Stage of health-related behaviour change after receiving information on personal disease risks and lifestyle advice, based on genetic and lifestyle factors, combined with prolonged lifestyle counselling

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The primary objective is to study the effect of prolonged lifestyle counselling after receiving Health Potential on stage of behaviour change. The secondary study objective is to study the effect of prolonged lifestyle counselling after receiving...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Lifestyle issues
Study type	Interventional

Summary

ID

NL-OMON46334

Source
ToetsingOnline

Brief title
Leef!-study part B

Condition

- Lifestyle issues

Synonym
Health related lifestyle behaviour, healthy lifestyle

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,De Stofberg Groep

Intervention

Keyword: Disease risk testing, Genetic testing, Health behaviour change, Lifestyle testing

Outcome measures

Primary outcome

The primary outcome parameter is stage of behaviour change.

Secondary outcome

The secondary study parameters are:

* Motivational regulation

* Attitude

* Behaviour-specific self-efficacy

* Risk perception

* Stress

* Discussion of test results with health professionals and/or family and

friends

* Test-related distress

Study description

Background summary

The prevalence of almost all chronic diseases has risen steeply due ageing populations across the world. In the Netherlands too, where 70% of people aged 65 and over has at least one chronic disease. This has led to the development

of services aimed at preventive health care. The Health Potential service provides personal disease risk information followed by lifestyle advice for 21 preventable common chronic diseases. The disease risk profile is based on genetic background, lifestyle, medical and occupational history. This information, delivered to the client in a face-to-face meeting, can assist in lifestyle decision-making.

Study objective

The primary objective is to study the effect of prolonged lifestyle counselling after receiving Health Potential on stage of behaviour change.

The secondary study objective is to study the effect of prolonged lifestyle counselling after receiving Health Potential to change determinants of behaviour change.

Study design

Part B of the Leef!-study exists of a two-armed randomised controlled pre-test/post-test trial among participants in the exposed condition of part A for whom consent is obtained for part B. Participants will be allocated at a 1:1 ratio.

This protocol refers to part B.

Intervention

The intervention consists of lifestyle counselling aimed at stimulating and supporting behaviour change. It consists of 4 additional sessions, following the face-to-face meeting during which the results of the purchased products are communicated to the client.

The counselling sessions take place at:
- 0 weeks, immediately following the first face-to-face meeting
- 1 week
- 4 weeks
-12 weeks

The lifestyle counselling is based on principles of motivational interviewing and follows 4 core questions of behaviour change, as developed by Operis (Operis BV, Rotterdam)

Study burden and risks

The inconvenience for the participant consists of the additional investment in time required to attend the lifestyle counselling. There is no additional

burden for the participant with regard to data collection in part B of the study.

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

Participation in Leef!-study part A, having purchased Health Potential and Stofberg Health Check (the exposed group)

Exclusion criteria

None

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	582
Type:	Anticipated

Ethics review

Approved WMO Date:	18-01-2017
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	NL57029.068.16
Other	Nog onbekend