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

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To examine the cross-cultural acceptability of four interventions in dementia care that typically aim to increase control over the end of life among people with dementia, and family and professional caregivers. Differences in acceptability between...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Observational non invasive

Summary

ID

NL-OMON54818

Source
ToetsingOnline

Brief title
CONT-END WP1

Condition

- Structural brain disorders

Synonym
Dementia, major neurocognitive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: ERC persoonlijke beurs toegewezen aan dr. J.T. van der Steen (grant-number: 771483)

Intervention

Keyword: Advance care planning, Dementia, End-of-life care, Euthanasia

Outcome measures

Primary outcome

The primary outcome is acceptability (i.e., whether the participants would want the interventions at the end of life; patients 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

Dementia is one of the public health top-priorities. The illness has a great impact on both the people who have it and their caregivers. Interventions that meet needs of people with dementia and their caregivers are needed. In dementia at the end of life, cognitive and physical decline imply that control is typically lost. This study will examine the acceptability of four end-of-life interventions in dementia which contain an element of striving for control. We purposefully selected four interventions (i.e., two types of advance care

planning, use of technology, and euthanasia), three groups with different roles and six countries, because we expect acceptability to differ within these dimensions. We will explore if and which demographic and personality characteristics, and variables indicating life view are associated with acceptability of the interventions.

Study objective

To examine the cross-cultural acceptability of four interventions in dementia care that typically aim to increase control over the end of life among people with dementia, and family and professional caregivers. Differences in acceptability between types of interventions, group (role), and countries will be investigated. We will explore as to why and in what situation participants feel the interventions are acceptable. Exploratory analyses will test associations with demographic and personality characteristics and life view.

Study design

Mixed-methods study design comprising a single measurement where participants will be interviewed (open-ended questions for qualitative data) and complete a questionnaire (quantitative data). The analysis of qualitative data and quantitative data will be integrated.

Study burden and risks

Participation entails a one-hour-assessment. There is a minimal risk of participants becoming upset by the sensitive nature of the questions and fatigue due to the assessment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

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 Dutch 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 Dutch 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
• 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

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2020
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	10-04-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	23-10-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	22-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	14-04-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL72354.058.19
Other	NL7985