Psychological Training

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22144

Source
Nationaal Trial Register

Brief title
Psychological Training

Health condition

Training the immune system in healthy subjects.

Het trainen van het immuunsysteem in gezonde proefpersonen.

Sponsors and support

Primary sponsor: Leiden University
Source(s) of monetary or material Support: European Research Council Consolidator Grant

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Vitality and well-being at the day of vaccination, at the test day 1 day after vaccination, and at the follow-up session.

2. Psychological and psychophysiological outcome measures assessed at each measuring point.

Study description

Background summary

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).

Study objective

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.

Study design

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.

Intervention

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.

Contacts

Public
LUMC
PO Box 9555
A.W.M. Evers
Leiden 2300 RB
The Netherlands
+31 (0)71 527 3627
Scientific
LUMC
PO Box 9555
A.W.M. Evers
Leiden 2300 RB
The Netherlands
+31 (0)71 527 3627

Eligibility criteria

Inclusion criteria

1. Male gender

2. Between 18 and 35 years old

3. Good understanding of written and spoken Dutch

4. Naive for tuberculosis

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2016

Enrollment:	60
Type:	Actual

Ethics review

Positive opinion
Date: 04-01-2016
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43991
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
n/a