Effect of Health games on Cognitive Function in Parkinson*s Disease

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

Summary

ID

NL-OMON43614

Source
ToetsingOnline

Brief title
Health game for cognition

Condition

- Other condition

Synonym
change in cognition; parkinson's disease

Health condition

neurologische aandoening

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: MyCognition LTD,Softwarebedrijf MyCognition LTD

Intervention

Keyword: cognition, Parkinson disease, video games

Outcome measures

Primary outcome

The primary endpoint is the "overall cognition compound score" from the standard neuropsychological battery that is based on the following cognitive domains: executive function/attention, memory, language and visual perception/construction at 12 and 24 weeks of follow-up. A compound score for overall (global) cognitive function will be calculated as the mean score of all test Z-scores (domains).

The change from baseline to the follow-up assessments will also be analyzed on a domain level by summing the standardized scores of the separate tests per domain.

A second primary outcome is the MyCQ score, which is an integral part of the AquaSnap game. Performances on the (monthly taken) MyCQ assessment are translated into a change in difficulty of AquaSnap.

Secondary outcome

Secondary outcome measures are mood, subjective cognition (complaints), functional cognitive status, quality of life, NART, MDS-UPDRS III,HADS, CFQ,

PDCFR, PDQ39, BIS, motor function, and AquaSnap evaluation.

The addition of the 24 week follow up assessment (as secondary endpoint) provides us information about the course of the effect and whether it persists in either those who continue and stop playing the game and the attractiveness of the game.

fMRI outcome: At two moments (baseline and week 12) 40 subjects will receive an MRI scan. The main study parameters of the fMRI sub-study are change in the activity of the resting-state network associated with executive function that covers several medial-frontal areas, including the anterior cingulate, paracingulate and occipital cortex. The fMRI sub-study will help to interpret the concurrent clinical improvements, and may serve as a surrogate outcome to detect subclinical improvements as proof-of-concept for the efficacy of the intervention, even in the face of a potential negative clinical outcome.

Study description

Background summary

Parkinson*s disease (PD) is a common neurodegenerative disorder that is characterized by both motor symptoms (tremor, slowness and poverty of movements, gait difficulties) and non-motor symptoms (cognitive impairment, depression, sleep disorders). In the last decades, these non-motor symptoms have been increasingly recognized as major contributors to the decreased quality of life in PD patients. Cognitive impairment is already noticeable in early non-demented stages of PD, and these cognitive deficits worsen with disease progression. The cumulative prevalence of dementia is as high as 80% in the advanced stages of PD.

Current treatment strategies are partially effective at best, and even with best medical management, cognitive impairment remains a common and debilitating problem for the majority of patients with PD. Therefore, adequate strategies to better treat cognitive impairment and to possibly decelerate the process of cognitive decline are urgently needed.

MyCognition developed a serious game called AquaSnap which might be able to interactively improve various cognitive functions. The compliance of PD patients might be higher compared to current therapies, due to the enjoying storyline in the game. This may lead to better results.

Study objective

The main aim of this phase-II-proof-of-principle study is to test whether the health game AquaSnap offers improvement of cognitive impairment in PD patients with mild cognitive impairment, using an RCT. The long-term ambition is to test whether the My-Cog intervention can also reduce the speed of cognitive decline, but this requires a different test design and is dependent upon positive findings here. Moreover, the study proposed here will provide information about the feasibility and compliance of the intervention in an elderly population of non-gamers with mild cognitive deficits.

Objective fMRI: The objective of the fMRI sub-study is creating a better understanding of the mechanisms responsible for MCI and locating the changes in various brain structures due to AquaSnap.

Study design

A randomized controlled trial. Subjects are randomized into two groups. Group A (N=111) will play AquaSnap for 12 weeks. Group A is offered to continue playing the game for second period of 12 weeks, but this is not obligatory. During this second period, group B (N=111) is offered to play AquaSnap for 12 weeks.

Study Design fMRI: 20 playing subjects (Group A) and 20 controlgroup (Group B) subjects will participate in the sub-study fMRI, which aims at providing us with evidence for a mechanistic explanation for the effect of the intervention.

Intervention

The subjects receive treatment as usual and an account for health game AquaSnap, which they can play at home on a computer of an iPad. In AquaSnap, five domains of cognitive functioning are trained: psychomotor speed, executive function, episodic memory, attention span, and working memory. Group A (N=111) is asked to play the game at least three times a week, for at least 30 minutes and during 12 weeks. After these 12 weeks they are allowed to continue playing

the game a second period of 12 weeks, but this is not obligatory. During this second period, group B (control group, N=111) is offered to play the game for 12 weeks free of choice.

Study burden and risks

Subjects are neuropsychologically assessed at three moments: baseline, week 12 and week 24 (follow-up). This assessment takes about 2-3 hours to complete. The MYCQ will be assessed at baseline, week 4, 8, 12, and 24 and will take about 30 minutes each time. All of the intervention subjects are required to play the game for 12 weeks in a row for at least 1,5 hour a week. We do not suspect to come across serious risks. Nonetheless, some of the subject may be sensitive to gaming addiction. The possible benefits for participants are improvements in cognitive functioning. The total burden will be about 27 hours.

fMRI burden and risks: Some subjects will join the fMRI sub-study. They will have two cerebral MRI scans with a duration of about one hour each. Risks will be prevented due to additional exclusion criteria (§10.3). However, there is a small chance of finding a disorder in the MRI scans. This will be shared immediately with the treating doctor.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Diagnosis of idiopathic PD according to the UK Brain Bank Criteria
- Cognitive impairment at baseline in line with the Level 1 criteria for MCI and a cut-off of 1.5 SD below the normative mean.
- Aged between 40 and 75 years old.
- Not receiving any other cognitive therapy or intensified physical activity during the study
- Relatively stable dopaminergic medication (and relatively stable stimulation parameters in case of a neurostimulator) within last three months, or the change in medication does not influence cognition (LED change of less than 50% increase or decrease).
- Must have access to internet.

Exclusion criteria

- Hoehn & Yahr stage 4 or 5
- Advanced problems in cognitive functioning: Montreal Cognitive Assessment (MoCa) < 19/30
- Habitual gamers (>1hr games/week in preceding year)
- Active depression or psychosis and/or treatment with anti-depressant or anti-psychotic drugs which influences cognition.
- Medication interfering with cognition including anticholinergic medication, benzodiazepines not used as sleep medication and stimulants (i.e. methylphenidate)
- Premorbid intelligence < 86 based on the Dutch National Adult Reading test (NART)
- Severe auditory or visual deficits
- History of active thyroid disease, stroke with residual deficits, severe hypertension or diabetes or head trauma interfering in cognition
- (MRI substudy exclusion: any piece of metal in the body, and/or claustrophobia).

Study design

Design

Study phase: 2

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2016
Enrollment:	222
Type:	Actual

Ethics review

Approved WMO Date:	17-12-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-10-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL51188.068.14