Cognitive remediation in psychiatric patients with an applied online cognitive game and assessment tool

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON44811

Source
ToetsingOnline

Brief title
Cognition game

Condition

- Cognitive and attention disorders and disturbances

Synonym
cognitive deficits; psychiatric disorders

Research involving
Human

Sponsors and support

Primary sponsor: MyCognition
Source(s) of monetary or material Support: MyCognition

Intervention

Keyword: Applied gaming, Cognitive deficits, Psychiatric disorders

Outcome measures

Primary outcome

The primary outcome measure of this research is cognitive functioning at 12

weeks.

Secondary outcome

The secondary outcome measures include the severity of symptoms, blood marker

abnormalities, electro-encephalogram (EEG), level of functioning and cortisol

level.

Study description

Background summary

A majority of patients with a psychiatric disorder such as major depressive disorder (MDD), schizophrenia or obsessive-compulsive disorder (OCD), suffers from cognitive dysfunction (e.g. in attention, memory, and planning ability). Cognitive dysfunction can play a major role in functional capacity and independence in everyday activities. Improving cognitive functioning in patients with psychiatric disorders may lead to being alble to keep or earlier return to employment and independent living and therefore to reduced healthcare and economic costs.
Availability of interventions to improve cognitive dysfunction is limited. The companies MyCognition and Preloaded have developed thegame Aquasnap designed to enhance and sustain performance leading to reduction in cognitive deficits. A potential advantage of tAquaSnap over and above existing cognitive remediation test batteries is that more subjects comply with treatment because playing the game is enjoyable.

Study objective

The primary objective of this study is to investigate in a randomized controlled trial (RCT) if AquaSnap can improve cognitive functioning in patients with DSM-IV-TR diagnosis of schizophrenia/schizoaffective disorder,

OCD or MDD who have cognitive deficits. Secondary objectives are to investigate 1) the usability and acceptability of AquaSnap 2) the association of changes in cognitive functioning with biological, psychosocial and clinical parameters.

Study design

The design is a randomized controlled trial. Subjects will be randomized at entry to one of two treatment groups: Current management (TAU) or Current management plus AquaSnap.

Intervention

Subjects will receive either Treatment as Usual (TAU) or TAU plus a link with which they can play AquaSanp at home, at least three times a week for at least half an hour for 12 weeks.

Study burden and risks

Subjects will be assessed at baseline, week 4, week 8 and week 12 with the MyCognition Cognitive Power Score (MYCQ). At baseline and week 12 they will also be assessed with the CANTAB, clinical self report scales, EEG hair cortisol and blood markers. Subjects in the treatment condition can play AquaSnap. Side effects of playing AquaSnap are not expected. Benefit for the patient may be improved cognitive functions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- DSM-IV-TR diagnosis of schizophrenia/schizo-affective disorder, obsessive compulsive disorder or major depressive disorder
- Fluent in Dutch
- Clinically stable
- Male or female 16 to 55 years

Exclusion criteria

- High risk of suicide (score of 2 or more on HAM-D suicide item)
- Unstable medical disorder
- Current substance abuse disorder
- History of a clinically significant abnormality of the neurological system (including dementia and other cognitive disorders or significant head injury) or any history of seizure (excluding febrile seizure).
- Premorbid IQ < 70

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL46634.018.13