Participant Information Sheet/Consent Form

The RECALL study (Pilot Randomised Controlled Trial)

<table>
<thead>
<tr>
<th>Title</th>
<th>The feasibility and effectiveness of trauma-focussed imaginal exposure for voice hearing following adverse life experiences: A pilot randomised controlled trial</th>
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<tbody>
<tr>
<td>Short Title</td>
<td>The RECALL trial</td>
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<tr>
<td>Principal Investigator</td>
<td>Dr Neil Thomas, Swinburne University and Monash Alfred Psychiatry Research Centre</td>
</tr>
</tbody>
</table>
| Associate Investigator(s)                                            | Prof Susan Rossell, Swinburne University and Monash Alfred Psychiatry Research Centre
Dr Sarah Bendall, Orygen Youth Health, University of Melbourne
Ms Imogen Bell, Swinburne University and Monash Alfred Psychiatry Research Centre
Dr Wei Lin Toh, Swinburne University and Monash Alfred Psychiatry Research Centre |
| Study Coordinator                                                    | Dr Rachel Brand, Swinburne University and Monash Alfred Psychiatry Research Centre                                                         |
| Location                                                             | The Voices Clinic, Monash Alfred Psychiatry Research Centre                                                                                 |

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 an intervention for people who hear voices (sometimes referred to as ‘auditory hallucinations’).

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.

Participant Information Sheet/Consent Form – The RECALL trial (436/16)

Version 3. 30/09/2016

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2 What is the purpose of this research?

This project aims to test the effects of a six-session intervention aiming to treat voice hearing experiences that are related to past traumatic events. The intervention is called ‘imaginal exposure’ and is a type of psychological treatment that has been shown to help with psychological difficulties after traumatic events (often known as ‘trauma-focussed treatments’). Imaginal exposure involves talking through traumatic events in order to process the emotions and meanings of the events and reduce their impact.

Recent research has found that voice hearing experiences are often related to past traumatic events. Traumatic events may play a role in the onset or maintenance of some people’s voice hearing experiences. Because we do not yet know how helpful trauma-focussed treatments are for treating voice hearing experiences, we have developed a project in which we can further understand how acceptable and effective these treatments might be.

This research has been initiated by the Principal investigator named on page one. The results of this research will be used by the researcher Rachel Brand to obtain a Doctor of Philosophy (PhD).

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. To find out the effects of imaginal exposure, we allocate people to one of two different groups; the treatment group (who will receive the treatment straight away), or the waitlist group (who will have the choice of receiving the study treatment or standard treatment at the Voices Clinic approximately 12 weeks following allocation). Each participant is allocated to their group by chance (random). This will help us to compare the two groups fairly.

The intervention

If you are allocated to the treatment group, you will complete the six-session imaginal exposure intervention. You will meet with a Clinical Psychologist for weekly sessions at the Voices Clinic at the Monash Alfred Psychiatry Research Centre. Each session will last for 90 minutes. The sessions will involve identifying traumatic events in your life that may be related to your voice hearing, understanding how they might be related, and then talking through the events repeatedly, in detail, in order to process the emotions and meaning of the events. You will also be asked to listen to audio recordings of sections of the sessions at home, several times each week. These audio recordings will be made using your smartphone or an audio recorder provided by the research team. These audio recordings will not be kept by the research team, and will be for your use only. You will be supported to make these recordings secure (e.g. using password protection) to protect your privacy.

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

As a first step, you will speak with a member of our research team to make sure that you are eligible to take part in the study. If you are eligible and agree to participate, you will meet up with a member of our research team in the next week or two to sign the consent form and to have an initial baseline interview before you are allocated to your treatment group. The baseline interview will involve completing some interviews and questionnaires about your current mental health, your experience of hearing voices, and any traumatic events that you have experienced and the impact this has had on you. You will also be asked to provide some demographic information, such as your age and education. This interview will take approximately three 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.

After this interview, if you are eligible to continue in the study, you will be asked to use a smartphone app to monitor your voice hearing experiences and memories of traumatic events for the next six days. The app will prompt you to complete a 1-2 minute questionnaire 10 times each day. If you have a smartphone, we will ask you to install the free app on your phone. If you do not have access to a smartphone, we have a limited number available that we can lend to participants.

You will be randomly allocated to the treatment or waitlist group within a few days of starting the smartphone monitoring. If you are allocated to the treatment group, the intervention will begin as soon as it can be practically arranged.
You will also meet with a member of our research team for another interview at seven and 11 weeks. Each follow-up assessment interview will take approximately 90 minutes. In week seven, you will also be asked to conduct another six days of monitoring using the smartphone app. The smartphone app assessment will be the same as that conducted in week one.

If you are in the treatment group, when you finish the treatment, you will also be given a questionnaire about your experience of the treatment. You will then have the option of taking part in a more in-depth interview about your experiences of the treatment, if you are interested in doing this.

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. A portion of the audio recordings from the second and final treatment sessions will be transcribed by a researcher. The part of the recording that will be transcribed will be your first imaginal exposure exercise from these sessions. The written version of this will be used to rate how your memory of the trauma has changed over treatment. You can change your mind about audio recording at any time. If you do change your mind, you can request that the recordings that have already made be erased.

4 Costs and reimbursement
There are no additional costs associated with participating in this research project. The interventions will be provided to you free of charge. You will not be reimbursed for the intervention appointments. However you will be reimbursed $30 at each assessment (there are five core assessments in total) towards costs such as travel, parking and phone data.

5 Can I take part in this project?
If you would like to take part in this study you need to:
• be aged 18-75
• have experienced voice hearing for at least 6 months
• currently experience voices at least twice weekly
• have experienced events in your life that might be considered to be traumatic (e.g. experiencing an event or events where your life was in danger, or being significantly mistreated, neglected or abused as a child, or having someone repeatedly bully, humiliate or intimidate you)
• think that your voice hearing experiences are related to the above traumatic events in some way
• be willing and able to undertake a treatment that involves talking about the above traumatic events in detail with a Clinical Psychologist
• have sufficient fluency in English

You will not be able to take part in this study if you:
• have had a change in psychiatric medication in the past month or are planning a change in the next three months
• have voices which are primarily caused by substance use, or you have substance dependence issues which may interfere with your participation
• have an intellectual disability
• are currently at acute risk of harming yourself or other people
6 Other relevant information about the research project

This is a project led by Swinburne University of Technology. We are expecting 30 participants to take part in this project. Participants are being recruited through the Voices Clinic at the Monash Alfred Psychiatry Research Centre, the Monash Alfred Psychiatry Research Centre Voices Research Participant Registry, and through advertising at a range of mental health services and online.

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 relationships with those treating you, or your relationships with Swinburne University, the Voices Clinic, 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 intervention offered through this project is additional to the standard treatment you are receiving. If you choose not to take part in this study but would like to receive the standard treatment at the Voices Clinic, you will continue your treatment with the Voices Clinic as usual.

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 assistance from a Clinical Psychologist to help you to reduce the impact that past traumatic events may be having on your mental health generally, and on voice hearing specifically.

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 and to briefly outline your experiences of traumatic events. In general, it is not anticipated that discussion of these topics would give rise to any long lasting negative effects. However, where experiences have been of a traumatic or difficult nature, there may be a possibility that recalling these events may cause you to feel upset or distressed. If you do feel distressed when being interviewed, 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. If you are allocated to receive the imaginal exposure treatment, this will involve talking through your traumatic experiences repeatedly and in detail with a Clinical Psychologist. This treatment may lead to short term distress, and you will be offered support from your Clinical Psychologist in managing this. If you do find this aspect of the treatment too distressing, you are free to discuss this with your psychologist, a member of the research team, or to withdraw at any time without any consequences for your ongoing treatment at the Voices Clinic.

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, whom you have current contact with, or alternatively a family member or friend. 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 a member of the research team, and the phone numbers for the research team can be found in Section 18.
Other risks
During the research project, if new information about the risks and benefits of the project become known to the researchers, you will 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. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

12 What happens when the research project ends?
At completion of the study period, participants from the treatment group will be offered standard treatment at the Voices Clinic, if they choose. Participants who have been in the waitlist group will be offered the study treatment and/or standard treatment at the Voices Clinic, depending on their preference.

We expect that the research project will be completed by late 2019. On completion of the project, we will provide a plain language report of the project results that we can send by post or email, if you request for this.

Part 2 How is the research project being conducted?

13 What will happen to information about me?
Confidentiality. By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Any information obtained for the purpose of this research project that can identify you will be treated as confidential. It will be disclosed only with your permission. There are, however, some exceptional circumstances in which the researchers and clinicians involved in the study have a legal or moral obligation to disclose confidential information, for example, if it is ordered by a court of law or if disclosing the information is considered necessary to prevent serious harm to you, another person, or the wider community.

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 been or will be discontinued. We will also inform your designated contact person if we become concerned about your safety or that of others.

Security. The information that we collect from you as part of this research project, including audio recordings and transcription from intervention sessions or assessments, will be stored securely at the Monash Alfred Psychiatry Research Centre. Only the research team involved in the study will have access to the information.

Publications. We hope that the findings from this project will be presented in scientific journals and at scientific conferences. The data from this project will 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 specific permission.

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 Reporting distress or psychological injury

If you suffer any distress or psychological injury 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 treatment and support.

15 Who is organising and funding the research?

Funding. This research has been funded by a grant from Swinburne University’s Faculty of Health, Arts and Design.

Co-ordination. It is being co-ordinated by the principle researcher, Dr Neil Thomas and by Rachel Brand, who is conducting this research as part of her PhD thesis.

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 ways of helping people with the experience of hearing voices is ongoing. We may do a follow-up study to look at how people’s experiences change over time, or do other studies on the experience of hearing voices. Therefore, we would like to obtain your permission to contact you in the future about other studies. If you provide your permission for us to contact you again, the Principal Investigator will retain your contact details and store them securely, separately from any data you provide. If we were to contact you, we would call you and ask if you wanted to participate in another study. You would be under no obligation to participate in any other study. You can also change your mind about being contacted again, and we will delete your contact details on request. You will be asked to indicate your willingness for this at the end of this consent form.

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:

For appointments and enquiries:

<table>
<thead>
<tr>
<th>Name</th>
<th>Dr Rachel Brand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position</td>
<td>Clinical Psychologist and PhD student</td>
</tr>
<tr>
<td>Telephone</td>
<td>(03) 9214 4840</td>
</tr>
</tbody>
</table>
For any medical issues or adverse events:

<table>
<thead>
<tr>
<th>Name</th>
<th>Dr Neil Thomas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position</td>
<td>Clinical Psychologist</td>
</tr>
<tr>
<td>Telephone</td>
<td>0430 409 510</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:neilthomas@swin.edu.au">neilthomas@swin.edu.au</a></td>
</tr>
</tbody>
</table>

You will need to tell the complaints officer the following Alfred Health project number: 436/16.
Consent Form

Title | The feasibility and effectiveness of trauma-focussed imaginal exposure for voice hearing following adverse life experiences: A pilot randomised controlled trial

Short Title | The RECALL trial

Principal Investigator | Dr Neil Thomas, Swinburne University and Monash Alfred Psychiatry Research Centre

Associate Investigator(s) | Prof Susan Rossell, Swinburne University and Monash Alfred Psychiatry Research Centre  
Dr Sarah Bendall, Orygen Youth Health, University of Melbourne  
Ms Imogen Bell, Swinburne University and Monash Alfred Psychiatry Research Centre  
Dr Wei Lin Toh, Swinburne University and Monash Alfred Psychiatry Research Centre

Study Coordinator | Dr Rachel Brand, Swinburne University and Monash Alfred Psychiatry Research Centre

Location | The Voices Clinic, Monash Alfred Psychiatry Research Centre

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 designated contact person 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 a researcher to contact and invite me to participate in future studies. I am aware that by agreeing to be contacted at some time in the future, I am not obliged to participate.

Participant Initials (please print) ____________________________________________
Signature ______________________ Date ________________________________