Approaches to advance care planning for persons with dementia and their family caregivers: a cluster-randomized controlled trial.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON56370

Source
ToetsingOnline

Brief title
CONT-END WP2

Condition

- Dementia and amnestic conditions

Synonym
Dementia

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: European Research Council

Intervention

Keyword: Advance care planning, Dementia, General practitioners, Wellbeing

Outcome measures

Primary outcome

The primary outcome is wellbeing of persons with dementia measured by Quality of Life in Late-Stage Dementia scale (QUALID).

Secondary outcome

The secondary outcomes are decisional conflict, self-efficacy to interact with physicians, and family caregiver perception of physician-family caregiver communication.

Study description

Background summary

In primary care practice, preferences for future care are often not discussed with persons with dementia. There is no evidence-based standard for general practitioners (GPs) to guide advance care planning (ACP) with persons with dementia. Research has indicated some beneficial effects in persons with dementia. ACP facilitates decision making and may increase control over care and treatment at the end of life. Since it is advised to start ACP early in case of dementia, GPs are well positioned to initiate ACP. There are different approaches to ACP, and up until now, there is lack of research on the effect of different ACP approaches and in subgroups.

Study objective

We aim to assess the effects of two approaches of ACP (detailed advance treatment orders versus global goal setting and coping based) on wellbeing of persons with dementia. In addition, we will assess effects on decisional conflict, self-efficacy to interact with physicians, and the perception of family caregivers on physician-family communication. We aim to determine if these effects differ by the readiness of the person with dementia or family

caregiver to engage in the particular ACP intervention. We will also explore whether these effects differ among subgroups. In addition, we will explore associations of various variables (e.g. gender, religion, coping strategies etc.) with the readiness of the person with dementia and the family caregiver to engage in the particular ACP intervention.

Study design

Cluster-randomized trial with separate control group of participants not clustered with practices.

Intervention

Both interventions include multiple interactive training sessions, forms to document results of ACP, and prompting of persons with dementia and their family caregiver by providing a question prompt list on palliative care in dementia. The contents of the training and forms match the focus of the respective intervention.

Study burden and risks

For GPs, there is no risk in study participation as there is no harm to the relationship, being responsible for applying the interventions in a person-centred manner. The burden for GPs is considerable, mainly due to advance care planning consultations which, for most GPs, will be consultations additional to usual care. The burden for the GPs consists of approaching persons with dementia and family caregivers from their practice for study inclusion and responding to some research-related questions later on. The main burden for the GPs randomized to one of the two intervention groups is that they will attend two training sessions, and are requested to conduct ACP. While the burden is increased for the GPs, we are introducing good research practice on ACP with dementia, which is currently not given much attention to in regular care. To all GPs, we lower the burden by selecting eligible persons with dementia from their GP practice and by giving complete and ready-to-send packages to the GP practice which they can send to the interested persons with dementia. We will also request accreditation points for the training.

For persons with dementia and family caregivers the risk is minimal. The burden consists of completing the questionnaires and an interview, and for persons with dementia and family caregivers in the intervention groups, attending one or more ACP consultations with the GP (which they may refuse).

This study on ACP for persons with dementia is of importance as this will result in more knowledge about different approaches to ACP in dementia. A better understanding is possible through inclusion of persons with dementia only. Persons with dementia allocated to the intervention groups may benefit as

there will be more opportunities during ACP consultations where they could express their preferences, possibly resulting into increased wellbeing.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for persons with dementia:
• diagnosis of irreversible dementia established by a physician;
• decisional capacity and the person can be interviewed (adequate memory, speech and language, and ability to make decisions);
• living at home;
• sufficient capacity of the Dutch language;
• adequate vision and hearing (can be achieved by using corrective lenses or hearing aid);

• the family caregiver is also willing to participate in the study.

Inclusion criteria for family caregivers of persons with dementia:
• at least 18 years old;
• sufficient capacity of the Dutch language;
• decisional capacity;
• adequate vision and hearing (can be achieved by using corrective lenses or hearing aid);
• the person with dementia is also willing to participate in the study.

Inclusion criteria for participating GPs:
• GPs who are willing to contact persons with dementia and their family caregivers from their practice in the Netherlands for study participation and who are willing to complete training and study requirements to conduct ACP conversations with persons with dementia and their family caregivers if randomized to an intervention group.

Exclusion criteria

Exclusion criteria for persons with dementia:
• currently affected by a severe psychiatric disorder (e.g., major depression, schizophrenia, substance abuse, PTSD) as diagnosed by a psychiatrist, psychologist, or physician;
• a life expectancy of less than four weeks;
• severe aphasia or another language disorder.

Exclusion criteria for family caregivers of persons with dementia:
• currently affected by a severe psychiatric disorder (e.g. major depression, schizophrenia, substance abuse, PTSD) as diagnosed by a psychiatrist, psychologist, or physician if known to the GP of the person with dementia;
• a life expectancy of less than four weeks if known to the GP of the person with dementia;
• severe aphasia or another language disorder if known to the GP of the person with dementia.

Exclusion criteria for GPs:
• GPs with no persons with dementia in their practice;
• GPs who plan to resign within one year.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-11-2020
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	29-10-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	04-02-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	08-09-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	26-01-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	08-06-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	09-09-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	29-09-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	28-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	08-12-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	31-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-09-2023
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	NL71865.058.20
Other	NL9009