# Digital biomarkers for early identification and treatment of neuropsychiatric symptoms in dementia

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Neurological disorders NEC |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON57063

**Source**
ToetsingOnline

**Brief title**
Digital Dementia Lab - NPS

### Condition

- Neurological disorders NEC

**Synonym**
cognitive decline, Dementia

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Alzheimer Nederland

## Intervention

**Keyword:** Daily life, Dementia, Neuropsychiatric symptoms, Wearables

## Outcome measures

### Primary outcome

Qualitative data collected with an evaluation form to assess the experience and acceptance of the wearables and ESM by patients with dementia and their primary caregivers.

### Secondary outcome

Biometric data (i.e. blood volume, skin conductance, body temperature, and motion/activity) derived from the smartwatch and behavioural data derived from the experience sampling questionnaire.

# Study description

### Background summary

Dementia is often primarily considered a cognitive disorder, but nearly all individuals with dementia exhibit neuropsychiatric symptoms (NPS), such as depression and anxiety, at some stage of the disease. NPS are associated with an increased risk of dementia progression, a higher rate of cognitive decline, and high caregiver burden. In the memory clinic, NPS are measured with subjective questionnaires that are administered at one specific moment in time, which do not take daily fluctuations over time in NPS into account. This hampers tailored treatment of NPS. It is our hypothesis that apps and wearables enable continuous (passive) health monitoring and more objective measurements of NPS during daily life.

### Study objective

Our main objective is to investigate the feasibility of measuring NPS in daily life with experience sampling and wearable technology. Our secondary objective is to investigate the presence of and fluctuations in NPS in the daily lives of patients with dementia.

### Study design

This is an observational study. Patients with dementia and their caregivers will be monitored for 14 consecutive days using experience sampling and smart watch technology. Biometric data will be continuously collected with the Empatica EmbracePlus. This smartwatch has a PPG sensor, EDA sensor, peripheral thermometer, accelerometer, and gyroscope in order to collect respectively information about the blood volume, skin conductance levels, body temperature, and motion/activity levels. Behavioural data will be collected using experience sampling in the caregiver. A questionnaire consisting of six to eight questions will be randomly administered to the caregiver seven times per day. An evaluation form will be administered to the patient and caregiver after the observation period.

### Study burden and risks

Participants will be continuously passively monitored for 14 consecutive days with a smartwatch, and caregivers will be prompted to answer six to eight questions seven times a day on their smartphone during this 14-day period. Both methods are non-invasive. It might occur that the wristband of the smartwatch causes some discomfort in patients, and/or that the caregiver questionnaire is prompted at an inconvenient time during the day. The burden, however, is minimal. There is no direct benefit for participants.

## 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

- >=18 years old
- Legal capacity
- Patient and primary caregiver are able to read Dutch
- A clinical dementia diagnosis
- Symptoms of depression and/or anxiety are present as indicated by the primary caregiver on the Neuropsychiatric Inventory
- Patient and primary caregiver live in the same house
- Primary caregiver is in possession of/- and makes use of their smartphone on a daily basis
- Participants are available for 14 consecutive days without interruption

### Exclusion criteria

- Other conditions (e.g. neurological or psychiatric) or medication that may affect anxiety and/or depression
- Other conditions or medication that are known to affect skin conductance, body temperature, and motion/activity levels

## Study design

### Design

**Study type:** Observational non invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-12-2024 |
| Enrollment: | 20 |
| Type: | Anticipated |

## Medical products/devices used

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| Generic name: | EmbracePlus |
| Registration: | Yes - CE intended use |

# Ethics review

Approved WMO

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| Date: | 24-10-2024 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL84028.078.24 |