

An RCT on the effectiveness of a serious game for first episode psychotic patients and patients with a developmental disorder with anxiety symptoms using cognitive bias modification (CBM).

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The objective of this study is to examine whether a serious game using Cognitive Bias Modification is effective on anxiety symptoms and self stigma regarding patients with a psychotic disorder or a developmental disorder.

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

Summary

ID

NL-OMON41529

Source

ToetsingOnline

Brief title

serious game for patients with social anxiety

Condition

- Other condition
- Schizophrenia and other psychotic disorders

Synonym

developmental disorder, psychosis

Health condition

patienten met een ontwikkelingsstoornis

Research involving

Human

Sponsors and support

Primary sponsor: GGZ Friesland (Leeuwarden)

Source(s) of monetary or material Support: GGZ Friesland, De Friesland zorgverzekeraar

Intervention

Keyword: anxiety, CBM, developmental disorder, psychosis, serious game

Outcome measures

Primary outcome

Anxiety symptoms measured with LSAS

Secondary outcome

self-stigma measured with ISMI.

game experiences using the GEQ.

Study description

Background summary

Patients with a psychotic disorder often suffer of anxiety symptoms. An evidence based intervention on anxiety disorder, cognitive bias modification (CBM), has shown to be effective in patients with psychotic disorder in two pilot studies. One of the recommendations was to improve the dull CBM scenario's in a more active way. An active way is due serious gaming. Serious games are computer games developed for educational use and has shown to be supportive for treatment aims.

Therefore three mental health care services together with a university of applied science developed a serious game. In this game CBM is integrated in order to minimize anxiety symptoms and self-stigma, an other factor common in patients with psychotic disorder and associated with anxiety symptoms. We believe that the intervention might also be effective for patients with developmental disorder with comorbid anxiety. When an intervention study examines that the intervention will be effective on anxiety symptoms and self-stigma in patients with a psychotic disorder and developmental disorder,

they might have benefit with this free, accessible intervention.

Study objective

The objective of this study is to examine whether a serious game using Cognitive Bias Modification is effective on anxiety symptoms and self stigma regarding patients with a psychotic disorder or a developmental disorder.

Study design

A randomised controlled trial with a cross over design.

Intervention

The intervention is a serious game using Cognitive Bias Modification designed to reduce anxiety symptoms and self-stigma in patients with a psychotic disorder or a developmental disorder.

Study burden and risks

Patients can play the game where and whenever he prefers, At baseline and during 2 follow-up moments they are assessed with a small amount of instrument (about 30 minutes).

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- * psychotic disorder according to miniSCAN
- * developmental disorder according to miniSCAN
- * anxiety symptoms determined with LSAS (score > 30).
- * > 18 years treated at Friesland mental health care services

Exclusion criteria

- * suiciderisk
- * psychosis, determined with PANSS-R ≥ 4

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	03-11-2015
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO	
Date:	23-10-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	09-06-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL45207.042.13