Innovative, Midlife Intervention for Dementia Deterrence: Feasibility Randomized Controlled Trial

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Primary Objective: Our primary objective is to test the feasibility of the online In-MINDD intervention through a primary care-based feasibility RCT. We hypothesize, that providing persons with information on their health profile and access to...

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

Summary

ID

NL-OMON42204

Source
ToetsingOnline

Brief title
In-MINDD

Condition

- Dementia and amnestic conditions

Synonym
Dementia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: European Union Seventh Framework Programme (FP7/2007-2013) under grant agreement No. 304979 (In-MINDD).

Intervention

Keyword: Dementia, Midlife, Prevention, Risk factors

Outcome measures

Primary outcome

Feasibility will be evaluated on the basis of:

•The number of participants that accomplish the online intervention. In addition, the number of excluded subjects, and the number of dropouts will be recorded. The researchers will try to contact withdrawn subjects, in order to clarify, the reason of the premature withdrawal (e.g. whether his or her reason were related to experimental set up). Mainly because this is part of the primary endpoint. Subjects will be informed that they are not obligated to give the reason why he or she has stopped with the experiment. These outcome measurements can give us crucial information about the applied intervention

•Use of the online support environment in terms of access to and time spent on the support environment

•Participants understanding of and attitudes towards their health profile and cognitive health score

•Participants views regarding supports and barriers to embed behavior changes into everyday life

•Perspectives of involved primary care practitioners on the cognitive health score, health profile, online intervention, and online support environment in terms of utility

Secondary outcome

The secondary outcome (surrogate endpoint) will be the change in LIfestyle for BRAin health (LIBRA) score, showing the gain in terms of brain health (room for improvement) someone can achieve by adopting a healthy lifestyle and adherence to disease management programs. The weight of each risk factor is based on an algorithm consisting of risk estimates retrieved from current meta-analyses and systematic reviews. Previous studies have used similar calculation of dementia risk. It consists of calculating the natural logarithm of a given risk factor, and using the factor with the lowest value (closest to zero) as the reference value. Each other factor*s weight is standardized against this reference value. In Table 1 of the rsearch protocol, the effect was lowest for low/moderate alcohol intake (relative risk (RR) = 0.74 --> ln (RR) = -0.30), so it was given a weight of one (i.e 0.30/0.30) and other risk factors were standardized by dividing them through 0.30. Summation of the weights for endorsed risk factors will yield a person*s In-MINDD dementia risk score.

These following risk factors are included in the algorithm: low/moderate alcohol intake, coronary heart disease, physical inactivity, chronic kidney disease, diabetes, cholesterol, smoking, midlife obesity, midlife hypertension, healthy diet/Mediterranean diet, depression and cognitive activity

Study description

Background summary

Dementia is an important public health problem in our ageing society. Despite recent advances in the epidemiology of dementia, there is a profound lack of

public awareness that dementia risk may depend to some extent on modifiable lifestyle factors. This lack of awareness is a major issue with important consequences: persons-at-risk do not seek help, they receive insufficient and inaccurate care as well as support from their social environment, and dementia is stigmatized. In addition, most people are unaware that health and life style adaptations, especially at midlife, might improve their cognitive health profile

The present feasibility study is part of the FP-7 funded In-MINDD (Innovative Midlife Intervention for Dementia Deterrence; http://inmindd.eu) project, which aims to decrease dementia risk and/or delay its onset through lifestyle interventions in midlife. The overall aims of In-MINDD are to: (1) develop a robust dementia risk model based on modifiable risk factors; (2) implement this risk model in collaboration with patients and practitioners, by designing and supporting an on-line user environment; and (3) test the feasibility and effectiveness of the In-MINDD system through a primary care-based feasibility RCT (present study). In addition, In-MINDD tries to communicate the message that dementia risk can and should be modified to a wide audience, including the general public, doctors, primary care nurses.

Study objective

Primary Objective:
Our primary objective is to test the feasibility of the online In-MINDD intervention through a primary care-based feasibility RCT. We hypothesize, that providing persons with information on their health profile and access to supportive on-line support environment is feasible.

By answering the following objectives we can largely explain whether the In-MINDD RCT is successful in achieving the primary objective:
-Comparison of the effectiveness of the online In-MINDD intervention in promoting cognitive health and lowering the prevalence/severity of individual dementia risk factors with care as usual
-Exploration of the usage of the online In-MINDD intervention by participants in terms of access to and time spent on the support environment
-Exploration of the feasibility of using the online In-MINDD intervention and support environment from the perspective of participants
-Exploration of participants understanding of and attitudes towards their health profile
-Exploration of the supports and barriers to embedding behavior changes into everyday life, and whether the online In-MINDD intervention helps or hinders participants make and maintain changes to individual health-related behaviors
-Exploration of the feasibility of using the online In-MINDD intervention from the perspective of primary care practitioners
-Understanding the primary care practitioners view of the utility of the health profile and how they relate that information to participants

Secondary Objective(s):
Our secondary objective (surrogate endpoint) is to test the effectiveness of the online In-MINDD intervention for behavioural change that might justify a large effectiveness RCT on dementia risk reduction. We hypothesize that providing persons with information on their health profile and access to supportive on-line support environment will influence their risk factor profile and as a result will reduce their overall dementia risk score within a six month period.

Study design

The study is a randomized feasibility RCT. Participants will be randomly assigned to the experimental group (In-MINDD arm) and the control group (control arm) after eligibility criteria are checked and after participants signed informed consent (see Figure 4). Participants, GPs, practice nurses, and the research team will know the arm to which participants are allocated. Participants can follow the online In-MINDD intervention from home.

Duration of participation
The total duration of the study participation will be six months. This six-months period is based on an estimation of time necessary to assess a behavioral intervention like the In-MINDD intervention (sufficient time to observe or to detect behavioral changes). Inclusion will start from July 2014.

Setting
The In-MINDD feasibility RCT will be based in four different primary care systems in Europe, namely: Netherlands (Maastricht University), Scotland (University of Glasgow), Ireland (Dublin City University) and France (Université Nice Sophia Antipolis). Within each country, the work will be located in general practices/family practices. A total of 6 general practices will be recruited in each country; within each practice, a total of 25 patients will be recruited, giving a total study population of 600 patients across the four countries. For the present study conducted in the Netherlands, we will recruit 150 participants. We will contact two GP associations within South Limburg (ZIO = Zorg In Ontwikkeling, Maastricht en Heuvelland; HOZL = Huisartsen Oostelijk Zuid-Limburg) to facilitate recruitment of general practices (preferably three practices in the Eastern and three in the Western region of South Limburg) based on their previous involvement in scientific research, their expertise in elderly and mental health care, and their interest in taking part in this particular study.

Intervention

The online In-MINDD intervention and support environment consists of the following (note: all webpages will be in Dutch):

•The In-MINDD Profiler, the study website that is used to gather the baseline collection, is based on an online self-administered questionnaire for individuals in midlife and takes approximately 15-25 minutes to complete (see Figure 1 for an example of a profiler screen). The questions included in the In-MINDD profiler were designed to collect the information from respondents in relation to those risk and protective factors for dementia that it has been decided to target in the In-MINDD intervention. Background information about participants and family medical history is also collected. The following provides a more detailed description of information collected via the In-MINDD profiler:
- Back ground (socio-demographic) information about users (i.e. age, sex, country of birth, marital status, employment status, educational attainment (localized to each country) level of occupational attainment, and living arrangements
- Information about the user*s health including height and weight (to calculate body mass index), total cholesterol level, blood pressure, diagnosis of cardiovascular disease, diabetes and chronic kidney disease.
- Information about family medical history (i.e. dementia, cardiovascular disease and diabetes)
- Information about alcohol consumption.

•Personalized information about the participant*s health profile (LIBRA score) and individual risk factor scores. The personal LIBRA profile will be presented using an *exploded doughnut* style chart, as shown in Figure 2 below. The LIBRA score ranges from 0-100, with a score of 100 indicating that an individual has no risk across all dementia risk factors that are included in the In-MINDD inventory. The adoption of a brain healthy lifestyle across all risk factors means that this person is at a reduced risk of developing dementia. The opposite holds for a score of 0. The LIBRA profile comprises three parts: (1) *Keep this up* - the sum of dementia risk factors for which the individual has no risk; (2) *Remember to manage well* - the sum of manageable risk factors for which the individual has risk. Note that three risk factors within the dementia risk model (i.e. cardiovascular disease, diabetes and chronic kidney disease), whilst not amenable to modification by way of active lifestyle change once a user has developed the condition, are important factors for chronic disease management; and (3) *Room for improvement* - the sum of the risk factors for which the individual has risk that can be modified through lifestyle change. As well as their overall LIBRA profile and score, more detailed textual information about individual risk factors that make up each segment of the personal LIBRA profile will also be presented. For example, with respect to the segment on room for improvement, individuals will be presented with a more detailed breakdown of the risk factors that can be modified by way of lifestyle changes, referred to as their LIBRA improvement space (Figure 3). See section 8.1.2 for the algorithm of the LIBRA score.

•A suite of information (self-help materials) about each of the modifiable risk factors for dementia. This will include information on links between the risk

factor and dementia, guidelines related to each risk factor (e.g. guidelines/recommendations around physical activity, alcohol consumption), suggestions for actions that can be taken to reduce the risk, and carefully selected localized websites

•Online personalized support, in which participants will be informed of personally most relevant risk factor(s) and invited to select one (or two or three at most) area(s) in which to make lifestyle changes. This selection of target factors will take place in consultation with the involved GP who remains medically responsible for the advice. Participants will be given suggestions about how to make lifestyle changes in this area. They will be invited via a reminder (by email) every month to review their health progress. This will ensure that advice is ongoing and tailored and in keeping with current best practice in health promotion i.e. not trying to get them to change everything at once. The support environment of each risk factor consists of the following sections/subpages: background/introduction, relation of risk factor with brain health, what can you do?, personalized plan, goals, and supportive weblinks.

•In-MINDD Forum, whereby participants can *Ask the Experts*. Experts are involved medical doctors/researchers in the field of health promotion/dementia prevention who are able to answers questions given their background/expertise. Participants will be invited to submit opinions, thoughts and questions about cognitive health promotion and experiences of participating in the study. Experts will review and respond directly to the participant. In addition, the most commonly asked questions will be used to inform the development of a (moderated) Frequently Asked Questions (FAQ) Page

•Blogs Page, whereby participants and In-MINDD researchers will be invited to start a Blog about their thoughts on cognitive health promotion, experience of participating in the study and an account of the lifestyle changes they have made to improve their cognitive health. The blog is moderated to ensure that the online In-MINDD community is constructive and beneficial to the readers of the blog. The In-MINDD research team and participants in the In-MINDD arm of the trial will be able to comment on the blog. There will be a set of rules outlining what is appropriate and inappropriate ti post and what should or shouldn*t be in posts and comments: (1) the In-MINDD blog is restricted to the In-MINDD research team and to participants allocated to the In-MINDD arm of the trial; (2) posts and comments shall cover topics that are relevant for the readers (research team, participants in the In-MINDD arm); (3) posts and comments shall be respectful to other people and their viewpoints; (4) profanity is not allowed on the blog page; (5) the blog moderators (a member of the research team in each of the four partner countries) have the ability to edit and delete posts and comments if they are not considered with the interests of the online In-MINDD community or do not comply with the In-MINDD blog rules and guidelines.

Study burden and risks

Participating in this study is without any foreseeable risk. Similar interventions have been conducted in the past. People can participate in the online In-MINDD intervention from their own home or workplace. The baseline measurement and follow-up measures are composed of demographics and questionnaires which are not considered burdensome or stressful. Those who take part in face-to-face interviews can stop the interview at any time and are free to ask the researcher to move on to another topic. We do not expect any negative effects through participating in the online programme. At the end of the online programme participants receive a message (disclaimer) stated that if they, after participating in the programme, are still worried about their cognitive health they should contact their GP. Participating in the study has an additional advantage to the participants. The intervention programme will increase knowledge about dementia risk factors, give people insight in their individual health profile, and provide them tools (strategies and tips) in order to improve their cognitive health.

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

-Registered with a participating general practice
-Age 40 - 60 on date of consent
-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 GP deems patient fit to participate
o Diabetes (diagnosis e.g. on a diabetes disease register)
o Hypertension
o Obesity (BMI >= 30)
o Current smoker
o High cholesterol
o Coronary heart disease (diagnosis e.g. on a coronary heart disease register)
o Self-reported sedentary lifestyle
o Self-reported lack of cognitive stimulation
- Medically stable
-Proficient in Dutch language
-Access to internet in order to communicate by email and access information online

Exclusion criteria

-Active episode of major depression, if GP 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2014
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	18-08-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-11-2014
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
ISRCTN	ISRCTN98553005
CCMO	NL48589.068.14

Study results

Date completed:	06-01-2016
Actual enrolment:	144