Managing Chronic Symptoms using Scientific Insights from N-of-1 Studies
Participant Information Sheet (version 2; 07.07.20)

Study Investigators	Institution
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Professor Geoffrey Mitchell, *Professor of General Practice & Palliative Care*	The University of Queensland
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Before you decide to participate in this study, it is important that you understand why the research is being conducted and what it will involve if you agree to participate. Please read the following information carefully. Please take your time to decide whether you wish to take part.

What is the purpose of the study?

This study aims to explore how symptoms fluctuate over time in individuals with Multiple Sclerosis (MS). Most of the existing research on MS has measured symptoms on very few occasions, which limits our understanding about how symptoms fluctuate over time. It is possible that factors such as physical activity, mood and sleep quantity/quality contribute to symptom severity. For example, poor sleep quality the previous night may worsen fatigue symptoms on the current day. The factors that influence the severity of symptoms may be different for different people and the study aims to explore this. The results from the study will help us to identify, design and evaluate treatments or services that can help individuals to manage the frequency and/or severity of MS symptoms.

What does participation in the study involve?

You will complete a questionnaire collecting your personal details and discuss the requirements of the study during the first face-to-face meeting with the researcher. During this meeting you will also receive a wrist-worn electronic diary, which has an integrated activity monitor that automatically records your movement. You will be asked to wear the electronic diary every day for a 6-week period.

During the 6-week data collection period, you will be asked to complete a brief questionnaire 3 times per day via the electronic diary in your natural environment, as you carry on with your usual daily routine. The questionnaire will assess how you feel at that moment, and the electronic diary will make an audible sound to remind you to complete the questionnaire. The questionnaire will take under 2 minutes to complete and you will be asked the same questions each day. Together with the researcher you will personally select questions most relevant to your symptoms during the first meeting.

We will contact you regularly (via phone, text or email) during the study period to see how you have been getting on and to discuss any issues that occur. You will receive personalised feedback about the data you provided at a follow-up meeting with the researcher. The feedback meeting will occur within 12 weeks after you have completed the 6-week data collection period. We will be able to show you data on your symptoms (e.g.

fatigue) over time and identify whether and to what extent other factors such as mood, physical activity and sleep influence the severity of your symptoms.

In order to obtain a representative picture of how your symptoms fluctuate over time we need to study you for a prolonged period of 6 weeks. During the first meeting, we will also ask you if you would be willing to extend your participation beyond the 6-week period. If you agree, you would be able to choose the length of time you would like to extend the study for (up to a maximum of 6 additional weeks). ***Please note: you are not under any obligation to extend your participation beyond the 6-week data collection period*.**

What is the duration of the study?

The study will involve a 6-week data collection period, two brief face-to-face meetings with the researcher, and a follow-up meeting. At the two brief meetings you will return the electronic diary to the researcher and receive a fully charged one. At the follow-up meeting you will receive feedback about your data. This meeting will occur after the 6-week study period has ended and will take no longer than 60 minutes. To reduce the number of face-to-face meetings required you will have the option of charging the device yourself during the data collection period (you will receive a charger at the start of the study and the researcher will email/text to remind you on the day that the device is due to be charged). You will also have the option of asking a family member or friend to return your device to the researchers at the end of the data collection period on your behalf. The follow-up meeting can be conducted face-to-face or via email and phone.

Where will the study take place?

The 6-week data collection period will involve completing questionnaires in your natural environment. Face-to-face meetings with the researcher will take place at a location of your preference (i.e. your home, university premises, or public place).

What are the risks of participating in the study?

Participation in the study will involve no physical or psychological risk. The aim of the study is to measure fatigue and related factors while you carry on with your usual daily routine. At no point will we ask that you change your usual routine (e.g. we won't ask you to alter your medications, physical activity or diet).

What are the benefits of participating in the study?

At the end of the study we will be able to provide you with personalised feedback about your symptoms over the course of the 6-week data collection period. The information you provide during the study will be useful for designing future interventions for reducing the frequency and/or severity of symptoms.

What happens if something goes wrong while participating in the study?

If you have any concerns while participating in the study you can contact the principal investigator to discuss them. Contact details for the principal investigator are provided at the end of this information sheet. If the principal investigator is unable to resolve your concern, or you wish to make a complaint regarding the study, we will provide you with the contact details of a University Ethics Coordinator.

What happens if I change my mind about participation?

You are free to withdraw from the study at any stage. You do not need to give a reason for withdrawing. If you decide to withdraw from the study you will return the electronic diary to the researcher and you will be offered the opportunity to receive personalised feedback about the data you provided if more than 2 weeks of data are available.

Are my data confidential?

Yes. All paperwork and electronic data you provide will be labelled using a unique number in order to maintain data anonymity. Therefore, there will be no means of identifying you by the answers you provide to any questions. Your personal contact details will be stored separately from the data you provide for the study.

What will happen to the data I provide?

Electronic data obtained from the activity monitor will be downloaded from the device to a password-protected computer and stored in an encrypted file, which only the study team will have access to. All paper-based documents you complete will be stored in a locked filing cabinet in a secure research unit, to which only the study team will have access.

What will happen at the end of the study?

You will receive personalised feedback about the data collected during the study at the final meeting with the researcher. The findings from several participants will be combined and reported in a scientific report and presented at national/international conferences or meetings. Data will be published and presented in an ***anonymous*** format; it will never be possible to identify individual participants.

Thank you for reading this information leaflet. If you have further questions please contact the lead researcher, Dr Suzanne McDonald, using the contact details provided at the end of this information sheet.

This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your participation in this study with project staff (contactable using the details at the end of this information sheet), if you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinator on.medicinelnr@uq.edu.au.

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