

Consent Form for Participation in a Research Study

Can a smartphone measure my neurological disease? A virtual, internet-based health study (EMPOWER)

Principal Investigator: Mark Kotter

Introduction

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. If there is anything you do not understand, you can contact the study investigators by email (info@movemed.io). Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary. This study has been approved by the University of Cambridge.

Why is this study being conducted?

The purpose of the study is to help develop better tools to assess neurological disease as the current assessments have many limitations. For example, they rely on an assessment by a doctor, which are infrequent, short and can vary depending on the experience of the professional. These measurements can greatly misrepresent the disease, for example catching symptoms on a good day or varying due to the experience of the assessor. These problems are linked to delayed access to care, which can limit the effectiveness of treatment.

Over the last 5 years we have been developing a simple mobile phone application at the University of Cambridge, which uses a series of short interactive games, alongside some background activity monitoring of your phone, to better represent neurological disease and empower those affected to take control of monitoring. Our preliminary results have shown that this combination is very promising, measuring problems such as balance and walking, dexterity, spasticity, and fatigue. However, to continue our development we need to perform a larger study and ask for individual feedback.

Please remember, these tools are still in development and the information provided cannot be used as a medical assessment at this time. If you have any concerns about your health, you should seek local medical review.

What does the study involve?

To enrol in the study, you must register at www.movemed.io/empower. An investigator will then follow up with you by email, to confirm you wish to participate and explain how to download and install the application. The application will perform some measurements in the background but will also prompt you to complete the inbuilt games at least weekly. You are free to perform these more frequently by opening the application at any time. The device does not capture location information, such as GPS. We would like you to complete these assessments over 12 consecutive weeks, but you are free to withdraw at any time, or can continue beyond 12 weeks if you wish.

When developing new assessments, we must compare them against current assessments. Therefore, at the beginning, after 6 weeks and after 12 weeks, a

survey will be sent to your email address for you to complete. This includes an assessment tool to measure your principal neurological disease, but also a measure of quality-of-life. In total this will less than 20 minutes.

Alongside the 12-week survey, we will also share with you a summary of your results. We will ask you to provide some additional feedback on your experience of using the system, and any insights you have into the results that were found.

What data will be collected and how will it be used?

We will require your name and email address to register you in this study and keep in contact. This personal information is stored separately to all other information, to maintain your privacy, and will be deleted after you leave the study. The other information collected relates to the assessments, either through the MoveMed Application, or the questionnaires.

Risks Related to Participating in the Study and Confidentiality

The only potential risk to participating in this study would be a loss of your personal data. We have many processes in place to prevent this, which meet the latest international standards. For example, your personal information and study data is stored separately. All data is stored and transmitted using encryption. The data for analysis will be done without access to your personal information. Data is hosted using Amazon Web Services in the United Kingdom, which are well recognised as a secure data provider and are used by many healthcare services.

Benefits Related to Participating in the Study

There is no direct benefit to you for participating in this research study. The data collected could eventually lead to improved care for those with a neurological condition.

Voluntary Participation

Your participation in this study is voluntary. If you agree to participate in this study, you have the right to withdraw at any time you choose. If you wish to do so please remove the application and/or contact the study team.

Questions about the Study

If you have any questions, please contact Benjamin Davies (info@movemed.io)

This study has been independently assessed and approved by the University of Cambridge. It is also supported and run with Myelopathy.org, a charity of Degenerative Cervical Myelopathy

BY REGISTERING TO PARTICIPATE IN THIS, IT IS TAKEN THAT YOU HAVE AGREED TO PARTICIPATE IN THIS RESEARCH STUDY