Participant Information Sheet/Consent Form

SMART-Therapy (Randomised Controlled Trial)

Title	Psychosocial intervention using online resources to promote personal recovery in users of mental health services: Randomised Controlled Trial
Short Title	SMART-Therapy RCT
Principal Investigator	**Dr Neil Thomas**, Swinburne University and Monash Alfred Psychiatry Research Centre
Associate Investigator(s)	**Assoc Prof John Farhall**, La Trobe University **Prof Mike Kyrios**, Swinburne University **Prof David Castle**, St Vincent's Health **Ms Cassy Nunan**, Mental Illness Fellowship of Victoria **Prof Susan Rossell**, Swinburne University and Monash Alfred Psychiatry Research Centre **Ms Emma Ladd**, Mental Illness Fellowship of Victoria **Ms Sue Farnan**, Mental Illness Fellowship of Victoria **Dr Ellie Fossey**, La Trobe University **Prof Leon Sterling**, Swinburne University **Prof Greg Murray**, Swinburne University **Assoc Prof Cathy Mihalopoulos**, Deakin Health Economics **Assoc Prof Denny Meyer**, Swinburne University **Dr Lisa Brophy**, Mind Australia **Prof Jayashri Kulkarni**, Monash Alfred Psychiatry Research Centre **Dr Nuwan Leitan**, Swinburne University **Ms Bronte McLeod**, Swinburne University **Ms Rosalie Frankish**, Swinburne University **Ms Tara Smark**, Swinburne University **Mr Robert Pasqual Bruno**, La Trobe University **Ms Chelsea Arnold**, Swinburne University
Study Coordinator	**Ms Fiona Foley**, Swinburne University
Location	Alfred Health, Mental Illness Fellowship, Mind Australia, Neami National, Uniting Care

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. The research project is aiming to evaluate the usefulness of mental health workers using online (Internet) resources during their appointments with people who use mental health services.

This Participant Information and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research.

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 healthcare worker.

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 you take part or not.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to participate in the research processes that are described;
- consent to the use of your personal and health information as described

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

2 What is the purpose of this research?

We are interested in examining how the Internet can be used to enhance mental health delivery for users of specialist mental health services. We have designed some specific online resources to promote self-management and recovery from persisting mental health problems including information, videos, audio recordings and exercises. We are interested in finding out how helpful this material is to mental health service users and workers. This content has been especially designed to help people with a history of psychotic experiences in their recovery, and the aim is that participants can complete these with the guidance of a mental health worker and/or on their own.

Because we do not yet know how helpful our resources are in helping people who use mental health services, we have developed a project in which we can find out the effects of using our resources.

This research has been initiated by the investigators named on page one.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. To find out how the Internet can be used we allocate people to one of two different interventions. The results are compared to see what the differences are. Each participant is allocated their intervention by chance (random). This will help us to compare the two interventions fairly.

The interventions

Both interventions will involve a research support worker meeting with you in addition to the usual treatment and care they receive. You will meet up with them for 8 sessions, usually once a week. Each session will last for about 50 minutes. The research support worker will talk with you, and will also have a tablet computer (e.g. iPad) which you will look at together during your meetings.

You will be allocated to either the **Health** intervention, or to the **Social** intervention which will determine the focus of your meetings. There is a 50/50 chance of being allocated to either intervention. Below are some details about each of the interventions:

Social **intervention**: This intervention will involve your research support worker talking with you about things that are of interest to you such as sport, current events, news, travel and hobbies. They will help you look at things related to this on the Internet, including watching videos, listening to audio and playing games.

Health **intervention**: This group will involve a research support worker talking with you about your mental health. They will help you to look at things related to mental health and recovery on a specific website we have developed on the Internet, including watching videos, listening to audio and doing therapy exercises. This intervention will also include the ability to interact with other users via the sharing of comments and use of discussion boards. You will be able to access the same website yourself between sessions and afterwards via your own internet connection.

While this project may find that one intervention is better than the other, both social interaction and health information have been found to be helpful to people with persisting mental health problems such as psychosis.

You can continue to receive the usual treatment and support from your mental health services during the course of your involvement in this project without restriction.

Assessments

If you agree to participate you will meet up with one of our research team in the next week or two for an interview to assess your psychiatric symptoms and to fill out some questionnaires before you are allocated to your intervention. This will take approximately 3 hours. We expect that each of the interviews can be completed in one meeting, but they could be held over more than one meeting if needed. In these interviews, we will be asking you for some background information about you, and we will also ask you to talk to us, in some detail, about your experience of symptoms and about your broader well-being, your service use and use of the Internet.

We may want to talk to a staff member and look at your medical records for your current and past diagnoses, medication, treatment and any risk issues. We need this information so that we can understand what treatment you have had and how this has affected your experiences.

After this time, your intervention will begin as soon as it can be practically arranged.

You will also meet up with one of our research team for another interview after 3, 6 and 9 months. Each follow-up assessment interview will take approximately 3 hours.

Optional parts of the study

The following parts of the study are optional. We will ask you whether you would be willing to do these when you sign the consent form.

Audio recording. If you give your permission, we would like to make audio recordings of the assessments and intervention sessions. Assessment session recordings will be checked to make sure that ratings are being completed consistently. Intervention session recordings will be randomly checked to make sure that the interventions are being delivered correctly, and to help discover what aspects of each intervention are most useful. You can change your mind about audio recording at any time.

Access to Medicare/Pharmaceutical Benefits Scheme data. We will also ask you to fill out a separate consent for the use of your Medicare and Pharmaceutical Benefits Scheme (PBS) data. Medicare collects information on your doctor visits and lab tests while the PBS collects information on the prescription medications you have filled at pharmacies. This information helps us understand costs that may be different due to the study group to which you are assigned. This separate consent is sent securely to the Department of Human Services who holds this information confidentially. In order to maintain confidentiality, the Department of Human Services will remove your name from your Medicare and PBS data and send it to us identified only by your study ID code. Your Medicare and PBS data will be stored in a password protected hard drive accessible only by investigators involved in the study. Investigators will only use your Medicare and PBS data for research purposes.

Use data for future research. We would also like your permission to indefinitely store and use the data we collect for this study for projects that are not described here. This will help us to maximize the outcome of our research effort and avoid the need to reapproach you. Any project using the data will have been approved by a Human Research Ethics Committee (HREC). The data will only be used in a coded way and researchers will not have access to your personalized data.

4 Costs and reimbursement

There are no additional costs associated with participating in this research project, nor will you be paid. The interventions will be provided to you free of charge. You will not be reimbursed for the intervention appointments. However when attending the assessments you will be reimbursed $30 at each time point towards travel and parking.

5 Can I take part in this project?

If you would like to take part in this study you will:

- be aged 18-65

- have a diagnosis of a functional psychotic disorder (schizophrenia-related disorder or bipolar disorder or major depressive disorder with the presence of a severe episode with psychotic features within the past 2 years)
- have sufficient fluency in English
- have not experienced a change in medication or in-patient admission in the previous 2 months.

6 Other relevant information about the research project

We are expecting 148 participants to take part in this project, across a number of mental health services.

This is a project led by Swinburne University of Technology with academic partners at La Trobe University and Deakin University. Participants are being recruited from a range of mental health services.

7 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 take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

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 Swinburne University or your local mental health service.

8 What are the alternatives to participation?

You do not have to participate in this research project to receive treatment or support from your mental health services. The interventions we offer through this project are additional to the standard treatment you are receiving.

9 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, we hope that this project may be able to benefit you by receiving additional social interaction or health information that may promote your mental health recovery.

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

There are no risks of physical harm involved in participating in this study.

Discomfort or distress

If you agree to participate in this research, you will be asked questions about your mental health and well-being. In general, it is not anticipated that discussion of these topics would give rise to any negative effects. However, where experiences have been of a traumatic or difficult nature, there may be a small possibility that recalling these events may cause you to feel upset or distressed. If you do feel distressed when being interviewed or during either of the interventions, please let the researcher

know. If you feel uncomfortable talking about difficult subjects then at any time you are free to say you don't want to talk about them, to have a break, or to discontinue your participation.

At the beginning, we will ask you to nominate a designated contact person who is not involved in this project. This could be a nurse, doctor, case manager or other support worker who you have current contact with. This is so that if you wanted any further support after any of the appointments, you know you can speak to that person. If we had any concerns about you, we would also encourage you to speak to that support person and we could help you to do that. Of course you can also speak to one of the research team, and the phone numbers for the research team are in Section 18.

Maintaining your privacy online

When people use the Internet, sites often encourage people to make public comments about what they have read. For example, if you take part in the *social* intervention, you might use sites like YouTube where people sometimes write comments on videos they have watched, or you might use another site which has discussion forums on particular topics. If you take part in the *health* intervention, the website we have developed also includes this ability to make public comments. Making comments can be useful in connecting with others, but if you do so it is important to be aware that anyone might be able to see what you have posted, so you will need to be careful not to post anything you would be uncomfortable about people seeing. You do not have to post any comments to take part in this trial, and if you do post comments you can do so using an alias rather than your real name.

Offensive internet content

Also be aware that the researchers are unable to fully control what you might see on the Internet. Most websites, including the one we have developed for the *health* intervention, allow other users to notify the owners of the website when content is offensive, so it can be removed quickly. However, it is still possible that you may see a discussion forum or comment which has offensive content, or accidently visit a website containing other content which offends you.

Other risks

During the research project, if new information about the risks and benefits of the project became known to the researchers, you would be told about this new information and one of the researchers would discuss whether this new information affects you.

11 What if I withdraw from this research project?

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 project can be measured properly and to comply with law. If you do not want them to do this, you must tell them before you join the research project.

12 What happens when the research project ends?

At completion of the study period (after follow-up assessment) participants in the **Health condition** will retain access to SMART resources until the end of the project (approx. late 2017).

We expect that the research project will be completed by late 2017. If you want to hear about the outcomes of the project you will be able to access information on it at smartinfo.org.au.

Part 2 How is the research project being conducted?

13 What will happen to information about me?

Confidentiality. It is desirable that your designated contact person be advised of your decision to participate in this research project. By signing the consent section, you agree to them being notified of your participation in the project and broad details of your involvement such as what the project involves, when you have been or will be seen by researchers, and when your involvement has or will discontinue. We would also inform your designated contact person if we were concerned about your safety or that of others.

With this exception, any information obtained in connection with this research project that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. Your name will not be used and all participants will be identified by a code number. Only people involved in the study will have access to the information.

Security. The information that we collect from you as part of this research project, including audio recordings of intervention sessions, will be stored securely in the National eTherapy Centre (NeTC) at Swinburne University of Technology for a minimum period of seven years. Confidential information you provide during the assessments will be stored completely separately and there would be no way of this being accessed via this website. The website developed for the *health* intervention will be maintained with best practice security standards.

The NeTC does its utmost to protect its website platform form security breaches by employing banking industry security features. NeTC online websites have a security certificate, which means they comply with the security requirements of a certification authority. However, the provision of services through NeTC websites are subject to security risks inherent in any internet service. Whilst the NeTC endeavours to ensure that personal information is secure, it is not possible to safeguard against all possible breaches of security. Participants are advised to ensure that the computer terminal from which you send messages from and access the SMART website is secure and to ensure that you log out of the SMART website after you have finished a session on it.

Publications. We hope that the findings from this project will be presented in scientific journals and at scientific conferences. Some data from this project may also be used for the purposes of a PhD thesis. In any publication, information will be provided in such a way that you cannot be identified, except with your permission.

Health records. Information about you may be obtained from your health records held at this, and other, health services for the purposes of this research. Information about your participation in this research project may be recorded in your health records.

Accessing information about you. In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

14 Complaints and compensation

If you suffer any injuries as a result of participating in this research project, you should contact the study team as soon as possible and you will be assisted with 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.

15 Who is organising and funding the research?

Funding. This research has been funded by the Victorian Department of Health's Mental Illness Research Fund.

Co-ordination. It is being co-ordinated by Swinburne University of Technology working in partnership with multiple mental health services.

Commercialisation. Although not planned at this time, it is possible that in the future Swinburne University and/or the researchers may seek to commercialise intellectual property arising from this research. You will not benefit financially from your involvement in this research project even if, for example, knowledge acquired from your participation proved to be of commercial value. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the researchers or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than ordinary wages).

16 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 Alfred Hospital.

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.

17 Future contact

Our study into effective interventions is ongoing. Therefore we would like to obtain your consent to contact you in the future. We would call you and ask if you wanted to participate in another study. If you do decide to participate in the current study you are under no obligation to participate in any future studies. If you do consent to us contacting you in the future, you can change your mind if we contact you at a later time.

18 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the following people:

Clinical contact and complaints contact person

Clinical

Name	Dr Neil Thomas
Position	Clinical Psychologist
Telephone	0430 409 510
Email	neilthomas@swin.edu.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:

Name	Ms Emily Bingle
Position	Research Governance Officer, Office of Ethics & Research Governance, Alfred Health
Telephone	(03) 9076 3619
Email	research@alfred.org.au

You will need to tell Ms Bingle the following Alfred Health project number: 139/14

Consent Form

Title	Psychosocial intervention using online resources to promote personal recovery in users of mental health services: Randomised Controlled Trial
Short Title	SMART-Therapy RCT
Principal Investigator	**Dr Neil Thomas**, Swinburne University and Monash Alfred Psychiatry Research Centre
Associate Investigator(s)	**Assoc Prof John Farhall**, La Trobe University **Prof Mike Kyrios**, Swinburne University **Prof David Castle**, St Vincent's Health **Ms Cassy Nunan**, Mental Illness Fellowship of Victoria **Prof Susan Rossell**, Swinburne University and Monash Alfred Psychiatry Research Centre **Ms Emma Ladd**, Mental Illness Fellowship of Victoria **Ms Sue Farnan**, Mental Illness Fellowship of Victoria **Dr Ellie Fossey**, La Trobe University **Prof Leon Sterling**, Swinburne University **Prof Greg Murray**, Swinburne University **Assoc Prof Cathy Mihalopoulos**, Deakin Health Economics **Assoc Prof Denny Meyer**, Swinburne University **Dr Lisa Brophy**, Mind Australia **Prof Jayashri Kulkarni**, Monash Alfred Psychiatry Research Centre **Dr Nuwan Leitan**, Swinburne University **Ms Bronte McLeod**, Swinburne University **Ms Rosalie Frankish**, Swinburne University **Ms Tara Smark**, Swinburne University **Mr Robert Pasqual Bruno**, La Trobe University **Ms Chelsea Arnold**, Swinburne University
Study Coordinator	**Ms Fiona Foley**, Swinburne University
Location	Alfred Health, Mental Illness Fellowship, Mind Australia, Neami National, Uniting Care

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals and hospitals outside this hospital to be contacted by the researchers and to release information to Swinburne University of Technology concerning my mental health and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

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.

I understand that I will be given a signed copy of this document to keep.

Participant Initials (please print) _____

Signature _____ Date _____

Declaration by Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.

In addition, I also give consent for the following optional activities:

I agree to audio-recording of interview and intervention sessions I attend as part of my involvement in this study. I recognise I can change my mind about this at any time.

Participant Initials (please print) _____

Signature _____ Date _____

I agree to allow the researchers to access my Medicare/PBS data for research purposes. (Fill in additional consent form).

Participant Initials (please print) _____

Signature _____ Date _____

I agree to the indefinite storage of my coded data for use in other closely related unspecified research projects.

Participant Initials (please print) _____

Signature _____ Date _____