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Exploring the feasibility and effects of technological visual training as a potential rehabilitation tool in Parkinson's

Submission date
06/04/2021

Recruitment status
No longer recruiting

Registration date
21/04/2021

Overall study status
Completed

Last Edited
19/12/2024

Condition category
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study aims to explore whether vision and balance can be improved with visual training for people with Parkinson's (PwP). Research has shown that PwP rely more heavily on their vision for day-to-day activities. Visual and cognitive (thinking) problems combined with balance issues increase the risk of falls. This risk in turn can lead to decreased physical activity and reduced quality of life for PwP. The study team aims to find out what effect visual training has on participants' visual abilities and whether this has any impact on their balance and walking. The study would also like to explore participants' experiences of using the visual training devices in this study.

Who can participate?
People over the age of 50 years with a diagnosis of Parkinson's by a movement disorder specialist. . Participants must be able to walk and stand without support or assistance from another person and have adequate hearing/vision capabilities to allow participation in all aspects of study. Medication must be stable for the previous 1 month and anticipated over a period of 6 months.

What does the study involve?
This study involves two different visual training interventions, one using technology and the other using pen and paper and game-based activities. Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). Participants will need to be available to visit the Gait Laboratory at Coach Lane Campus, Northumbria University on two separate occasions during the study for assessments of their vision, balance and gait. (Travel expenses will be reimbursed and refreshments will be provided).

After the initial assessment, participants will undertake a period of visual training which will involve a physiotherapist visiting them at home twice a week for 4 weeks. After they have completed this training, participants will be invited back to the Gait Lab for a final time to be reassessed

What are the possible benefits and risks of participating?
It is hoped that this work will increase understanding of visual training in PwP and will aid in the future development of more effective treatments for vision and balance problems experienced by PwP. In addition, participants may experience improvements in their visual function and/or balance as a result of the training they receive as part of this research and will receive feedback about this at the end of the study. With participants' permission, their local doctor or relevant medical practitioner will be informed of any findings from the assessments that may warrant further attention.

There are no significant risks in taking part in this research although involvement in the study will require a significant time commitment as detailed above. Participants will need to be available for 5 consecutive weeks which will include making 2 separate visits (lasting 2-3 h each) to the Clinical Gait Lab, as well as having time to allow a physiotherapist to visit their home for a 4-week period to undertake visual training exercises. While all visits will be arranged at the participants' convenience, they may find the schedule is difficult to accommodate.

Participants will be asked to undertake some training using special glasses called “Strobe Glasses”. Training with these glasses has been shown to improve hand-eye coordination and reaction times. The lenses flicker between clear and opaque and some people may experience a feeling of slight motion sickness when wearing them for the first time (or if using them for prolonged periods). Participants who use prescription glasses will need to be able to manage without these for short periods (up to 10 min) to allow them to wear the strobe glasses.

Where is the study run from?
Northumbria University (UK)

When is the study starting and how long is it expected to run for?
From May 2021 to November 2022

Who is funding the study?
Senaptec Inc. (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
287526

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 48327, IRAS 287526

Study information

Scientific Title
Technological visual training in Parkinson's disease: a pilot randomised cross-over trial

Acronym
TVT-PD

Study objectives
1. People with Parkinson’s will find visual training using stroboscopic eyewear and a mobile application acceptable and more engaging than standard (pen & paper) methods and will not experience any adverse events from the interventions
2. Participants who undertake technological visual training using a combination of stroboscopic eyewear and a mobile application will show greater improvement in visual attention performance, compared to participants who undertake visual training using standard (pen & paper) methods

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/03/2021, South Central - Berkshire B Research Ethics Committee (Reading Business Centre, Fountain House, 2 Queens Walk, Reading, Berkshire, RG1 7QF; +44 (0)207 104 8226; berkshireb.rec@hra.nhs.uk), ref: 21/SC/0042

Study design
Randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
See additional file ISRCTN46164906_PIS_v2.0_09Mar2021

Health condition(s) or problem(s) studied
Parkinson's Disease

Interventions
Current interventions as of 24/05/2022:

This is now a parallel group design which means that after participants have been screened for eligibility, they will be assessed, and randomly allocated to one of two intervention groups (group A - technology-based or group B - standard care) using a computer-generated random number sequence. They will then receive 4-weeks of visuo-cognitive training, involving twice weekly visits from a Physiotherapist in their own homes.

Following the informed written consent procedure, participants (n=40) will be required to answer some demographic questions, such as education level, falls history, and activity level. They then will complete clinical assessments (such as the Unified Parkinson's Disease Rating scale) and a battery of neuropsychology and opthalmological assessments, which involve answering some questions and completing some pen and paper or computerised tasks.

All assessments will take place at the Clinical Gait Lab at the Coach Lane Campus, Northumbria University. Participants will undergo a total of 2 assessments: one at baseline and the other on completion of the 4-week intervention. All training interventions will take place in participants' own homes and with a qualified physiotherapist from the research team present at all times. Participants will receive two visits
per week for 4 weeks so they will receive a total of 8 home visits over the study period.

Participants allocated to group A (technology based intervention) will be invited to answer some questions in the form of a semi-structured interview to explore their experiences of using the visual training technology.

Participants will be involved with the study for a period of 5 consecutive weeks.

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Previous interventions:

This is a cross-over trial which means after participants have been screened for eligibility, they will be assessed, randomly split into two equal size groups (group A and group B) using a computer-generated random number sequence, and then have two 4-week training periods involving two different visual training interventions.

Following the informed written consent procedure, participants (n=40) will be required to answer some demographic questions, such as education level, falls history, and activity level. They then will complete clinical assessments (such as the Unified Parkinson's Disease Rating scale) and a battery of neuropsychology and opthalmological assessments, which involve answering some questions and completing some pen and paper or computerised tasks.

All assessments will take place at the Clinical Gait Lab at the Coach Lane Campus, Northumbria University. Participants will undergo a total of 3 assessments: at baseline, after the first 4-week intervention, and after the second 4-week intervention. There will be a two-week break between training periods so that the effects of the first intervention have worn off before participants start the next intervention. Participants will receive the following two interventions (the order depending on whether they are in Group A or Group B):
1. Technological visual training (TVT), an intervention involving visual training with strobe glasses and a mobile application.
2. Active control intervention involving tasks, drills, and modified games that are currently used in clinical practice.

All training interventions will take place in participants' own homes and with a qualified physiotherapist from the research team present at all times. Participants will receive two visits per week for 4 weeks for each of the training interventions (TVT and active control) so they will receive a total of 16 home visits over the study period.

During the final visit of the second intervention arm, participants will be invited to answer some questions in the form of a semi-structured interview to explore their experiences of using the visual training technology.

Participants will be involved with the study for a period of 12 consecutive weeks.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 24/05/2022:

Feasibilty measures
Visual attention measured using the Visual Trail Making Test (TMT) Parts A and B at baseline and after the intervention period.

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Previous primary outcome measure:

Visual attention measured using the Visual Trail Making Test (TMT) Parts A and B at baseline, 4, and 12 weeks

Secondary outcome measures
1. Mood measured using the Geriatric depression scale (GDS-15) at baseline
2. General cognition measured using the following:
2.1. Montreal cognitive assessment (MoCA) at baseline
2.2. The Penn Parkinson's Daily Activities Questionnaire-15 (PDAQ-15) at baseline, 4, and 12 weeks
2.3. Attention Computer Battery at baseline, 4, and 12 weeks
3. Visuospatial ability measured using Benton’s Judgement of Line Orientation Test and the Clock copying task (Royall’s CLOX 1 + 2) at baseline, 4, and 12 weeks
4. Visual acuity measured using LogMAR at baseline, 4, and 12 weeks
5. Contrast sensitivity measured using the Mars Letter Contrast Sensitivity Test at baseline, 4, and 12 weeks
6. Visual and sensorimotor skills measured using Senaptec Sensory Station at baseline, 4, and 12 weeks
7. Parkinson's disease status measured using the Hoehn & Yahr (H & Y) scale at baseline
8. Motor symptoms measured using the Unified Parkinson's Disease Rating Scale (UPDRS-III) at baseline, 4, and 12 weeks
9. Freezing of Gait measured using the new Freezing of Gait questionnaire (FOGQ) at baseline, 4, and 12 weeks
10. Falls measured using the Falls efficacy scale- International (FES-I) at baseline, 4, and 12 weeks
11. Quality of Life measured using Parkinson’s Disease Questionnaire- 39 (PDQ-39) at baseline, 4, and 12 weeks
12. Balance measured using Mini Best Test at baseline, 4, and 12 weeks
13. Gait measured using Timed up and Go and the 10 m walk test at baseline, 4, and 12 weeks
14. Fatigue measured using the Fatigue Severity Scale at baseline, 4, and 12 weeks
15. Participation (effort/motivation) measured using Pittsburgh Rehabilitation Participation Scale at baseline, 4, and 12 weeks
16. Usability of visual training technology measured using Systems Usability Scale at either 4

weeks or 12 weeks
17. Participant experience measured using Semi-structured Interviews at 12 weeks

Overall study start date
01/10/2020

Completion date
30/11/2022

Eligibility

Key inclusion criteria
1. Clinical diagnosis of Parkinson's by a movement disorder specialist according to UK brain bank criteria (Hoehn and Yahr stage I-III)
2. Aged >50 years
3. Able to walk and stand without support or assistance from another person
4. Have adequate hearing/vision capabilities to allow participation in all aspects of the study (if participant wears prescription glasses, they must be comfortable to remove these for short periods of up to 5 min at a time in order to take part in activities whilst wearing strobe glasses)
5. Stable medication for the previous 1 month and anticipated over a period of 6 months.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Total final enrolment
40

Key exclusion criteria
1. History of epilepsy, seizures, migraines, severe motion sickness, or sensitivity to light
2. Psychiatric co-morbidity (such as major depressive disorder as determined by a geriatric depression scale [GDS-15] score <10)
3. Clinical diagnosis of dementia or other severe cognitive impairment
4. History of stroke, traumatic brain injury, MS, or neurological disorders other than Parkinson's disease
5. Acute lower back or lower extremity pain, peripheral neuropathy, or rheumatic and orthopaedic diseases
6. Unstable medical conditions including cardio-vascular instability in the past 6 months
7. Unable to comply with the testing protocol
8. Currently participating in another interfering research project or undergoing any interfering therapy
9. Have not had the opportunity to receive a COVID-19 vaccine (individuals may still be included

in the study if they have been offered the vaccine but have declined due to personal circumstances)
10. If experiencing COVID-19 symptoms individuals will be managed as per the latest government guidelines

Date of first enrolment
03/05/2021

Date of final enrolment
28/10/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Tyneside General Hospital
Rake Ln
Tyne and Wear
North Shields
United Kingdom
NE29 8NH

Study participating centre
Gateshead - Queen Elizabeth Hospital
Queen Elizabeth Hospital
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NE9 6SX

Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/049e6bc10

Funder(s)

Funder type
Industry

Funder Name
Senaptec Inc.

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 02/06/2023:
The study protocol has been published: https://doi.org/10.1371/journal.pone.0275738
Qualitative findings from the cross-over trial have been accepted for publication in PLOS ONE, awaiting online publication.
Further qualitative and main results are planned for publication in peer-reviewed journals.

Previous publication and dissemination plan:
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date. The specific data sharing plans are still being established but we will make data available at the end of the trial. Participants will provide their written consent for their anonymised data to be archived in a suitable discipline data repository, with potential to be used in future by other researchers.

Data from the study will only be accessed directly by the research team on the application and will be securely password protected. The data will be kept and stored according to the university's regulations and will be destroyed as such when the study is complete. No personal or identifiable data will be uploaded to any repository or shared with any outside parties, as that would be a breach of data security. Information will be kept in accordance to GDPR and will be destroyed according to the appropriate timescales. Once the study has completed its main objectives, data will be stored for 10 years after which it will be disposed of.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2.0	09/03/2021	21/04/2021	No	Yes
Participant information sheet	version 3.0	11/10/2021	24/05/2022	No	Yes
Protocol article		07/10/2022	19/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article	Experiences	15/06/2023	19/12/2023	Yes	No
Results article		18/12/2024	19/12/2024	Yes	No