The effects of a psychological expectancy training directed at optimizing immune function

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The primary study objective is to evaluate the psychophysiological effects of a psychological expectancy training directed at optimizing immune function compared to a control group in healthy male subjects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43991

Source
ToetsingOnline

Brief title
Psychological expectancy training

Condition

- Other condition

Synonym
not applicable

Health condition

Het onderzoek wordt bij gezonde mensen uitgevoerd. Uitkomsten uit deze lijn van onderzoek bieden nieuwe handvatten voor verklaringsmodellen en therapeutische interventies voor gezonde mensen en patiënten met inflammatoire aandoeningen waarbij een verandering in de inflammatoire respons optreedt.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Conditioning, Expectancies, Immune function, Vitality

Outcome measures

Primary outcome

The primary study outcome is vitality measured by the composite of the Subjective Vitality Scale and the Checklist Individual Strength after the psychological expectancy training at 6 weeks compared to baseline.

Secondary outcome

The following secondary outcomes are assessed:

1) Vitality and well-being at the day of vaccination, at the test day 1 day after vaccination (10 weeks after the start of the study), and at the follow up session (14 weeks after the start of the study).

2) Inflammatory responses (e.g., CRP, IL-6, TNF-*) measured in blood at five time points (at screening, the day of vaccination, twice (start and end of day) at the test day 1 day after vaccination (10 weeks after the start of the study), and at the follow up session (14 weeks after the start of the study).

3) LPS stimulated blood at screening, at the day of vaccination and at the start of the test day 1 day after vaccination.

4) Salivary physiological responses (e.g., cortisol, alpha amylase) measured at

the same time points as the blood samples and additionally after each stress task 1 day after vaccination (10 weeks after the start of the study).

5) Psychological well-being assessed by NRS scores 1 day after vaccination (at the start of the test day and after each stress task) and assessed by positive and negative mood measured at the same time points as the blood samples.

6) Performance on stress tasks (Paced Auditory Serial Addition Task, Cold Pressor Test, Trier Social Stress Test) assessed at the test day 1 day after vaccination.

7) Heart rate, heart rate variability and skin conductance are sampled during screening and during the test day 1 day after vaccination (10 weeks after the start of the study) and finally during follow up.

Demographic variables, self-reported measures of e.g., personality characteristics and the 5-HTTLPR genotypes and other candidate genotypes will be assessed as possible predictors of vitality and inflammatory responses.

Study description

Background summary

A previous study revealed that inflammatory reactions to a in-vivo LPS stimulation can be reduced after an extensive training where psychological factors and exercise were combined. There is evidence that psychological interventions alone can also induce anti-inflammatory effects, but studies so far are small and the effects are inconsistent. Expectancy mechanisms such as conditioning or verbal suggestions could improve outcomes of psychological interventions.

Study objective

The primary study objective is to evaluate the psychophysiological effects of a psychological expectancy training directed at optimizing immune function

compared to a control group in healthy male subjects.

Study design

This randomized trial involves a psychological expectancy training aimed at improving immune function (experimental group) compared to a control group. After the screening, subjects are randomized to an online training (including 'serious game' elements) of 6 weeks, supervised by an e-coach, or the control group that receives no training. This period is followed by the vaccination with BCG (Bacillus Calmette-Guérin, the current vaccine against tuberculosis), one day later a test day, and 4 weeks later a follow-up session (14 weeks after the start of the study).

Intervention

The experimental group will receive a psychological training directed at optimizing immune function in healthy male subjects.

Study burden and risks

The BCG-vaccine of Intervax is a non-registered vaccine; BCG-vaccins are widely used throughout the world. It is a live-attenuated vaccine and is contraindicated for persons with impaired cellular immunity. In view of our outcome measures BCG will also not be given to persons with a positive QuantiFERON® -TB Gold In-Tube blood test. In case of a positive QuantiFERON® -TB Gold In-Tube test, the subject will be counseled by the investigator. The *Tuberculose bestrijding van GGD Hollands Midden* will be contacted. If the investigator and/or the GGD think it necessary, the participant will be referred to this department for further counseling and management.
Most vaccinees will develop a local reaction at the site of injection, which will heal spontaneously leaving a small scar. Temporary enlargement of regional lymph nodes is sometimes observed. This does not require treatment. In rare cases vaccination may lead to disseminated infection with BCG. This condition requires treatment with isoniazid and rifampicin, to which the vaccine strain is fully susceptible. Following BCG vaccination future tuberculin skin tests will show a positive reaction. This means that for participants in this trial the skin test can no longer be used to screen for tuberculosis. Should the need arise to test BCG vaccinated individuals for suspected TB, the standard approach including direct sputum-smear microscopy, chest X-ray radiography and bacterial culture can still be applied. In addition to this a QuantiFERON® -TB Gold In-Tube blood test can be performed instead of the skin test.
The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, although uncommon, faintness from the procedure. Blood sampling and vaccination will be performed at the LUMC by trained personnel to avoid these risks as much as possible.

Burden of study participation is moderate with an expected time investment for participants of 2 hours for the screening sessions, one hour on the vaccination day, one test day of four hours and a total of 75 minutes for the five blood sample sessions (at screening, after the training, twice during the test day 1 day after vaccination, and at follow up (4 weeks after vaccination, 10 weeks after start training). The training consists of an online training (including 'serious game' elements) during 6 weeks, supervised by an e-coach. This results in a total time investment of approximately 15 hours for each participant with a total study duration of 14 weeks per participant. There are no direct benefits for subjects participating in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy male adult volunteers between 18 and 35 years of age.
Good understanding of written and spoken Dutch.
Naive for tuberculosis.

Exclusion criteria

History of inflammatory or cardiovascular diseases
Known hypersensitivity or allergy to any of the vaccine components
History exposure to open TB, (latent) TB disease or treatment
BCG vaccination at any time prior to entering the trial
Live vaccination (measles, mumps, rubella, oral polio, oral typhoid, varicella or yellow fever) 4 weeks or less prior to the BCG vaccination
Treatment with immune modulating drugs (systemic steroids, azathioprine, cyclosporine, anti-TNFa, immunoglobulines, cytostatics) 3 months or less prior to enrolment
(History of) disease affecting the lymphoid organs (Hodgkin*s disease, lymphoma, leukaemia, sarcoidosis)
Known congenital or acquired immune deficiencies (e.g. HIV)
Psychiatric (DSM-V) or somatic conditions that interfere with the participant's safety and/or the study protocol (assessed during screening) such as personality disorders, schizophrenia, or haemophilia.
Professional sport player or extreme exercise (assessed during screening)
Excessive drinking or drug use
Active participation in other clinical trials
Not giving consent to inform the participant*s General Practicioner of the BCG vaccination

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	27-08-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-10-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-01-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-02-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-06-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	15-11-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22144
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL52434.058.15
OMON	NL-OMON22144