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	Panic Program Uplift - Comparing two versions of iCBT (Study 1) for panic
Short Title	Panic Program Uplift
Protocol Number	SVH 18/148
Project Sponsor	St Vincent's Hospital, Sydney School of Psychology, University of New South Wales
Coordinating Principal Investigator/ Principal Investigator	Dr Alison Mahoney
Associate Investigator(s)	Dr Jill Newby Ms Eileen Stech Dr Ashlee Grierson Ms Aileen Chen Ms Amy Joubert
Location	St Vincent's Hospital, Sydney School of Psychology, University of New South Wales, Sydney

Part 1 What does my participation involve?

1 Introduction

You are invited to participate in a research study comparing two versions of internet-delivered cognitive behaviour therapy for panic disorder. The study is being conducted by a team of researchers from the Clinical Research Unit for Anxiety and Depression (CRUfAD) at St Vincent's Hospital, Sydney and the University of New South Wales.

You may be eligible to participate in this study if, according to your responses on our application (both online questionnaires and via a phone interview) we consider you to meet criteria for panic disorder. This research project is testing what strategies are necessary and most important to include in an online course for panic disorder.

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. 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 to 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.

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 begin 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 take part in the research project whatever group you are assigned to, and complete the treatment program that is described for that group.
- Consent to the use of your personal and health information as described.

If you have any questions about the study contact the research team before providing your consent. You can do this by emailing research@thiswayupclinic.org or select the button at the bottom of the consent page to send 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 versions of internet-delivered cognitive behavioural therapy (iCBT) for panic disorder. A team of health professional and academics at St Vincent's Hospital, Sydney developed an iCBT course over 10 years ago, and there have been several studies showing that the course can improve symptoms of panic disorder. The program includes various strategies, including helping people to calm their physical symptoms, challenge their thinking, and face their fears. Research groups around the world have included different combinations of these strategies in the iCBT programs they have developed and tested. More research is needed to clarify what strategies are necessary and most important to include in iCBT programs. To answer this question, we will directly compare two versions of an iCBT program. People about to do the course will be randomly allocated to one of two groups: 1) the existing iCBT program that includes various strategies, or 2) a new adaption of iCBT that focuses on helping people face their fears.

A team of health professionals and academics at St Vincent's Hospital, Sydney, and the University of New South Wales, Sydney, have developed both online courses. Both courses include evidence-based strategies for overcoming panic and anxiety, drawn from the best available research on cognitive behavioural therapy. Each course has six lessons that tell the recovery story of a person with panic disorder. Each lesson is accompanied by information and action plans for you to carry out over the following 5 – 10 days, and doing all this will take some 3-4 hours each week. The course requires work and is not to be taken lightly. The six lessons will take you 6-8 weeks to complete. We will measure your progress by questionnaires each time you begin a lesson, at one week post treatment, 3 months post treatment, and 6 months post treatment.

This research has been initiated by Dr Alison Mahoney, Dr Jill Newby, Ms Eileen Stech, Dr Ashlee Grierson, Ms Aileen Chen and Ms Amy Joubert from the Clinical Research Unit for Anxiety and Depression (CRUfAD) and the School of Psychology, University of New South Wales.

3 What does participation in this research involve?

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. If you are accepted into the study, your General Practitioner will be notified of your enrolment via a letter.

If our program is not suitable for you, you will be notified on-screen as well as 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 researchers don't know the best way to help people with a particular disorder so comparisons need to be made between people accessing different types of resources. In this research study we are comparing people who receive one of two versions of an iCBT program. The two groups will complete a 6 lesson online program that includes reading an illustrated story of a person recovering from panic and anxiety, reading lesson summaries and practicing specific tasks using activity worksheets.

Both groups will complete sets of key questionnaires. These sets of questionnaires will need to be completed before each Lesson of the program, 1 week after finishing treatment (post-questionnaires), at 3-month follow-up, and 6-month follow-up. Completing study measurements is an important aspect of participating in a research study. They help us monitor your progress through treatment, make informed decisions about your treatment, and they provide us with valuable information necessary to evaluate and improve the treatments we offer. If you decide to apply for this study, we kindly ask that you are willing and committed to completing these measurements. If you are not willing to complete the study questionnaires you may withdraw your consent to participate in this study by emailing research@thiswayupclinic.org.

To ensure the groups are similar to start with, a computer will randomly allocate each person one of the two groups, like the flip of a coin. Neither the researchers nor the participant can decide which treatment the participant receives. Both groups will commence treatment immediately. You will have up to 8 weeks to complete the program via a secure website, www.virtualclinic.org.au, with a new lesson becoming available 5 days after the previous lesson. A username (your email address) and password is required for you to access the online program, and you will be emailed details about how to do this. Participation does not require high levels of computer training but does require basic computer skills in order to access the lessons and activities. Each time you log on to the website to complete a lesson, we will take that as a sign of your continued consent to participate.

Access to the program via www.virtualclinic.org.au will finish at Week 8 if you do not complete all the Lessons within the study timeframe. However if you complete all 6 lessons within the 8-week time period, as well as complete your post-treatment questionnaires, you will be provided an additional 3 months access to the program via the Virtual Clinic. To help you complete the lessons within this timeframe, we will monitor your progress throughout the program and will contact you via e-mail or text message (SMS) if we notice you haven't accessed the lessons lately. **The total time commitment for participants is 8 months maximum.**

Note: We use an external online portal to schedule and send SMS messages. If we send you an SMS message, we will enter your mobile number and first name into the portal, no sensitive

health information will be entered. SMS message will only be used to prompt you to complete lessons or questionnaires.

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 computer (the program is not compatible with smartphones) and reliable internet connection. A printer is also recommended. You will be required to spend 3-4 hours per week reviewing the lesson content and practising the skills related to overcoming anxiety and panic.

All participants will have full access to their general practitioner throughout the course of the study. During the application process, we will assess what treatment (including medication) you are currently receiving for your panic, anxiety and/or depression. Eligible participants will be asked not to change medication or start other treatment during the course of the study (including follow-up period). Please inform the research team if you change medications and/or receive other treatments by emailing research@thiswayupclinic.org.

5 Other relevant information about the research project

We are aiming to recruit up to 120 participants for this research study. 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 decide to withdraw, you need to let us know via e-mail that you do not wish to continue participating in this study. Your withdrawal will be acknowledged and no further communication will occur. Participants in the treatment groups who do not access the program for 3 weeks will be sent an automated email stating that they will be withdrawn from the study if they do not access Lesson 1 within the next 7 days. Participants who do not access Lesson 1 after a further 7 days will be withdrawn.

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?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include medication or Cognitive Behaviour Therapy with a psychologist or online courses. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

This study aims to further medical knowledge and we anticipate that most people who complete the course will benefit, however it may not 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 evaluation.

10 What will happen to my results?

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

11 Can I have other treatments during this research project?

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.

Some medications for anxiety can continue to be taken during the study. You cannot have started any new medication or changed dosage within the 8 weeks prior to starting the study. You cannot receive additional cognitive behavioural therapy in any format (e.g. online course, with a therapist) for panic disorder during the research project. You should contact the research team about any changes to medication or other treatments you receive during your participation in the research project.

12 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). 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.

13 Could this research project be stopped unexpectedly?

We cannot think of any reason why this research project will 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 anxiety, such as your local GP.

14 What happens when the research project ends?

At the end of the research study, the effectiveness of the treatment program in reducing panic symptoms will be evaluated. This information will not be available use until results have been finalised. At the end of the treatment program, clinicians in CRUfAD can direct you to alternative resources should additional assistance for managing your panic symptoms 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?

15 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.

16 Complaints and compensation

There are no known harms from participating in this study. If you do suffer any injuries or complications as a result of this study, you should contact the research team or your GP who will assist you in arranging appropriate medical treatment. 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.

17 Who is organising and funding the research?

This study is funded by an Australian Government Research Training Program (RTP) Scholarship awarded to Ms Stech and an Australian National Medical Research Council and Medical Research Future Fund (NHMRC/MRFF) Career Development Fellowship awarded to Dr Newby. This study is also sponsored by the Clinical Research Unit for Anxiety and Depression, St Vincent's Hospital.

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, HREC/18/SVH/170

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 Alison Mahoney, Dr Jill Newby or Ms Eileen Stech. If you would like to know more at any stage, please do not hesitate to contact the researchers.

Clinical contact person

Name	Dr Jill Newby
Position	CRUfAD Research Director and Senior Lecturer at the University of New South Wales

Telephone	02 8382 1400
Email	j.newby@unsw.edu.au

Research Study contact person

Name	Dr Alison Mahoney
Position	Senior Clinical Psychologist, Director, Anxiety Disorders Clinic
Telephone	02 8382 1400
Email	alison.mahoney@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*

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Location	St Vincent's Hospital, Sydney School of Psychology, University of New South Wales, 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 Alison Mahoney or Dr Jill Newby on (02) 8382 1400, and complaints may be directed to the St Vincent's Hospital Research Office on (02) 8382 4960.
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: _____