INFORMATION SHEET FOR PARTICIPANTS

IRAS No: 276707

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

INVEST feasibility study

Invitation Paragraph

I would like to invite you to participate in this research project which forms part of my PhD research. The study is being sponsored by King's College London. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the project?

The treatment of dizziness consists of exercises called 'vestibular rehabilitation'. There is evidence to show that not everyone improves with this treatment. New studies suggest that it may be better to look at each person individually and teach them to think about their dizziness and the way they move in a different way. Using the latest evidence from neuroscience and psychology to enhance the usual vestibular exercises.

The purpose of the project is to assess whether it is possible to conduct a full-scale main study. To do this we will collect important information that is needed to design a larger study alongside interviews with participants.

Why have I been invited to take part?

You are being invited to participate in this project because you have experienced dizziness for at least three months. In order to ensure that you are eligible to take part in the study, you will need to complete a screening questionnaire. Once you return the completed screening questionnaire, a member of the research team will notify you of your eligibility.

What will happen if I take part?

For each participant, the study will take 4 months overall and your participation will involve the following:

- Attend an appointment to complete baseline questionnaires (about 20-30 minutes) and a balance test (about 10-15 minutes).

- You will then be randomly allocated (like the flip of a coin) by a computer to one of two treatment approaches. You will not be able to choose the treatment group you are assigned to. The study is conducted this way to ensure that the results are reliable. Below we provide more detail of what each approach will include
- You will be asked to attend another appointment to complete the same questionnaires and balance test after 4 months to see if there has been any change.

The two treatments are:

1) Treatment as usual physiotherapy
The role of being in this group is very important to the study because the outcomes gained by this group set the bar to know whether the new treatment is any better or not. You will receive six sessions of vestibular rehabilitation offered by the physiotherapist you would normally see at St George's Hospital. The treatment will be delivered as normal and is not determined by the study.

2) Psychologically informed physiotherapy
If you are allocated to this group, you will be asked to attend six sessions with a trained physiotherapist over a 4-month period. The first session will be 1 hour and the rest 30 minutes each. Each session will take place in St George's Hospital at times convenient to you. The exercises in each group will be similar but the treatment in this group will include a manual, which includes information about dizziness and all factors that can contribute to it. You will be assisted to increase your physical activity levels and look at different ways to manage your physical symptoms and emotional well-being.

At the end of the treatment you may be asked to be interviewed by a researcher. The researcher will be a different person to your therapist. They will ask you questions about your experience of the trial, such as your level of satisfaction and what you learnt. You can choose for the interview to take place face-to-face or over the phone. Taking part in the interview is not essential to your participation in the study.

As part of participation you will be asked to provide permission for us to access:

- Hospital records: Information from your health records will allow us to confirm information about your test results and diagnosis.
- Video: You may be asked if it would OK if some of your treatment sessions were video recorded. The purpose of these videos is to make sure that your physiotherapist is delivering the rehabilitation in the ideal way. The videos will not be used for any other purpose and will be destroyed after that use. If you are not comfortable with this, you can just decline the invitation. It will not affect your treatment in any way nor your relationship with your physiotherapist or any of the research team.

We will also inform your GP (General practitioner) of your involvement if you choose to take part.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision

about taking part. If you decide to take part we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

Costs

There are no costs to participants associated with the project. Any travel expenses will be reimbursed.

What are the possible risks of taking part?

- Participation will require some time commitment to attend physiotherapy and complete the questionnaires and tests as described above.
- Participants in both groups will undergo a clinical examination and be prescribed movements to do in the clinic and at home. It is possible these may worsen your dizziness, especially in the short term. If you do experience any increase in dizziness, please bring this to the attention of your treating physiotherapist.
- It is possible that completing the questionnaires may cause you some distress, but this is rare. If the questions cause you any concerns or upset you, please stop answering the questions and speak to the researcher.
- Some of the questionnaires ask you about your mood. Depending on your responses, the researcher may ask you questions to assess your safety and make appropriate support services available to you if needed.

What are the possible benefits of taking part?

- If randomised to the usual physiotherapy care group, you will be greatly helping the study by your experience setting the benchmark by which we will know whether the physiotherapy protocol being studied is any better or not. Without this, our study would not be possible.
- If randomised to the new treatment group, you will receive physiotherapy treatment from a qualified physiotherapist who has taken the extra training required for them to deliver it.
- We anticipate the results of this research will allow us to:
    - Improve the knowledge we have about this health condition.
    - Inform health care practitioners about better ways of managing people with the same health condition as you.
    - Inform a future research study in persistent dizziness.

How will you use information about me?

Your data will be processed in accordance with the General Data Protection Regulation 2018 (GDPR).

- We will need to use information from you and your medical records for this research project. This information will include your name, hospital number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.
- People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
- All collected data, video-recordings, and interview transcripts (if you decided to take part in the interview) will be identified by the code number. This is to ensure your anonymity and confidentiality. Your personal information, such your name and contact details will be stored separately from all the collected data.

- The data will be stored securely in a locked cabinet in the Health Psychology department of King's College London. Electronic files will be locked, and password protected.
- Your study data will be retained for 4-years and subsequently disposed of securely. Everything discussed during the sessions or interview will remain completely anonymous unless you tell us something to indicate that your own health and safety is currently in danger.
- We will write our reports in a way that no-one can work out that you took part in the study.

Where can I find out more about how my information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by contacting King's College London's Data Protection Officer, Mr Albert Chan at info-compliance@kcl.ac.uk

What if I change my mind about taking part?

You are free withdraw at any point of the project, without having to give a reason. Withdrawing from the project will not affect you in any way. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the project, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

How is the project being funded?

This project is being funded by the National Institute for Health Research (NIHR). You can find more information about them by visiting their website (www.nihr.ac.uk).

What will happen to the results of the project?

The results of the project will be summarised in my PhD thesis. The study will also be presented at scientific meetings and written up for publication in scientific journal. We will make sure we write the reports about the study in a way that no-one can work out that you took part in the study. We will write to you at the end of the research and inform you of the publication of the main results of the research. This is likely to be in 2021.

Who should I contact for further information?

If you have any questions or require more information about this project, please contact me using the following contact details:

David Herdman
Email: david.herdman@kcl.ac.uk
Tel: +44 (0)207 188 0178

What if I have further questions, or if something goes wrong?

If this project has harmed you in any way or if you wish to make a complaint about the conduct of the project you should first contact the research team at King's College London

using the details below for further advice and information. If something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against King's College London and/or NHS Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Professor Rona Moss-Morris
Email: rona.moss-morris@kcl.ac.uk
Tel: +44 (0)207 188 0178

You can also contact St George's University Hospitals NHS Foundation Trust Patient Advice and Liaison Service (PALS):

Email: pals@stgeorges.nhs.uk
Tel: +44 (0)208 725 2453

Thank you for reading this information sheet and for considering taking part in this research.