

Deal-iD Study: Dealing with daily challenges in Dementia.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24805

Source

Nationaal Trial Register

Brief title

Deal-iD

Health condition

Alzheimer's Disease / Ziekte van Alzheimer

Sponsors and support

Primary sponsor: Maastricht University

Source(s) of monetary or material Support: Alzheimer Nederland

Intervention

Outcome measures

Primary outcome

1. Feasibility of the PsyMate: assessed by examining objective measures of compliance with the PsyMate, as well as through subjective participants ratings of the difficulty, time burden, and overall acceptability of the methodology;
2. Validity of the PsyMate: Assessed by examining the presence of expected patterns among

variables assessed using the PsyMate, as well as by the concordance between ESM measurements and standard retrospective measurements of the same construct.

Secondary outcome

Reactivity effects of using the PsyMate: assessed by comparing the outcomes of the retrospective questionnaires filled out before and after the ESM data collection.

Study description

Background summary

Rationale and objectives:

A vast majority of the dementia patients is living at home and is cared for by their spouses. Spousal caregivers often provide years of extensive care for their partner and must adapt to a continuously changing and demanding situation. The prevalence of psychological and physical problems in caregivers increases rapidly in moderate to severe dementia. More than 80% of the caregivers are at risk of reaching their upper limits during the disease process. Ecologically valid information on how caregivers perceive and react on a daily basis to the challenges of dementia is lacking. Insight into daily caregiver perceptions, moods, and activities in the presence and absence of the dementia patient uncovers subtle and fine-drawn patterns of interaction between patient and caregiver in the flow of daily life. The Experience Sampling Methodology (ESM) is an innovative technique that is specifically appropriate for this kind of momentary assessment in daily life. To our knowledge, there is only one study that employed this methodology with spousal caregivers of dementia patients. Therefore, our primary objective is to evaluate the feasibility and validity of using the ESM, specifically the PsyMate, in this target population. A secondary objective is to examine potential reactivity effects of performing the ESM.

Study design and population:

The study involves a pilot study in which twenty spousal caregivers of community dwelling patients with dementia will be included.

Caregivers will be recruited in Mental Health Institutions and Memory Clinics in the southern regions of the Netherlands.

Intervention:

Participants will be asked to collect ESM data using the PsyMate over a 6-day period. The PsyMate will generate ten signals a day at unpredictable moments between 07:30 and 22:30h. After each signal, short reports of the current context (activity, company, patient present, location), appraisals of the current situation, subjective caregiver burden and mood will be collected. Before and after ESM data collection participants will be asked to fill out a number of retrospective questionnaires concerning their mood, perceived stress, sense of competence, feelings of control, quality of life, coping style, and patient behavior. In addition, they will be asked to fill out a questionnaire about their general experiences using the PsyMate.

Main study parameters:

1. Feasibility will be assessed by examining compliance with the PsyMate as well as through subjective participants ratings of the difficulty, time burden, and overall acceptability of the methodology;
2. Validity will be assessed by examining the presence of expected patterns among variables assessed using the PsyMate, as well as by the concordance between ESM measurements and standard retrospective measurements of the same construct;
3. Potential reactivity effects will be assessed by comparing the outcomes of the retrospective questionnaires filled out before and after the ESM data collection.

Study objective

N/A

Study design

ESM data will be collected over a 6-day period.

Intervention

Participants will be asked to carry an electronic diary, the PsyMate, with them for 6 consecutive days. The Psymate is a small, electronic touch-screen device that is designed to monitor experiences and behavior in daily life by signaling patients and recording and time-stamping their responses.

The PsyMate will generate ten signals a day at unpredictable moments between 07:30 and 22:30h. After each signal, short reports of the current context (activity, company, patient present, location), appraisals of the current situation, subjective caregiver burden and mood will be collected. Furthermore, participants will be asked to fill out a morning and evening questionnaire generated by the PsyMate at the beginning and end of each day.

Before and after ESM data collection participants will be asked to fill out a number of retrospective questionnaires concerning their mood, perceived stress, sense of competence, feelings of control, quality of life, coping style, and patient behavior. In addition, they will be asked to fill out a questionnaire about their general experiences using the PsyMate.

Contacts

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Eligibility criteria

Inclusion criteria

1. Spousal caregiver of a patient that is diagnosed with dementia;
2. Caregiver and patient share a household;
3. Written informed consent is obtained.

Exclusion criteria

1. Caregivers who have insufficient cognitive abilities to engage in the ESM (based on clinical judgment);
2. Caregivers who are overburdened (based on clinical judgment).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	31
Type:	Actual

Ethics review

Positive opinion	
Date:	14-08-2012
Application type:	First submission

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
NTR-new	NL3424
NTR-old	NTR3574
Other	METC azM/UM : 41834
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

VAN KNIPPENBERG RJM, DE VUGT ME, PONDS RW, MYIN-GERMEYS I, VAN TWILLERT B, VERHEY FRJ. Dealing with daily challenges in dementia (deal-id study): an experience sampling study to assess caregiver functioning in the flow of daily life. Int J Geriatr Psychiatry 2016; DOI: 10.1002/gps.4552

VAN KNIPPENBERG RJM, DE VUGT ME, PONDS RW, MYIN-GERMEYS I, VERHEY FRJ. Dealing with daily challenges in dementia (Deal-id study): An experience sampling study to assess caregivers' sense of competence and experienced positive affect in daily life. American Journal of Geriatric Psychiatry, accepted for publication.