LIGHT (Lifestyle Intervention in the memory clinics of General and academic Hospitals Trial): Secondary prevention of dementia in memory clinics: implementation and (cost-) effectiveness of an integrated lifestyle intervention

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57198

Source
ToetsingOnline

Brief title
LIGHT

Condition

- Other condition

Synonym
Dementia risk profile; brain health

Health condition

Risicofactoren voor dementiebij mensen met geheugenklachten

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMW - Leefstijl in de Zorg

Intervention

Keyword: dementia risk, lifestyle intervention, memory clinic, Prevention

Outcome measures

Primary outcome

The primary outcome will be change in participants* dementia risk profile as measured by the LIfestyle for BRAin Health (LIBRA) score between baseline and 12 months.

Secondary outcome

Secondary outcomes include cognitive functions (episodic memory, executive functions, information processing speed, and attention). Other secondary outcomes include measures of body mass index (height and weight), office systolic and diastolic blood pressure, and lab measures including cholesterol levels (total, HDL, LDL, triglycerides), HbA1c levels, creatinine-based eGFR levels. Smoking, alcohol intake and current relevant medical conditions (coronary heart disease, kidney disease, type 2 diabetes, depression, hearing loss, sleep disorders) will be assessed through self-report. Additional questionnaires include health-related quality of life and capabilities, instrumental activities of daily living, health locus of control, self-efficacy, mastery, healthy diet, physical activity, cognitive stimulation,

stress, and depressive symptoms, sleep quality, social support and feelings of loneliness, and lastly knowledge on dementia risk and protective factors. For cost-effectiveness, questionnaires on resource utilization, medical consumption, and productivity costs are administered. Additional measures include change in diagnosis (if applicable), demographics (age, sex, educational level, socioeconomic position (household income), paid/voluntary work hours, ethnicity, marital status, living situation), medication use, hearing loss. For process evaluation, questionnaires and interviews are administered on implementation, mechanisms of impact and contact (e.g., appointments with lifestyle coach, use of the breinzorg.nl self-management tool, use of the voucher program, experiences and usefulness, etc.).

Study description

Background summary

Dementia prevention through lifestyle has much potential but is not implemented in routine care. Patients referred to memory clinics, such as people with mild cognitive impairment (MCI) and subjective cognitive disorder (SCD), are at high risk for dementia and tend to have a worse health and lifestyle profile. While they might greatly benefit from lifestyle changes, there is no offer to help them make those changes.

Study objective

The primary objectives are to examine both the (cost-)effectiveness of an innovative 1-year lifestyle intervention on lifestyle change measured by the validated Lifestyle for Brain Health Score (LIBRA) in older adults with a subjective cognitive disorder (SCD) and mild cognitive impairment (MCI); and to identify possibilities, barriers, and facilitators for sustainable implementation of the lifestyle intervention.

Study design

Multicenter, randomized controlled trial comparing Group A (tailored lifestyle intervention) with Group B (general health advice)

Intervention

Participants are randomly allocated on a 1:1 ratio to participate either in Group A (tailored lifestyle intervention) or Group B (general health advice) for a duration of 12 months. The lifestyle intervention comprises three parts 1) Lifestyle coaching, 2) a voucher program, and 3) online self-management. Group B will receive general health advice.

Study burden and risks

- Study participation might be beneficial, as it can improve brain health and overall health.
- Drawing blood samples might cause mild pain and sometimes a bruise.
- Measurements may take some time, therefore also possible to fill out online.
- Sports activities performed as part of the study may increase chances of injuries or tripping.
- Intervention based on motivational and educational approach, no participant will be forced to follow certain guidelines.

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

1) Being >=50 years;
2) Having a diagnosis of SCD or MCI;
3) Having at least two modifiable risk factors for dementia

Exclusion criteria

1) Having a diagnosis of dementia;
2) Conditions affecting safe and continuous engagement in the intervention (e.g. under treatment for current malignant diseases, major psychiatric disorders (e.g. major de-pression, psychosis, bipolar disorder), other conditions preventing co-operation as judged by the local study nurse or consulted physician at the local study site;
3) Participation in any other intervention study at time of pre-screening.
4) Insufficient understanding of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-10-2024

Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO Date:	23-12-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL86513.068.24