

Participant Information Sheet

Researcher: My name is Soumi Krishnan and I am a first-year medical student from the College of Health and Medicine at the Australian National University (ANU). This research project is supervised by Dr Jo Lane and Professor Nicolas Cherbuin from the National Centre for Epidemiology and Population Health (NCEPH) and the research team for this study also includes Professor Christian Lueck, Ms Carmel Poyser, Dr Yixuan Zhao (from the ANU), and Professor Black and Associate Professor Begley (from Curtin University).

Project Title: Impact of MS-related fatigue on what and how people with multiple sclerosis (MS) eat and drink

General Outline of the Project:

- **Description and Methodology:**

I am conducting research to explore and identify the impact of MS-related fatigue on what and how people with MS eat and drink and how people with fatigue manage what and how they eat and drink when fatigued. Involvement in this study will include you discussing the study with a member of the research team, completing online consent followed by online questionnaires and a one-on-one structured interview.

- **Participants:**

The study aims to interview up to 15 people living with a confirmed diagnosis of MS with current or past symptoms of fatigue aged 18 years or older. People diagnosed with any type of MS (relapsing remitting or progressive) can participate.

- **Use of Data and Feedback:**

Data from this project will be de-identified and used to produce a report as part of my postgraduate research project and may be used to contribute to future publications and presented at conferences/seminars or summarised for websites or media. A summary of the research will also be made available to you via email and on the ANU Our Health in Our Hands Website (<https://www.anu.edu.au/research/research-initiatives/our-health-in-our-hands>) and may also be made available to MS organisations and support groups.

Participant Involvement:

- **Voluntary Participation & Withdrawal:** Participation in this research is entirely voluntary and you may decline to take part, or withdraw from the research, at any time before the findings from the study are submitted for publication without having to give a reason and without any negative consequences. If you complete the questionnaires and then do not participate in the interview, your data will not be used in the study and your withdrawal from the study will be reported in study publications. After the results of this study have been submitted for publication, it will not be possible to withdraw from this study. You may also decline to answer any question within the interview or questionnaire.

- **What does participation in the research entail?**

If you would like to participate in this study, a member of the research team will arrange a time with you to talk through the study documents and answer any questions you have. After this discussion, if you would like to participate, you will be emailed a link to an online consent form to sign where you will provide consent for your interview to be audio-recorded using a hand-held recording device and transcribed.

With your consent, we will contact your treating doctor (optional) to confirm your diagnosis of MS by providing your name and date of birth. We will ask for your treating doctor to confirm your date of diagnosis (if known) and type of MS, as it is standard practice when publishing research on MS to specify if your MS diagnosis was self-reported and/or confirmed by a healthcare professional. If your treating doctor requests your signed consent form before they provide confirmation about your MS diagnosis, this will be provided.

Once you provide consent, you will be asked to complete an online questionnaire that takes 20-minutes that asks for your basic demographic information (e.g., age and sex), about your MS (diagnosis, signs and symptoms, treatment team and medication), and to complete questionnaires that will ask about your fatigue, symptom severity and mood.

You will then be invited to participate in a one-on-one semi-structured interview that will take approximately 60-minutes to complete that will ask you to describe your experiences of MS and fatigue and the impact MS-related fatigue has on what and how you eat and drink and how you manage what and how you eat and drink when fatigued. The interview will be audio-recorded and transcribed verbatim and analysed to determine themes across participants. All identifying information in the interviews will be removed (e.g., it will say “Dr x at x said”).

You will be asked whether you provide consent to be contacted by the research team for this project about participating in future ANU MS-related studies, however you do not have to participate in any future ANU MS-related studies and any future studies will require additional consent to be provided by you at that time.

- **Location and Duration:** The online questionnaire will be conducted prior to the interview and the one-on-one interview and will be conducted via telephone or zoom. You will be required for only one interview, however the interview can be conducted over multiple sessions and rescheduled if required.
- **Risks:** This study poses very little risk to you, however, talking about your MS, fatigue and the impact of MS-related fatigue may contribute to uncomfortable feelings e.g., feeling distressed or sad. If this occurs, you can discuss this with the study researchers or seek support from a support person, the MS support service (MS Connect) or Lifeline (contact information for support organisations is on the last page of this participant information sheet).
- **Benefits:** There will be no direct benefits to you as a result of your participation in this study. However, the findings from this study may provide information for future dietary and fatigue management education, support and intervention programs, and guide the development of educational resources about the impact of MS-related fatigue on what and how people with MS eat and drink, for people with MS, their family members and healthcare professionals.

Exclusion criteria:

- **Participant Limitation:** To participate in this study you must be 18 years or older, have been diagnosed with MS by a healthcare professional and have had or are currently experiencing symptoms of fatigue.

Confidentiality:

- **Confidentiality:** Confidentiality will be protected as far as the law allows. Each researcher in this study will maintain strict confidentiality regarding all information obtained from you. To maintain confidentiality, you will be assigned a unique identification number after you have provided written consent to participate in the study. The unique identification number will be used to label data (audio files, interview transcripts and questionnaires). Your personal information (date of birth and information from treating doctors) will be in identified form and stored separately from your other files. Access to the data you provide will be restricted to selected members of the research team. No individual will be identified in the publication or presentation of results from this study. Any identifying information in the interview transcripts will be removed.

Privacy Notice:

In collecting your personal information within this research, the ANU must comply with the Privacy Act 1988. The ANU Privacy Policy is available at https://policies.anu.edu.au/ppi/document/ANUP_010007 and it contains information about how a person can:

- Access or seek correction to their personal information;
- Complain about a breach of an Australian Privacy Principle by ANU, and how ANU will handle the complaint.

Data Storage:

- **Where:** Data will be de-identified and stored electronically on password-protected computers at the National Centre for Epidemiology and Population Health (NCEPH) at the ANU in a locked room in a security-pass secured building. If you have consented to collection of information from your treating doctor, the related personal information (date of birth, date of diagnosis, type of MS) will stored separately from your questionnaire and interview responses in folders that only selected research members will be able to access.
- **How long:** Your data (including questionnaire data and transcripts of audio-recordings) will be stored for at least five years after the date of the final publication arising from this research. The audio-recording of your interview will be deleted once the study has been published.
- **Handling of Data following the required storage period:** Following this time, all data for this study will be destroyed.

Queries and Concerns:

- **Contact Details for More Information:** For any questions or further information regarding this study please refer to the following contacts:

Soumi Krishnan: soumi.krishnan@anu.edu.au

Dr Jo Lane (Supervisor): jo.lane@anu.edu.au (+61 2 6125 1485)

Professor Nicolas Cherbuin (Supervisor): nicolas.cherbuin@anu.edu.au (+61 2 6125 3858)

- **Contact Details if in Distress:** If you would like support, please contact:

Lifeline Australia on 13 11 14

24-hour support service

Website: <http://www.lifeline.org.au>

MS Plus on 1800 042 138

830am to 5pm Monday to Friday

Website: <https://www.msplus.org.au/support-services>

Ethics Committee Clearance:

The ethical aspects of this research have been approved by the ANU Human Research Ethics Committee (Protocol 2022/412). If you have any concerns or complaints about how this research has been conducted, please contact:

Ethics Manager

The ANU Human Research Ethics Committee

The Australian National University

Telephone: +61 2 6125 3427

Email: Human.Ethics.Officer@anu.edu.au