Effects of different advance care planning approaches in dementia

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27353

Bron
Nationaal Trial Register

Verkorte titel
CONT-END WP2

Aandoening

Dementia

Ondersteuning

Primaire sponsor: Leiden University Medical Center, Leiden, the Netherlands
Overige ondersteuning: European Research Council (ERC), personal grant award to Jenny van der Steen, PhD (grant agreement number 771483)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is wellbeing of persons with dementia measured by the Quality of Life

in Late-Stage Dementia scale (QUALID) with observable indicators of wellbeing.

Toelichting onderzoek

Achtergrond van het onderzoek

In dementia, inevitable cognitive and physical decline imply that control is typically lost. Advance care planning (ACP) may increase control over care and treatment at the end of life. Since it is advised to start ACP early in case of dementia, general practitioners are well positioned to initiate ACP. However, ACP is often not implemented in general practice, and it is unknown what the effective or ineffective elements of or approach to ACP are for persons with dementia and their family caregivers.

There are different approaches to ACP. In this study we aim to assess the effects of two approaches to ACP in dementia. One approach focuses on (medical) advance treatment orders in detail; and the other approach focuses on assessing preferences and global aims to guide future care, acceptance, and coping with the disease. In a cluster-randomized controlled trial with both explanatory and pragmatic elements, we examine effects of these two approaches compared with usual care on the wellbeing of people with dementia. We also assess effects on decisional conflict, self-efficacy to interact with physicians, and family caregiver perception of physician-family caregiver communication. In addition, we aim to determine if these effects are moderated by the readiness of the person with dementia or the family caregiver to engage in the particular ACP intervention.

We plan to recruit 45 general practitioners from different general practices who will include 279 persons with dementia and their family caregivers. Fifteen general practitioners will receive interactive training and supportive materials for physician, family and person with dementia for one approach, and 15 other general practitioners will receive a similarly structured training and supportive materials to apply the other approach. The practitioners randomized to the control condition will not receive training and provide usual care. General practitioners are invited to bring their practice nurse to the training and involve them in delivering the intervention. For the baseline assessment, the researchers will interview the persons with dementia. Their family caregivers will complete questionnaires at baseline and afterwards, semi-annually. The persons with dementia will thus be followed until death or as long as possible. After death, their family caregiver will be asked to participate in an interview. We will describe and explore effects on family caregiver’s decision regret regarding health care decisions at the end of life, family caregiver’s satisfaction with care (evaluation of quality of care) at the end of life and comfort in dying of the person with dementia.

Doel van het onderzoek

We hypothesize that ACP increases the wellbeing of persons with dementia somewhat, but that the effect is larger when the intervention matches the physician’s estimated readiness of

the person with dementia or family caregiver to engage in the particular ACP intervention.

We hypothesize that ACP decreases family caregiver's decisional conflict, increases self-efficacy to interact with physicians, and increases favorable family caregiver perception of physician-family caregiver communication. We also hypothesize that these effects are larger when the intervention matches the physician's estimated readiness of the family caregiver to engage in the particular ACP intervention.

We will explore whether demographics, dementia severity, family caregiver burden, symptoms of depression, personality (coping strategy, locus of control), life view (illness perception, death anxiety, religion), and ACP-related items (stage of change concerning ACP, and matching physician-person with dementia-family preferred approaches to ACP) are associated with the physician's estimated readiness of the person with dementia and the family caregiver for the particular ACP intervention. We will also explore if any of these factors moderates effects of the intervention.

Onderzoeksopzet

Baseline assessment pre-intervention and follow-up assessments semi-annually.

Onderzoeksproduct en/of interventie

Intervention type 1 focuses on setting (medical) advance treatment orders in detail with persons with dementia and their family caregivers during the process of ACP.

Intervention type 2 focuses on assessing preferences and global aims to guide future care, acceptance, and coping with the disease with persons with dementia and their family caregivers during the process of ACP.

Both interventions include multiple interactive training sessions for general practitioners and, if preferred, also their practice nurse; forms to document results of ACP conversations; and prompting of persons with dementia and their family caregiver by providing a question prompt list to consider personal questions for the GP on a future with dementia. The contents of training, form and question prompt list match the focus of the respective intervention.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

We aim to include 45 general practitioners from different practices. Each general practitioner is invited to bring a practice nurse to receive the training and participate in delivering the intervention. The targeted total sample size is 279 persons with dementia and their family caregivers.

Inclusion criteria for 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.

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2020
Aantal proefpersonen:	279
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
The data management plan considers restricted access. Any data sharing requests to the PI

and Academic center regarding deidentified data will be considered after the study has concluded, within the constraints of the informed consent, and after publication of the main study results.

Ethische beoordeling

Positief advies

Datum:	31-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9009
Ander register	METC Leiden Den Haag Delft : CCMO reference NL71865.058.20; METC Leiden Den Haag Delft reference P20.064

Resultaten