Monitor-Mi Study
Digital Self-Monitoring in People with Mild Cognitive Impairment

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We hypothesis that the PsyMate application on a smartphone is feasible and valide to collect data in real life in people with mild cognitive impairment.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24090

Bron
Nationaal Trial Register

Verkorte titel
Monito-Mi Study

Aandoening

- mild cognitive impairment

- experience sampling method

- feasibility

- eHealth

Ondersteuning

Primaire sponsor: Academic Hospital Maastricht, Prof dr Frans Verhey
Overige ondersteuning: This project is funded by the Marie Curie Innovative Training Network (ITN) action, H2020-MSCA-ITN-2015, under grant agreement number 676265.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is to evaluate the feasibility and validity of the ESM use implemented in the PsyMate application in people with MCI.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale and objectives: 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. Therefore, 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 and population: The study involves a feasibility study in which thirty people with MCI will be included.

Procedure: Participants will be asked to collect ESM data using the PsyMate application over a six-day period. The PsyMate will generate eight signals a day at unpredictable moments between 07:30 and 22:30h. After each signal, short reports of the current mood, subjective

cognition, context (activity, company, location) and appraisals of the current situation will be collected. Furthermore, a morning and evening questionnaire will ask the participant to reflect on the last night/day. Before the ESM data collection, participants will be asked to fill out a number of retrospective questionnaires concerning their cognition, activities of daily living, perceived stress, general and health related well-being, coping, awareness of deficits and psychiatric symptoms.

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. An observation of the individual performing the application on the smartphone will give further insight into the feasibility.

(2) Validity will be assessed by examining the presence of expected patterns among variables in daily life of the person with MCI using the PsyMate and by examining the concordance between ESM measurements and standard retrospective measurements of the same construct.

Nature and extent of the burden and risks associated with participation: To our knowledge, there are no major risks associated with the use of the PsyMate application. We do not expect the PsyMate 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 PsyMate questions to a number that is acceptable according to the literature.

Doel van het onderzoek

We hypothesis that the PsyMate application on a smartphone is feasible and valide to collect data in real life in people with mild cognitive impairment.

Onderzoeksopzet

(1) Orientation session circa 2 hours

(2) ESM training session circa 30 minutes

(3) ESM period, 6 days, 8 beeps/day, 5 min/beep, morning and evening questionnaire 2min/beep

(4) debriefing sessions circa 1 hour

Onderzoeksproduct en/of interventie

Before entering the study, participants will be screened to make sure that they meet all of the inclusion criteria. After informed consent is obtained, the study protocol for each participant includes: (1) an orientation session, (2) ESM preparation session (3) momentary assessment during a six-day ESM period, and (4) a debriefing session.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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 as well as the relevant other.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2018
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	11-12-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50741
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6740
NTR-old	NTR6918
CCMO	NL64310.068.17
OMON	NL-OMON50741

Resultaten

Samenvatting resultaten
Bartels, S. L., Van Knippenberg, R. J., Malinowsky, C., Verhey, F. R., & de Vugt, M. E. (2020). Smartphone-Based Experience Sampling in People With Mild Cognitive Impairment: Feasibility and Usability Study. JMIR aging, 3(2), e19852.

Knippenberg, R. J. M. et al. Dealing with daily challenges in dementia (deal-id study): an experience sampling study to assess caregiver functioning in the flow of daily life. International Journal of Geriatric Psychiatry, doi:10.1002/gps.4552 (2016).