Healthy Participant Information Sheet (HC)

Study Title: Validation of Smartphone-based Assessments in Multiple Sclerosis

Introduction

You are invited to take part in a study that is assessing a smartphone-based app to monitor symptoms in people with Multiple Sclerosis (MS). To allow you to make an informed decision as to whether or not you want to take part, this document describes the purpose of the study and the data that will be collected. Taking part in this study is your choice. Not participating or withdrawing from the study will not affect your medical care. If you are a student at the University of Plymouth, not participating will not affect your studies in any way.

Please take your time to read the following information carefully. If you have any questions, please contact the study team at floodlight@plymouth.ac.uk or the Chief Investigator Prof Jon Marsden by telephone on 01752 587 590.

Why are you invited to participate?

You were selected as a possible participant because you are a healthy participant in the 18-70 year age range.

What is the purpose of this study?

We are working with a pharmaceutical company, Roche, who is developing a smartphone app (study app referred to here as Floodlight) that can be used to monitor the symptoms of people with MS. This could help clinicians to monitor the effects of treatments more accurately and regularly and so help with decisions about symptom and disease management.

The purpose of this study is to see how measurements of walking and balance made by Floodlight compare with measures of walking and balance made using specialised body-worn sensors. We aim to assess this in 75 people with MS and compare the results to 25 health participants of a similar age.

We will assess the app when you are walking in either the community or in a laboratory. We will assess the signals coming from the app when the smartphone is worn at different locations around the body. We would like people to undertake the tests using the smartphone app everyday when at home for 2 weeks. This is because repeated tests could give a more reliable picture of people's symptoms to help inform clinical monitoring and monitoring in future clinical trials.This information will help to optimize the app so that it will become a better tool to monitor walking and balance in people with MS.

Do I have to take part?

The study is completely voluntary. Taking part in this study is your choice; not participating or withdrawing from the study will not affect your current or future medical care in any way.

What would I have to do if I took part?

If you agree to participate in the study, we will discuss the study to check you understand what is involved and then ask you to sign a Consent Form, only then data will start being collected.

Initial Visit: This and the final visit will involve travelling to the Brain Research Imaging Centre (BRIC) on Plymouth Science Park next to Derriford Hospital. At this visit we will record information about your year of birth, sex, and educational level. We will undertake routine clinical tests such as looking at your ability to move your arms and legs as well as a short thinking test looking at your ability to process information quickly.

At this first visit, we will ask you to do two short walking assessments in a corridor, during which you will be carrying smartphones with Floodlight and wear two small sensors on your shoes to collect data about your gait.

Furthermore, you will receive a smartphone and training on the use of the smartphone app, and supporting materials to help you complete the app tests successfully at home. Finally, we will show you how to perform the smartphone-based tests at home over the next 2 weeks and how to use 2 sensors that attach to your shoes which can measure how you move. We will provide a booklet to remind you what to do and you will be able

to email or phone team members for help at any stage. This visit will take about 2 hours. Free parking close to the building can be arranged if you are coming by car.

Using the smartphone app at home: After the first visit, there will be a 2-week period when we ask you to use the study smartphone at home. You will be asked to perform some tests looking at finger movements, balance and walking using the smartphone app every day for 2 weeks. The tests will take approximately 5 to 10 minutes each day. The walking test should be executed, if possible, indoors or outdoors on alternate days. The thinking test only needs to be performed once a week. No alcohol should be consumed in the hours prior to these tests. We will also ask if you can carry the study smartphone on you and wear the sensors when you walk around for at least 15 minutes ("free living walking"). During free living walking we will ask you to record the environment you walked in, such as how flat the terrain was or about the ground conditions.

Towards the end of the 2-week period we will ask you to complete a questionnaire about your experience with the Floodlight study app.

Final Visit: During this visit we will measure your walking and balance using specialised sensors that are placed on your body. We will compare these measures to the signals recorded from smartphones that will be placed around your waist and in pockets of shorts that we will supply. We will ask you to undertake tests of walking on a treadmill and walking in a corridor. We will also look at your balance when you are standing. To make sure you are safe while walking on the treadmill and undertaking the balance tasks, you will wear a safety harness. We will give you plenty of rest. It is fine if you cannot manage all of the tests because they are too difficult or too tiring.

When you are performing the different tests we will also video your walking and balancing. This is to see if the smartphone app data agrees with clinicians' views about your walking and balancing ability. The videos will be anonymised by pixelating the face so you cannot be identified. You will be shown such pixelated videos during the initial visit to show you how the process of pixelation makes the person in the video unidentifiable.

Furthermore, you will be asked to perform the finger and thinking tests you were performing at home under the supervision of the researcher. Here we will also video the way you interact with the app and we will ensure your face is not part of the video so you cannot be identified. This final visit will take around 2½ hours. Free parking close to the building can be arranged if you are coming by car. We can also arrange a taxi up to £17.50 per trip.

What are my obligations if I take part in this study?

If you decide to take part in this study, you will be requested to do the following:

- Keep your study appointments
- If you cannot attend an appointment, please contact the study personnel as soon as possible to schedule a new appointment. Contact details are at the end of the form.
- Keep your study smartphone in good working order and charge the smartphone and the shoe sensors daily. Inform the study center immediately in the event of damage, malfunctioning or loss of the smartphone or the shoe sensors.

Are there any risks to taking part?

We will not ask you to undertake activities that you cannot easily do. The tests of walking and balance may cause some fatigue. When testing your walking and balance there is a risk you may fall. To prevent any falls you will wear a safety harness for tests when you are in the laboratory.

Are there benefits to taking part in the study?

There is no direct medical benefit to you from taking part in this study. The information gained from this study may help researchers and health care practitioners to learn more about MS. It will also help to develop the smartphone app that could be used to monitor symptoms in people with MS. This in turn could help clinicians alike make decisions about future management of people's condition.

Will I be paid for taking part in this study?

You will not be paid for your participation in this study. We can pay for your travel from your usual home or place of work up to an upper limit of £35 per visit.

Can I stop being in the study?

You can leave this study at any time. Withdrawing from this study will not affect your care in any way either now or in the future.

Who is financing and conducting this research?

This study is being financed by F. Hoffmann-La Roche Ltd. The study is being conducted under the direction of Prof Jon Marsden at the University of Plymouth. Roche is providing financial support to cover the Study Site's costs to collect the information for the study. Team members in Roche will analyse and store the anonymized data; they will not have access to any personal information. Roche are acting as the sponsor of the study which means that the company provides indemnity insurance and ensures correct data management occurs for this study.

Will my medical and personal information be kept private?

Your study data will be labeled with a patient identification number (ID) that is unique to you and not related to or derived from information that identifies you (such as your name, your picture, or any other personally identifying information). Roche, Roche affiliates, and Roche's representatives will only have access to anonymized study data labeled with a patient ID number.

Roche, Roche affiliates, and Roche's collaborators and licensees (people and companies who partner with Roche) may use study data labeled with your patient ID number. Your study data may also be shared with independent researchers or government agencies, but only after personal information that can identify you has been removed. Your study data may be combined with other people's data and/or linked to other data collected from you. Your study data may be used to help better understand why people get diseases and how to best prevent, diagnose, and treat diseases, and to develop and provide access to new medicines, medical devices, and healthcare solutions.

Your name and address (which we need in order to contact you) will be securely stored on University of Plymouth premises and kept separate from the other information you supply during the project. Your personal contact details will be securely stored for the duration of the study. We will not pass this information onto anyone else and will delete this information once the study has finished.

All other information collected about you during the course of this research will be kept strictly confidential. We will store your data using a unique code rather than your name. All information will be stored electronically on University of Plymouth servers which are password protected and encrypted. All information will be handled in compliance with the General Data Protection Regulations (2018). 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. Some of your anonymised information will be sent to Switzerland where Roche is based. They must follow our rules about keeping your information safe.

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 study, we will keep the information about you that we have already obtained.

Individuals from the University of Plymouth and regulatory organisations may look at your research records to check the accuracy of the research study. The research team will pass these details to the regulatory organisations along with the information collected from you. The only people in the University of Plymouth who will have access to information that identifies you will be people who need to contact you to arrange an appointment or to provide a summary of study findings or audit the data collection process.

What will happen to the results of the research study?

We aim to publish the results of this study in an academic journal and present at relevant national and international conferences. We will ask if you want to be sent a summary of the key findings or a copy of any publications at the time of the study. If this is the case we will keep your personal details on record up to the point of sending

you the summary after which we will delete them. If the results of the study are published, your identity will remain anonymous.

Who has approved this study?

This study has been reviewed and approved by {Name of IRB/EC}, an organization that is responsible for protecting the rights, safety, and well-being of patients who take part in research studies.

What if there is a problem?

In the unlikely event you are harmed by taking part in this study, there are no special compensation arrangements. However, neglectful harm will be covered by the insurance scheme of Roche Pharmaceuticals, who is sponsoring this study. If you are harmed due to someone's negligence, you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about this study, please contact the Chief Investigator Prof Jon Marsden using the contact details below.

If you have a question about any aspect of this study, please speak to the research team who will do their best to answer your questions.

Contact for further information

If you would like any further information about this study, please contact:

Chief Investigator
Prof Jon Marsden
Faculty of Health
School of Health Professions
University of Plymouth
Email: floodlight@plymouth.ac.uk
Tel: 01752 587 5900

Thank you for reading this