



Department of Public Health & Sport Sciences,
University of Exeter

College of Health, Medicine and Life
Sciences

Department of Health Sciences,
Brunel University London



University
of Exeter

PARTICIPANT INFORMATION SHEET

Project: Weight-shift training to overcome freezing of gait in daily life

You are invited to take part in this research study. If you are interested in taking part, please contact us to express an interest using the details at the end of this document. Before you decide, 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 and discuss it with others if you wish. Ask us for help if there is anything that is unclear or if you would like more information. Take time to decide whether you wish to take part. Thank you for reading.

What is the purpose of the study?

The research project is looking at the topic of freezing of gait in Parkinson's. This study is funded by Parkinson's UK, and organised by the University of Exeter and Brunel University London.

Freezing of gait is the feeling of one's feet being stuck to the floor. It is well-known that freezing of gait can cause many problems in daily life, such as falls and anxiety. Therefore, it is important to find out more about the causes of freezing of gait and to develop ways of overcoming it. This project aims to contribute to both aims. By observing how people move, we will find out more about the causes of freezing of gait and identify factors that make freezing of gait better/worse. We will also evaluate the effectiveness of a new strategy designed specifically to help people overcome freezing of gait and start walking when they choose to. To achieve this, we seek participants that are willing to be visited at their homes for the research team to make recordings of their movements while they carry out daily tasks, such as walking and turning.

Why have I been invited to participate?

It is likely that you have received this Information Sheet through the Parkinson's UK network or through related community/research groups or local branches. If someone has passed this Information Sheet on to you, it is likely because they believe you are a potential participant.

For this project, we are recruiting **people over the age of 55, with an existing diagnosis of Parkinson's disease who experience freezing of gait** at home and who are **able to walk from one room to another without a walker/frame or physical support from another person 'off' medication**. You will also be required to live within reasonable distance from Brunel University London campus (approximately 1 hour), and have sufficient command of the English language to provide informed consent independently.

Unfortunately, we cannot recruit people using a deep brain stimulator (DBS), a Levodopa pump, or with unstable medical condition or experiencing other conditions that affect balance and walking.

Do I have to take part?

As participation is entirely voluntary, it is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. Even if you decide to take part, you are still free to withdraw your participation and/or your data at any time, without giving a reason and with no repercussions. If you decide to stop during a measurement session, we will quickly remove all equipment and leave as soon as possible. You may withdraw by expressing your wish verbally or in writing to the researchers. Alternatively, you can contact Dr Uri Rosenblum Belzer (or Dr Elmar Kal / Prof Meriel Norris), by email/phone (see contacts below). If you decide to withdraw you will be asked whether you want your data to be destroyed as well.

What will happen to me if I take part?

If you want to volunteer for this study, please contact us to express your interest (please see contact details below). We will contact you by telephone or video call, depending on your preference. This will be an opportunity for you to ask questions about the study and for researchers to ask you some general questions to ensure you're eligible to participate in the study. If eligible we will email you a unique participant code and the consent form, and a link to a few online questionnaires about your background and freezing of gait. After you signed the consent form, we will contact you again to obtain more information to help us plan the 1st home visit. Specifically, we will ask what day and time we could best come to your home for this visit, **considering that the first part of testing will take place before you take your morning Parkinson's medications (which you therefore will be asked to postpone by up to 1.5 hours)**. Further, we will also discuss any questions you may have regarding the online questionnaires you received earlier. If you prefer not to complete all these questionnaires online, you will be offered the option of completing them during our first visit (see study parts below).

On the day before the 1st home visit we will call you again as a brief reminder of the visit.

This study has 4 parts:

- 1) **First Home Visit.** We will arrange a home visit based on your availability. **If you wish, you may ask a partner or a friend to join you during this visit for support.** During the home visit we will record your walking, both before and after you take your morning Parkinson's medications. The testing session will take about 5 hours, including time for you to rest. When discussing a suitable date and time, please consider the length of the visit and that we need to record your walking behaviour before and after you take your Parkinson's medication.

Once arrived, a researcher will answer your questions and, if you are still happy to proceed, they will ask to verbally re-confirm your consent to participate. At this point, the researchers will prepare the equipment required for the study. Particularly, you will wear insoles (inside your shoes), sensors that measure your movement (little boxes, taped to your legs and lower back under your clothes) and smart glasses (that allow us to measure where you are looking while walking). We will also ask your permission to place a tripod with a video camera in the areas where you are walking, to record information about potential freezing events. Once you feel comfortable with (moving with) the equipment, we will ask you to perform tasks that are typical of everyday life, such as starting to walk, moving through doorways, and turning. We will ask you to perform these tasks in the areas of your home where you tend to experience freezing of gait the most.

We do not need access to your entire house, we will follow your lead on the areas where you would like us to test you. A researcher will always walk alongside you during these walking tasks to ensure your safety. At this point, it should be time for you to take your

morning medications, and the testing will stop for 30-60 minutes. After this time, we will ask you to perform the exact same tasks you did before. The reason for this is that we aim to gain a good understanding of your freezing, both in situations prior to medication taking full effect, and once medication has started working optimally. After the final walking assessments, we will take all the equipment off you, and we will ask you to complete some brief forms.

At the end of the first visit, we will give you an internet link to specific training videos designed to help you step from a freeze. We will ask you to watch the videos as many times as you need to learn the strategy shown.

As part of the study, the research team is required to identify the following:

- Areas in your home where we will set up our equipment and take measurements of your standing and walking. This would be a relatively small space, like the corner of a table, where we can place a laptop and a small box required for registering your movements.
- Whether a socket is available to plug in some equipment during the visit. Some of the equipment works better when plugged in, but this is not essential. The total energy requirements of the instruments do not exceed 700W per hour, so less than a common microwave. If you prefer, we can use battery-powered instruments instead.

We recognise that your home is a private and personal space. Before, during and after the visit we will maintain the utmost level of privacy and confidentiality.

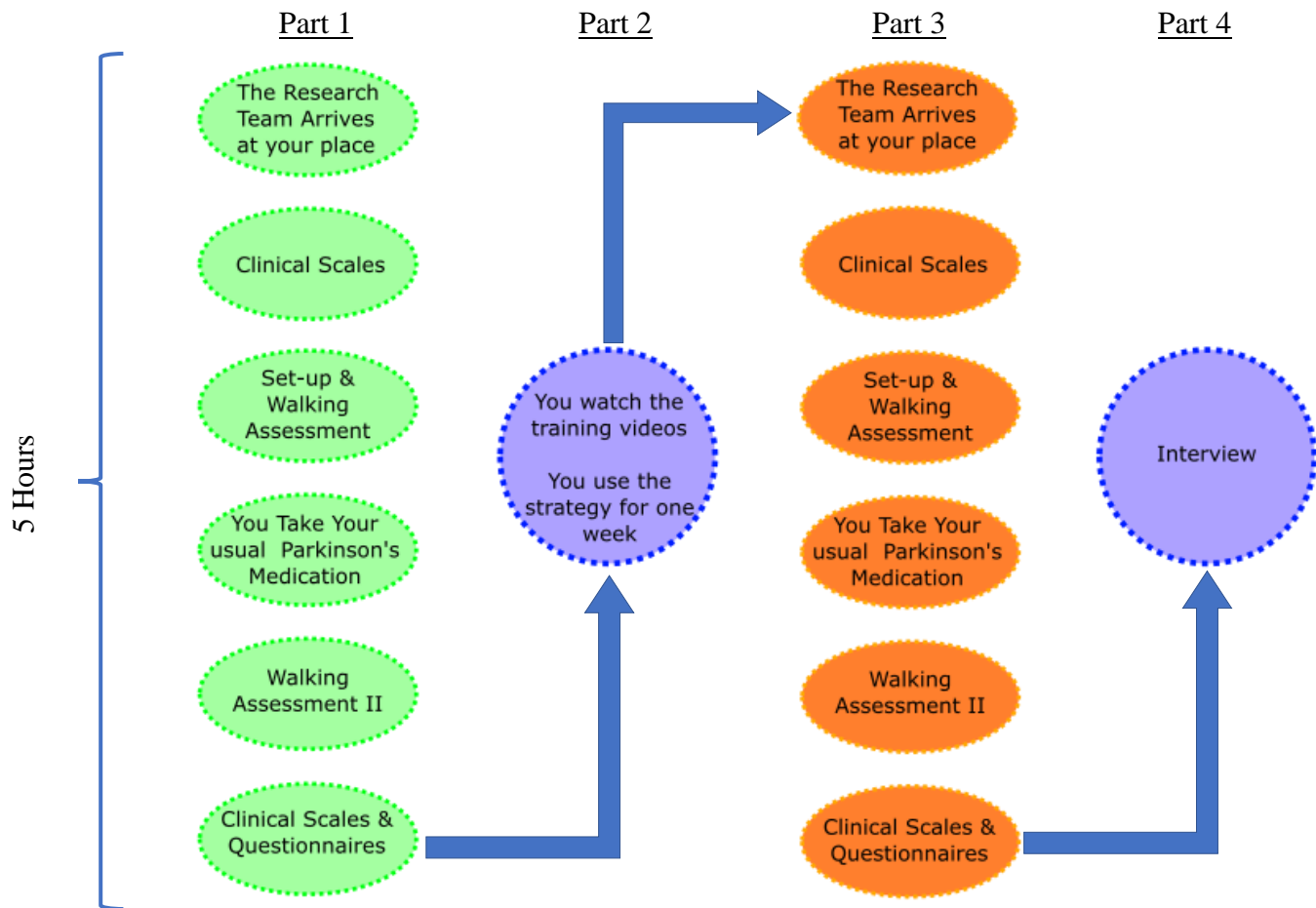
- 2) **Training.** You will have one week to watch the training videos, practice, and use the strategy at your own pace. We will contact you by phone twice in this phase: 3 days after the home visit and the night before the second and final home visit. During these contacts, we will ask you general questions about the training, and we will discuss arrangements for the second visit.
- 3) **Second home visit.** We will arrange a second home visit, one week after the first visit. The procedure for the second home visit will be identical to the first home visit described above. This visit allows us to test whether your freezing experience has changed following your training.
- 4) **Interview.** Finally, one week after the second visit we will contact you to ask you some questions about using the strategy you have learned. We highly value your insights and are keen on understanding if and how you have implemented the strategy. The interview will take approximately 30 to 60 minutes and is specifically designed to collect information about your perception of the strategy.

During the interview, we will ask:

1. How you feel about the strategy and any changes you have observed when applying it in different contexts.
2. The potential uses of the strategy and whether it influences the success of steps following freezing events.
3. The extent to which you have practiced the strategy and how this practice has affected your ability to utilize it effectively.

The interview will be conducted remotely, either through a phone call or an online video call, depending on your preferences. Regardless of the format, the interview will be recorded (either using a Dictaphone or the online platform used for the recording).

The diagram below shows the various activities planned:



Are there any lifestyle restrictions?

Your morning Parkinson's medication dose will be postponed by up to 1.5 hours. Also, the home visit is relatively long and will take about 5 hours. Please take this into account when setting the visit time with us. Finally, two researchers with research equipment will be in your home for the entire testing session which may restrict your family's free movement in your home and can potentially feel awkward.

What are the possible disadvantages and risks of taking part?

It is possible that you will become tired during the home visits, especially during the part of the visit when the testing is performed before you take your Parkinson's medication. During the assessments, especially before you take your medications, there is a risk of falling. To ensure your safety, a team of two researchers will be attending the measurements, to ensure that one can walk with you at all times and minimise risk. We acknowledge that having two people in your home for the entire time of the visit, about five hours, might cause some discomfort.

Please note that the research team that will visit your house are fully vaccinated. Prior to a home visit, they will discuss with you if you would like the researchers to wear a face mask to further reduce the risk of spreading COVID-19. We would like to ask you to inform us prior to a home visit if you (or other members of your household) have COVID-like symptoms and either a high temperature or do not feel well enough to go about your normal daily activities. Similarly, the research team will inform you if this applies to them. In either case, we would then reschedule the visit at a later date.

What are the possible benefits of taking part?

There is no direct benefit from taking part. The training interventions used in this study are designed to help people overcome freezing. However, we do not currently know if you will benefit from this in real life. This study aims to investigate this question.

What if something goes wrong?

If something goes wrong, any complaints can be addressed to the Chair of the Research Ethics Committee (Professor Louise Mansfield at Brunel University London, contact details to be found at the end of this form). If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it.

Will my taking part in this study be kept confidential?

Brunel University London processes personal data for the purpose of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing:

Data-Protection@brunel.ac.uk.

You will be explicitly asked in the consent form whether videos and/or photos of you, recorded during the experiment could be used when disseminating the results of the study (e.g., publications, conferences, meetings etc.). Allowing the use of your image is completely optional, therefore you can opt out and still participate in the study. In case you decide to opt out your videos/photos will not be shared in any form. Pseudonymised data will be stored for

10 years after the completion of the study. Please note that anonymised data recorded in this study may be shared with other researchers or uploaded to a repository accessible upon request.

All information which is collected about you during the research will be kept strictly confidential. Any information about you which leaves the University, will have your name and other personal details removed so that you cannot be directly identified from it (with the exception of videos/images if you explicitly consent to these being used for dissemination purposes). Data will be stored on a secure digital location (OneDrive – Business) to which only the named researchers (Prof Norris, Dr Kal, Dr Rosenblum Belzer) will have access. Access is shared securely through personalised link with Dr Will Young and Dr Yuri Russo at the University of Exeter (our research collaborators).

Will I be recorded, and how will the recording be used?

Yes. with your permission, we will video-record your activities of daily living during the home visits. Using the consent form, we will explicitly ask you to grant permission for these recordings to be made, as well as for how these recording would be used. We will ask you for permission to use these videos for the purpose of analysis of stepping out of freezing attempts. However, you may additionally grant us permission to use these recordings for the purpose of scientific publications and presentations, if you so wish. Allowing the use of your images and videos is completely optional, therefore you can opt out and still participate in the study.

With your permission we will also be audio recording the final interview. These recordings will be transcribed and then deleted. All will be stored on the secure OneDrive as noted above.

What will happen to the results of the research study?

Results will be submitted for publication to peer-reviewed scientific journals, and for presentations at (inter)national conferences. Furthermore, anonymous data will be uploaded to a repository available to the research community to expedite research in this area and encourage international research collaborations on the topic of Parkinson's and freezing of gait. During the project, participants will be informed of the outcomes through a newsletter/bulletin that will be shared through Parkinson's UK.

You will not be identified by name in any of these publications/presentations. Video material will only be used in such publications or presentations, without revealing your face, only if you explicitly consent to this on the consent form. As stated earlier, you can withdraw your consent at any time, without giving a reason and with no repercussions. You may retract such consent at any time by contacting the research team (see contacts at the bottom of the page).

Who is organising and funding the research?

This research is organised by the Department of Health Sciences of Brunel University London (in collaboration with the Department of Public Health & Sport Sciences of University of Exeter) The research is funded by Parkinson's UK (G-2007).

What are the indemnity arrangements?

Brunel University London provides appropriate insurance cover for research which has received ethical approval.

Who has reviewed the study?

The study has been reviewed by the College of Health, Medicine and Life Sciences Research Ethics Committee at Brunel University London and the FHLS Sports and Health Sciences

Ethics Committee at University of Exeter.

Research Integrity

Brunel University London is committed to compliance with the [Universities UK Research Integrity Concordat](#). You are entitled to expect the highest level of integrity from the researchers during this research.

Contact for further information and complaints

For general information / if you're interested in participation, please contact the researchers:

Participation Brunel:

Uri Rosenblum Belzer

Uri.rosenblumbelzer@brunel.ac.uk

Phone:

Elmar Kal

elmar.kal@brunel.ac.uk

For complaints and questions about the conduct of the Research:

Principal Investigator:

Will Young

w.young@exeter.ac.uk

Co-Principal Investigator:

Meriel Norris

Meriel.Norris@brunel.ac.uk

If you feel your complaint has not been handled to your satisfaction, or you wish to file a complaint:

Ethics Committee Brunel:

Professor Louise Mansfield, Chair College of Health, Medicine and Life Sciences Research Ethics Committee - (Louise.mansfield@brunel.ac.uk)

For Data Protection inquiries:

Data-Protection@brunel.ac.uk

Thank you for your interest in this project.