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The cognition game study

Submission date	Recruitment status	[ ] Prospectively registered
06/09/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/09/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/12/2019	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
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 maintenance or earlier return to employment and independent living and therefore to reduced healthcare and economic burden. Availability of interventions to improve cognitive dysfunction is limited. The companies MyCognition and Preloaded have developed AquaSnap which is designed to enhance and sustain performance leading to reduction in cognitive deficits. A potential advantage of AquaSnap over and above existing cognitive remediation test batteries is that more subjects comply with treatment because playing the game is enjoyable. The aim of this study is to investigate a newly developed online cognitive game (AquaSnap) to help psychiatric patients to improve their cognitive functioning.

Who can participate?
Adults aged 16 to 55 years old who have a diagnosis of schizophrenia/schizoaffective disorder, obsessive compulsive disorder or major depressive disorder

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive treatment as usual. Those in the second group receive treatment as usual as well as are given 12 weeks of cognitive training through playing AquaSnap. They are asked for play for a minimum of one hour a week. The game has an incorporated new cognitive assessment tool that changes the difficulty level of the game. Participants are followed up 12 weeks after the study to assess their cognitive function and the severity of their symptoms.

What are the possible benefits and risks of participating?
The possible benefit is for the subject might be improved cognitive functions for those who have played the game. There are no expected risks or side effects related to participating.

Where is the study run from?
Academisch Medisch Centrum (Netherlands)

When is the study starting and how long is it expected to run for?
December 2013 to June 2017

Who is funding the study?
Academisch Medisch Centrum (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
NL 46634.018.13

Study information

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

Acronym
The Cognition Game Study

Study objectives
We expect that subjects that play the cognitive game for 12 weeks improve more in cognitive functioning compared to subjects that were in the treatment as usual condition.

Ethics approval required

Old ethics approval format

Ethics approval(s)
The Medical Ethical Committee of the Academic Medical Center Amsterdam, 22/04/2014, ref: 2013_375#B2014352

Study design
Single center blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cognitive impairment in psychiatric patients (we included subjects with schizophrenia/schizo-affective disorder, major depressive disorder and obsessive compulsive disorder

Interventions
Participants are randomly assigned to either treatment as usual (TAU) or the intervention plus TAU. All recruited participants are randomly assigned after completion of screening and baseline measurement in a 1:1 ratio. The intervention group was asked to play the game at home for at least 1 hour a week for 12 weeks. The TAU group was not given any extra instructions, but was offered a chance to play the game after followup measurement was completed. Both groups returned to the clinic for final measurement at 12 weeks.

The intervention group receive 12 weeks of cognitive training through the means of a newly developed online cognitive game that could be played from home. Subjects were asked to play a minimum of 1 hour a week. The games are developed as an adaptable training, which means the speed and difficulty level of the game changes according to the level of the player. The difficulty and intensity of the game is adjusted to the MyCQ scores (an incorporated new cognitive assessment tool) of the player, so that more impaired domains are trained more intensively. The control group received treatment as usual and could play the game after the trial was finished.

AquaSnap has an aquatic team whereby players have to explore the ocean and take photographs of fish. The player can choose where to dive and complete missions while diving. Taking the best photographs and completing missions will give the player experience points and coins, which then can be used to discover new areas on the map where the player can dive deeper into the ocean and encounter more unique fish. To train each cognitive domain, specific tasks, or loops, have been developed. These loops represent different ways to photograph a fish and are focused on training one of the five key-domains of cognition, however some loops train more than one domain. A series of loops are combined into an underwater dive. The game gets more difficult as the player proceeds further into the ocean and unlocks new areas. AquaSnap is an adaptable training, which means the speed and difficulty level of the game changes according to the level of the player. The difficulty and intensity of the game is adjusted to the cognitive scores of the player, so that more impaired domains are trained more intensively. The game can be reached online and can be accessed either through a laptop, PC, smartphone or tablet.

Intervention Type
Other

Primary outcome(s)
Cognitive functioning is measured using CANTAB and MyCQ at baseline and 12 weeks after the intervention.

Key secondary outcome(s))
1. Cognitive functioning is asssessed using the MyCQ at week 4 and week 8
2. Severity of symptoms is measured using PANSS for psychotic patients, YBOCS for OCD patients and IDS for depressed patients at baseline and 12 weeks
3. Blood marker abnormalities is measured using blood collection at baseline
4. Electro-encephalogram (EEG) is measured using the P300 and Mismatch negativity and resting state at baseline and 12 weeks
5. Level of functioning is measured using GAF Score at baseline and 12 weeks
6. Cortisol level is measured using hair analysis at baseline and 12 weeks

Completion date
13/06/2017

Eligibility

Key inclusion criteria
1. Ability to give informed consent
2. Where participants are of legal childhood age, consent will also be obtained from one of the participant's parents. Both the parent and participant will be required to sign the consent form in such a case. It will be the investigator's responsibility to determine whether a participant of legal childhood age has the capacity to consent to the study.
3. Age 16 - 55 years old
4. DSM-IV-TR diagnosis of schizophrenia/schizoaffective disorder, obsessive compulsive disorder or major depressive disorder
5. Fluent in Dutch
6. Clinically stable

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. High risk of suicide (score of 2 or more on HAM-D suicide item)
2. Unstable medical disorder
3. Having met the criteria for a substance abuse disorder in the last three months (measured by the MINI-plus)
4. 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)
5. Premorbid IQ < 70

Date of first enrolment
28/05/2014

Date of final enrolment
15/02/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center Amsterdam
Meibergdreef 5
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
MyCognition

Funder(s)

Funder type
University/education

Funder Name
Academisch Medisch Centrum

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Funder Name
MyCognition

Results and Publications

Individual participant data (IPD) sharing plan
An anonymized dataset will be available on reasonable request and deposited in a public online data repository as soon as possible (before the end of this year). To access the data before that time, one can contact me: Anna Domen, Dept. of Psychiatry Academic Medical Center Amsterdam, Netherlands, email: a.c.domen@amc.uva.nl, tel: + 31(0) 208913671

IPD sharing plan summary
Available on request