t Vincent's Hospital

Participant Information Sheet/Consent Form

Non-Interventional Study – *Adult Providing Own Consent*

Title	Partnering with consumers accessing THIS WAY UP: an analysis of focus group and interview responses.
Short Title	THIS WAY UP's Consumers Focus Groups and Interviews
Protocol Number	2021/ETH00569
Project Sponsor	St Vincent's Hospital Sydney
Coordinating Principal Investigator/ Principal Investigator	Dr Michael Millard
Associate Investigator(s)	Dr Alison Mahoney, Dr Hila Haskelberg, Dr Ashlee Grierson, Ms Katie Dobinson, Dr Christine Shiner, Ms Jay Court
Location	St Vincent's Hospital, Sydney

Part 1 What does my participation involve?

1 Introduction

You are invited to participate in this research project because you are a consumer or service user of THIS WAY UP, a digital mental health service based at St Vincent's Hospital. You may be an individual with mental health difficulties, a clinician, a carer, a family member and/or a support person.

This research project will involve participation in a focus group or individual interview. Through these focus groups and interviews, we hope to provide you with an opportunity to share your experiences and perspectives about the usability of THIS WAY UP as a service. The information you provide will be helpful in planning, designing, measuring and evaluating a relevant and useful service for our consumers and service users.

This Participant Information Sheet/Consent Form tells you about the focus groups and interviews. It explains what is involved. Knowing what is involved will help you decide if you want to take part in the focus groups or interviews.

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 about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. Taking part in this research will have no impact on any care you may receive at St Vincent's Hospital.

If you decide you want to take part in the research project, you will be asked to indicate that you consent to the information on this form. By indicating that you consent, you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to the tests and research that are described
• Consent to the use of your personal information as described.

You can request to be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

As part of our ongoing commitment to high-quality mental health care, we are hoping to improve our digital mental health service, THIS WAY UP by providing our consumers and service users with more opportunities to be a part of the service's governance, planning, design, measurement and evaluation. These opportunities will made available in the form of focus groups and individual interviews; a space where you can share your thoughts on the usability of THIS WAY UP. We believe mental health services that are based on partnerships with our consumers and service users will undoubtedly improve access to and use of our service, whilst also reducing barriers to care.

3 What does participation in this research involve?

If you are eligible to participate in this research project, and after you have read this Participant Information and Consent Form, you will be asked to provide consent to participate in the focus group or interview electronically via our online research platform, Virtual Clinic. Once you have provided your consent to participate, you will be contacted by a member of the research team with more information about the time and date of the focus group or interview.

At the focus group, our team members will ask for your input and thoughts. The focus groups will consist of between 4-8 participants, and will be audio-recorded to ensure that we have an accurate record of all the feedback provided. Depending on your preference, the focus group will take place either online using one of our communication platforms (Pexip, My Virtual Care or Microsoft Teams) or face-to-face at St Vincent's Hospital, Sydney during work hours. It should take approximately 1-2 hours to complete. Further instructions on how to participate in either an online or face-to-face focus group, and the time and date of the session, will be provided closer to the time.

At the interview, our team members will ask for your input and thoughts. The interview will conducted individually, and will be audio-recorded to ensure that we have an accurate record of all the feedback provided. Depending on your preference, the interview will take place either online using one of our communication platforms (Pexip, My Virtual Care or Microsoft Teams) or face-to-face at St Vincent's Hospital, Sydney during work hours. It should take approximately 1-2 hours to complete. Further instructions on how to participate in either an online or face-to-face interview, and the time and date of the session, will be provided closer to the time.

There are no costs associated with participating in this research project, nor will you be paid. However to compensate you for your time, you will be provided with a small gift voucher, The gift card value will be dependent on the time necessary for you to commit to the focus group or interview, i.e. 1 hour = $50; 2+ hours = $100. If you participate in a face-to-face focus group session, you will be provided with light refreshments.

4 What do I have to do?

There are no restrictions for participation in the focus group or interview. We are simply looking for you to share your experiences and perspectives as a consumer, and the most helpful ways of providing you with a useful and high-quality mental health service.

5 Other relevant information about the research project

We will recruit up to 400 people to participate in a focus group or interview over a period of 5 years. There will be 4-8 participants per focus group and one participant per interview.

This research project is being conducted by the research team at the Clinical Research Unit for Anxiety and Depression (CRUfAD) at St Vincent's Hospital, Sydney. This project is self-funded via THIS WAY UP at St Vincent's Hospital, Sydney.

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.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your care, your relationship with those treating you, or your relationship with St Vincent's Hospital.

If you wish to withdraw from the focus group or interview once it has started, you can do so at any time without having to give a reason. No further contact with you will occur.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. There will be no clear benefit to you from your participation in this research, other than the knowledge that you are contributing to improving THIS WAY UP as a digital mental health service.

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

There are no known risks related to participating in these focus groups or interviews. If you suffer any injuries or complications as a result of this research, you should contact the study team or your GP as soon as possible, who will assist you in arranging appropriate support and treatment. You do not give up any legal rights to compensation by participating in this study. If you suffer any distress or psychological injury as a result of this study, you should contact the study team as soon as possible, who will assist you in arranging appropriate treatment and support.

10 Can I have other treatments during this research project?

Whilst you are participating in this research project, you will be able to continue with any treatments that you are currently undertaking.

11 What if I withdraw from this research project?

Participation in this study is voluntary. If you wish to withdraw from the research project, 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. If you do not want them to do this, you must tell them before you join the research project.

12 Could this research project be stopped unexpectedly?

We cannot think of any reason why this research project will need to cease before completion. If it does need to cease, we will contact you via email or phone.

13 What happens when the focus group and interviews end?

We will analyse all of the feedback provided in these focus groups and interviews. This feedback will be used to improve the safety, quality, performance and effectiveness of our service. We plan to publish the results of the focus group in peer-reviewed journals, in presentations at conferences or in other professional forums. In any publication, information will be provided in such a way that you cannot be identified. Results may be discussed with the Human Ethics Research Committee (HREC) for monitoring purposes.

Part 2 How is the research project being conducted?

14 What will happen to information about me?

By deciding to continue, you consent to the study researchers collecting and using personal information about you for the purpose of improving our service. Any information obtained in connection with this survey that can identify you will be held by Survey Monkey, where your information will be held overseas in the US on Survey Monkey's secure system. After 90 days past the completion of the study, your data will be purged from the Survey Monkey system and only stored on secure password protected computers in a secure location at St. Vincent's Hospital for 15 years before being permanently destroyed. Researchers will allocate you a unique identifier and use data associated with this identifier. 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. 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.

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 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.

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.

15 Complaints and compensation

There are no known harms from participating in this study. If you 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. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. You may be able to seek compensation through the courts.

16 Who is organising and funding the research?

This research project is being conducted by the research team at Clinical Research Unit for Anxiety and Depression (CRUfAD) at St Vincent's Hospital, Sydney. This project is self-funded via THIS WAY UP at St Vincent's Hospital, Sydney.

17 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, 2021/ETH00569.

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.

18 Further information and who to contact

If you want any further information concerning this project, you can contact the principal study investigator on 02 8382 1400 or any of the following people:

Clinical contact person

Name	Dr Michael Millard
Position	Director, Clinical Research Unit for Anxiety and Depression
Telephone	02 8382 1400
Email	research@thiswayupclinic.org

Research Study contact person

Name	Dr Michael Millard
Position	Director, Clinical Research Unit for Anxiety and Depression
Telephone	02 8382 1400
Email	research@thiswayupclinic.org

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:

Reviewing HREC approving this research

Reviewing HREC name	*St Vincent's Hospital Sydney HREC*
Telephone	*02 8382 4960*
Email	*Svhs.research@svha.org.au*

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

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

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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 Michael Millard 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 can request to be emailed a copy of this document to keep.

Yes, I consent

I do not consent

Name of Participant: _____