

Early Diagnosis Dyadic Intervention'(EDDI), an intervention for community-dwelling people with dementia and their caregivers: a pilot study

Published: 22-05-2013

Last updated: 26-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39750

Source

ToetsingOnline

Brief title

EDDI

Condition

- Other condition
- Dementia and amnestic conditions

Synonym

communication skills, mood

Health condition

affect, stress en self-efficacy

Research involving

Human

Sponsors and support

Primary sponsor: Trimbos-instituut

Source(s) of monetary or material Support: Innovatiefonds

Zorgverzekeraars;LVCrementoria;RCOAK;Fonds Nuts Ohra

Intervention

Keyword: - caregivers, - casemanagers, - people with dementia, - preventive intervention

Outcome measures

Primary outcome

Effect evaluation:

person with dementia: affect, stress, self-esteem

caregiver: depressive complaints, stress, self-efficacy

dyadic communication

Proces evaluation:

- appreciation of the intervention by persons with dementia and their caregivers
- appreciation of the intervention by case managers
- fit of the intervention to the needs of the participants
- feasibility of the intervention
- extent to which casemanagers are equipped to apply the intervention

Secondary outcome

Quality of life of person with dementia

Study description

Background summary

Autonomy and involvement of people with dementia in making decisions about appropriate care is very important to ensure the quality of life of people with dementia (Menne & Whitlatch, 2007). Nevertheless, the care needs of people with dementia are still unknown, although communicating about the opportunities and choices and making decisions are often still possible during the initial phase of the disease process (Clark et al, 2008). Moreover the caregivers do not always know the preferences of the person with dementia regarding the care they would like to receive now and in the future. Meanwhile research shows that people with dementia have strong preferences regarding the care they would like to receive (Hamann et al, 2011).

Both people with dementia and their caregivers report less health problems and a higher quality of life when are involved in the care program as a pair (Smits et al, 2007). There is much evidence that caregivers can develop many psychological problems. For example, approximately 25 % has a major depression, but also anxiety disorders are common (Pot, 2007). Moreover, greater involvement of 'pairs' frequently leads to postponement of admission (Smits et al, 2007). At the moment, the Netherlands is lacking of evidence-based preventive interventions in the early stages of dementia which can be given in pairs, and is also focused on the person with dementia and the caregiver and the relationship between them.

In this project, a Dutch version of an American 'Early Diagnosis Dyadic Intervention ' (EDDI) will be developed, assessed and implemented. This intervention is aimed at increasing the quality of life of the pair, improvement of affect and self-efficacy and decrease of the stress. The intervention is designed to improve communication between the person with dementia and their caregivers by changing their perception about the disease and its consequences. An important goal is to prepare the pair for the future that lies ahead of them, especially when the person with dementia is no longer able to express his or her needs.

Study objective

Objective of the project is to the American EDDI translate and adapt to the Dutch situation. Then, in a pilot study there will be examined whether the intervention is applicable to people with dementia and their caregiver, and if so, under what conditions they should be offered. It also examined whether the intervention is feasible for casemanagers. If the intervention is feasible and there is evidence that the intervention has an impact, an RCT will be performed.

Study design

The pilot study consists of two parts:

1. Translate and adapt the EDDI intervention so it is suitable for the Dutch situation. After the pilot study, the results are used to further adjust the intervention.
2. A pilot study to investigate the feasibility and effects of the intervention (process and effect evaluation).

Questions in the evaluation study:

1. How do participants value the intervention? (process evaluation)
- 2 Does de intervention fit the needs of the participants? (process evaluation)
3. How do case managers value the intervention? (process evaluation)
- 4 What is the feasibility of the intervention (process evaluation)
- 5 Were the case managers equipped to apply the intervenion?
6. What is the impact of the intervention on affect, self-esteem and stress in people with dementia and on depressive complaints, self-efficay and stress on their caregivers? (effect evaluation)
- 7 What is the impact of the intervention on the communication between the person with dementia and the caregiver?

This pilot study follows a one group pretest-posttest design. A process evaluation is conducted under casemanagers and participants. Case managers will fill in an evaluation form each session. Ten participants (combination person with dementia and his / her caregiver) will be having an interview in which the experience with the intervention will be discussed.

Intervention

The main objective of the Dutch intervention is to anticipate future problems. It is intended that the person with dementia and the caregiver learn to communicate about the future, their health and how they can ask assistance from family, friends and professional caregivers. These subjects will be discussed at an early stage of the dementia, so that the values **and preferences for both the person with dementia and the caregiver can be taken into account.

The modified version of Early Diagnosis Dyadic Intervention '(EDDI) consists of four sessions. The intervention consists of psycho-education (focused on the knowledge of dementia and its effects), communication about the risks (for the relationship, the caregiver and the person with dementia), communication between the person with dementia and the caregiver and education aimed at a positive attitude towards calling in assistance in the future.

The intervention consists of 4 sessions. The first session lasts about 90 minutes, the next three sessions about 60 minutes. The sessions are offered once every two weeks, but this can be less/more frequent, depening on the clients's wishes. Each session has a theme:

1. Dementia and communication

2. Values **and preferences regarding care
3. Care for yourself and for each other
4. Help from others

During the sessions, the person with dementia and the caregiver independently make a short assignment. These assignments will be discussed with each other and with the case manager.

Study burden and risks

In order to follow the adjusted EDDI, a time investment of 1x1,5 hours and 3x1 hour (total 4.5 hours) during 4-8 weeks is required. The interviews will take up to one hour. Eight couples will get an additional interview to review the process. This interview will also take up to an hour.

We expect that the intervention will improve the wellbeing of the participants and the risk of getting (mental) damage by participating in the study or the intervention is very small (see risk analysis research protocol, p 18-20).

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

- The caregiver is responsible for the person with dementia, is well aware of the life of the person with dementia and is able to notice changes in this person.
- The caregiver and person with dementia do not live far away from each other and they have a close relationship, the caregiver provides care at least an hour a day.
- The diagnosis dementia has been established (all types except frontotemporal dementia)
- * The score on the MMSE is equal to, or greater than 18
- The client couple has some insight into the disease and is willing to talk about dementia and its consequences
- The client is open to psychosocial counseling
- The client pair has a firm grasp of the Dutch language
- The client has or will have a casemanager

Exclusion criteria

- The caregiver receives treatment for depression or anxiety, the nurse of the Alzheimer center will judge if this is the case
- The person with dementia has Frontotemporal Dementia

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	09-10-2013
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO	
Date:	22-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL42239.041.12