Daydream: training in relaxation and attentional focusing; a pilot study

Published: 03-09-2013
Last updated: 22-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON38846

Source
ToetsingOnline

Brief title
Daydream

Condition

- Schizophrenia and other psychotic disorders

Synonym
Schizophrenia ; psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Applied game, Attentional focus, Neurofeedback, Psychosis

Outcome measures

Primary outcome

To investigate whether psychotic patients are able to play the game, reach the target level and improve over time, the game results will be evaluated (duration to reach/maintain the target level and improvement over time). User experience will be evaluated with short questionnaires.

Secondary outcome

User feedback will be used to improve the game or adapt game settings. Results will also be used to choose which conditions will be used in a subsequent study and to calculate sample size for a larger randomized control study.

Study description

Background summary

There is a need for cost-effective treatment approaches in mental health care. Applied computer games have been found promising additional training tools for patients with medical or psychiatric diseases (DeShazo et al., 2010; Oord, Ponsioen, Geurts, Brink, Prins, 2012). In the present pilot study we aim to investigate the usability of an applied game as a training tool to decrease stress and increase attentional focussing in psychotic patients.

Study objective

The objective of this pilot study is to collect data in psychotic patients to design a subsequent larger randomised control study. An applied game using biofeedback has been developed by an independent game studio based. This game will be used to investigate whether psychotic patients are able to play the game, reach the target level (relaxation, concentration or attentiveness), and whether playing the game repeatedly, improves their performance. User experience will be evaluated to investigate usability, as well as positive or

negative effects of playing the game.

Study design

The game comprises three training conditions (relaxation, concentration and attentiveness) teaching individuals to relax, to regulate heart rate and to focus attention. Patients will consecutively be assigned to one of the three conditions.

Intervention

A training period of 10 days will be offered. The game will be played for 10 minutes twice a day. The patient is seated behind a computer, wearing a lightweight, wireless headset with one dry sensor on the forehead or an earclip attached to the earlobe. Biofeedback is used to play the game: e.g. the computer game reacts to the biological state of the player (level of concentration, attentiveness or relaxation) so that the player reaches a higher level in the game.

Study burden and risks

There are no known risks associated with playing the game. However, since psychotic patients are vulnerable, they may experience stress, tiredness or increase of positive symptoms during or just after playing the game. Therefore, the study is conducted in the clinic and a research assistant is present to help the patient in case of questions or distress. Benefits may be positive feelings during or after playing the game.

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

- Signed informed consent form
- DSM-IV diagnosis schizofrenia, schizofreniform disorder, schizoaffective disorder or psychose NAO.
- Age 18-30 years

Exclusion criteria

- patients who are not capable to understand the study outline and/or provide written informed consent.
- patients who are coercively admitted to the ward will not be invited to participate
- Conditions placing patients at risk according to the judgment of the clinical staff, such as severe anxiety, behavioral problems, medical conditions, etc.
- patients who use more than 6 mg lorazepam a day (or equivalent dosage of other benzodiazepines)

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):	08-01-2014
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	03-09-2013
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	NL44946.041.13