Psychological Training

Gepubliceerd: 04-01-2016 Laatst bijgewerkt: 15-05-2024

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22144

Bron
Nationaal Trial Register

Verkorte titel
Psychological Training

Aandoening

Training the immune system in healthy subjects.

Het trainen van het immuunsysteem in gezonde proefpersonen.

Ondersteuning

Primaire sponsor: Leiden University
Overige ondersteuning: European Research Council Consolidator Grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is the difference between the trained and control groups in self-reported vitality directly after the training compared to baseline.

Toelichting onderzoek

Achtergrond van het onderzoek

The main aim of this study is to evaluate the psychophysiological effects of a psychological training aimed at improving immune function in healthy male volunteers. The training consists of an internet-delivered guided psychological training, based on cognitive-behavioral principles. The control condition will not receive any training. A BCG-vaccination will be conducted after 10 weeks. Effects on vitality and other psychological and psychophysiological outcome measures will be examined, both in rest (after 10 and 14 weeks) and in response to stressors (1 day after vaccination).

Doel van het onderzoek

The aim of the study is to investigate the effects of a psychological training directed at optimizing immune function in healthy young men. It is expected that the training will lead to improved self-reported vitality (primary hypothesis), both in rest and in response to immunological (BCG vaccination) and psychological and physical stressors.

Onderzoeksopzet

The study consists of 5 sessions during the course of 14 weeks. First of all, participants will be screened for medical and psychological conditions. Thereafter, a training period preceded by a face-to-face intake session with the e-Coach will take place for the participants assigned to the experimental group (week 4 to 10). Afterwards, a vaccination session will take place, immediately followed by a test day (after 10 weeks). Finally, a follow-up session will take place after 14 weeks.

Onderzoeksproduct en/of interventie

This randomized trial involves a psychological training aimed at optimizing immune function. After screening, subjects are randomized to a training (experimental group) or control condition. The training consists of an internet-delivered guided psychological training, based on cognitive-behavioral principles. The control condition will not receive any training.

The training period is followed by a vaccination with BCG as an immunological stressor.

One day after application of the BCG-vaccination, a test day is planned in which participants will be shortly exposed to psychological and physical stressors.

Finally, a follow-up session is planned at 4 weeks after vaccination.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male gender

2. Between 18 and 35 years old

3. Good understanding of written and spoken Dutch

4. Naive for tuberculosis

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History of inflammatory or cardiovascular diseases

2. Known hypersensitivity or allergy to any of the vaccine components

3. History of tuberculosis disease or treatment

4. BCG vaccination at any time prior to entering the trial (asked during screening, indicated by the presence of a scar or as mentioned on the vaccination card)

5. Live vaccination (measles, mumps, rubella, oral polio, oral typhoid or yellow fever) 4 weeks or less prior to the BCG vaccination

6. Treatment with immune modulating drugs 3 months or less prior to enrolment

7. (History of) Disease affecting the lymphoid organs

8. Known congenital or acquired immune deficiencies (e.g., HIV)

9. Psychiatric (DSM-V) or somatic conditions that interfere with the participant's safety and/or the study protocol, such as personality disorders, schizophrenia, or haemophilia

10. Professional sport player or extreme exercise

11. Active participation in other clinical trials

12. Not giving consent to inform the participant’s General Practitioner of the BCG vaccination

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2016

Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	04-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43991
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5466
NTR-old	NTR5610
CCMO	NL52434.058.15
OMON	NL-OMON43991

Resultaten

Samenvatting resultaten
n/a