



Queen Margaret University

EDINBURGH

Study Title: Validation of accelerometers in the measurement of physical activity and sedentary behaviour in people with Parkinson's Disease.

**Participant Information Sheet
Version 4: 17/12/2015**

Short title: Accuracy of motion sensors for measuring physical activity in people with Parkinson's Disease.

You are being invited to take part in a research study. Before you decide whether or not to take part, 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. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The purpose of the study is to explore how accurate activity monitors are at measuring physical activity in people with Parkinson's disease. Two of the proposed monitors are credit card sized and are worn on a belt around the waist with a second attachment worn on your thigh. The thigh monitor is lightweight and attached using adhesive tape. We may also ask you to wear a "Fitbit" (wrist-worn band) during the study.

Why have I been asked to take part?

For this study we are recruiting a group of people who have Parkinson's disease and a group of people similarly aged people who do not have Parkinson's disease. To take part you need to be independently mobile with or without a walking aid and able to walk independently for up to 5 minutes. People with other health problems which interfere with activities of daily living or who have a known allergy to adhesive tape should not take part.

Do I have to take part?

No, it is up to you to decide whether or not 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. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will happen if I take part?

If you agree to participate in the study, you will be asked to meet the researcher at QMU. When you come we ask that you wear comfortable clothing and if possible to wear trousers or a skirt that has a pocket. You will have chance to ask questions about the study and if you are happy to take part you will be asked to fill out a consent form. Once we have your consent we will ask for information about your age and we will measure your height and weight. You will then be fitted with the activity monitors, two of which are light-weight credit-card sized units which are worn on a belt around the waist. One part of the monitor is attached using adhesive tape to the front of your thigh. You may also be asked to wear a wrist worn "Fitbit" monitor. Once you are wearing the monitors we will ask you to complete some short activities such as standing up and sitting down, a slow walk for 5 minutes and a fast walk for 5 minutes. You will also be monitored doing simple daily tasks such as washing a cup, folding towels or simply sitting reading a book. All activities will be interspersed with rests. We will then ask you to walk outdoors around the QMU campus for a short time. During these activities we will video you as we wish to determine the accuracy of the activity monitors. The whole procedure should take no longer than 60 minutes. You can take as many rests as you wish during the study and if anything becomes difficult for you – then you can stop.

You will then be given the monitors to take home with you to wear at home for 1 week. The monitors are worn during waking hours and should be removed for water activities e.g. swimming and bathing.

What are the possible benefits of taking part?

You may not get a direct benefit from taking part in this study. We can send you follow up information regarding how accurate the monitors were in detecting walking steps, speed and distance. The information we gain from this study will help inform researchers regarding methods of measuring physical activity and sedentary behaviour.

What are the possible disadvantages and risks of taking part?

It is not thought that there are many disadvantages; however, it is a slight possibility that you may be tired after the various walking tasks, however this should be no greater than everyday walking. If you become tired at any point, you can stop and have a rest during the study. There is also a slight risk that your skin becomes irritated from wearing the accelerometer on your thigh attached with adhesive tape. If you experience any skin irritation you should immediately remove the monitor and discontinue the study.

What happens when the study is finished?

During the study, and once the study is finished, your anonymised data will be stored securely in a password protected folder on the University computer server. Data collected in the study will be kept for up to 5 years at which point it will be destroyed by the lead researchers.

Will my taking part in the study be kept confidential?

All the information we collect during the course of the research will be kept confidential. Any video recording will be deleted once activity information (eg the number of steps you walked, how long you walked for etc) has been extracted. Your name will be removed from the data so that it will not be possible to identify you from the data.

What will happen to the results of the study?

The data from this research will be used for a final year student research project and may be published in an academic journal or presented at a conference.

Who is organising the research and why?

This study has been organised by Gillian Baer and Jane Hislop who are physiotherapy lecturers at Queen Margaret University. A group of final year physiotherapy students from Queen Margaret University will be involved in data collection under the supervision of Gillian and Jane.

Who has reviewed the study?

The study proposal has been reviewed by Queen Margaret University Divisional Research Ethics Committee.

If you have any further questions about the study please contact:

Jane Hislop

**Physiotherapy Division
School of Health Sciences
Queen Margaret University
Musselburgh
East Lothian EH21 6UU
Tel: 0131474 0000
Ask for "Jane Hislop" when prompted
Email: jhislop@qmu.ac.uk**

Dr. Gillian Baer

**Physiotherapy Division
School of Health Sciences
Queen Margaret University
Musselburgh
East Lothian EH21 6UU
Tel: 0131474 0000
Ask for "Gillian Baer" when prompted
GBaer@qmu.ac.uk**

To volunteer to take part in the study please contact Jane Hislop (details above)

If you would like to discuss this study with someone independent of the study please contact: Dr Judith Lane – jlane@qmu.ac.uk - Tel: 01314740000

If you wish to make a complaint about the study please contact:
Dr Lynne Flynn Head of Division, Queen Margaret University, Musselburgh, EH21 6UU.
(lflynn@qmu.ac.uk)

Thank you for taking the time reading this information sheet.

Participant consent form



Queen Margaret University
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Centre Number: Queen Margaret University

CONSENT FORM

Title of Project: Validation of accelerometers and Smart phone Apps in the measurement of physical activity and sedentary behaviour in people with Parkinson's Disease

Name of Researcher: Jane Hislop, Gillian Baer

Please initial box

1. I confirm that I have read and understand the information sheet dated 17/12/2015 (version 4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

3. I understand that relevant sections of the data collected during the study may be looked at by the researchers, where it is relevant to this research project. I give permission for these individuals to have access to this information

4. I understand that I may be videoed and that I will wear small activity monitors. I understand that all data will be anonymised when downloaded and that the video will be deleted

5. I agree to take part in the above study

Consent Form. Version 4 17/12/2015

Name of Participant

Date

Signature

Name of Person taking
consent

Date

Signature