What is the attainability of a study examining the stress-reducing effect of a new neurofeedback device?

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The aim of the present pilot study is to obtain insight in the attainability of a study investigating the effectiveness of NeuroCARE NFT in more than average stressed but otherwise healthy young adults, using the current design. The claims that...

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

Summary

ID

NL-OMON31743

Source
ToetsingOnline

Brief title
stressreduction by a new neurofeedback device

Condition

- Other condition

Synonym
Healthy volunteers

Health condition

Het heeft niet betrekking op mensen met een aandoening: gezonde vrijwilligers die meer dan gemiddeld gestresst zijn maar verder gezond, zijn de doelgroep

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Research Eindhoven

Intervention

Keyword: Double blind experiment, Healthy subjects, Neurofeedback, Stress-reduction

Outcome measures

Primary outcome

The primary objective is to investigate stress, sleep, cognitive function and

mood in a group of more than average stressed healthy subjects undergoing an 8

week NeuroCARE NFT program or a placebo program.

The following assessments will be performed:

(1) Assessment of stress

* Objective stress level, measured by Heart Rate Variability (standarddeviation

of RR-intervalls and intensity of the HF component of the ECG spectrum will be

analyzed)

* Subjective stress level, measured by POMS short form and a stress rating scale

(2) Assessment of sleep

* Objective sleep-assessment with SenseWear PRO2 Body Monitoring System

* Subjective sleep-assessments with a sleep log and a Dutch translation of the

Karolinksa Sleepiness Scale (KSS)

(3) Mood

Measured by POMS short form

(4) Cognitive function

Measures of:

* declarative long term memory (CVLT)

* selective attention (D2 concentration test)

* working memory (calculations, Digit Symbol - Coding WAIS III)

* executive function (Stroop Colour Word Test, Letter Fluency test)

Secondary outcome

n.a.

Study description

Background summary

Neurofeedback training (NFT) is an operant conditioning paradigm through which participants can learn to influence parameters of their electrical brain activity, as measured by the electroencephalogram (EEG), through (audio or visual) feedback of their brain activity. The EEG-feedback is used to reinforce the desired electrical brain response.

Some successes with NFT have been reported in enhancing functioning in healthy volunteers and in lessening complaints in neuropsychiatric patients. However, because thorough controlled studies on NFT in healthy volunteers are lacking, there is still no consesus considering the effectiveness of NFT.

The Canada based Zengar institute has developed a new NF apparatus called NeuroCARE. In several countries, including the Netherlands, people without medical or scientific training offer NeuroCARE NFT and make profit out of *the treatment* of psychiatric patients and healthy people with this technique. It is claimed by these practitioners that the NeuroCARE NFT is effective in reducing symptoms in a wide variety of psychiatric disorders and in improving functioning of healthy persons.

In the manual of the NeuroCARE course it is claimed explicitlly that the

programm is effective in (1) reducing stress, (2) improving mood (3) improving sleep, and (4) inproving cognitive functioning in healthy volunteers.

To our knowledge the effectiveness of the NeuroCARE NFT has never been studied. We would like to investigate whether NeuroCARE NFT is indeed effective on the afore mentioned points. The current pilot study is especially aimed at the attainability of a study on the effectiveness of NeuroCARE NFT.

Study objective

The aim of the present pilot study is to obtain insight in the attainability of a study investigating the effectiveness of NeuroCARE NFT in more than average stressed but otherwise healthy young adults, using the current design. The claims that NeuroCARE NFT will lead to improvements in (1) relaxation (2) mood (3) cognitive performance and (4) sleep will be tested in a double blind equivalent sham control group design experiment. We hope to invetigate this more thoroughly in a possible continuation study.

Study design

This is a double blind randomised experiment. Subject will be randomly assigned to:
1) a group receiving real NeuroCARE NFT
or
2) a group receivin mock NeuroCARE NFT

Subject will get 16 NF sessions of 1 hour each. Subject and staff conducting the dependent measurements (testers) are blind for study condition. The trainer is not blind, but does not conduct any dependent measures. Furthermore, the trainers' behaviour, communication between trainer and subject an between trainer and tester will be strandardised.

On different points in time , measures of stress, mood, sleep and conitive functioning wil be obtained (before and after, and some during the complete training programm).

We will analyse whether the 'real NFT group' will show greater improvement on the above mentioned measures than the 'mock NFT group'.

Intervention

Subjects receive 16 sessions of neurofeedback training of 40 minutes each. During NFT, Subject will be placed in a chair in supine position by the assistant in a dimly lit room. The subject is connected to the NF equipment with 2 EEG electrodes and listens to his or her favourite music for 40 minutes. NeuroCARE software gives feedback by short interruptions of the music. With

this feedback, it is claimed that brainactivity can be influenced and alterations on psycho(phisio)logical level can be realized.

Study burden and risks

Subjects will be asked to follow a 8 week during NF programm. During this period, subjects will have to come to the hospital twice a week for about an hour. Furthermore, they will be asked to wear the Sensewear sleepmonitor for 5 consecutive nights an to fill out a sleep log for 5 days.
The total time-investment that will be asked of the subjects amounts to about 18 1/2 hours. No invasive measurements will be done. The financial compensation amouts to 315 euros (¤17,50 per visit). Participation in the study does not lead to any direct risks. At the most, subject could feel a little tired temporary during a neurofeedback session.

Contacts

Public
Philips Research

High Tech Campus 34; 5656 AE Eindhoven
Postbox WB 41 Eindhoven
Nederland
Scientific
Philips Research

High Tech Campus 34; 5656 AE Eindhoven
Postbox WB 41 Eindhoven
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1) A score of at least 1 standard deviation above the reported mean of the Perceived Stress Questionnaire
2) 18 - 30 years old
3) Written informed consent

Exclusion criteria

1) Evidence of a significant psychiatric (e.g. sleep disorder or major depression), neurological (e.g. epilepsy) or other medical (particularly cardiovascular and adrenocortical) disorder at the time of inclusion
2) Pregnancy at the time of inclusion (based on the subjective report of the subject)
3) The excessive use of medication, particularly corticosteroid medication at the time of inclusion
4) Significant alcohol abuse at the time of inclusion
5) An education level that is lower than high school
6) With occurrence of certain medical diseases (for example fever) a subject can be temporarily be excluded from the intervention

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2008
Enrollment:	30

Type:	Actual

Ethics review

Approved WMO Date:	22-01-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-03-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL17397.041.07