

Behaviour change as a result of genetic disease risk testing combined with lifestyle counselling

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26622

Source

Nationaal Trial Register

Brief title

Leef!-study part B

Health condition

Health behaviour, lifestyle, diet, exercise, environmental exposures, genetic disease risk testing, lifestyle counselling

Sponsors and support

Primary sponsor: Maastricht University Medical Centre
Stofberg Preventie en Coaching

Source(s) of monetary or material Support: This project will be funded by the Maastricht University Interfaculty Program 'Eatwell'

Intervention

Outcome measures

Primary outcome

Stage of behaviour change

Secondary outcome

Motivational regulation, Attitude, Behaviour-specific self-efficacy, Risk perception, Perceived stress, Discussion of test results with health professionals and/or family and friends, Test-related distress

Study description

Background summary

Rationale: With a rapidly ageing population it is essential to consolidate efforts to prevent disease from occurring in order to reduce the burden on the health care system and economy. Health Potential could contribute to this. Health Potential is a service that provides information on personal disease risks followed by lifestyle advice for 21 preventable common chronic diseases, based on an individual's genetic background, lifestyle, medical history, occupational history and other characteristics. This information, which is delivered to the client in a face-to-face meeting, can be used to direct lifestyle decision making.

Objective: The primary objective is to study the effect of additional lifestyle counselling after receiving Health Potential on stage of behaviour change. The secondary study objective is to study the effect of additional lifestyle counselling after receiving Health Potential to change determinants of behaviour change. The hypothesis is that additional lifestyle counselling will lead to better lifestyle choices compared to no additional lifestyle counselling.

Study design: The full Leef!-study consists of two integrated designs: (1) a two-armed non-randomised controlled pre-test/post-test trial (part A), followed by (2) a two-armed randomised controlled pre-test/post-test trial among participants in the exposed condition of part A for whom consent is obtained (part B). This registration refers only to Leef!-study part B.

Study population: Clients of the Stofberg Groep purchasing Health Potential and the Stofberg Health Check (together named Personalised Health Check; PHC) who are willing to participate in part B.

Intervention: Four additional lifestyle counselling sessions at 0 weeks, 1 week, 4 weeks and 12 weeks.

Primary study parameters: The primary outcome parameter is stage of behaviour change.

Study objective

The hypothesis is that receiving additional counselling will lead to greater improvements in behaviour change compared to no additional counselling.

Study design

Outcome parameters are measured at $t=-6w$ (baseline), $t=0$, $t=1w$, $t=4w$, $t=12w$, $t=6m$, and $t=1y$.

Intervention

The intervention consists of four additional lifestyle counselling sessions with a counsellor of approximately 60 minutes. The sessions will take place at $t=0$ weeks, $t=1$ week, $t=4$ weeks, and $t=12$ weeks.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must participate in part A of the Leef!-study and have purchased the Health Potential and the current health check.

Exclusion criteria

None

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2017
Enrollment:	384
Type:	Anticipated

Ethics review

Positive opinion	
Date:	24-02-2017
Application type:	First submission

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
NTR-new	NL5865
NTR-old	NTR6289
Other	METC AzM/UM : 163014

Study results

Summary results

- Wesselius, A., and M. P. Zeegers. "Direct-to-consumer genetic testing." *oa Epidemiology* 1.4 (2013).

- Al-Zalabani, Abdulmohsen H., et al. "Modifiable risk factors for the prevention of bladder cancer: a systematic review of meta-analyses." *European journal of epidemiology* 31.9 (2016): 811-851.

- Stewart, K., et al. "Behavioural changes and psychological responses after receiving direct-to-consumer genetic test results: a systematic review and meta-analysis." Submitted.

- Elahi, IRN, et al. "The association between soft drinks consumption and asthma: a systematic review and meta-analysis." Submitted.