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VISUAL TRAINING IN PARKINSON'S

PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you.

**One of our team will go through the information sheet with you and answer any questions you have.
Please talk to others about the study if you wish.**

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear.

Principal investigator: Dr Sam Stuart
Email: **sam.stuart@northumbria.ac.uk**

PhD Researcher: Julia Das
Email: **julia.das@northumbria.ac.uk**



VISUAL TRAINING IN PARKINSON'S

Summary sheet

WE INVITE YOU TO TAKE PART IN A RESEARCH STUDY

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with friends or relatives if you wish. Take time to decide whether or not you wish to take part.
- You are free to decide whether or not to take part in this study. If chose not to take part, this will not affect the care you receive in the future.
- Please ask us if there is anything that is not clear or if you would like more information.

IMPORTANT THINGS YOU NEED TO KNOW

- We want to find out whether vision and balance can be improved with visual training for people with Parkinson's (PwP).
- We would also like to explore people's experiences of using the visual training devices in this study.
- This study has two different visual training options. Regardless of what group you are in, you will receive both training interventions.
- You will need to be available to visit the Gait Laboratory at Coach Lane Campus, Northumbria University on three separate occasions during the study.
- All other interventions will take place in your own home with a qualified physiotherapist.
- You can stop taking part in this study at any time without giving a reason.

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HOW TO CONTACT US

If you have any questions about this study, please talk to a member of the research team on **0191 227 3343**.

You may also discuss the study with any members of the Northumbria Healthcare PD team who are contactable via the Parkinson's office on **0191 293 4167**, Monday to Friday between 9am-5pm.

PARTICIPANT INFORMATION: PART 1

What is the purpose of the study?

This study is being undertaken as part of an educational project (PhD) and 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 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. We are interested in finding out what effect visual training has on participants' visual abilities and whether this has any impact on their balance and walking. We would also like to explore participants' experiences of using the visual training devices in this study.

Why have I been invited?

You have been invited to participate in this study because you have Parkinson's and are eligible to take part in a visual training programme.

Do I have to take part?

No, it is entirely up to you whether you choose to take part.

If you do decide to participate, you will be asked to sign a consent form, but you will still be free to withdraw from the study at any time without giving a reason. Choosing not to take part or withdrawing from the study will not impact on any care you are currently receiving or that you may receive in the future.

**If you wish to withdraw from the research, please contact Julia Das on
Tel: 0191 XXXXXXX or email: julia.das@northumbria.ac.uk**

What will happen to me if I decide to take part?

Once you have had time to read this information sheet and ask any questions, you will be asked to sign a form stating that you understand this information and give your consent to participate in the study.

This is a 'cross-over trial' which means participants will be assessed, randomly split into two groups and then have two 4-week training periods involving different visual training interventions. There will be a 2-week break between training periods so that the effects of the training have worn off before you start the next intervention. You will be reassessed after each 4-week training block. You will be involved in this study for a total of 12 consecutive weeks (see *Figure 1* on page 5 for a summary of the timeline and activities).

All assessments and training interventions will be conducted by Julia Das, a qualified physiotherapist (with experience in treating PwP) and PhD student at Northumbria University or by other members of Dr Sam Stuart's team.

Once you have agreed to take part in the study, we will telephone you to arrange for you to come into the Gait Laboratory at Northumbria University for an initial assessment. This visit will last approximately 2-3 hours and initial screening will be carried out using vision assessments and a brief hearing test involving repeating sentences. You will be able to take rests as required throughout this assessment.

If you are unable to meet a minimum level on the vision and hearing screening tests then you will be unable to participate in the study.

We will then ask you questions about your health, education history, occupation, activity levels and falls. We will also carry out a number of assessments and questionnaires which give us information about your movement and balance. These involve tasks such as walking short distances at a comfortable speed in a straight line while being timed, standing on one leg or with your feet close together for as long as you can manage and turning around in a circle.

In addition, you will also be asked to complete some screen-based assessments of your visual function. Don't worry if you do not have experience with computers, as the tests **only** involve touching a button or screen to make a response. There will be someone with you to assist or explain at all times and you can **do them sitting or standing**. You will also be supported by a member of the research team to complete some tests of memory, language and problem-solving.

We will be using sensors to monitor your movement during the sessions in the lab. You will be asked to wear small wearable sensors over your clothes to give us information about how you are moving and lightweight glasses which will track your eye movements during the assessments.

**We kindly ask participants to bring only essential belongings with them into the Gait Lab (including your usual medications).
Please wear comfortable clothes and footwear when you attend the Gait Lab.**

What happens after the first visit to the Gait Lab?

You will be allocated to one of two groups which will determine whether you start with 4 weeks of standard visual training or 4 weeks of technological visual training (see page 9 for more details of what the visual training will involve). You will receive a telephone call from the researcher prior to starting the visits so you can ask any further questions about the sessions. This will be an opportunity for us to get to know you a little bit better and to help you feel comfortable with the visiting therapist. We will then arrange a convenient time to visit you at home to start the visual training programme. You will need to have time to allow the research physiotherapist to visit you at home twice a week for 4 consecutive weeks. Each visit will last approximately one hour and will be arranged at your convenience. You will be given the researcher's contact details if you need to rearrange a planned visit.

After the 4 weeks of visual training at home, you will be invited back to the Gait Lab for some more tests of your vision, balance and walking. This will be by a different member of the research team and will last between 2-3 hours.

Once you have completed your first 4-week training period and have been reassessed in the Gait Lab, you will then have a 2 week break before starting your second 4-weeks of visual training. This will again involve a researcher coming out to your home for twice weekly visits to help you with the visual training. During the final home visit, you will also be invited to answer some questions about your experiences of the visual training interventions you received. These questions will be recorded on a dictaphone (voice recorder) and we will use your feedback to help us determine how user-friendly the technology is for PwP and how it compares to standard

visual training. We may use quotes from these discussions when we write up our research, but we will not include your name or personal details if we do this.

At the end of this period of training, you will be invited back to the Gait Lab one last time for us to do some final tests of your vision, walking and balance.

The diagram below summarises the timeline and activities for participants:

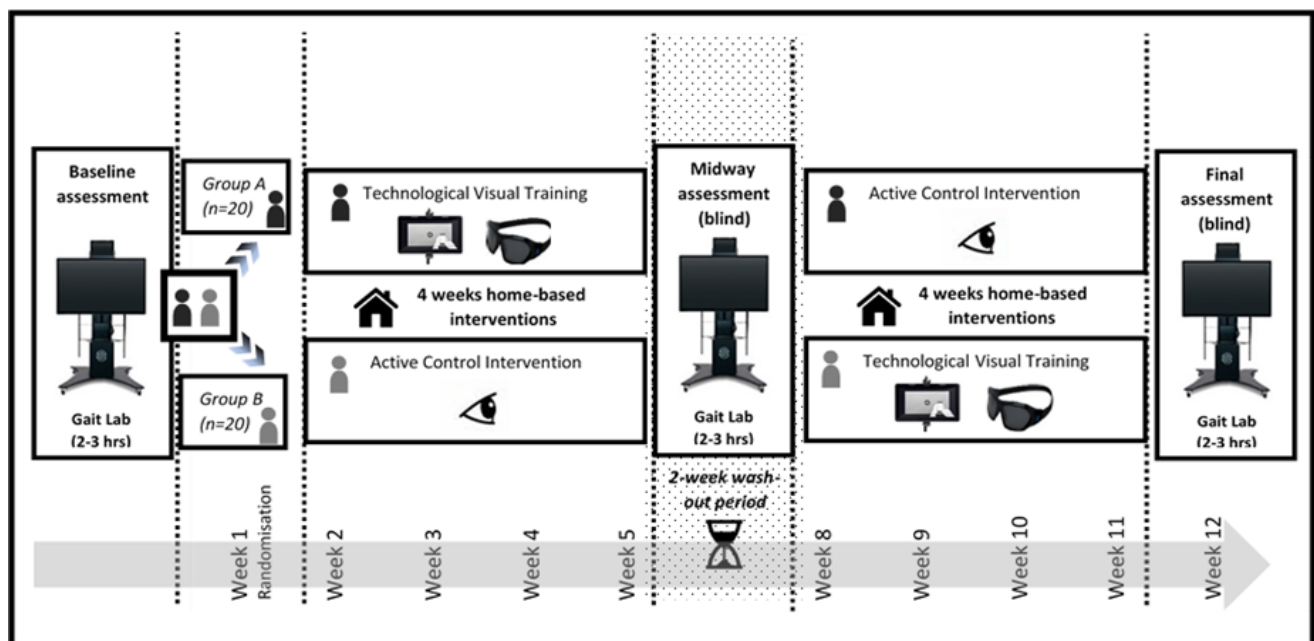


Figure 1. Timeline and activities

What are the possible disadvantages or risks of taking part?

There are no significant risks in taking part in this research.

Involvement in the study will require a significant time commitment. You will need to be available for 12 consecutive weeks which will include you making 3 separate visits (lasting 2-3 hours each) to the Clinical Gait Lab, as well as having time to allow a physiotherapist to visit your home for two 4-week periods to undertake visual training exercises. (You will be able to go away during the 2-week wash-out period between interventions should you wish). While we will ensure all visits are arranged at your convenience, you may find the schedule is difficult to accommodate. You may also find the laboratory-based assessments tiring although all of the activities are short and you can rest as often as you need to. It is important to think about

how you might be affected by the sessions and whether you might need to take some rest at home after completing the assessments and training tasks.

You will be asked to undertake some training using special glasses called “Strobe Glasses” (see image below). Training with these glasses has been shown to improve hand eye co-ordination 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). If you use prescription glasses, you will need to be able to manage without these for short periods (up to 10 minutes) to allow you to wear the strobe glasses.



You will be given time to trial the strobe glasses before starting any procedures to make sure you are happy using them. A qualified physiotherapist from the study team will be with you at all times to help you. If you do feel uncomfortable when wearing these glasses, we will discontinue their use and provide adequate rest periods between sessions to ensure your comfort. You do not have to continue using the strobe glasses if you do experience any symptoms as a result of wearing them, and they can be removed at any time during testing and training.

What are the possible benefits of taking part?

It is hoped that this work will increase our 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, you may experience improvements in your visual function and/or balance as a result of the training you receive as part of this research and we will be able to give you feedback about this at the end of the study.

With your permission, we will inform your local doctor or relevant medical practitioner of any findings from our assessments that may warrant further attention.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time. All information collected is useful and may still be utilised. **Your withdrawal would not affect the care that you receive in the future.**

If you have memory problems, if these get worse, it could make it difficult for you to tell us if you do not want to carry on. Therefore we will discuss this with you and your relative or carer (if applicable) before starting any tests. In the event of you being unable to tell us yourself, your relative or carer can express concerns about you carrying on, and therefore we will withdraw your participation in the study, as a result. We will still store and use the information we have collected from you up to the date of your withdrawal from the study.

MORE INFORMATION ABOUT THE TESTS AND VISUAL TRAINING

Tests will be carried out in the Clinical Gait Laboratory, Coach Lane Campus, Northumbria University. (This is an accessible building with it's own parking at ground level.) Several of the assessments may be carried out in your own home if you would prefer.

CORE ASSESSMENTS

- **Questionnaires**

The researcher will ask you specific questions about how you manage with day-to-day activities and some other specific questions relating to your Parkinsons'.

- **Memory and Concentration Tests**

The researcher will perform some tests of your memory and concentration. These include pen and paper testing to begin with. Please do not worry if you have difficulties with your writing as the researcher will be able to help you with these tasks if needed. The next part will use a small computer. Please do not worry if you have no experience of using computers; you will still be able to do the test and a researcher will be present to assist you as needed.

- **Movement assessment**

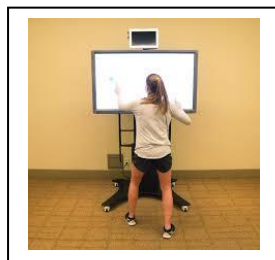
The researcher will perform some tests of your body movements. These include movements such as walking and opening and closing your hand.

- **Gait (walking) assessment**

Questionnaires about your walking and how confident you feel about your balance and mobility may be used. Walking assessments utilising the state-of-the-art on-site gait laboratory will be performed. The tests require no prior training, you can take breaks as needed and a researcher will walk with you in case you feel unsteady at any point.

- **Visual assessment**

You will complete some tasks using the Senaptec Sensory Station (see images below). This is a state-of-the-art sensory evaluation & training station based at the Gait Laboratory. It assesses visual and sensorimotor skills such as visual clarity, contrast sensitivity, reaction time and hand-eye co-ordination.



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VISUAL TRAINING

Visual training sessions will take place in your own home with guidance from a research physiotherapist. Full explanations will be given prior to you completing these activities and the researcher will be present throughout to provide guidance and ensure your safety and comfort.

- **Standard visual training**

These sessions will include a series of activities used in traditional vision therapy to work different parts of your visual system. For example, there will be exercises to challenge your focus by looking at objects at varying distances, there will be activities to improve your hand-eye co-ordination such as throwing and catching and there will be pattern recognition games to improve your attention and visual memory.

- **Technological visual training**

Part of these sessions will involve using a touch screen tablet to undertake various visual training games involving for example, hand-eye co-ordination, decision making, depth perception and near/far focus. These can be done seated or standing.



For the other part of the session, you will be given the strobe glasses to wear whilst performing simple throwing/catching activities as well as training games on the tablet.



PART 2: FURTHER INFORMATION

This section details the organisation of the study and complaint procedures if you are not happy with the conduct of the study.

What if there is a problem?

This is an intervention study involving assessment and visual training. Sometimes previously unrecognised medical issues may be identified during the course of the assessment that may require further attention. In this instance the researcher who assesses you will take appropriate action. This will usually mean writing to your General Practitioner (GP) who can assess matters further.

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact number 0191 227 3343).

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure (Details can be obtained from the hospital) and the Records and Information Officer at Northumbria University: Duncan James (dp.officer@northumbria.ac.uk).

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against Northumbria University, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

NHS Indemnity does not offer no-fault compensation (i.e. for non-negligent harm) and Northumbria healthcare NHS Foundation Trust is unable to agree in advance to pay compensation for non-negligent harm. Northumbria University has agreed to provide indemnity insurance for the study, and we will be following university and government

guidance for the COVID-19 pandemic; with personal protective equipment and infection control measures in place.

Will my taking part in the study be kept confidential?

All information which is collected about you during the research will be kept strictly confidential in accordance with data protection laws. All information we keep about you will be saved under a special study number (e.g. PD01) to ensure confidentiality.

In accordance with data protection legislation, all data collected as part of this study are anonymised with participants being assigned a unique study number (e.g. PD01). All electronically stored data (e.g. videos) will be named using the individuals study number to ensure confidentiality. Facial features will be recognisable from the video and/or photographs. A video and/or photograph(s) help us to verify the data and if you agree, we may use it for presentations at conferences or seminars. However, this is not an essential aspect of the testing and if you would rather not have your video and/or photographs taken this is not a problem. The only information we will retain for our database will be the age and sex of participants and whether they are a patient. We will keep one hard copy of the assessment in the Clinical Gait Laboratory, Northumbria University. This is the only place where we store any personal details like names and addresses. This information is kept locked away and is only available to people directly running the study. These people will treat your information in the strictest confidence. This personal data (e.g. name, address, telephone number etc.) will be stored for up to 12 months and will then be deleted/destroyed, as per the principles of data minimisation. Dr Sam Stuart, the **Principal investigator** of this study, is ultimately responsible for the protection of this information.

There is one important exception to the guarantee of confidentiality. If you tell us something that suggests that you or others are being placed at risk of significant harm, we are obliged to pass this information on. We will talk to you about the procedures involved before the information is shared.

What are my rights as a participant in this study?

Participants have the right to request access to a copy of their computerised personal data and to do so individuals should submit a Subject Access Request Form (contact Dr Sam Stuart to request this). Participants have a right, in certain circumstances, to have inaccurate personal data rectified and a right to object to decisions regarding their personal data being taken by automated means. If participants are dissatisfied with the University's processing of personal data obtained in this study, they have the right to complain to the Information Commissioner's Office. For more information see the ICO website (<https://ico.org.uk/>).

How will my data be stored, and for how long will it be stored?

The results of any tests are kept strictly confidential. All paper data, including the questionnaires, original test scores and your consent forms will be kept in locked storage. All electronic data; including video recordings, will be stored on University servers/computers, which are password protected. All data will be stored in accordance with University guidelines and the Data Protection Act (2018).

Following the end of the study, our plan is to register the anonymous test data with a university linked online data repository (such as figshare.com) so that other researchers may be able to use the data in future, if you have given explicit consent for this. If you agree to us sharing the information you provide with other researchers (e.g. by making it available in a data archive) then your personal details will not be included unless you explicitly request this. We will keep all of the anonymous test data at the university for 10 years, after which it will be securely disposed of.

Who is the Data Controller?

The University of Northumbria will act as the Data Controller for this study. This means that the University is responsible for looking after your information and using it properly.

What is the legal basis for using my personal data?

According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e), General Data Protection Regulation (applicable in the UK and EU from 25 May 2018)).

Will I be reimbursed for taking part?

Participants will not receive payment for their involvement in the study. However, reasonable travel expenses will be paid so that participants can attend the Gait Lab at Coach Lane Campus, Northumbria University. This will be in the form of arranged taxis or reimbursement of mileage. Light refreshments such as tea, coffee and water will be available during your visits to the Gait Lab.

What will happen to the results of the research study?

The results of this study will be written up reports which we will aim to publish in recognised scientific journals. We will also present the findings at international meetings. In any report or publication, we will not use your name or give any information that could identify you. If you would like copies of any publications then you can contact the researchers involved to request them.

Participants in the study will be sent an annual newsletter that briefly details the progress of the study. Key findings will be outlined in a final newsletter at the end of the study. If participants express an interest we will provide specific feedback on results of the tests.

Who is organising and funding the research?

Members of Dr Sam Stuart's research team will conduct this work. Sam Stuart will supervise the running of the study and will conduct the assessments, together with members of the Northumbria University Research team. The work is supported by a Northumbria University PhD studentship and funding and equipment provided to Northumbria University from Senaptec Inc.

Who has reviewed the study?

This study has been reviewed and approved by the **South Central – Berkshire B Research Ethics Committee** (Ref. 21/SC/0042) and the Northumbria University Research Ethics Committee.

We are trying to improve the quality of clinical and research standards. This is being achieved through 'clinical governance'. As part of this process, this study may be reviewed by a clinical governance team. Such a team would need to look at any information that you provide us with to make sure that the research was carried out in accordance with proper procedures.

Thank you for taking the time to read this. You may keep this information sheet.

Further General Information:

If you would like any further general information or advice on attending a research study then please contact the Patient Advice and Liaison Service (PALS) on:

Freephone: 0800 0320202 / Text: 01670 511098.

Email: northoftynepals@nhct.nhs.uk

Website: <https://www.northumbria.nhs.uk/get-involved/share-your-feedback/patient-advice-and-liaison-service-pals/>

You can also write to PALS at their Freepost address.

Freepost: RLTC-SGHH-EGXJ

North of Tyne PALS

The Old Stables

Grey's Yard

Morpeth

NE61 1QD

Contact for further information:

- **Records and Information Officer at Northumbria University: Duncan James (dp.officer@northumbria.ac.uk).**

If your request is urgent, please call +44 (0)191 243 7357

You can find out more about how we use your information at:

www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/legal-services-team/gdpr/gdpr---privacy-notice/ or by contacting a member of the research team

Contact for further study specific information:

Dr Sam Stuart

Vice Chancellors Senior Research Fellow

Department of Sport, Exercise and Rehabilitation

Northumbria University, Northumberland Building (Room NB318)

Newcastle upon Tyne

NE1 8ST

Tel: 0191 227 3343

Email: sam.stuart@northumbria.ac.uk

You may also discuss the study with any members of the Northumbria Healthcare PD team who are contactable via the Parkinson's office on [0191 293 4167](tel:01912934167), Monday to Friday between 9am-5pm.

GLOSSARY

We have tried to avoid the use of technical language and abbreviations in this booklet. Those that we have included are shown in the glossary below. Please do not hesitate to speak to one of the research team if you are unsure about any of the terms used in this booklet.

Dictaphone A sound recording device used to record speech.

We will only be using this during the last home visit to record the answers to the questions we ask you about your experience of the visual training. We will ask for your permission to start recording and you can ask for the recording to be stopped at any time.

Gait The word “gait” is a medical term to describe a person's pattern of walking.

Gait Laboratory (Gait Lab) The clinical gait lab is a large room at Coach Lane University which has equipment for measuring your visual function, walking and movement.

The gait lab is located on the ground floor with direct access to the carpark. You do not need to walk through the university campus to access the gait lab. There are toilets located next to the gait lab and a small waiting area for carers or family members if they wish to accompany you.

GP General Practitioner – this is the medical doctor who you are registered with.

PhD Doctor of Philosophy – this is an advanced research degree.

PD Parkinson's disease

PwP People with Parkinson's

Strobe glasses These are specialist “state-of-the-art” glasses that flicker between clear and opaque and are designed to strengthen the connections between your eyes, brain, and body.