Daydream: the effect of training on the brain; an ERP study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON45309

Source
ToetsingOnline

Brief title
Daydream

Condition

- Psychiatric disorders NEC

Synonym
psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: W.M. de Hoop stichting en Vrienden van UMC Utrecht

Intervention

Keyword: neurofeedback game EEG

Outcome measures

Primary outcome

The correlation between the levels within the two different conditions of the game with the ratio of intended brainwave frequencies (derived from the EEG assessments) that is said to be induced by these conditions.

Secondary outcome

1. The correlation between the ratio of intended brainwave activity for each condition and the level that is reached by an individual subject in that particular condition.

2. The correlation between number of sessions and the ratio of intended brainwave frequencies of the two different conditions of the game.

3. Difference between baseline and follow-up session on cognitive testing.

Study description

Background summary

Patients with psychosis often suffer from anxiety and distress. A technique that has been increasingly recognised as effective in reducing stress and anxiety is mindfulness. Given the popularity of computer games nowadays, mindfulness training by means of a neurofeedback game may increase the patient*s willingness and motivation that is so frequently lacking in other forms of therapies. Computerized interventions therefore offer promising ways to supplement or perhaps replace more expensive face-to-face interventions.

Study objective

The aim of this study is to validate whether the Daydream game conditions indeed trigger the brain activity as mentioned in the manual. In addition, it

will be investigated whether playing the game induces an increase in intended brainwave activity and cognitive functioning after practice.

Study design

Longitudinal within subject design (5 measurements).

Intervention

Playing the two conditions of the Daydream game for 20 minutes (10 minutes per condition) per session, on 5 days within a period of 2 weeks. The participant is seated behind a computer, wearing an EEG cap (64 electrodes) and a lightweight, wireless headset with one dry sensor on the forehead and an ear clip attached to the earlobe. Neurofeedback is used to play the game: the computer game reacts to the ratio of alpha and beta frequencies in the brain activity of the player. Through continuous registration of alpha and beta ratio by the sensor placed on the forehead the player reaches a higher or lower level in the game.

Study burden and risks

Participants will be asked to visit the psychophysiological laboratory on 5 days within a period of maximal 2 weeks. The participant will be subject to questionnaires, neuropsychological testing and playing the neurofeedback game Daydream. EEG assessments are administered during the game. There is no physical or physiological discomfort associated with participation. In addition, there are no known risks for healthy volunteers of playing the Daydream game or EEG measurements.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Good Physical and Mental Health meeting criteria "never mentally ill".
- Age between 18 and 45 years.
- Male.
- Written informed consent of the subject.

Exclusion criteria

- Current use of any medication;
- Any subject who has received any investigational medication within 30 days prior to the start of this study;
- History of neurologic illness;
- History of psychiatric illness in first-degree relatives, evaluated with DSM-IV criteria;
- History of alcohol and drug abuse;
- Participants who are unable to understand the study outline and/or provide written informed consent;
- Participants who fail to attend less than four out of the five sessions (because this disrupts the training).
- Use of stimulants (e.g. caffeine, nicotine, drugs) 1 hour prior to the training session

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	11-01-2017
Application type:	First submission
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	NL59464.041.16