Monitor-Mi Study: Digital Self-Monitoring in People with Mild Cognitive Impairment. An evaluation of the feasibility and validity of the PsyMate application in people with mild cognitive impairment

Published: 06-06-2018
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- Our primary objective is to evaluate the feasibility and validity of using the ESM, specifically implemented in the smartphone application called PsyMate, in an MCI population.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON50741

Source
ToetsingOnline

Brief title
Monitor-Mi Study

Condition

- Other condition

Synonym
Experience Sampling in People with Mild Cognitive Impairment

Health condition

People with Mild Cognitive Impairment (MCI) (and their relevant others)

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: - Experience Sampling Method (ESM), - Feasibility, - Mild Cognitive Impairment, - Technology

Outcome measures

Primary outcome

- 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.

- Validity of the ESM in people with MCI: (1) internal validity will be

determined in the context of person with MCI by examining the presence of

expected patterns among variables in daily life of the participant using the

ESM (e.g., associations between daily stressors and mood states) and (2)

ecological validity by examining the concordance between ESM measurements and

standard retrospective measurements of the same construct e.g. 'mood' through

12 ESM items and retrospective measures.

Secondary outcome

/

Study description

Background summary

Individuals diagnosed with mild cognitive impairment (MCI) experience a decline in at least one cognitive domain while their functional abilities are mostly preserved. Studies reveal, however, that complex task can be difficult to handle for people with MCI. Additionally, they have an increased risk for psychological symptoms such as anxiety and depression, potentially further complicating the management of everyday life. Research investigating on emotions, behavior and cognition in people with MCI uses normally retrospective measures. This is particularly questionable in a population with potential difficulties to recall past information. Ecologically valid information on how people with MCI perceive and react to challenges on a daily basis is lacking. The Experience Sampling Methodology (ESM) is an innovative technique that is specifically appropriate to collect individual information in everyday life. ESM can reveal pattern of activities and context, related emotions as well as their fluctuations in daily lives. This real-time information may give the individual, the caregiver, clinician as well as research insight into the condition and could contribute to a better self-management. To our knowledge, ESM has not been used in MCI yet.

Study objective

- Our primary objective is to evaluate the feasibility and validity of using the ESM, specifically implemented in the smartphone application called PsyMate, in an MCI population.

Study design

The study involves a feasibility study in which thirty people with MCI will be included. Furthermore thirty relevant other of the person with MCI will be ask to provide additional information.

Study burden and risks

To our knowledge, there are no major risks associated with the use of the PsyMate application. We do not expect the ESM questions to be too confronting or emotionally stressful to cause any psychological harm to the participants, because the questions concern the daily activities of the person with MCI, which should be mainly preserved according to diagnostic criteria. However, we acknowledge that the ESM can be time-consuming and demanding for participants. We took this into account by limiting the number of ESM 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

Person with MCI:
- Having a clinical diagnosis of MCI, according to Petersen (2004) criteria.
- In possession of a smartphone with an operation system from android or iOS.
- Written informed consent is obtained from the person with MCI., Relevant other:
-Written informed consent is obtained from the relevant other of the person with MCI

Exclusion criteria

- Subjects with MCI who have insufficient cognitive abilities to engage with the PsyMate application (based on clinical judgment).
- Subjects with MCI who have severe health problems (based on clinical judgment) such as a diagnosis of somatic, psychiatric or neurological disorder potentially causing cognitive dysfunction.

- If the person with MCI or the relevant other does not wish to take part, study participation is not permitted.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-07-2018
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	06-06-2018
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

ID: 24090
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64310.068.17
Other	NTR (TC = 6918)
OMON	NL-OMON24090

Study results

Date completed: 01-01-2021

Actual enrolment: 44

Summary results
Trial ended prematurely