable among the interventions under study.

B. Types of interventions by groups with different roles with respect to the person with dementia (respondent type)
H3. The advance care planning intervention with detailed advance treatment orders (1a) will be most often acceptable in physicians.
H4. Euthanasia will be least often acceptable in physicians.
We do not propose hypotheses on acceptability rated by people with dementia compared to the other groups because not enough is known about their views on this matter to formulate specific hypotheses.

C. Types of interventions by country
H5. The advance care planning intervention with detailed advance treatment orders (1a) will be most often acceptable in countries where patients have high autonomy in decision making about medical procedures and care, and where people may feel they need a defense against medical overtreatment, while sanctity of life is not necessarily a dominant principle, in particular, the USA.
H6. Technology for symptom monitoring when unable to self-report such as use of cameras in the dying phase will be most often acceptable in technology-minded countries (Japan, Israel, and the USA).
H7. Euthanasia will be most often acceptable in countries that have euthanasia or physician assisted suicide regulation already in place for a while (in particular the Netherlands and Switzerland) and the least acceptable in countries where ending life is highly controversial (Germany, Israel and Japan).

D. Types of intervention by other characteristics
H8. Demographics, variables indicating life view such as religion, attitudes regarding life-prolonging treatment and death and dying, and variables indicating personality such as coping strategy are associated with acceptability of the interventions that differ in the extent to which they increase control over the end of life of people with dementia.

**Study design**

The study consists of a one-time assessment. Data will be collected per participating country, starting with the Netherlands.

**Intervention**

Not applicable.

# Contacts

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# Eligibility criteria

## Inclusion criteria

The person with dementia:
• has a diagnosis of irreversible dementia established by a physician
• has been informed about and is aware of his or her diagnosis
• has a family caregiver (spouse, friend, partner, daughter/son, etc.) who is willing to participate in the study
• has decision making capacity and is able to communicate through sufficient memory and language
• has sufficient capacity of the local or English language to participate in the interview
• is able to understand and sign the consent form
• has adequate vision and hearing (can be achieved by using corrective lenses and hearing aid if required)
• consents to participate.

The family caregiver:
• is willing and able to participate in the study
• the person with dementia they care for is willing and able to participate
• is at least 18 years old
• has sufficient capacity of the local or English language to participate in the interview
• consents to participate.

The physician:
• practices a specialty that includes provision of end-of-life care for individuals living with dementia (depending on the country, the specialty could be primary care physicians such as general practitioners and elderly care physicians, geriatricians, geriatric psychiatrist, neurologists)
• is willing and able to participate in the study

• consents to participate.

### Exclusion criteria

• The person with dementia is currently affected by a severe psychiatric disorder (e.g., major depression, schizophrenia, substance abuse, PTSD) as diagnosed by a psychiatrist, psychologist, or physician.
• The person is expected to die in a few weeks.

## Study design

### Design

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-01-2020 |
| Enrollment: | 900 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** No

**Plan description**
Not applicable

## Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL7985 |
| Other | None yet : Not yet available |

# Study results