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Gait assessment algorithm evaluation through wrist-worn research-grade activity monitoring and clinical assessment

PARTICIPANT INFORMATION SHEET

Central University Research Ethics Committee Reference: [1000079]

1. Introductory paragraph

You are being invited to take part in a research project. 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 if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

2. Why is this research being conducted?

While the use of physical activity monitors (e.g Fitbits, Garmin, Apple watches) and step counters is popular, the correspondence between clinically used walking metrics (aka "gait") and wearable measures is not clear. The use of physical activity monitors in medical research allows clinicians and scientists to assess how movement and exercise changes with different medical conditions. Your participation in this study will allow us to determine the accuracy of gait assessment methods (i.e. a study of how you walk and the features of your walking patterns) and help to develop new and improved gait assessment methods for medical research.

3. Why have I been invited to take part?

You have been invited to participate in this study because you are 18 years or older, have not self-reported a lower limb injury in the past three months and currently do not use an assistive device for walking. We are intending to invite 100 volunteers to participate in this study.

4. Do I have to take part?

No, your participation in this study is entirely voluntary. Throughout this information sheet, the study requirements and data collection will be described in full. If you do choose to participate in the study, and later change your mind, you can withdraw at any time, without giving a reason and without penalty.

However, please do note that once data has been processed and anonymised for subsequent analysis, it will not be possible to withdraw your data from the study. Therefore, we provide a commitment that you can have yourself withdrawn from the study until 3 months after data collection.

5. What will happen to me if I take part in the research?

Study Overview

If you agree to take part in this study, a member of the research team will contact you to arrange an initial meeting online. This meeting will last approximately 30 minutes. During this time, the researcher will explain this participant information sheet in detail, answer any questions you may have, and, if you are happy to proceed, ask for your written consent to participate.

We will collect some basic information including your height, weight, biological sex, and arm dominance. You will also be asked to complete a short questionnaire and take part in a brief interview about your symptoms and general health. These questionnaires will be distributed online and can be completed on a laptop/computer or smartphone. These questionnaires will comprise of asking about symptoms regarding your dizziness and any symptoms of anxiety and depression as these have been found to be linked to dizziness. After this meeting, should you decide to take part, you will be sent a parcel with one small, lightweight, waterproof wrist-worn activity monitor (Axivity devices), to be worn on your dominant wrist. These devices have a similar size and feel to a watch.

Activity Monitoring at Home

You will be asked to continue wearing the wrist monitor during your normal daily activities for 7 consecutive days. This includes while sleeping, bathing, or swimming. The monitor does not track your location, record conversations, or store any personal identifying information. It simply collects movement data such as:

- Arm and wrist motion
- Frequency and intensity of physical activity
- Duration of movement and rest periods

This data will help us better understand daily movement patterns and improve the accuracy of wearable sensors in detecting gait and activity levels.

Returning the Device

At the end of the 7-day monitoring period, a member of the research team will arrange with you a convenient time to return the device. You will have the option to return it using a pre-paid, pre-addressed envelope provided to you when you receive the device in the post. We will also follow up with you by phone or email near the end of the monitoring period to confirm return arrangements and answer any questions.

To ensure all monitors are returned, we will keep a record of which device is assigned to each participant and contact participants as needed if a return is delayed. Participants are reminded that the devices are loaned for research purposes and should not be kept.

Image courtesy of Axivity Limited (www.axivity.com)

Figure 1: Wrist-mounted accelerometer for counting steps and activity tracking in research studies

6. What are the possible disadvantages and risks in taking part?

There are no anticipated risks or disadvantages to taking part in this study. If you find the activity monitors to be uncomfortable, please feel free to adjust the strap tightness, or take them off at any time. Although we encourage devices to be worn continuously, there is no limit to how long they can be taken off for- this is at your discretion and comfort.

7. Are there any benefits in taking part?

There will be no direct benefit to you from participating in the study. However, your participation will enable improved future research involving physical activity monitors and will allow for an increased understanding of physical activity monitoring to be applied within medical research and clinical care, including machine learning activity classification and gait assessment models. Further, following data processing, we will provide you with a physical activity summary based on the wearable sensor data that you provide and gait assessment lab results.

8. What information will be collected and why is the collection of this information relevant for achieving the research objectives?

The data you provide by wearing the physical activity monitors, completing questionnaires, and participating in a gait assessment will help researchers evaluate and improve current research methods. These improvements will support future research both within the University of Oxford.

To help us understand how gait and physical activity may vary across individuals, we will collect the following identifiable information: your name, contact details (email and/or phone number), age, biological sex, height, weight, and arm dominance. These details are used to personalise your

assessment and ensure data quality and accuracy in our analyses. Your contact information will only be used to arrange appointments and follow up regarding device return, if needed.

Types of Data Collected

- Wearable device data: movement data (acceleration and orientation) from your wrists during daily activities
- Gait assessment data: walking patterns, posture, balance
- Questionnaire and interview data: information about your symptoms and relevant health background to clarify eligibility. You will complete a questionnaire booklet for this.
- Basic demographic and physical characteristics: age, biological sex, height, weight, arm dominance

Once the study is complete and all necessary arrangements (such as return of the monitors) are finalised, your identifiable information—including your name and contact details—will be securely deleted. Consent forms, which are part of the research record, will be stored securely and separately from the research data for 3 years, as required for auditing purposes.

Your de-identified research data will be securely stored at the University of Oxford and may be analysed alongside data from other participants. Results may be included in scientific publications and presentations, but you will not be identifiable in any outputs.

Any physical copies of your contact information will be stored in a locked location at the Big Data Institute, a research centre that is part of the University of Oxford. These will also be securely destroyed once they are no longer required.

9. Will the research be published? Could I be identified from any publications or other research outputs?

The University of Oxford is dedicated to the publication of research to further the community knowledge base. The findings from the research may be written up in academic publications, conference presentations, and reports from study funders and/or collaborators. We want to reassure you as a potential participant, that you will not be identified from any report or publication placed in the public domain. At the end of the research study, your de-identified activity data will be made publicly available via an open-source data-sharing platform to enable other researchers the ability to utilise data for their own research studies.

10. Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the research. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available from the University's Information Compliance web site at https://compliance.admin.ox.ac.uk/individual-rights.

11. Who has reviewed this research?

This research has received favourable opinion from a subcommittee of the University of Oxford Central University Research Ethics Committee. (Ethics reference: MS IDREC 1000079)

12. Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this research, please contact Dr Shay Sivanathan and members of the Oxford Neurosurgery research team at (shay.sivanathan@ouh.nhs.uk) and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) team at rgea.complaints@admin.ox.ac.uk or on +44 (0)1865 616480.

13. Further Information and Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact: shay.sivanathan@ouh.nhs.uk

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