

# Deal-iD Study: Dealing with daily challenges in Dementia - An evaluation of the feasibility and validity of the PsyMate in spousal caregivers of dementia patients

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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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON36885

### Source

ToetsingOnline

### Brief title

Deal-iD Study

### Condition

- Other condition

### Synonym

Caregiver burden/stress in partners of dementia patients

### Health condition

Psychische belasting/stress bij partners van patiënten met de ziekte van Alzheimer

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** - Alzheimer's Disease, - Caregivers, - Experience Sampling Methodology (ESM), - PsyMate

## Outcome measures

### Primary outcome

- 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.
- Validity of the PsyMate: assessed by examining the presence of expected patterns among variables in daily life of the caregiver using the PsyMate and by examining the concordance between ESM measurements and standard retrospective measurements of the same construct.

### Secondary outcome

- Potential 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

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. More studies are needed to extend our knowledge about the use of the ESM in this target population.

### **Study objective**

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**

This study involves a pilot study to evaluate the feasibility and validity of the PsyMate in spousal caregivers of dementia patients.

### **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.

### **Study burden and risks**

To our knowledge, there are no major risks associated with the use of the PsyMate. We don't expect the PsyMate questions to be too confronting or emotionally stressful to cause any psychological harm to the participants, because the questions concern the overall daily functioning of the caregiver.

However, we acknowledge that the ESM can be time-consuming and demanding for participants. We have tried to take this into account by limiting the number of PsyMate questions to a number that is acceptable according to the literature.

## 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**

- Spousal caregiver of a patiënt that is diagnosed with dementia.
- Caregiver and patient share a household.
- Written informed consent is obtained.

## Exclusion criteria

- Caregivers who have insufficient cognitive abilities to engage in the ESM (based on clinical judgment).
- Caregivers who are overburdened or have severe health problems (based on clinical judgment).

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 19-02-2013

Enrollment: 30

Type: Actual

## Ethics review

Approved WMO

Date: 28-11-2012

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## 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
Other	3574
CCMO	NL41834.068.12