PARTICIPANT INFORMATION AND CONSENT FORM


**Full project title:** The Impact of a Mindfulness-Based Intervention for Auditory Hallucinations on Attention and Subjective Experience

**Principal Researcher:** Dr Neil Thomas

**Associate Researchers:** Professor Susan Rossell, Dr Matthew Hughes, Dr William Woods, Dr Erica Neil, Mr Eric Tan, Miss Stephanie Louise, Miss Sarah Lancaster.

1. **Introduction**

You are invited to take part in this research project. The research project is aiming to evaluate the outcomes of an intervention for people who hear voices (or experience 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. Participation in this project is in addition to the usual care you receive from mental health services, and will not make any difference to the other care you receive.

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 project?**

The purpose of this project is to examine the effects of a four-week course in mindfulness on changes in the experience of voices and attention.

Mindfulness is a particular skill in deliberately focusing attention and becoming less caught up in thought or distracting sounds in the environment. It can be learnt through meditation-like exercises, which involve practising sustained attention for periods of a few minutes or more at a time.

We know from previous research that mindfulness-based interventions have been found to be effective for the treatment for a range of physical and mental health problems. More recently, there has been encouraging findings for the use of mindfulness-based interventions for people
who hear voices. These studies suggest that mindfulness might be useful in reducing the intensity of voices and/or how much impact they have.

We hope this study will help us better understand what processes are involved in hearing voices, how mindfulness works, and how treatments can be developed that help people respond to voices more effectively.

A total of 16 people will participate in this project.

This research has been initiated by the investigators named above. It is supported by a grant from the National Health and Medical Research Council and by Swinburne University's Faculty of Health, Arts and Design.

3. What does participation in this research project involve?

There are two main parts of this project.

1. Assessments. Completion of a series of assessments including interviews and computer-based tasks that will be conducted over four sessions (approximately 1.5-2.5 hours per session) and held at the Monash Alfred Psychiatry Research Centre (MAPrc) and the Brain and Psychological Sciences Research Centre, Swinburne University. These assessments will help us to understand how things change over time in relation to learning skills in mindfulness. A list of visits can be seen below.

- **Week 1, Session 1:** Demographics and clinical interview (including computer-based and paper and pencil attention tasks) – 2 - 2.5 hours
- **Week 5, Session 2:** Clinical interview (including computer-based and paper and pencil attention tasks) – 1.5-2 hours
- **Week 10, Session 3:** Clinical interview (including computer-based and paper and pencil attention tasks) – 1.5-2 hours
- **Week 18, Session 4:** Clinical interview (including computer-based and paper and pencil attention tasks) – 1.5-2 hours

2. Mindfulness Course. Taking part in a four-week mindfulness course that will be held at the Voices Clinic, Monash Alfred Psychiatry Research Centre.

**Assessments**

We will ask you to meet up with a member of our research team to complete some interviews and computer-based tasks within the next couple of weeks, then again in five weeks time, then again five weeks after that and then again 8 weeks after that. Each appointment will last approximately 1.5-2.5 hours.

All participants will be asked to fill in a standard questionnaire that asks questions about their demographic information for example, age and education. In addition, they will be asked to complete a short interview, which asks questions about their mental health. Additionally, all participants will be required to complete some computer-based or paper-and-pencil measures that are designed to assess thinking abilities, such as attention and inhibition.

**Study Day restrictions.** On each of the four testing days we ask that you follow these restrictions:

- No caffeine-containing products on the testing day
- No alcohol in the 24 hours before the testing session.

This is because caffeine and alcohol have been shown to affect cognitive performance. Should you breach these restrictions, please contact us prior to coming to the research centre so we can rearrange your testing session.
Mindfulness Course

The mindfulness course will involve meeting with a clinician once a week for four weeks. Meetings will last for one hour. Each meeting will involve one-on-one practice in guided exercises designed to improve your attention alongside discussions about mindful responding as an alternative to usual reactions to voices and non-judgemental awareness of voices. The sessions will be held at the Voices Clinic at the Monash Alfred Psychiatry Research Centre, weekly, with the first session lasting up to two hours and the following sessions usually lasting up to an hour.

We will be asking people who take part in this to practice mindfulness at home as well. We will provide you with an audio CD on which you will have some guided exercises. These require practising once per day for about 15-20 minutes. Participation will also involve documenting this home practice in a diary.

The clinician you will meet with will be a provisional psychologist who is undertaking a PhD in Clinical Psychology. The work they will do with you will be supervised by a clinical psychologist who has extensive experience in helping people deal with hearing voices.

Optional data contribution to a bio-databank

In addition, we will ask you to permit us to store test data collected for this project in the research bio-databank: Cognitive and genetic explanations of mental illnesses bio-databank (CAGEMIS). This will be administered by Prof Susan Rossell at the Monash Alfred Psychiatry Research Centre. This bio-databank is aiming to collect cognitive and genetic information on patients with schizophrenia from this and future related projects. You will be asked to indicate your willingness to contribute at the end of this consent form.

If you consent to contribute your test data, you will need to complete a separate participant information sheet and consent form. Agreeing to contribute your test data to the bio-databank does not require you to undergo any additional tests or measures. This is optional, and your decision to take part or not to take part in this additional component will not affect your participation in this current study. The purpose of this bio-databank is to provide information that can be used for future, ethically approved, research into schizophrenia.

4. What are the possible benefits?

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 through learning a skill, which may help you to cope more effectively with hearing voices.

We also hope this study will benefit others in the future who experience voices by helping us to understand whether what we are doing in this project is a useful approach and how best to use it.

5. What are the possible risks?

Interviews and mindfulness course. Discussing voices and other experiences as part of the interviews and mindfulness course may involve discussing things, which are emotional or distressing. Additionally, sometimes people report that mindfulness can lead to increased awareness of unpleasant thoughts or memories. Where experiences have been of a traumatic or difficult nature, there is a possibility that recalling these events may cause you to feel upset or distressed. If you do feel distressed when being interviewed or during the intervention, please let the interviewer or clinician know. If you feel uncomfortable talking about these things 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.

6. **What if new information arises during this research project?**

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and the researcher will discuss whether this new information affects you.

7. **Can I have other treatments during this research project?**

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.

8. **Are there alternatives to participation?**

Participation in this research is not your only option in dealing with hearing voices. Other options include seeing a therapist to talk about your voices, attending a peer-support group, or asking for a review of your medication. You can take time to discuss these options with your doctor or healthcare worker before deciding upon participation in this project.

9. **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 are not obliged 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 routine treatment, your relationship with those treating you, or your relationship with The Voices Clinic, Monash Alfred Psychiatry Research Centre, or Swinburne University.

10. **What if I withdraw from this research project?**

If you decide to leave the project, the researchers would like to keep the information about you that has been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you join the research project.

11. **How will I be informed of the results of this research project?**

On completion of the project we will provide a plain language report of the project results that we can send you a copy of by post or email if you request this.

12. **What else do I need to know?**

- **What will happen to information about me?**

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 concerns about your safety or that of others.
With this exception, any information that can identify you obtained for the purpose of this research project will be treated as confidential and securely stored. It will be disclosed only with your permission, or in compliance with the law.

This study involves the collection of information about your use of illegal drugs, e.g. marijuana. We will generally not disclose that information without your consent but there may be circumstances where we have to do so for legal reasons. In that case, the information could potentially be used against you in legal proceedings or otherwise (i.e. Information about drug use may be considered relevant in a criminal investigations). To our knowledge, researchers at this institution have not been required by law to provide information. If we were ever required to do so, we would do our best to notify you before disclosing it.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Miss Stephanie Louise will be using the results of this research project to obtain her Doctor of Philosophy (Clinical Psychology) degree. However, in any research report, publication and/or presentation, information will be provided in such a way that you cannot be identified.

The information that we collect from you as part of this research project will be stored securely at the Monash Alfred Psychiatry Research Centre. Additionally, if you give your permission, information you provide us may also be used for other projects related to this research project, which we have not planned at this stage.

- **How can I access my information?**
  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.

- **What happens if I am injured as a result of participating in this research project?**
  If you suffer an injury as a result of your participation in this research project, please contact the research staff. Hospital care and treatment will be provided by the public health care system (Medicare) at no cost to you if you are eligible for Medicare benefits and elect to be treated as a public patient.

- **Is this research project approved?**
  The ethical aspects of this research project have been approved by the Human Research Ethics Committee of Alfred Health.

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

- **Will I receive any reimbursement?**
  Yes, you will be reimbursed $30, at the end of each of the four assessment sessions (clinical assessments), for your time and travel costs to attend these sessions.

- **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.
13. Consent

I, …………………………………………………………………………………… (Name of participant)
agree to participate in a research project entitled: The Impact of a Mindfulness-Based Intervention for Auditory Hallucinations on Attention and Subjective Experience

Conducted by: Dr Neil Thomas, Professor Susan Rossell, Dr Matthew Hughes, Dr Will Woods, Dr Erica Neill, Mr Eric Tan, Ms Stephanie Louise, Ms Sarah Lancaster.

My agreement is based on the understanding that:

- I agree to participate in this activity, realizing that my identity will remain confidential, and that I may withdraw at any time.
- I freely agree to participate in this project according to the conditions on the Participant Information.
- I will be given a copy of the Participant Information and Consent Form to keep.
- My consent to participate in this project is given freely.
- The researcher has agreed not to reveal my identity and personal details if information about the project is published or presented in any public form.
- I understand the time involved in each of the recording and testing sessions.

I have read this document and I understand the purposes, procedures and risks of this research project as described within it.

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.

☐ I agree to be given the information sheet and consent form for ‘Cognitive and genetic explanations of mental illnesses’ bio-databank for consideration.

☐ I have participated in the related study (Project 430/11) An MEG study of auditory verbal hallucinations and inhibition in patients with schizophrenia. If you answer yes to this, we will ask you to complete a separate form to indicate whether you agree to have your results from this previous project released to the current researchers. This will allow us to use data from this study instead of repeating the assessments again.

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

Participant’s name (printed) ……………………………………………………

Signature ………………………………………………………………………

Date ………………………………………………………………………

Name of witness to participant’s signature (printed) ……………………………

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.

Researcher’s name (printed) …………………………………………………

Signature ………………………………………………………………………

Date ………………………………………………………………………

Note: All parties signing the consent section must date their own signature.
EXTENDED USE OF INFORMATION FOR OTHER PROJECTS
I am aware that the information I provide as part of the project described above may also be used at a future time for other related research projects. I understand that any additional use of the information I have provided will be treated as confidential as outlined above.

☐ I agree for information to be used for other related projects.
☐ I do not wish for my information to be used for other related projects.

SIGNED:................................................................. DATE:.................................

FUTURE CONTACT REGARDING OTHER PROJECTS
I understand that if I give my permission, the researchers may contact me to invite me to participate in future studies. I am aware that by agreeing to be contacted some time in the future I am not obliged to participate.

☐ I agree to be contacted by the researchers of the above project about future projects.
☐ I do not wish to be contacted regarding future projects.

SIGNED:................................................................. DATE:.................................
14. Who can I contact?

Who you may need to contact will depend on the nature of your query, therefore, please note the following:

For further information or appointments
If you want any further information concerning this project you can contact:

Name: Dr Neil Thomas  
Role: Principal Researcher  
Telephone: (03) 9214 8742

Name: Professor Susan Rossell  
Role: Associate Researcher  
Telephone: (03) 9214 8173

Monash Alfred Psychiatry Research Centre  
PO Box 315, Prahran 3181, Victoria, Australia  
Level 4, 607 St Kilda Road, Melbourne 3004, Australia  
Tel: 03 9076 6564

Brain and Psychological Sciences Research Centre,  
Faculty of Health, Arts and Design,  
Swinburne University of Technology  
Mail H99  
PO Box 218  
Hawthorn VIC 3122  
Australia

For complaints:
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  
Department: Office of Ethics & Research Governance  
Institution: Alfred Health  
Telephone: 03 9076 3619

You will need to tell Ms Bingle the following Alfred Health project number: 138/14.