

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

Gepubliceerd: 07-01-2016 Laatste bijgewerkt: 13-12-2022

To evaluate the effects of a versatile web-based health game on cognition and compliance in Parkinson's disease with mild cognitive impairment.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21375

Bron

NTR

Aandoening

mild cognitive impairment

Ondersteuning

Primaire sponsor: University Medical Centre Maastricht

Overige ondersteuning: University Medical Centre Maastricht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

cognition as measured by a standard neuropsychological assessment and online assessment

Toelichting onderzoek

Achtergrond van het onderzoek

Cognitive impairment is an important non-motor symptom in PD and major determinant of the quality of life. The study aims to evaluate the effects of a versatile web-based health game on cognition and compliance in Parkinson's disease with mild cognitive impairment.

Doel van het onderzoek

To evaluate the effects of a versatile web-based health game on cognition and compliance in Parkinson's disease with mild cognitive impairment.

Onderzoeksopzet

baseline: $t=0$

12 weeks: $t=1$

24 weeks: $t=2$

Cognition is measured on all timepoints by calculating a z-score on a standard neuropsychological assessment and several self report questionnaires (HADS, CFQ, PD-CFR, Pre-R-ODS, PDQ39, and BIS-11).

Compliance is measured on all timepoints.

Motor symptoms are measured on all timepoints using the UPDRS-PD part III (motor symptoms).

Biological endpoints are measured on $t=0$ and $t=1$ in a subgroup of 40 participants using functional magnetic resonance imaging (fMRI).

Onderzoeksproduct en/of interventie

The intervention group receives a computerized cognitive training (health game) for a first period of 12 weeks. During this first period, the control group is placed on a waiting list. At the start of the second period of 12 weeks, both the intervention and the control group are allowed to receive the cognitive training.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 cutoff 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,

Stable dopaminergic medication within last 3 months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Hoehn & Yahr stage 4 or 5,

Advanced problems in cognitive functioning: Montreal Cognitive Assessment (MoCa) < 21/30,

Habitual gamers (>1hr games/week in preceding year),

Active depression or psychosis and/or treatment with antidepressant or antipsychotic drugs,

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,

Excessive daytime sleepiness (Epworth Sleepiness Scale score >10),

(MRI substudy exclusion: any piece of metal in the body, and/or claustrophobia).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2016

Aantal proefpersonen: 222
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 07-01-2016
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5502
NTR-old	NTR5637
Ander register	MEC/IRB Maastricht : 141128

Resultaten