Dementia risk reduction in the general practice: a tailored approach

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To test 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…

Ethical review	Approved WMO
Status	Completed
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON56196

Source
ToetsingOnline

Brief title
Dementia risk reduction in the general practice

Condition

- Dementia and amnestic conditions

Synonym
cognitive decline, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw projectnumber: 733050511

Intervention

Keyword: Dementia, lifestyle, primary prevention, risk factors

Outcome measures

Primary outcome

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.

Secondary outcome

A secondary study endpoint is the frequency and severity of the 12 individual LIBRA factors present within study participants at baseline and at follow-up.

Study description

Background summary

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.

Study objective

To test 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 in this digital health app.

Study design

Primary care-based Proof-of-Concept (PoC) trial with embedded ESM pilot study

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.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Registered with a participating general practice
- Age 40-60 years old on date of consent
- Medically stable
- Proficient in Dutch language
- Access to internet in order to use the smartphone application

• Owns a smartphone
• Presence of any one (or more) of the following risk factors:
o Depression - previous history or active episode of minor depression as recorded on medical record - if general practitioner deems patient fit to participate
o Diabetes type 2 (diagnosis e.g. on a diabetes disease register)
o Hypertension
o Obesity (BMI >= 30)
o Current smoker
o Hyperlipidemia
o More than moderate consumption of alcohol (>1 standard unit per day)
o Coronary heart disease
o Chronic kidney disease
o Inactive to moderately inactive lifestyle
o Lack of cognitive activity
o Unhealthy diet

Exclusion criteria

• ¬Active episode of major depression, if general practitioner deems patient too severely ill to participate, recorded in medical record or assessed by a validated instrument
• People who are unable to give informed consent
• People who have 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-12-2021
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	MyBraincoach app
Registration:	No

Ethics review

Approved WMO Date:	25-05-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-10-2022
Application type:	Amendment
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
CCMO	NL75147.068.20
Other	NL9773

Study results

Date completed: 18-09-2023

Results posted: 21-08-2024

First publication
01-01-1900

URL result
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