# The Effect of Biofeedback Training on Physiology Regulation in Dutch Soldiers returning from Deployment

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

# Summary

### ID

NL-OMON34417

**Source** ToetsingOnline

**Brief title** The Effect of Biofeedback Training on soldiers

### Condition

• Other condition

Synonym healthy soldiers

#### **Health condition**

Het heeft geen betrekking op mensen met een aandoening: gezonde militairen (die hun missie hebben kunnen afronden) zijn onze doelgroep

#### **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** Ministerie van Defensie **Source(s) of monetary or material Support:** Ministerie van OC&W,Ministerie van Defensie i.s.m. TNO en Philips Research,Philips Research,TNO

### Intervention

Keyword: Biofeedback, Healthy Dutch soldiers, Neurofeedback, Physiology Regulation

### **Outcome measures**

#### **Primary outcome**

(see H3 protocol)

Assessment of relaxation level/stress:

Heart rate variability (HRV)

Galvanic Skin Response (GSR)

Respiration

Cortisol level

QEEG

Reaction times and accuracy (Cognitive task N-Back)

Heart rate (variability) during the IAPS pictures task

Subjective Stress level (Perceived Stress Scale and shortened Vas-SACL (last

only in NFT))

Assessment of Self-Efficacy

Coping Self-Efficacy questionnare

#### Secondary outcome

(see H3 protocol)

Assessment of Fatique

CIS-20 questionnaire

Assessment of Physical Complaints and Anxiety

4DKL questionnaire

Assessment of Sleep

Pittsburgh Sleep Quality Index (PSQI)

Assessment of Depression

The above-mentioned 4DKL will be used to measure symptoms of depression.

Assessment of Burnout

Utrechtse Burnout Scale (UBOS)

Assessment of cognitive functioning in the NFT:

reaction times and accuracy during Mental rotation Task 2D (MRT2D)

reaction times and accuracy during Stroop Color Word Test (SCWT)

Post Deployment Reintegration

Post-Deployment Reintegration Scale (PDRS)

# **Study description**

#### **Background summary**

Biofeedback training (BFT) aims to train individuals in awareness of and control over their peripheral stress responses. The underlying philosophy is that by controlling the primary stress responses to at least some extent, the impact of stress on performance and quality of life (QoL) may be significantly reduced. Additionally, specific techniques necessary to obtain this goal may stimulate relaxation and as such recuperation after stressful events, or (psychologically) demanding periods.

Neurofeedback training (NFT) represents a sophisticated form of biofeedback based on specific aspects of cortical activity. It forms part of an operant conditioning paradigm in which a person can learn how to modify the amplitude and/or frequency of the electrophysiological aspects of his/her own brain. The aim of such a technique is to teach the individual what specific states of cortical arousal feel like and how to activate them voluntarily.

About 1.800 Dutch soldiers were serving in Uruzgan, as part of a NATO International Security Assis-tance Force (ISAF) operation. As of August 1 (2010), the deployment is scheduled to start a redeployment phase. This implies that last rotations of military personnel will be active in Uruzgan, preparing for departure. Deployed military personnel are at risk for development of posttraumatic stress disorder (PTSD). In recent years the focus has shifted from studies on core features of PTSD to secondary prevention of stress-related problems and complaints.

Because deployment to a warzone is associated with chronic hyper arousal in military persons -in order of COL Vermetten (Military Mental Health, Department of Defence)- our aim here is to enhance the relaxation level of returning soldiers and therefore create better functioning in daily life after deployment.

Thus, one aim of this project will be to examine the effect of NFT to enhance the alpha power incorporating random feedback controls and utilizing a balanced double blind procedure to explore the beneficial consequences for healthy military persons returning from Uruzgan.

Increasing peripheral stress management may be another potentially beneficial approach when aiming at a reduction in post-deployment psychological burden. To be able to investigate this we propose to use a modified version the Biofeedback game developed for medical professionals by the Utrecht Medical Centre.

#### **Study objective**

According to the proponents of NFT, it has profound effects upon four domains. It is said that NFT reduces stress, improves cognitive functioning, leads to a better overall mood, and ameliorates sleep. Biofeedback has been suggested to improve stress management skills, general well being and reduce symptoms of depression and anxiety. We wish to assess the validity of these claims in a military context, in a scientifically sound way, measuring:

With questionnaires: Stress level Self-Efficacy Fatique Physical complaints Anxiety Sleep

With cognitive tasks: N-Back IAPS pictures task Mental rotation task (NFT only) Stroop task (NFT only)

With physiological measures: Brain activity (QEEG) Respiration Galvanis skin response heart rate variability Cortisol (intake Dexamethason and 3 x saliva extraction)

### Study design

This is a balanced and controlled experiment in which hundred sixty (N=160) soldiers will be assigned to:

 Audio-based NFT to enhance the alpha power, the feedback is given by changing the charac-teristic of the subject\*s favourite music (N=40)
Random beta control group with a randomized frequency conditioning program (i.e. every ses-sion a different 4 Hz frequency bin between 12 and 20 Hz will be used), the feedback is given by changing the characteristic of the subject\*s favourite music (N=40)

BFT (N=40): an interactive computer game with different events each controlled by changes in either SCL (skin conductance level) and HRV. It is a modified version of a medical game currently used by the Patient Safety Centre of the Utrecht Medical Centre (UMC) for the training of medical professionals.
Treatment as usual (TAU) control group (N=40): 30 minutes of non-sports leisure time (read-ing papers, books, listening to music) every workday for two weeks.

These are the measurements per period: Entrance Examination: Sign Informed Consent Sign General Information

Balance groups by time period since returning, deployment experience (in months),

age, and sex

T0 (pre measurement): QEEG, HRV, GSR, Respiration, Cortisol N-Back task IAPS pictures task Post Deployment Reintegration

Stress level, self-efficacy, fatique, physical complaints, anxiety, sleep depression, burnout

Instrumental Alpha NFT and Control group: Conditioning (training): 10x EEG, HRV, GSR, Respiration Cognitive tasks (Stroop and Mental rotation) and shortened vas-SACL Biofeedback and Control group:

T1 (post measurement): QEEG, HRV, GSR, Respiration, Cortisol N-Back task IAPS pictures task Post Deployment Reintegration

Stress level, self-efficacy, fatique, physical complaints, anxiety, sleep depression, burnout

T2 (follow up after three months) QEEG, HRV, GSR, Respiration, Cortisol N-Back task IAPS pictures task Post Deployment Reintegration

Stress level, self-efficacy, fatique, physical complaints, anxiety, sleep depression, burnout

#### Intervention

The intervention will consist of 10 sessions of training.

In the NF- and random beta feedback training (N = 80, total of 45 min), EEG measurements will take place. In addition to the EEG measurement of the brain activity at P3-A1 and P4-A2, also heart rate variability, respiration and

galvanic skin response will be captured time synchronously using the NeXus10 Amplifier from TMSi (see Appendix X and Appendix XI for conformity). Between trainings in one session, cognitive performance will be tested by the Stroop task and the Mental Rotation Task. A shortened visual analogue SACL is used to measure relaxation levels between tasks (neurofeedback versus cognitive task). Next to heart rate variability and galvanic skin response needed for the biofeedbacktraining (total of 20 min), no variables are measured during the biofeedback training. The treatment as usual will consist of 30 min relaxation, without any measuring.

#### Study burden and risks

Participants will be asked to follow a BFT/NFT program of 2 weeks. The total of time they are joining our investigation will be 13.5 hours. No invasive measurements will be done. Participation in the study does not lead to any direct risks.

# Contacts

**Public** Ministerie van Defensie

Plein 4 postbus 20701, 2500 ES DEN HAAG NL **Scientific** Ministerie van Defensie

Plein 4 postbus 20701, 2500 ES DEN HAAG NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

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

### **Inclusion criteria**

18  $\ast$  55 years old healthy soldiers, recently returned from deployment, and written informed consent

## **Exclusion criteria**

Use of psychotropic medication and significant alcohol abuse (" Because we use soldiers that have finished their deployment, we may assume these persons are fit and healthy, without any mental or medical diagnose" Kol-arts dr. H.G.J.M. Vermetten)

# Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2011
Enrollment:	160
Туре:	Actual

# **Ethics review**

Approved WMO Application type: Review commission:

First submission METC Brabant (Tilburg)

# **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 CCMO ID NL34819.008.10