

The cognition game study

Submission date 06/09/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/09/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/12/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 to 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?
Miss Anna Domen
a.c.domen@amc.uva.nl

Contact information

Type(s)
Public

Contact name
Miss Anna Domen

ORCID ID
<http://orcid.org/0000-0001-7932-4101>

Contact details
Academisch Medisch Centrum
Meibergdreef 5
Amsterdam
Netherlands
1105 AZ
+31 208913671
a.c.domen@amsterdamumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Cognitive impairment in psychiatric patients (we included subjects with schizophrenia/schizoaffective 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 measure

Cognitive functioning is measured using CANTAB and MyCQ at baseline and 12 weeks after the intervention.

Secondary outcome measures

1. Cognitive functioning is assessed 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

Overall study start date

01/12/2013

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

Age group

Adult

Sex

Both

Target number of participants

60

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

Sponsor details

25 Moorgate

London

United Kingdom
EC2R 6AY

Sponsor type
Other

Website
<http://www.mycognition.com/>

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

Publication and dissemination plan

Analysis and write up of the results has started and we plan to submit a paper on the study effect to a peer-reviewed journal at the beginning of 2018. An article on the validity of the new assessment tool developed in concurrence with the cognitive game (the MyCQ) has already been submitted.

Intention to publish date
30/06/2020

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