Chief Investigators
Professor Blake Dear
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PARTICIPANT INFORMATION AND CONSENT FORM

Examining the feasibility and helpfulness of an internet-delivered intervention for adults with medically managed Atrial Fibrillation (AF)

You are invited to participate in a research trial of an online treatment program designed to help Australian adults adjust to and manage the impacts of chronic physical health conditions. The program is designed to provide good information and skills for managing the impact of atrial fibrillation (AF) on people's day-to-day lives and emotional wellbeing.

The research team have been developing the course over the last several years based on feedback from thousands of adults living with different chronic physical health conditions. To date, the results have been very encouraging, with participants reporting significant reductions in their disability levels and improvements in their emotional wellbeing.

This research is being conducted by:

- Professor Blake Dear, Director eCentreClinic and Clinical Psychologist, Macquarie University
- A/Professor Chrishan Nalliah, Cardiologist, Department of Cardiology, Macquarie University Hospital
- A/Prof Kaleab Asrress, Cardiologist, Department of Cardiology, Macquarie University Hospital
- Dr Kais Hyasat, Cardiologist, Department of Cardiology, Macquarie University Hospital
- Dr Amelia Scott, Clinical Psychologist / Research Fellow, eCentreClinic, Macquarie University
- Dr Madelyne Bisby, Clinical Psychologist / Research Fellow, eCentreClinic, Macquarie University
- Ms Shanika Chandra, Clinical Psychologist, eCentreClinic, Macquarie University
- Ms Noni Jervis, Clinical Psychologist, eCentreClinic, Macquarie University

Before you decide to participate in this research trial, it is important for you to understand why the research is being done and what participation will involve. Please take the time to read the following information carefully and discuss with others, including your primary physician or specialist, 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.

1. What is the purpose of this research trial?

The purpose of this research is to examine the helpfulness and acceptability of an online treatment program designed for people with medically managed atrial fibrillation (AF). We have been evaluating this treatment for people with a broad range of significant chronic health conditions, with very encouraging results.

We now want to explore the helpfulness of this treatment for people with atrial AF that is affecting their day-to-day lives and emotional wellbeing. Several research trials overseas have found similar treatments to be helpful for people struggling with AF and its impacts.

2. What is the background to the trial?

Research tells us that chronic conditions like AF have a very significant impact on people's day-to-day lives and their emotional wellbeing. Some chronic physical health conditions can cause significant physical symptoms that are not treatable but can impact peoples' lives and can cause stress and affect peoples' emotional wellbeing. This is also true for people with AF.

We know that access to good information and learning several practical psychological skills can make a big difference to many people. However, research also indicates that many people cannot access the kinds of services that provide this information and teach these skills. We are developing a broad range of internet-delivered psychological treatment programs to help people manage significant physical health conditions.

We are now interested to develop a program that is helpful for people struggling with AF.

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

People are eligible to participate in this trial if:

(a) They have been diagnosed with atrial fibrillation by a doctor
(b) If they have comorbid conditions, AF is a primary condition (e.g., the AF is having the largest impact on their wellbeing)
(c) The medical management of their AF is stable (e.g., no new procedures, medication changes planned)
(d) They are concerned about their AF symptoms
(e) Their AF symptoms are impacting their quality of life or mental health
(f) They are aged 18 years or older
(g) They are living in Australia

Currently, we cannot include people who:

(a) Are at imminent risk of suicide or unable to keep themselves safe
(b) Do not have access to an internet-connected device
(c) Are unable to read and understand English
(d) Have a reversible cause for their AF (i.e., hypothyroidism, infection, anaemia etc)
(e) Have an immediate and significant life-limiting condition

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 this research trial involve?

Once you have read this information sheet and decide you wish to participate, you can apply to participate in the research trial via the eCentreClinic website (www.ecentreclinic.org). This application process takes about 20 to 30 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. Following completion of these questionnaires, we will contact eligible participants via telephone to talk more about the course, ensure it is likely to be helpful and address any questions or concerns you may have.

Suitable and interested participants will be enrolled in the online intervention at a time that is suitable for them. The intervention consists of 5 online lessons. You will be asked to complete these lessons over 8 weeks and to complete some simple exercises that will help you to think through the ideas in the lessons and practice the skills. Each lesson provides information and skills that are proven to help in managing the impact of your health condition on your day-to-day activities and emotional wellbeing. Each lesson takes about 20 to 30 minutes to complete and the exercises will take a further 1 to 2 hours each week. Through the course you will be provided with lots of additional resources, and stories and examples from previous participants with different chronic conditions and difficulties, including those with atrial fibrillation.

You will also receive weekly automatic emails, and be provided with the option of brief weekly contact with an eCentreClinic psychologist. These services are to help guide and support you as you go through the course.

5. What else does this research trial involve?

Participants will be asked to complete questionnaires as a part of this research trial. These questionnaires are essential. They help us to evaluate the course and also to understand how people manage the impacts of their condition over the long term.

Participants will be asked to complete online questionnaires:

- Week 1 of the course (approx. 15 to 20 minutes)
- Mid-way through the course (approx. 10 to 15 minutes)
- At the end of the course (approx. 15 to 25 minutes)
- 3 months after the course (approx. 10 to 15 minutes)

Importantly, participants will have ongoing access to the course for the duration of your participation in this research. We will also provide some feedback about participants' responses each time they complete the questionnaires.

6. How will we collect data for the study?

The majority of data for this project will be collected from you via the questionnaires described above. However, we will also ask your permission to request some basic data from either your GP or cardiologist. You can participate in the study without allowing us to contact your doctors. However, this data is very helpful for this research.

The information we will request is information about:

- Any physical comorbidities you may have and your medications
- Confirmation of the type of AF you have (paroxysmal versus persistent
- Any transthoracic echocardiographic data that might be available
- Your AF burden (time and % in AF)
- Your history of prior procedures and surgeries for AF

7. How is this research being paid for?

There are no costs for participants in this research trial, and participants cannot be remunerated for their participation.

This research is being funded by the Australian National Health and Medical Research Council (NHMRC) via an Investigator Grant to Dr Blake Dear.

Australian Government
National Health and Medical Research Council

8. Will I benefit from participating in this research trial?

Based on our previous research, we expect that you will find this course helpful. For example, based on previous research, we know that more than 90% of participants find the course worth their time and would recommend it to others. However, we cannot guarantee or promise that you will receive any benefit from participating.

9. Are there risks to participating in this research trial?

There are no known risks associated with participating in this research or the course. 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.

The course is based on leading face-to-face psychological programs for adults with chronic conditions, including atrial fibrillation. 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 in how they manage their conditions and the difficulties they are experience.

Importantly, any distress usually reduces over time as people learn several skills for managing their conditions and their emotional wellbeing. Participants are also provided with access to an eCentreClinic psychologist to help them through the course and to manage any psychological distress.

PLEASE NOTE: If you feel at risk of self-harm or become concerned about your health, please contact your GP or contact emergency services on 000. If you have concerns about your physical health, please also contact your GP or medical specialist, or in a health emergency, emergency services on 000.

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

Participation in this research trial is 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. You can also choose to withdraw from the research without any repercussion.

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.

11. How will my confidentiality be protected?

Confidentiality arrangements will follow Australian Law. 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.

PLEASE NOTE: We are required by law to report any instances where we become concerned about your personal safety or the personal safety of others, particularly children.

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. Moreover, only the eCentreClinic will have access to your personal information.

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

You are welcome to request a copy of any research manuscripts that are published. You are also welcome to contact the research team to discuss this research and ask any questions you may have at any time.

PARTICIPANT CONSENT FORM

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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 applying, you consent to the points below:

1. You would like to participate in the intervention and research trial.
2. You have read the Participant Information Statement for the research trial.
3. You can raise any questions or concerns with us 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. 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.
6. Research data gathered from the present research may be used in future studies not described in the Participant Information Statement; however, all data would be in a de-identified format and all uses will be subject to approval from an Australian Human Research Ethics Committee.

7. You can raise any questions or concerns about this research project with Professor Blake Dear (contact@ecentreclinic.org).

☐ You consent to us contacting your GP or Cardiologist to collect the basic cardiac and health information described above in section 6.

If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the 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 Blake Dear by **emailing the text below back 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, Australia.