



The University of Sydney



brain&mind
RESEARCH INSTITUTE

100 Mallett Street
Camperdown NSW 2050
Ph: 02 9351 0799
Fax: 02 9351 0652

ABN 15 211 513 464

CHIEF INVESTIGATORS

Professor Ian Hickie
Associate Professor Nick Glozier
Dr Sharon Naismith
Professor Helen Christensen
Professor Bruce Neal

A/Professor Nick Glozier
Telephone: +61 2 9515
5861
Facsimile: +61 2 9515
6442

Email: nglozier@usyd.edu.au
Web: www.usyd.edu.au/

**RESEARCH STUDY:
A Randomised Controlled Trial of a Web-based Intervention
to improve Mood, Cognitive Function and Adherence in
People with Cardiovascular Disease - CREDO**

PARTICIPANT INFORMATION STATEMENT

What is the CREDO Research Study?

The CREDO Research Study is for participants in the 45 and Up Study.

Depression and cardiovascular disease are common in our community and often present together. The object of this research study is to investigate the effectiveness of an evidence-based internet program for depressive symptoms in patients being treated for cardiovascular disease.

Who is conducting the CREDO Research Study?

The CREDO Research Study is being conducted by a team at the University of Sydney and Australian National University. It is led by Professor Ian Hickie and Associate Professor Nick Glozier of the Brain and Mind Research Institute at the University of Sydney.

The study has been funded by the Heart Foundation and beyondblue: *the national depression initiative*.

What does the CREDO Research Study involve?

If you agree to participate in this study, you will be asked to do up to six things:

1. Initial contact: Visit the CREDO Research Study website [*to be inserted*] and log on using your unique ID number. This is the number provided in the email sent from the 45 and Up Study inviting you to participate.
2. Questionnaires: Here you will be asked to complete a short questionnaire (which will take approximately 10 minutes) including questions about your email details, medical history, mood and current medications and some lifestyle habits such as exercise.
3. Memory and thinking skills (“cognitive”) tests: If you are eligible, you will then be given a link to download a program onto your computer which has three tests of memory and thinking skills. You will be able to practise these tests in your own time. When you are comfortable with these tests and feel that you are ready, you will click on the button to take the skill test for the study. This test will take around 10 minutes. The results will be reported back to you later in the study.
4. Intervention: We will then email you to see if you still wish to take part. If you do so you will be allocated to one of two internet programs. Both of these have lots of health information and ask you to visit them once a week for ten weeks. We will ask if you are willing to be contacted by phone during this time to see if you need any help with the sites.
5. Questionnaires and cognitive tests: At the end of this time you will be asked to take the questionnaires and cognitive tests again. Your results and any changes will be provided to you.
6. At six and twelve months after you have completed the intervention, you will be contacted via e-mail and/or phone and again asked to complete the questionnaires about your mood and medications as well as the cognitive tasks. If you are unable to complete the mood questionnaire online you will be asked to do so over the telephone.

How much of my time is involved?

We anticipate that you will need around half an hour to an hour every week for ten weeks to complete the tasks that will be asked of you in the respective internet programs. Also, over the course of the project you will be asked to fill out four online questionnaires and complete cognitive tasks – once before starting your program, once at the end of the program and another six months and then again twelve months later. We anticipate each questionnaire will take about 20 minutes to complete.

How will my information be used?

All information collected will be treated completely confidentially and used for health research only. Your information may be used within health research for approved 45 and Up Study research projects to investigate factors affecting the health of Australians in mid to later life. All 45 and Up Study research projects must

demonstrate that they are in the public interest and have the potential to provide important information to improve health.

The information collected in the CREDO Research Study will be linked to the health information you have already given to the 45 and Up Study and to information from your health and other records that you allowed the 45 and Up Study to access. These include NSW hospital records, cancer records, Medicare and other records (call 1300 45 11 45 or visit www.45andUp.org.au for more information).

How do I know my information will be treated confidentially?

The 45 and Up Study is bound by Commonwealth and State privacy legislation and guidelines, including the Health Records and Information Privacy Act and the NSW Health Privacy Manual. The 45 and Up Study has strict procedures and systems to safeguard confidentiality.

The information you provide will be identified by an ID number and your identifying details (such as name and address) will be removed from the information you give to the CREDO Research Study as soon as possible and stored separately.

Hard copy and online survey answers, website data, and all information collected over the phone will be recorded and stored in a password protected computer at the Brain and Mind Research Institute and will only be accessible to authorised research staff. We are committed to maintaining the security of all the information that will be collected throughout this project. No information will be released in a way that would allow for an individual to be identified, except as is required by law.

All information gathered online will be stored on the University of Sydney Faculty of Medicine server and is subject to all reasonable security measures. However, any user of the Internet and the World Wide Web should be aware that it is an insecure public network that gives rise to a potential risk that a user's transactions are being viewed, intercepted or modified by another party or that data which the user downloads may contain computer viruses or other defects.

The conduct of the 45 and Up Study is overseen by the University of NSW Human Research Ethics Committee and the conduct of the CREDO Research Study is overseen by the University of Sydney Human Research Ethics Committee.

By agreeing to be part of the CREDO Research Study, you agree to the 45 and Up Coordinating Centre providing your completed questionnaire to the CREDO Researchers.

How will the CREDO Study benefit me?

We believe that you will find your participation in this trial interesting and valuable. We anticipate that many of you will benefit personally from the study and your participation in the research project will help us to understand more about the methods and resources that may be helpful for promoting improved wellbeing in patients being treated for cardiovascular disease.

Are there any risks/discomforts or side effects associated with this study?

Taking part in the study is considered to be of very low risk. Sometimes, the cognitive tests may cause mild anxiety (i.e. feeling nervous). However, this gets better after a little practice.

Will anyone else know the results?

All aspects of the study, including results, will be strictly confidential and only researchers directly associated with the study will have access to information on participants, except as required by law. A report of the study may be submitted for publication or presented at scientific meetings, but individual participants will not be identifiable in such a report or presentation. We will also include a summary of the results on the 45 and Up Study website (www.45andUp.org.au). The results will also be included in the 45 and Up Study's participant newsletter.

The information you give will be held in a secure location for 15 years after publications, after which time any identifying information will be destroyed.

Will I be told of the findings of the study?

You will receive a summary of the study's findings via email once the project is completed. You will also be provided with your individual test scores. The summary of findings will also be published on the 45 and Up Study website (www.45andUp.org.au) and in the 45 and Up Study's participant newsletter.

Can I tell other people about the 45 and Up Study and the CREDO Study?

Yes. Please note, however, that the 45 and Up Study is no longer accepting new participants and that invitations to participate in the CREDO Research Study have only been sent to a random sample of 45 and Up Study participants.

What if I don't want to take part?

Participation in this study is entirely voluntary. If you do not wish to participate, you need take no further action.

Can I withdraw from the CREDO Research Study?

Your participation in the CREDO Research Study is completely voluntary. You are not obliged to take part and, if you do take part, you can withdraw at any time by calling the 45 and Up Study Helpline on 1300 45 11 45. You can withdraw from the CREDO Research Study and still remain in the 45 and Up Study.

How can I get more information?

If you would like to know more about the 45 and Up Study, please visit the Study's website www.45andUp.org.au or call the 45 and Up Study Helpline on 1300 45 11 45.

You can also write to:
Associate Professor Emily Banks
Scientific Director
The 45 and Up Study
PO Box 123
Broadway NSW 2007

If you have a concern or complaint about the conduct of the 45 and Up Study, you can contact:

Ethics Secretariat
The University of NSW
Sydney NSW 2052
Tel: 02 9385 4234
Email: ethics.sec@unsw.edu.au

Sometimes people who are very distressed have thoughts of harming themselves. If, at any time you feel this way we suggest that you contact Lifeline on 13 11 14 or seek help from your doctor.

Any person with concerns or complaints about the conduct of the CREDO Research Study can contact the Manager, Ethics Administration, University of Sydney on (02) 8627 8175 (Telephone); (02) 8627 8180 (Facsimile) or gabriody@usyd.edu.au (Email).

You can save or print this information sheet to keep.