

Department of Clinical Engineering

Cambridge University Hospital
Hills Road
Cambridge
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Clinical lead: Prof. Manohar Bance
Chief Investigator: Dr Thomas Stone

Participant Information Sheet

Study Title: A non-interventional, investigation into the relationship between head and whole-body movement in participants with and without balance disorders

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

We want to understand how head movement is related to the movement of the whole body. E.g. how our legs move during walking and how we use our body to balance. Lots of people wear hearing aids today and people who wear hearing aids are often the same people at risk of falls and have other balance problems. Hearing aids provide a good place to put sensors to measure movement but at the moment we don't know how to link head movement to whole body movement. This study seeks to increase our understanding of this link.

Why have I been Invited?

You have been invited to take part because you don't consider that you have any problems with balance or dizziness.

Do I have to take part?

No.

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No, it is entirely your decision. You will have the opportunity to ask any questions and address any concerns you may have before we ask for your explicit, informed consent to participate in the study. You will be asked to sign a form to confirm your decision.

You are free to stop taking part at any time without giving a reason. Stopping will not affect the care you are receiving. If you do stop, we would like to use the movement data collected up to the time you stopped. We would only do this if you told us that we could.

In the event of a loss of capacity, the research team would retain personal data collected and continue to use it confidentially in connection with the purposes for which consent was sought. This could include further research after the current project has ended.

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

If you decide to take part, we will ask you if we can take extra measurements in addition to your standard care.

Movement measurements

We will measure your walking pattern by using a motion capture system the motion capture system includes collecting video of you walking (the video is of the whole body including the face). We will ask you to walk up and down the walkway a number of times to collect all the measurements. To take the measurements we need to place sensors on your legs and back as shown in the picture below.

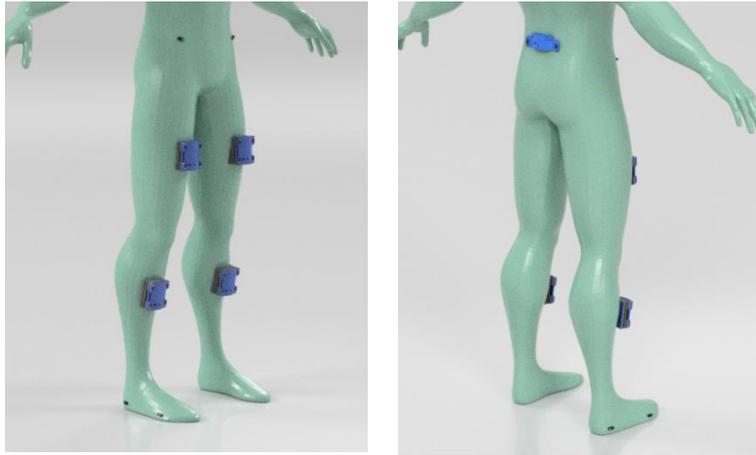
These are the marker locations

The markers are about 9mm round and shown below.

About the size of a 1p coin

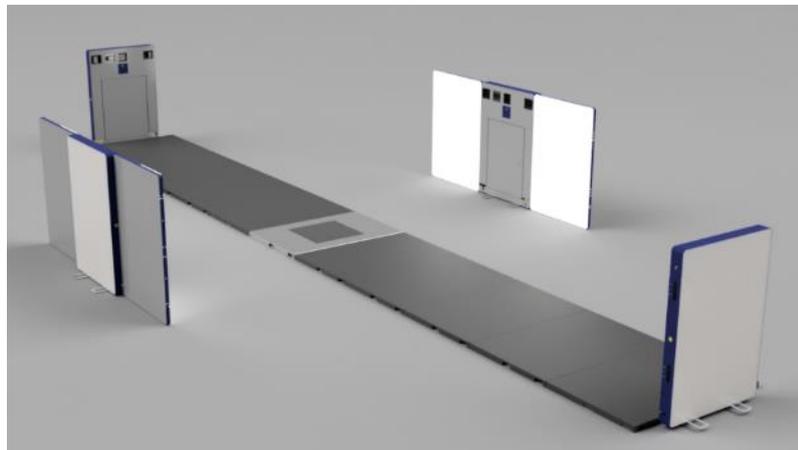
The motion sensors may also look like this depending on the clinic you attend:

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The sensors are attached using a Velcro strap or skin friendly double-sided sticky tape.

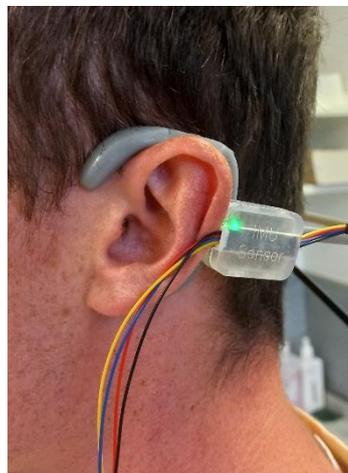
This is what the walkway and cameras look like.



Eye movement and brain activity

We will also measure electrical signals generated from eye movement (EOG) and brain activity (EEG). This will require placing electrodes on the skin.

The head mounted sensors and electrodes look like this:



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You will be asked to do 4 tasks wearing all these sensors:

- Standing still
- Walking along the 8m walkway approximately six times
- Walking with another competing stimulus.
 - This can be sounds playing, changing light level or virtual worlds, but nothing surprising or shocking like loud bangs.
 - This also includes walking over different surfaces such as a solid floor or a slightly soft floor (like walking on a rubber mat).
 - You will be made fully aware of the conditions before you start.
- Standing up and walking from a sitting position.

You only have to do these movements to the best of your abilities that means what you consider is safe and reasonable for you to do.

You will need to wear a pair of shorts and a t-shirt to take the measurements. These will be provided for you.

What Should I consider?

If you choose to take part, you will be asked to attend a movement scan appointment which you will be able to book online. We hope to be able to provide a location that is very convenient to you. The appointment takes about 45 minutes.

You will need to wear a pair of shorts and a t-shirt to take the measurements. These will be provided for you if needed.

Are there any possible disadvantages or risks from taking part?

Movement measurements are very safe and commonly used measurements and don't have any increased risk than that of walking along a corridor.

EOG and EEG are very safe and commonly used clinical measurements.

You will need to wear a pair of shorts and have markers placed on you. This is not uncomfortable but can be time consuming to place the markers correctly.

Most people do not find the process a problem however the process of being videoed and motion tracked can feel a little odd at first.

What are the possible benefits of taking part?

There are no direct benefits of taking part. This study hopes to improve care for patients in the future.

Will my general practitioner be informed of my participation?

We don't need to inform your GP that you are taking part.

Will my taking part in the study be kept confidential?

Data collected during this study will be kept confidential. This means we will only tell those who have a need or right to know.

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Each participant in the study will be allocated a unique identifier which will be used to associate the data collected. Only the Chief investigator has access to the information that links the unique identifier to your personal identification. We will destroy any direct personal identification after the study and only anonymised data will be retained.

The study tests may use a 3rd party service (Joint Analytics Ltd.) that collects the movement data and communicates it securely to clinicians and patients via the internet. Participants need to agree to the terms and conditions of the use of this service in order to access it.

It is very hard to completely anonymise video, therefore we cannot guarantee that video will be anonymised.

The study team will not retain video data after the end of the study.

Responsible members of the Cambridge University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

We will not be able to reimburse travel costs for attending the functional movement analysis sessions in this study.

What will happen to my data?

We will be using information from your medical records in order to undertake this study. Research is a task that we perform in the public interest. Cambridge University Hospitals NHS Foundation Trust, as sponsor, is the data controller. This means that we, as Cambridge University Hospitals NHS Foundation Trust researchers, are responsible for looking after your information and using it properly in compliance with the Data Protection Act 2018 and General Data Protection Regulations (GDPR). We will use the minimum personally identifiable information possible. We will keep identifiable information about you (including interview recordings) for 12 months after the study has finished. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the Cambridge University Hospitals NHS Foundation Trust for five years after the end of the study.

Movement data might be collected using a third-party service provider. They act as a data processor on behalf of Cambridge University Hospital who have the responsibility, under the Data Protection Act 2018 and GDPR, to ensure their data processors meet all requirements to protect data. The terms for using the third-party services are given in their standard terms and conditions which you will be able to review before agreeing to participate in the study.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data and how we meet our responsibilities, is available at www.cuh.nhs.uk/patient-privacy/

How will we use information about you?

We will need to use information from you for this research project.

This information will includes your:

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- Name
- NHS number, Hospital Number
- Contact details (email / phone number)

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.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

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 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.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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/
- at www.cuh.nhs.uk/patient-privacy/
- by asking one of the research team
- by contacting the Trust's Data Protection Officer cuh.gdpr@nhs.net

What will happen to the results of the study?

Our intention is to publish our findings from this study. However, we will not use any identifiable data in any of our publications, including presentations.

If for any reason we would like to use identifiable information, it will be necessary for us to obtain separate and specific consent from you for this.

What if there is a problem?

if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you should use the contact details at the bottom of this sheet.

You may wish to obtain independent advice on your involvement in this study (or any other aspect of your medical care) through the Patient Advice and Liaison Service (PALS)

Patient Advice and Liaison Service (PALS)

Box 53, Cambridge University Hospital NHS Foundation Trust

Addenbrooke's Hospital, Hills Road, Cambridge, CB2 0QQ

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Telephone: 01223 216756

Email: pals@addenbrookes.nhs.uk

How have patients and the public been involved in this study?

The public have been involved in the preparation of the protocol and participant information. The documentation has been reviewed by the Cambridge University Hospital patient and public involvement committee.

Who is organising and funding the study?

This study is sponsored by Cambridge University Hospital NHS foundation Trust. This study is funded by Anglia Ruskin University.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a research ethics committee, to protect participants' interests. This study has been reviewed and given favourable opinion by 23/EM/0145 research ethics committee.

This study has been peer reviewed by the Cambridge University Hospital Research department peer review process

This study has also been reviewed by the Anglia Ruskin Research assessment committee.

Further information and contact details.

For further information please contact

<p>Dr. Thomas Stone Cambridge Clinical Measurement Laboratory Cambridge University Hospital, Box 152, Hills Road, CB2 0QQ</p>	<p>add-tr.ccmc@nhs.net</p>
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Thank you for taking the time to read this information and for considering taking part in this study.