

Plain Language Statement

Neuroepidemiology Unit
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The University of Melbourne



Project: An Online Educational Course for people with Multiple Sclerosis: A randomised controlled trial of course effectiveness

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Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you would like to take part in this research.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about.

Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time.

What is this research about?

This study aims to compare the effectiveness of the two online courses (the MS Online intervention course and the MS Online standard-care course) in improving outcomes in people with MS through a randomised controlled trial. The two online courses deliver information about possible modifications to lifestyle behaviours that may affect health outcomes.

The courses were developed at The University of Melbourne after consultation with people with MS and a team of clinicians specialising in MS and were found to be feasible in a small group on people with MS. This research project explores the impact of two online educational courses related to lifestyle on the physical and mental health of people living with MS.

This study is the first of its kind. Over 1000 participants will be recruited from the US, Australia, New Zealand, the UK and Canada to take part in the study.

What will I be asked to do?

Should you agree to participate in this study you will be asked to:

- Complete a baseline survey related to your life and health. This survey will be completed online and will take approximately 1 hour to complete.
- Complete the Multiple Sclerosis Online course related to diet, exercise, sunlight and vitamin D, stress reduction and other information about multiple sclerosis. The course comprises 7 modules of approximately one hour each and the modules must be completed within a six-week period.
- Complete a survey related to your life and health at 6 months, 1 year and 2.5 years after completing the Online course. This survey will be completed online and will take approximately 1 hour to complete.
- One month and 12 months after completing the Online course, you may be invited to participate in a 30-60 minute phone or internet interview about your experience of the Online course and any impact it may have had on you. However, you have the option to decline participating in these interviews. If you do agree to participate in an interview, the interview will be audio-taped and transcribed by voice recognition software.

What are the possible benefits?

The study will provide valuable insight into how we think about managing MS and will help to determine whether people with multiple sclerosis would benefit from undertaking an MS online course related to lifestyle modifications.

There are no costs associated with participating in this research project, nor will you be reimbursed for participating in this research. However, you may be provided with the opportunity to learn more about multiple sclerosis and how you could change your lifestyle to improve your health and wellbeing.

We intend to make the multiple sclerosis online course freely available to all people with multiple sclerosis worldwide following the completion of this trial.

What are the possible risks?

We anticipate there will be no physical risks following watching online educational course modules and completing surveys related to your lifestyle and health online. While we also anticipate that there will be no associated psychological risks involved in participating in this study, we will provide links to online help resources at the end of each survey you complete.

If you participate in any interviews, at the end of the interview you will be asked whether or not any of the questions asked, raised any issues for you. In the event that any issues were raised, researchers will provide links to online help resources and ask you to reach out if you require any further assistance.

If you are feeling distressed about your participation at any time during the study, you will be able to reach out to researchers using the contact details provided.

Do I have to take part?

No. Participation is completely voluntary. You are able to withdraw at any time. If you decide to withdraw from this research project, please notify a member of the research team of your decision to withdraw to avoid any future correspondence requesting you to complete follow-up surveys from the research team.

As a result of your withdrawal, research staff will not collect additional data information from you but data already collected will be retained and will form part of the research project. If you do not want researchers to do this, you must notify the research team before you join the research project.

Withdrawing participants will be contacted and provided links to online help resources.

Will I hear about the results of this project?

Results of the study will be publicised through international conference presentations and in peer-review international journals that have open access to ensure findings will be readily available for both the academic and general community.

Study participants will be emailed with a plain language summary of results at the end of the study period.

What will happen to information about me?

By consenting to participate below you consent to research staff collecting and analysing your personal information for the research project. Any information obtained in connection with this research project that can identify you will remain confidential by implementing codes to hide the identity of participants (that is, the data will be re-identifiable).

Participant survey data will be stored as part of a dataset specific for this project. Audio data transcribed from interviews will be stored as edited word documents. Data will be stored on the secure server at the University of Melbourne. Data will be stored indefinitely following completion of the study.

Only specified researchers involved in this study at The University of Melbourne will have access to study data.

Data collection and analysis will only be performed to address the aims associated with this research project and will not be used for any other purpose without your permission. Your information will only be disclosed with your permission, except as required by law.

In accordance with relevant Australian privacy laws and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information that you disagree with, be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Where can I get further information?

If you would like more information about the project, please contact the researchers;

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Who can I contact if I have any concerns about the project?

This project has human research ethics approval from The University of Melbourne [HREC ID 22140]. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 8344 1376 or Email: research-integrity@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team and/or the name or ethics ID number of the research project.