Dementia risk reduction in the general practice: a tailored approach

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We hypothesize that providing persons with information on their personal LIfestyle for BRAin health (LIBRA) profile and access to behavior change support through a smartphone application is feasible.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25703

Bron
Nationaal Trial Register

Verkorte titel
Dementia risk reduction in the general practice (PRIMA-Brain)

Aandoening

Dementia / cognitive decline

Ondersteuning

Primaire sponsor: Maastricht University Medical Center
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main endpoint of the PoC trial is the feasibility of the intervention. It will be evaluated on the basis of the following endpoints:

1. The difference in total LIBRA score change between the intervention and control group.
2. Use of the app
3. Participants' awareness of modifiable dementia risk and protective factors at baseline and after 3 months
4. Participants' understandings of and attitudes towards their health profile and the MijnBreincoach app
5. Participants views regarding supports and barriers to embed behavior changes into everyday life and, and whether the MijnBreincoach app helps or hinders participants make and maintain changes to individual health-related behaviors
6. Perspectives of involved primary care practitioners on the LIBRA score, and the MijnBreincoach app in terms of acceptability, demand, integration and implementation.
7. Further, the number of excluded individuals, and the number of dropouts will be recorded.

The main endpoint of the embedded pilot study will be the usability of ESM-based questionnaires and feedback. This will be evaluated based on:
1. The obtained data points coming from the ESM-questionnaires will be examined in an exploratory manner. These will include measures of:
- Context (time, location, social context)
- Current activity
- (Social cognitive) determinants of behavior
- Positive and negative affect
2. The subjective experiences of the participants on the ESM-questionnaires and the ESM-feedback

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Dementia is an important public health problem in our aging society. As there is currently no treatment available, attention is shifting towards preventive strategies. Robust evidence indicates that health and lifestyle factors influence dementia risk. Yet, these findings have not been translated in public risk reduction strategies.

Objective: To evaluate the feasibility of supplying a tailored, digital health app, designed to increase insight in how to reduce one's dementia risk, in the general practice. Secondly, we aim to explore the usability of experience sampling method (ESM) technology as a form of coaching that could be added to this digital health app.

Study design: Primary care-based Proof-of-Concept (PoC) trial with embedded ESM pilot study
Study population: 40 to 60 years old volunteers, both men and women, who meet the eligibility criteria

Intervention: In the PoC trial, both the intervention (n=90) and control group (n=90) will get one session of personal face-to-face general practitioner (GP) guidance about living a brain-healthy lifestyle (based on their individual "LIfestyle for BRAin health'' (LIBRA) score; a

validated risk score that assesses how brain-healthy one's current lifestyle is, based on 12 modifiable risk and protective factors for dementia). The intervention group will additionally get access to the personalized digital health app called MijnBreincoach. This app provides the user with daily messages (e.g. tip, quiz, challenge, information) regarding a LIBRA risk or protective factor that the user chose to focus on. Within the ESM pilot study, one additional group of participants (n=20) will get access to the MijnBreincoach app but participants will also be asked to respond to ESM questionnaires and they will receive ESM-based feedback. The total duration of study participation will be 3 months.

Main study parameters/endpoints: Feasibility will be evaluated on the basis of: (1) difference in change in LIBRA scores between groups; (2) use of the health app (percentage of completers, access to and time spent on app); (3) the number of excluded individuals and dropouts; (4) participants' understandings, attitudes and views towards their LIBRA profile and the health app, including their role when embedding behavior change into everyday life; and (5) perspectives of involved primary care practitioners on the LIBRA profile and health app in terms of acceptability, demand, integration and implementation.
Usability of ESM technology will be evaluated based on ESM-derived data points, response rates and participants' subjective experiences regarding the method and its feedback.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The participants need to fill in an online questionnaire at the start of the study. Afterwards, all participants need to plan one appointment with their GP or practice nurse. This appointment will consist of a blood pressure measurement (if no recent measurement is available), and a discussion of the participant's LIBRA profile along with personal advice and setting sustainable and realistic lifestyle goals. After this appointment, the intervention group will get access to the MijnBreincoach app which they can use on a daily basis at their own discretion. After 3 months, online questionnaires will be administered. These are not considered burdensome or stressful. A subsample of participants (n=10) from the intervention group and ESM-pilot study, and involved health care professionals (n=4) will be asked to participate in a short interview at the end of the study. The ESM- group will additionally be asked to collect ESM data for 6 consecutive days. Specifically, they will receive a short questionnaire at 10 random moments during the day (between 7:30 AM and 10:30 PM), after which they will receive personal feedback. No negative effects because of participation are expected, as use of provided information is at the discretion of the participant and drawn from authoritative public health resources. Participating in the study has an additional advantage to the participants. The study will increase knowledge about modifiable dementia risk factors, give people insight in their individual health profile, and provide them with strategies and tips to promote their cognitive health.

Doel van het onderzoek

We hypothesize that providing persons with information on their personal LIfestyle for BRAin health (LIBRA) profile and access to behavior change support through a smartphone application is feasible.

Onderzoeksopzet

1. Baseline questionnaire
2. GP visit to discuss brain health
3. Three months after GP visit: follow-up questionnaires and interviews

Onderzoeksproduct en/of interventie

The intervention that will be tested in both the PoC trial and pilot study consists of the following:

• One session of personalized GP guidance concerning dementia risk reduction
• Access to a smartphone application, called “MijnBreincoach”.

Within the pilot study, the participants’ treatment will consist of the above explained parts. Additionally, participants will receive ESM questionnaires (10 per day) for 6 consecutive days and personalized, ESM-based feedback.

The control group will get the session of personalized GP guidance concerning dementia risk reduction (care-as-usual).

Contactpersonen

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Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Registered with a participating general practice

• Age 40 – 60 on date of consent
• Presence of one (or more) of the following risk factors:
- Depression – previous history or active episode of minor depression as recorded on medical record – if GP deems patient fit to participate
- Diabetes type 2 (diagnosis e.g. on a diabetes disease register) o Hypertension
- Obesity (BMI ≥ 30)
- Current smoker
- Hyperlipidemia
- More than moderate consumption of alcohol (>1 standard drink per day)
- Coronary heart disease
- Chronic kidney disease
- Inactive to moderately inactive lifestyle (assessed using the European Prospective Investigation into Cancer and Nutrition (EPIC) Physical activity questionnaire)
- Unhealthy diet (defined as non-adherence to the Mediterranean diet, assessed using the Mediterranean Diet Adherence Screener (MEDAS))
- Lack of cognitive activity (assessed using the Cognitive Reserve Index questionnaire (CRIq))
• Proficient in Dutch language
• Access to internet in order to use the smartphone application
• Owns a smartphone

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Active episode of major depression, while GP deems patient unfit to participate, recorded in medical record or assessed by a validated instrument
• People unable to give IC
• People with dementia
• People with certain conditions because of which they cannot make the suggested lifestyle changes by default (e.g. special dietary requirements due to e.g. bariatric surgery or coeliac disease); movement constraints (e.g. due to cerebral palsy or hemiparesis)
• People who have previously used the MijnBreincoach app

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	06-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9773
Ander register	METC azM/UM (Maastricht) : METC20-080

Resultaten