

Online Life Story Book: A study on its effect for people with early dementia and their caregivers

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

Summary

ID

NL-OMON43313

Source

ToetsingOnline

Brief title

Online Life Story Book

Condition

- Other condition

Synonym

neuropsychiatric symptoms in early dementia

Health condition

neuropsychiatrische symptomen

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: ZonMW-Memorabel, Alzheimer Nederland;PGGM

Intervention

Keyword: early dementia, e-health, informal caregivers

Outcome measures

Primary outcome

The main study parameters are Neuropsychiatric symptoms (NPS) at follow-up (i.e., six months after the first measurement). NPS are measured with the NeuroPsychiatric Inventory (NPI).

Secondary outcome

- 1) The burden and quality of life of the informal caregiver are assessed with the EDIZ, the emotional burden scale of the NPI, and the CarerQol.
- 2) The health economic evaluation will be carried out based on the reported care consumption and quality of life (EQ5D) of the person with dementia.
- 3) The longer term effect on (time to) nursing home admittance will be carried out in month 18 together with the general practitioner).
- 4) The experiences with the intervention will be assessed with interviews with 28 stakeholders (persons with dementia, informal caregivers, volunteers, and professionals) and the use and complexity of the life story book will be assessed through a content analysis of 20 life story books.

Study description

Background summary

At present, about 260.000 people with dementia live in the Netherlands. This number will double over the coming twenty years. Dementia has a high burden for patients, informal caregivers and society. About two thirds of persons with dementia is estimated to live at home, but this number will increase given changes in long-term care. However, living at home with a good quality of life is not easy to achieve. Dementia is often accompanied by neuropsychiatric symptoms like apathy, agitation, hallucinations, depression, and anxiety. This is also related to the quality of life of the patient. Whereas the cognitive deterioration can hardly be influenced, it is possible to reduce neuropsychiatric symptoms. A good fit with the personal world of the person with dementia is an important condition for interventions. Reminiscence interventions can contribute as the recollection of valuable personal memories can give feelings of pleasure and trust. Memories are part of the autobiographical memory system that remains in tact for a relatively long time in dementia. The Online Life Story Book (OLSB) is an intervention that nicely ties in with these changes in care for persons with dementia. The current study therefore wants to assess the effectiveness of this intervention for people with early dementia and their informal caregivers.

Study objective

The primary objective of the study is to assess the effectiveness of the intervention *Online Life Story Book* on the primary outcome neuropsychiatric symptoms of persons with early dementia, in comparison to care as usual. The study has four secondary objectives: 1) to study the effectiveness of the intervention OLSB on the burden and quality of life of the primary informal caregiver; 2) to provide a first health economic evaluation by analysing the effects on the quality of life and care consumption of the person with early dementia; 3) to study the (time to) nursing home admittance as a longer term effect; 4) to evaluate the experiences of different stakeholders (patients, informal caregivers, volunteers, and professionals) as well as the use and complexity of the life story books.

Study design

A randomized controlled trial with individual randomization to one of two conditions is conducted: 1) the intervention condition: participants in the intervention *Online Life Story Book*; 2) the control condition: participants receive care as usual. Participants (persons with early dementia and their primary caregivers) fill out questionnaires at baseline, post-interventions (three months after baseline) and follow-up (six months after baseline).

Intervention

The Online Life Story Book is an e-health application that allows to place personal memories on a dynamic timeline. The timeline is easily marked with historical years. Memories like life events, anecdotes, photos, movies, voice fragments, music, recipes, preferences, and activities can be placed on the timeline. A trained volunteer assists the person with dementia and his or her informal caregiver in making the Online Life Story Book. The online version can be printed and both the online and printed version can be used to recollect personal memories.

Study burden and risks

The person with dementia and the informal caregiver fill out questionnaires at three moments in time (baseline, post-intervention, and follow-up) with a total time investment of 80 minutes for the person with dementia and 130 minutes for the informal caregiver. Participants are free to collaborate in the study. They may quit without reason and without consequences for the care they receive. The volunteer will visit the person with dementia and the informal caregiver five times for about one hour over the course of eight weeks. The informal caregiver will spend about one hour after each visit to collect materials that the volunteer will add to the Online Life Story Book. After the online life story book has been made the person with dementia and the informal caregiver are advised to spend one hour a week to recollect personal memories. Volunteers receive a training in which they gain insight into the personal world of dementia patients and their caregivers. They are also trained in communication skills and technical skills. They learn how to deal with negative memories and with privacy issues and to refer persons to their general practitioner when complaints worsen. There are no known negative effects of reminiscence. A possible side effect might be the recollection of negative memories. Therefore, persons with traumatic memories are excluded.

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:

- 1.Mild Cognitive Impairment or early dementia (Clinical Dementia Rating 0.5 or 1; Morris, 1993);
- 2.Living at home and receiving informal care;
- 3.Being mentally competent to provide informed consent

Exclusion criteria

Exclusion criterion is past psychotrauma (module posttraumatic stress disorder assessed with the Mini International Neuropsychiatric Interview)

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 29-06-2016
Enrollment: 106
Type: Actual

Ethics review

Approved WMO
Date: 28-04-2016
Application type: First submission
Review commission: METC Twente (Enschede)

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	NL56914.044.16