Behaviour change as a result of genetic disease risk testing

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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.

Ethische beoordeling Positief advies

Status Werving nog niet gestart

Type aandoening -

Onderzoekstype Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21041

Bron

NTR

Verkorte titel

Leef!-study part A

Aandoening

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

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre

Stofberg Preventie en Coaching

Overige ondersteuning: This project will be funded by the Maastricht University

Interfaculty Program 'Eatwell'

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel: Parallel

Toewijzing: Niet-gerandomiseerd

Blindering: Open / niet geblindeerd

Controle: Geneesmiddel

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-11-2017

Aantal proefpersonen: 350

Type: Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 24-02-2017

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register ID

NTR-new NL5864 NTR-old NTR6288

Ander register METC AzM/UM: 16-4-077

Resultaten

Samenvatting resultaten

• 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.