

Behaviour change as a result of genetic disease risk testing

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21041

Source

NTR

Brief title

Leef!-study part A

Health condition

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

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 Health Potential to change behaviour and intention to change behaviour. The secondary study objectives are (1) to study the effect of Health Potential to change determinants of behaviour change and (2) to study characteristics of the Health Potential customers. The hypothesis is that receiving Health Potential, in combination with a standard health check (i.e. the Stofberg Health Check), will lead to better lifestyle choices when compared to receiving the standard health check alone.

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 A.

Study population and exposures: Clients purchasing a personalised health check, consisting of Health Potential and a current health check, are considered the exposed group, and will be compared to clients purchasing a current health check only.

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

Study objective

The is that receiving Health Potential, in combination with a current health status check, the Stofberg Health Check, will lead to greater improvements in behaviour change compared to receiving the Stofberg Health Check only.

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 studied service is the genetic disease prevention service Health Potential. This service will estimate a personal disease risk of a carefully selected list of 12 preventable common chronic diseases that have both a genetic and a lifestyle component of development. Participants purchasing Personalised Health Check (Health Potential + current health check) are considered the exposed group; participants purchasing the current health check only are considered the control group.

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

Apparently healthy, both physically and psychologically

Age ≥ 18 years

Dutch language level such that more complex texts can be understood (similar to language proficiency level B2)

Authorised to make autonomous decisions

Internet access and e-mail address for the filling in of questionnaires

Able to independently visit the counselling clinic

Exclusion criteria

Dietary or other guidelines that need to be followed by prescription of a health professional (such as gluten-free diet in case of coeliac disease)

Pregnant or trying to become pregnant

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending

Start date (anticipated):	01-11-2017
Enrollment:	350
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	NL5864
NTR-old	NTR6288
Other	METC AzM/UM : 16-4-077

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.