SCHOOL OF PSYCHOLOGICAL SCIENCES
Faculty of Medicine,
Health and Human Sciences

MACQUARIE University
SYDNEY·AUSTRALIA

PARTICIPANT INFORMATION AND CONSENT FORM

Macquarie University HREC Project Number: 520262100568913 / 21005

Research Project Title: The Momentum Course: Randomised controlled trial of a remotely-delivered health behaviour change intervention

Chief Investigator: Dr Andreea Heriseanu, Clinical Psychologist / Research Fellow, Macquarie University

You are invited to participate in a research trial of a self-management course, the Momentum Course. This Course is designed to provide good information and skills to help people improve their health-promoting behaviours.

This research is being conducted by:

- Dr Andreea Heriseanu, Clinical Psychologist / Research Fellow, Macquarie University
- A/Prof Milena Gandy, Clinical Psychologist / Senior Researcher, Macquarie University.
- Professor Blake Dear, Director eCentreClinic / Clinical Psychologist, Macquarie University

This Participant Information Sheet/Consent Form tells you about the research project, and what is involved. Knowing what is involved will help you decide if you want to participate. Please take the time to read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or GP or other healthcare professional, as needed.

PLEASE NOTE: You are also welcome to contact the eCentreClinic via email contact@ecentreclinic.org with any questions regarding this research or your participation at any point. You can contact Dr Andreea Heriseanu directly on 02 9850 9656.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the research that are described
- Consent to the use of your personal and health information as described.

1. What is the purpose of this research trial?

The purpose of this research is to test whether the program helps with improving behaviours related to cardiovascular health, such as exercise and diet quality. We also aim to gather feedback from participants to inform further improvements to the program.

Research tells us that there are lots of good strategies that people with a cardiovascular condition or cardiovascular risk can use to improve their health-promoting behaviours such as diet and exercise. However, research also indicates that there are a number of barriers that people experience, such as availability, cost, and access to self-management programs that provide this information and teach these skills. We also know that a lot of people with cardiovascular conditions or increased risk may also struggle with their emotional wellbeing (such as anxiety or low mood), which represents an additional barrier to improving their health-promoting behaviours. We are interested to understand whether people with poor emotional wellbeing may also benefit from the Momentum Course.

2. How is this research being paid for?

There are no costs for participants in this research trial and participants cannot be paid for their participation. This research is funded via the eCentreClinic, Macquarie University and by Dr Heriseanu's Macquarie University Research Fellowship (MQRF).

3. Who is eligible to participate in this research trial?

<u>You are eligible to participate in this trial if:</u>

(1) you are aged 18 or over;

(2) you are living in Australia;

(3) you have a cardiovascular (heart or blood vessel) condition (such as a previous heart attack or stroke, heart disease, coronary artery disease) **and/or** a condition that increases your risk of developing a cardiovascular condition (such as diabetes or pre-diabetes, high blood pressure, high cholesterol, elevated waist circumference or weight, being a regular smoker);

(4) your cardiovascular condition or risk factor is stable, and your health is being actively managed by your GP or a medical specialist (e.g. cardiologist);

(5) you have at least mild symptoms of anxiety or depression;

(6) you want information and skills to help improve your health-promoting behaviours (diet quality and/or exercise).

<u>Currently, we cannot include people who:</u>

(1) are imminently suicidal or unable to keep themselves safe;

(2) have been told by their doctor that they should **not** exercise or change their diet;

(2) do not have access to a computer and the internet;

(3) are unable to read or understand English.

PLEASE NOTE: We strongly recommend you discuss your participation in the course with your doctors and any other health professionals involved in the management of your health conditions.

4. What does participation in this research involve?

Once you have read this information sheet and decide you wish to participate, you can submit an application to participate in the research trial via the eCentreClinic website (www.ecentreclinic.org). This application process takes about 10 to 15 minutes and involves completing some questionnaires via the eCentreClinic website. These questionnaires assist us in understanding your symptoms and difficulties as well as whether the course is likely to be helpful for you. Eligible applicants will be contacted by a member of the eCentreClinic team to conduct a brief telephone interview, discuss the course and answer your questions.

Eligible participants will be randomly allocated to one of two groups: (1) a group who receive access to the course immediately (i.e., the Treatment Group); or (2) a group who receive delayed access to the course (i.e., the Control Group). The delayed access group receive the course 19 weeks following the immediate access group. There are no other differences between the two groups.

Once you are allocated to one of the two groups, you will be provided with a start date for the course and you will be able to create a login name and password for accessing the course platform.

The Momentum Course consists of 4 modules. You will be asked to complete these modules over 6 weeks and to complete some worksheets that will help you to remember the material you have learned. Each module provides important information about techniques for starting and maintaining health-promoting behaviours and managing challenges (e.g. physical symptoms, unhelpful thoughts, emotional wellbeing, and other problems). Each module has illustrated examples of how people learn these techniques. Each module takes about 30 minutes to complete and the home-based tasks will take a further 4 hours each week.

You will also receive weekly automatic emails, and will also have the option of brief phone and/or private message support from an eCentreClinic mental health clinician as you work through the course, as well as in the 12 weeks following the end of the course.

We will ask you to complete online questionnaires:

- Before the course starts (time needed: 10 to 15 minutes);
- Each week of the course (Weeks 1-5; time needed: 1-2 minutes).
- At the end of the course (Week 7: time needed: 10 to 15 minutes)
- 12 weeks after the course (Week 19: time needed: 10 to 15 minutes).
- Approximately 6 months after the course (time needed: 10 to 15 minutes).
- Approximately 15 months after the course (time needed: 10 to 15 minutes).

These questionnaires will help determine whether the course has been helpful. We will also ask you for feedback about your experience of the course and things you believe we can improve for future participants.

You may also be randomly selected to wear a small wrist-based device for 7 continuous days that will record your physical activity (movement) before you start the course, 6 weeks later, and 18 weeks later. The device would be mailed to you together with a pre-paid return satchel.

Once you have completed the course, a clinician from the eCentreClinic will contact you regarding your results and answer any questions you might have. You will have access to the Momentum Course for approximately 6 months, should you participate in the research.

5. What are the possible benefits of taking part?

Based on existing research, we expect that you will find this course interesting and helpful. The strategies in this course have been shown in other research studies to help people improve their health-promoting behaviours and their emotional wellbeing. Also, based on previous research from our other courses, we know that more than 90% of participants find our courses worth their time and that they would recommend them to others. However, we cannot guarantee or promise that you will receive any benefit from participating.

6. What are the possible risks and disadvantages of taking part?

There are no known discomforts or risks associated with participating in this kind of course. It is very unlikely that the present study will result in physical harm. However, we strongly encourage all participants to talk to their health professionals about their participation in this course. This is particularly important where participants are unsure about some aspects of the course and what may and may not be relevant in terms of their physical health conditions.

Psychological treatment programs can be confronting and distressing at times for some people, especially early on in treatment. This is partly because helpful psychological treatments require people to think about the difficulties they are having and how they might use different skills or make certain changes to manage their emotional wellbeing. Importantly, any distress usually reduces over time as people learn about emotional wellbeing and several skills for managing their emotional wellbeing. Participants are also provided with access to an eCentreClinic mental health professional to help them through the course and to manage any psychological distress.

Importantly, if you become distressed or concerned, you are invited to contact Dr Andreea Heriseanu (02 9850 9656) or any of your other health professionals to discuss this distress. You are also welcome to withdraw from this research at any time and we are available during business hours to discuss your symptoms and further treatment options with you.

PLEASE NOTE: If you experience a significant deterioration in your mood or feel at risk of self-harm or become concerned about your health, please arrange to see your GP or contact emergency services on 000.

Other Available Support Services
Lifeline: 13 11 14
Beyond Blue: 1300 224 636
Suicide Callback Service: 1300 659 467

7. What if I do not want to participate or I want to withdraw later?

Participation in this research trial is entirely voluntary. It is up to you whether or not you decide to participate and your decision will not impact your relationship with the research investigators or their respective institutions. Importantly, you can also choose to withdraw from the research at any time without any consequence.

You may elect to not continue with the course (i.e. the treatment program), while still remaining in the research (i.e. completing the questionnaires). Importantly, any information and data you provide up until your withdrawal cannot be deleted or withdrawn; consistent with the standard principles for health research.

8. How will my confidentiality be protected?

Any identifiable information that is collected about you will remain entirely confidential and will not be disclosed without your express permission - unless we are required to do so by law. Importantly, where we hold significant concerns about your personal safety or the safety of others, particularly children, we are legally required to notify emergency and other governmental services. We will publish the results of this research and discuss these results at national and international scientific conferences; however, in any publication, information will be presented in such a way that you cannot be identified. Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored and only accessible to key researchers at the eCentreClinic. Your personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws.

You may be contacted and invited by the research team in the future to participate in related projects.

9. Can I see a copy of the published research?

We will ask all participants whether they would like to receive a copy of any published manuscripts resulting from this research. So, you are welcome to request a copy of any research manuscripts that are published. You are also welcome to contact Dr Andreea Heriseanu or the eCentreClinic (contact@ecentreclinic.org) to discuss this research and ask any questions you may have at any time.

10. Who has reviewed the research project?

The ethical aspects of this research project have been approved by the Macquarie University Human Research Ethics Committee.

This project will be carried out according to the National Statement on Ethical Conduction in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

PARTICIPANT CONSENT FORM

The Momentum Course: Randomised controlled trial of a remotely-delivered health behaviour change intervention

Once you have read this Participant Information and Consent form, you can click the "Consent" button to start your application to participate in this research trial.

Importantly, by submitting an application, you consent to the points below:

1. You would like to participate in the Momentum Course.
2. You have read the Participant Information Statement, which explains the aims of the study and nature of your participation.
3. You have the opportunity to raise any questions or concerns with us, regarding this research, at any time.
4. You can withdraw from the research trial at any time without prejudicing your relationship with the researchers or Macquarie University, Sydney Australia.
5. The eCentreClinic may contact crisis or emergency services, as required by law, if there are significant concerns about my safety or someone else's safety during the course.
6. Research data gathered from the present research may be published in a de-identified format; that is, in an entirely anonymous format where individuals cannot be identified.
7. Research data gathered from the present research may be used in future studies not described in the Participant Information Statement. All data would be in a de-identified format and the research would be subject to approval from a Human Research Ethics Committee.
8. You may be contacted and invited by the research team in the future to participate in related projects.
9. You can raise any questions or concerns about this research project with Dr Andreea Heriseanu (02 9850 9656) or any staff (contact@ecentreclinic.org) at the eCentreClinic at any time.

If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Macquarie University Ethics Review Committee through the Director, Research Ethics and Integrity (telephone +612 9850 7854; email ethics@mq.edu.au). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

REVOCATION OF CONSENT FORM

If at any time you wish to withdraw from this study, please contact Dr Andreea Heriseanu or email the below text to contact@ecentreclinic.org.

I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with Macquarie University.