

10th December 2018

**Participant information sheet.**

### **UREC Registration:** No:181198

### Study title

**Investigating the usability of an app to assess fatigue after acquired brain injury**

### Invitation paragraph

You are being invited to take part in a research study. 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. Feel free to ask 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?

Fatigue is often experienced after acquired brain injury and people usually manage their fatigue strategies such as planning and pacing. In order to use strategies, the individual needs to build a picture of how their fatigue affects them in daily life. Usually, the person fills in a daily diary sheet of sleep, rest, activity and fatigue. Apps on smart phones are able to collect “in the moment” information about people’s fatigue experiences and to collect information about sleep and rest patterns. This information could help the person with brain injury, their carers and their therapists to learn about their fatigue more effectively, and identify triggers and patterns of fatigue.

We have developed an early prototype of an app, based on interviews with people with brain injury. The app works on android mobile phones and asks the user to rate their fatigue, identify what they were doing and to complete a reaction time test. The app collects information about the phone screen turning on and off as this relates to sleep patterns.

The aim of this study is to investigate the usability of the mobile phone app to assess fatigue after acquired brain injury. This involves finding out users views about the design of the app, ease of use and how the app works in everyday life.

### Why have I been invited to participate?

You have been invited because you have experienced a brain injury (such as a stroke or head injury), you experience fatigue, and you use an android smart phone. To participate you must also be over the age of 18 and able to give consent to participate in the research.

We hope to recruit between 5 and 10 people for this part of the study.

### Do I have to take part?

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 to me if I take part?

### If you decide to participate you will be invited to use the app for up to 4 days. The flowchart below explains what to expect if you take part in the study.

**Study flowchart**

|  |  |  |
| --- | --- | --- |
| **Parts of study** | **What to expect** | **Time taken** |
| Part 1 | You would meet with the researcher at Oxford Brookes University to learn how to collect the app and learn how to use it. The app would be installed on your phone but there is an option to use a phone purchased for the study.  You would be loaned an activity monitor and the researcher would explain how to use it.  You would complete a short questionnaire which involves answering three questions about you and your phone use. | Up to 45 minutes. |
| Part 2 | You would respond to the app prompts on the mobile phone over the next 6 days. The phone app would ask you to:   * rate your energy levels * answer a question about what you are doing when the phone app alerted you * complete the reaction time test.   The app will **not** alert you between the hours of 8pm and 10 am. | The phone will prompt between 6 and 8 times a day. Responding to each prompt will take up to 2 minutes. You can ignore the prompt if you wish to. |
| Part 3 | After 6 days of using the app, you would be asked to meet with the researcher. This involves complete a short questionnaire about the app.  The research will also interview you to find out about your experiences of using the app.  This may take place at Oxford Brookes, at your home or on skype (video call).  The researcher will remove the app from your phone as needed. You will return any loaned equipment. | This meeting will take about 45 minutes. |

### What are the possible disadvantages and risks of taking part?

### There is a risk that you would find focusing on your fatigue upsetting. If you are affected in any way by the topic of this study, the interviewer will provide you with information on who to contact for further support.

### The main disadvantage of taking part in the study is that it takes up some of your time. We will reimburse you for public transport costs or parking costs.

### What are the possible benefits of taking part?

There are no direct benefits for you in taking part in the study. This study contributes towards the development of a usable app for assessing people’s experience of fatigue after brain injury. Such an app may then support more effective interventions for fatigue after brain injury.

### Will what I say in this study be kept confidential?

All information that is collected from you during the course of the research will be kept strictly confidential (subject to legal limitations) according to good clinical guidelines and the general data protection regulation. Data will be stored in line with the University’s storage policy, encrypted, stored according to security standard ISO27001 and kept for a minimum of 10 years. Your data will only be accessed by the research team. All data handled outside of the research group (by means of scientific publication or reports) will be anonymised whereby nobody will be able to trace the data back to you as being you. No audio recordings will be reported as part of the study findings and or shared with people outside the research group.

The activity monitor collects information about your physical activity (number of steps taken) and your sleep patterns.

All data from the app is de- identified, encrypted and streamed to a secure server. The app collects data from the two questions you answer, your reaction times and when your phone turns on and off. When the app alerts you, it will collect the noise level and your physical activity level ( number of steps you have done) as recorded by the phone.

### What should I do if I want to take part?

If you would like to take part, please contact Leisle Ezekiel by phone or email on the contact details at the end of this information sheet.

### What will happen to the results of the research study?

The results of the research form part of a thesis for a MPhil/PhD study. The results will also be summarised in a short report and sent to the participants (if requested) and Headway Oxford.

The study will also be written up and submitted for publication in a journal and for presentation a relevant health care conference.

If you would like a copy of the study report, please contact Leisle Ezekiel (see below for contact details.)

### Who is organising and funding the research?

Leisle Ezekiel is a research student at Department of Sports and Health Sciences, Oxford Brookes University and is conducting the research as part of studying for her MPhil/PhD.

The research is being funded through the Dawes Research Fund at Oxford Brookes University.

### Who has reviewed the study?

The research study been approved by the University Research Ethics Committee, Oxford Brookes University.

### Contact for Further Information

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If you have any concerns about the way in which the study has been conducted, please contact they should contact the Chair of the University Research Ethics Committee on [ethics@brookes.ac.uk](https://mail.google.com/a/brookes.ac.uk/mail/?extsrc=mailto&url=mailto%3Aethics@brookes.ac.uk).

### Thank you for taking the time to read the information sheet.