St Vincent's Hospital

The Clinical Research Unit for Anxiety & Depression
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www.crufad.org
www.virtualclinic.org.au

Participant Information Sheet/Consent Form

Title	A comparison of internet-based cognitive behavioural therapy for insomnia versus internet-based cognitive behavioural therapy for anxiety in a comorbid sample
Short Title	iCBT for insomnia versus iCBT for anxiety
Protocol Number	2018/ETH00086
Project Sponsor	St Vincent's Hospital, Sydney
Coordinating Principal Investigator/ Principal Investigator	Dr Elizabeth Mason, Senior Clinical Psychologist
Associate Investigator(s)	Ms Amanda Sie Dr Alison Mahoney Dr Jill Newby Dr Ashlee Grierson
Location	St Vincent's Hospital, Sydney

Part 1 What does my participation involve?

1 Introduction

You are invited to participate in a research study comparing two online Cognitive Behavioural Therapy (CBT) programs for individuals with insomnia and anxiety.

This Participant Information Sheet tells you about the research project. It explains what the study involves, and will help you decide if you want to take part in the research before applying online.

Please read this information carefully. You will be asked if you would like to ask questions about the study before you consent to apply. Before deciding whether or not to take part, you might also want to talk about it with a relative, friend or your local doctor (GP).

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 this study, you will be asked to type in your full name and click the 'Yes, I consent' button to proceed with your application. By typing your full name you are telling us that you:

- Understand what you have read in this Participant Information Sheet
- Consent to take part in the application process, and if eligible, become a participant of the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

If you have any questions about the study, please contact the research team before providing your consent. You can do this by emailing research@thiswayupclinic.org.au or select the button at the bottom of the consent page to send the Virtual Clinic an email with your query. Once you have consented, you will be emailed a copy of this Participant Information Sheet to keep.

2 What is the purpose of this research?

The purpose of this study is to compare two internet-delivered CBT programs – one designed to target insomnia (iCBT-I) and one designed to target anxiety (iCBT-A). CBT skills have been shown to help people feel less anxious and reduce insomnia. We are aiming to compare these two internet-based CBT programs to see if they equally reduce symptoms of insomnia and anxiety.

3 What does participation in this research involve?

If you agree to participate, you will be asked to provide online consent to participate in the application process after reading this information sheet by typing your full name and clicking the 'Yes, I consent' button at the bottom of the consent page that follows this section. Each time you log on to do a lesson, we will take that as a sign of continued consent to participate.

After you consent, you will then be required to answer some questions to see if you are suitable for the study. These include questions about your past and current mental health. You will also be asked to provide your personal contact details (e.g., name, address, phone number) and your GP contact details. As your safety is very important to us, your GP contact details are required in order to proceed with the online application. We will only contact your GP if we are concerned about your safety, and only after attempting to contact you first.

If our program is not suitable for you, you will be notified on-screen and provided with an email containing detailed information about where you might seek further support that is better suited to you and immediate care if required. Other applications will require more information to determine if this study is right for you, and you will be notified of this at the end of your application on-screen and via email. If more information is required, a Virtual Clinic staff member will contact you via telephone to ask a few more questions. After this telephone interview, the Virtual Clinic staff member will inform you whether this Program is suitable for you or will redirect you to more appropriate care, including alternate services and support.

If the program appears right for you, you will be accepted into the study as a participant.

Sometimes doctors/psychologists don't know the best way of treating patients with a particular condition so comparisons need to be made between different treatments. To do this, study participants are put into groups which receive different treatments, and the results are compared to see whether one treatment is better. To ensure the groups are similar to start with, a computer allocates each person into a group randomly, like the flip of a coin. Neither the doctor nor the participant can decide which treatment the participant receives. If you agree to participate, you will be randomly allocated to one of the two groups so that we can compare the two groups.

Both treatment groups (iCBT-I and iCBT-A) will receive access to an online treatment program, plus contact with staff from the Clinical Research Unit for Anxiety and Depression (CRUfAD).

The treatment program consists of 4 lessons/modules and will last up to 8 weeks, though your participation in the research study will go beyond this. For both groups, we will measure changes in symptom levels over the course of treatment and for a time afterwards to see if changes are maintained, and to compare outcomes of the treatment groups with one another. We will also measure time spent on the lessons and on homework activities between lessons, as well as satisfaction with this mode of treatment. To do this, we will ask you to complete questionnaires online, which will take around 20-40 minutes to complete. Below we explain what we ask of you regarding the completion of online questionnaires. Completing questionnaires is an important part of being in a research study, so please be sure you are willing and committed to do this.

We will measure changes throughout the program at the following times via online questionnaires: 1. before the program; 2. at the beginning of each lesson; 3. in the middle of the program; 4. immediately after the program; and 5. three months after completing the program. This means the total duration of participation in the study is approximately 5 months (that is, 8 weeks to complete the treatment program plus completing final questionnaires 3 months after completing the treatment program). You will not be required to do anything as part of the study in the 3 month period between completing the post-treatment questionnaires and final set of questionnaires at 3-month follow up.

You will also be asked to complete a diary of your sleep for 10 days at the start and at end of the program. This involves making note of things like what time you went to bed and what time you woke up, and will take approximately 3 minutes each morning. This is an important part of being in the study, and you will only be eligible to access to the course material if this sleep diary is completed. Please be sure you are willing and committed to do this. To help you to complete the sleep diary, we will be sending daily text message (SMS) reminders for the 10 day period. To help you to complete the other questionnaires and lessons within the study timeframe, we will monitor your progress and may contact you via e-mail, phone call, or text message (SMS).

Note: We use an SMS gateway to schedule and send SMS. If we send you an SMS, we will enter your mobile number and first name into the portal, no sensitive health information will be entered. Text messages will only be used to prompt you to complete the sleep diary, questionnaires, or the lessons.

The treatment programs will be conducted online. As part of the study, you will log on to www.virtualclinic.org.au to access the lessons. Each lesson involves new educational material and homework tasks. Each lesson will take between 20-60 minutes to complete. Between each lesson, there will also be practice exercises to complete based on what you cover in the lesson. This is a critical element of the Program. We suggest spending 1 to 3 hours on these practice exercises each week between lessons.

For the internet-based cognitive behavioural program for insomnia, there are four lessons to complete over up to 8 weeks. It includes psycho-education about insomnia and how it is maintained, as well as specific strategies to manage insomnia and change unhelpful behaviours and thinking patterns which maintain poor sleep.

For the internet-based cognitive behavioural program for anxiety, there are four lessons to complete over up to 8 weeks. It includes psycho-education about anxiety and how it is maintained, as well as specific strategies to manage anxiety and change unhelpful behaviours and thinking patterns which maintain anxiety.

Note: This study aims to further medical knowledge and we anticipate that most people who complete the program will benefit, however it may or may not directly benefit you. Participation in this study will not cost you anything other than costs associated with using your computer or accessing the internet. You will not be paid.

4 What do I have to do?

For this research study, you are required to access and complete the treatment program and questionnaires online. In order to participate, you will need to have regular access to a desktop computer (the program is not compatible with tablets or smartphones), reliable internet connection, and a printer. You will be required to spend 2-3 hours per week reviewing the lesson content and practising the skills, as well as completing a sleep diary at the start and end of the program.

Any medications and treatment that you are already receiving for your symptoms can continue during the course of the research trial. All participants will have full access to their general practitioner throughout the course of the study.

5 Other relevant information about the research project

For this research study, we will recruit approximately 100 people who will be randomly placed into either of the two treatment programs. The study will be conducted by the study researchers at the Clinical Research Unit for Anxiety and Depression (CRUfAD), which is a collaboration between St Vincent's Hospital, Sydney and the University of New South Wales.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to withdraw, you need to let us know via e-mail that you do not wish to continue participating in this study.

If you do decide to apply for this study, you will need to provide consent before proceeding to the online application. You will be emailed a copy of this information sheet for your records once you consent. You can also download or print this information sheet from the online application page.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you, or your relationship with St Vincent's Hospital or the University of New South Wales.

7 What are the alternatives to participation?

Participation in this study is not your only option. You should discuss standard care options available to you, with your GP and/or other mental health care providers. Please note that you can withdraw from this study at any time without prejudicing your relationship with St Vincent's Hospital, Sydney or the University of New South Wales.

8 What are the possible benefits of taking part?

This study aims to further medical knowledge and may improve symptoms of insomnia and anxiety. However it may or may not directly benefit you.

9 What are the possible risks and disadvantages of taking part?

There are no known risks associated with taking part in this study. If you have concerns during or following participation in this study, you may direct them to a member of the research team who will arrange appropriate assistance.

10 What will happen to my results?

We plan to publish the aggregated results in peer-reviewed journals, at presentations and conferences, or in other professional forums. Individual results will not be analysed. In any publication, information will be provided in such a way that you cannot be identified as a participant. Please let the researchers know if you would like to be personally informed of the research results. Results may also be discussed with the Human Ethics Research Committee (HREC) for monitoring purposes.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the researchers will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, the researchers will make arrangements for your regular health care to continue. If you decide to continue in the research project, you will be asked to sign an updated consent form.

Also, on receiving new information, your study clinician might consider it to be in your best interests to withdraw you from the research project. If this happens, s/he will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important during the application process, to tell the research team about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also contact the research team and supervising clinician about any changes to other treatments you are receiving during your participation in the research project.

13 What if I withdraw from this research project?

Participation in this study is voluntary. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason by contacting the research team via email (research@thiswayupclinic.org) or phone (02 8382 1400).

If you do withdraw your consent during the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research study can be measured properly and comply with law. You should be aware that data collected by the researchers up to the time you withdraw will form part of the research study results.

14 Could this research project be stopped unexpectedly?

We cannot think of any reason why this research project would need to be stopped before completion. If it does need to be stopped, we will contact you via email or phone. We will also provide information on where to seek further help with your mental health, such as your local GP, or mental health care professional.

15 What happens when the research project ends?

At the end of the research study, the usefulness of the treatment programs in reducing insomnia and anxiety symptoms will be evaluated. At the end of the treatment program, clinicians in CRUfAD can direct you to alternative resources should additional assistance for managing your insomnia and/or anxiety be required. Please let the researchers know if you would like to be personally informed of the research results.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. All data will be stored in our secure electronic database and in your research trial medical record which is maintained by St Vincent's Hospital as a confidential document. Only the researchers will have access to your details which will be held securely at St. Vincent's Hospital for 15 years before being permanently destroyed. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, St Vincent's Hospital Sydney Limited, the institution relevant to this Participant Information Sheet, St Vincent's Hospital and the Human Research Ethics Committee or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Information about your participation in this research project may be recorded in your health records.

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

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

There are no known risks for participating in this study. If you experience any difficulties or complications, you should contact the study clinician or your GP who will arrange appropriate help. To ensure your safety, we are asking all participants to provide us with the contact details of their GP. This is so we can contact them if we have any concerns for your safety. We will not contact them under any other circumstances and will always endeavour to speak with you first.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

This study has been approved by St Vincent's Hospital HREC. Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on 02 8382 4960 and quote 2018/ETH00086.

18 Who is organising and funding the research?

The study is paid for by a grant from St Vincent's Hospital awarded to the Clinical Research Unit for Anxiety and Depression at St Vincent's Hospital. No money is paid directly to individual researchers.

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of St Vincent's Hospital, Sydney reference number 2018/ETH00086.

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

20 Further information and who to contact

When you have read this information, you are welcome to contact the researchers, Dr Elizabeth Mason, Dr Alison Mahoney or Dr Ashlee Grierson. If you would like to know more at any stage, please do not hesitate to contact the researchers.

Clinical contact person

Name	Dr Elizabeth Mason
Position	CRUfAD Senior Clinical Psychologist/Researcher
Telephone	02 8382 1400
Email	elizabeth.mason@svha.org.au

Clinical contact person

Name	Ms Amanda Sie
Position	CRUfAD Senior Clinical Psychologist
Telephone	02 8382 1400
Email	Amanda.sie@svha.org.au

Clinical contact person

Name	Dr Alison Mahoney
Position	CRUfAD Senior Clinical Psychologist/Clinical Director
Telephone	02 8382 1400
Email	alison.mahoney@svha.org.au

Research Study contact person

Name	Dr Ashlee Grierson
Position	Clinical Trials Coordinator
Telephone	02 8382 1400
Email	ashlee.grierson@svha.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Local HREC Office contact (Single Site - Research Governance Officer)

Position	Research Governance Officer
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au

Thank you for taking the time to consider this study.

If you wish to take part in this study, please continue to the consent form on-screen.
After you consent, you will be emailed a copy of this information sheet to keep for your records.

Consent Form - *Adult providing own consent*

Title	A comparison of internet-based cognitive behavioural therapy for insomnia versus internet-based cognitive behavioural therapy for anxiety in a comorbid sample
Short Title	iCBT for insomnia versus iCBT for anxiety
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Associate Investigator(s)	Ms Amanda Sie Dr Alison Mahoney Dr Jill Newby Dr Ashlee Grierson
Location	St Vincent's Hospital, Sydney

Declaration by Participant

1. I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
2. I understand the purpose and aim of the research study, why I have been selected, the nature of my participation, and the possible risks and benefits.
3. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
4. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
5. I freely agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
6. I understand that if I have any questions relating to my participation in this research, I may contact Dr Elizabeth Mason on 8382 1400, and complaints may be directed to the St Vincent's Hospital Research Office on (02) 8382 4960 email: SVHS.research@SVHA.org.au.
7. I understand that I will be emailed a copy of this document to keep.

Yes, I consent

I do not consent

Name of Participant:_____