Participant Information Sheet

Electrical Vestibular Stimulation as a diagnostic for peripheral vestibular dysfunction

Description of Research

The vestibular system is the part of the inner ear used to maintain balance. When it goes wrong this can lead to dizziness, loss of balance and blurred vision. It is therefore important to be able to test vestibular function accurately. The purpose of this research is to develop a faster, better vestibular test called Electrical Vestibular Stimulation. EVS involves a very small electrical stimulus delivered behind the ears. This evokes an eye movement which we record with a camera. We plan to compare the accuracy of EVS with three other existing diagnostic tests. The outcomes of this research are:

a) To validate EVS in people with a diagnosed vestibular disorder.
b) To determine the diagnostic potential of EVS in people who have not yet received a diagnosis.
c) Gather your thoughts and feelings about the experience of the testing you received

Why are we inviting you to participate?

We will study participants with Vestibular Schwannoma and Meniere's disease because they have a well-defined vestibular disorder which will help us determine if our new EVS test works. We will also study patients who have other suspected or confirmed peripheral vestibular disorders (balance conditions due to an issue with the balance organ in the ear). This will let us know how useful EVS is for diagnosis. You have therefore been invited, either because you have a confirmed or suspected peripheral vestibular disorder.

We CANNOT include you if you have any of the following conditions:

- An electronic implant (e.g., Pacemaker, Bone-anchored hearing aid)
- Neurological disorders such as Parkinson's disease, Stroke, Cerebellar ataxia
- Uncontrolled heart disease or angina, or recent heart attack (within 6 months)
- Recent eye or ear surgery (within 6 months)
- Uncontrolled mental illness (e.g., psychosis)

If you have any of the following you can still be included, but you should let us know in advance:

- Severe tinnitus
- Neck pain

What will it involve?

The study will involve a single visit to the School of Sport, Exercise & Rehabilitation Sciences, University of Birmingham. It will last approximately 3 ½ hours (including breaks) during which you will experience the following tests of vestibular function, all of which are non-invasive. At the end of the testing you will receive a questionnaire about the tests you underwent. You will also be asked

whether you would be interested in taking part in an optional interview on a separate date to get more detail about your thoughts and feelings of the tests you received. If you are interested you may be contacted at a later date to arrange a time to conduct the interview. We aim to only interview a small number of participants so you may not be contacted even if you indicate you are interested.

1) Electrical Vestibular Stimulation (EVS)

EVS is a safe and painless method of testing inner ear function. Two electrodes will be placed on the skin immediately behind your ears. A very small current (up to ~5mA and 30s duration) is then passed between the electrodes to produce eye movements. You may feel this current on your skin as a tingling sensation, but it should not be painful. All volunteers will be given an initial test of the stimulus before being asked if they are happy to continue. We record the eye movement in darkness using an infrared camera. This test lasts approximately 30 minutes.

2) Caloric irrigation

Caloric irrigation is an established test of inner ear function which you may have experienced previously in clinic. It involves either cool (30^{O} C) or warm (44^{O} C) water being poured into the external ear canal while you lie on a couch. Calorics evoke a spinning sensation and an eye movement which we will record by camera. This test lasts approximately 40 minutes.

3) Video Head Impulse Testing (vHIT)

vHIT involves very small rotations of the head. The experimenter will hold your head with their hands on either side and produce small fast rotations of the head. The resulting eye movement will be measured using small lightweight goggles with cameras. This test lasts 5-10 minutes.

4) Vestibular-Evoked Myogenic Potentials (VEMPs)

VEMPs are a technique for assessing the function of the otolith organs (a part of the vestibular system). Small recording electrodes are placed on the skin over the neck muscles or around the eyes. Very brief tones are then delivered through headphones or bone-conducted vibrations. This test lasts approximately 45 minutes.

5) Questionnaire about the testing you received
   This will be a short questionnaire about your experience of balance testing previously and ask you questions about how you felt during each balance test to assess your comfort during these. This will take around 5 minutes to complete

6) Voluntary separate interview about the testing you received (at a later date) – This will only occur in a small number of participants.

   If you are contacted and agree to take part:
   You will be sent a link to your email to join a Microsoft Teams meeting which will be audio recorded. You will be asked questions about your experience of receiving your diagnosis, your previous experience of balance testing and the testing you received as part of this project. This will last around 30 minutes

Will I benefit in any way from participating?

There is unlikely to be any direct benefit for you. It is possible that EVS may prove useful for diagnosis within the duration of the project. In this case, it may aid your diagnosis if you have not yet received one. However, the main purpose of the project is to help with diagnosis of future patients once we have validated EVS.

Are there any risks?

Other than EVS all the tests are regularly used in hospital clinics.

EVS itself is a safe technique which has been applied to humans for many years for research. We use a CE-marked stimulator approved for use on human participants. EVS can sometimes cause discomfort at the site of the stimulating electrode behind the ear. However, this is usually alleviated by repositioning the electrode. All participants will be given a test stimulus at the beginning of the session to check that they are happy to continue.

Caloric irrigation can exacerbate any pre-existing outer ear problems such as a perforated eardrum. To avoid such issues, we will carefully examine the outer ear using an otoscope. Caloric irrigation can cause a spinning sensation, and this is occasionally accompanied by feelings of dizziness or nausea. However, this usually subsides within a minute or two of stopping the test.

Because the vHIT test involves head rotations, it may cause neck discomfort if you have any pre-existing neck pain. We will ask you about this beforehand.

VEMPs are a non-invasive test with minimal risk. If you have severe tinnitus it can make this worse. Again, we will ask you about this beforehand.

The questionnaire or patient interview will only focus on your experience of getting your diagnosis, the balance testing you received as part of that and your testing experience as part of this trial. If you do not wish to answer a particular question then you can leave it blank or say you would rather not answer in the interview. You will not be pressured to answer anything you do not want to.

In the unlikely event that you experience lasting symptoms of dizziness or nausea you will be able to rest on the couch in the laboratory for as long as necessary. In the event that your journey home is affected, we can arrange a taxi. If you experience any other medical emergency, we have trained first aiders within the department.

Can I withdraw once I have agreed to participate?

Yes. If you agree to participate you are free to withdraw at any time prior to or during the study without having to give a reason. If you decide to withdraw (or not to participate in the first place) this will have no impact upon your normal medical care. Please contact the Research Assistant or Principal Investigator if you wish to withdraw (see Contact Details below).

Confidentiality

All data will be treated confidentially and stored on password-protected computers in locked offices at the University of Birmingham for up to 10 years. Only the researchers directly involved in

this study will have access to this data. Anonymised data will be submitted for publication, and you will not be identifiable.

How will we use information about you?

In this research study we will use information from your medical records including:

- Name
- NHS number
- Contact details
- Age, weight, height
- Medication currently taken

Such information will not be shared beyond the research team, and we will only use information that we need for the research study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it or use it in publications, and also to provide reference data for comparison with future research.

We will make sure no-one can work out who you are from the reports we write.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We would like to continue collecting information about your health from your hospital. In particular, if you do not already have a clear diagnosis when you are participating in this study, we would like to update our records if and when you do receive a diagnosis. If you do not want this to happen, tell us and we will stop collecting any further data.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

at www.hra.nhs.uk/information-about-patients/
by asking one of the research team
by sending an email to the Data Protection Officer - dataprotection@contacts.bham.ac.uk

Will I be paid to take part?

No. You will receive remuneration for travel and lunch costs (please bring receipts).

What will happen should an abnormality be discovered?

If the results exhibit any abnormality, you will be able to discuss this with the ENT registrar/consultant working on the project.

Who is sponsoring and funding the study?

The University of Birmingham is the Sponsor and the study has been funded by a grant from the Medical Research Council (Funder's reference: MR/X013944/1).

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC). This study has been reviewed and given favourable opinion by London - City & East Research Ethics Committee and the Research and Development department at your hospital.

What if there is a problem?

If you have any concerns about this study you can speak to the researchers in the first instance, contact details are provided below. If you are not satisfied with their response, you can contact the Patient Advice and Liaison Service (PALS): Queen Elizabeth Hospital Birmingham
Telephone Number: 0121 371 3280
Email: PALS@UHB.nhs.uk
Address: Mindelson Way, Edgbaston, Birmingham, B15 2WB.

Contact details for the research team

If you are interested in taking part in the study please telephone or whatsapp this number: **07568061036**

This is the research project's phone number which will be answered 9am -5pm Monday to Friday by one of the research team below. If your call isn't answered, please leave a voicemail with your contact number and one of the research team will get back to you shortly

Alternatively you can email: balancestudy@contacts.bham.ac.uk

Please leave contact details and a member of the research team will get back to you to arrange a time for you to take part

Research Team:

Principal Investigator: Dr Raymond Reynolds (email: r.f.reynolds@bham.ac.uk; tel: 0121 414 4107). Associate Professor in Motor Control. School of Sport, Exercise & Rehabilitation Sciences, University of Birmingham

Ear, Nose and Throat Consultant: Mr. Richard Irving

Ear, Nose and Throat Surgical Registrar and Clinical Research Fellow: Mr. Peter Gaskell

Post-Doctoral Fellow: Dr. Raphael Hamel

This Information Sheet is available in large print.
Please ask the Research Assistant if you require this.