



## Participant Information Sheet

<b>Title</b>	Physical activity combined with Acceptance and Commitment Therapy for individuals with Alopecia Areata: A randomised controlled trial
<b>Project Sponsor</b>	Australian Alopecia Areata Foundation (AAAF)
<b>Principal Investigator</b>	Dr Jason Wong
<b>Associate Investigator(s)</b>	Professor Gerard Kennedy Dr Isaac Selva Raj Miss Yamuna Rajoo
<b>Location</b>	Australia

### Part 1 What does my participation involve?

#### 1 Introduction

You are invited to take part in this research project because you may have been diagnosed Alopecia Areata (AA). The research project is randomised controlled trial for individuals with AA titled: Physical activity combined with Acceptance and Commitment Therapy for individuals with Alopecia Areata: a randomised controlled trial.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the questionnaires and treatments 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 do not 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 your general practitioner.

Participation in this research is voluntary. If you do not wish to take part, you do not have to.

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

- Understand what you have read
- Voluntarily consent to take part in the research project
- Voluntarily consent to complete questionnaires and treatments that are described
- Voluntarily consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet to keep.

## **2 What is the purpose of this research?**

The purpose of this study is to investigate the benefits of you coming to acceptance of the condition of Alopecia Areata and the beneficial impact that physical activity participation may have on your mental wellbeing. This study will utilise Acceptance and Commitment Therapy (ACT) and Physical Activity (PA) to improve daily functioning and mental wellbeing in people with Alopecia Areata. The results of this research will be used by the Yamuna Rajoo to obtain a Doctor of Philosophy degree. This research has been initiated by the researcher, Yamuna Rajoo, Dr Jason Wong, Professor Gerard Kennedy and Dr Isaac Selva Raj. This research has been funded by Australian Alopecia Areata Foundation (AAAF).

## **3 What does participation in this research involve?**

You will be participating in a randomised controlled research trial. Consent will be obtained online via the platform, Qualtrics. You will be randomly allocated into any one of the following groups: (1) Physical Activity only; (2) Acceptance and Commitment Therapy only; (3) Physical Activity and Acceptance and Commitment Therapy together; or (4) Doing your usual activities only (control condition). The self-help ACT program contains a series of steps delivered in a week-by-week manner, teaching you how to re-establish daily routines and increase activities that provide positive feelings while reducing negative feelings. The ACT programme consists six sessions with audio segments and printable and interactive worksheets which will be delivered to you via an online Qualtrics program with each session lasting an hour. Automated reminder emails will be sent once a week by the researchers following your registration to take part in the trial.

To measure physical activity, a Fitbit device will be posted to your home address once you are eligible and agree to participate. You will be asked to wear the Fitbit as much as possible during the six-week intervention and perform PA to the level of your current ability. Data collected will include average weekly step count, distance travelled and minutes of activity. You will be instructed in how to use it.

Questionnaires will be used to measure distress, acceptance and PA levels and to obtain demographic information during the intervention and six months after the intervention.

Note:

1. This intervention requires a commitment for six weeks which includes personal time commitment and potential changes to lifestyle (performing PA).
2. At the end of the trial all participants will be given unlimited access to the online ACT resources.

## **4 What do I have to do?**

You will be asked to commit to six-week intervention programme consisting of either; PA and ACT, PA or ACT alone or only your usual activity (control condition). PA level will be measured using a Fitbit Inspire while the ACT therapy will be carried out online using the Qualtrics software. The Fitbit will be posted to you once you agree to participate.

### **Participation during COVID-19 pandemic**

The researchers acknowledge that the current COVID-19 pandemic may impact some traditional forms of physical activity. Information will be provided to participants about suitable PA options that are available with current regulations and guidelines, with updates provided if relevant guidelines change. Participation in this research is not limited by changes to your previously normal PA levels or distress and acceptance levels in relation to the current pandemic. If you were to begin the study and then get sick, you are welcome to withdraw from the study as per section 9. You may also contact researchers to discuss restarting your participation at a later

date. Options are available to delay beginning your intervention up to June 20<sup>th</sup>. You may register your interest in this study and delay commencing participation and intervention until that date.

## **5 Other relevant information about the research project**

This study will involve approximately 48 participants.

## **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 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 relationship with relationship with the researchers or with RMIT University.

## **7 What are the possible benefits of taking part?**

This study may benefit the wider community by adding new scientific knowledge about the benefits of both ACT and PA on mental health. We cannot guarantee or promise that you will receive benefits from this research; however, you may appreciate contributing to knowledge that may help others.

## **8 What are the possible risks and disadvantages of taking part?**

You may feel that some of the questions we ask are upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed because of your participation in the research project, you are advised to contact your General Practitioner (Doctor) for advice and support. You can get immediate help from Beyond Blue Support Service at no cost. Trained mental health professionals will be assisting you to address your distress. The hotline is available 24 hours and 7 days a week. You also can opt for online chat assistance available on the website from 3pm to 12am, 7 days a week.

Beyond Blue Support Service

Tel: 1300-22-4636

Website: <https://www.beyondblue.org.au>

Online chat available at:

<https://online.beyondblue.org.au/WebModules/Chat/InitialInformation.aspx>

If you suffer from any injuries or complications because of this research project, especially when performing physical activity, you are advised to seek medical treatment from your general practitioner. 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.

## **9 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the research team will not collect additional personal information from you. You should be aware that data collected by the research team up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

## **10 What happens when the research project ends?**

This project will use an external online site to collect data... The site we are using is Qualtrics. If you agree to participate in this study the responses you provide will be stored on their host computer server. Once we have completed our data collection we will import the data to the RMIT computer server where it will be stored securely for seven years. The data on the host server will then be deleted and expunged. The online self-help ACT will be available online for all participants upon the completion of the study. The participants will be provided with a summary of the results as a report when the research project is completed.

## **Part 2 How is the research project being conducted?**

### **11 What will happen to information about me?**

By signing the consent form you consent to 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. This project will use an external site to collect data in a survey format. The computer site we are using is Qualtrics. If you agree to participate in this study, the responses you provide to the study will be stored on a host computer server that is used by Qualtrics. 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. The research data (i.e., the raw information) will be kept securely at RMIT University for seven years, before being destroyed.

### **12 Who is organising and funding the research?**

This research project is being conducted by RMIT University and is being funded by Australian Alopecia Areata Foundation (AAAF). By taking part in this research project you agree that anonymous data generated may be provided to RMIT University and Australian Alopecia Areata Foundation. RMIT University and Australian Alopecia Areata Foundation may directly or indirectly benefit financially from your data or from knowledge acquired through analysis of your data. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

You will be only reimbursed (allowed to keep) with the Fitbit Inspire if you complete the six-week intervention programme.

### **13 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 RMIT University.

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.

## 14 Further information and who to contact

If you want any further information concerning this project, you can contact the researcher on:

### Research contact person

Name	Dr Jason Wong
Position	Principal Investigator
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Name	Professor Gerard Kennedy
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Name	Dr Isaac Selva Raj
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Email	isaacselva.raj@rmit.edu.au

Name	Ms Yamuna Rajoo
Position	Co-Investigator
Telephone	04 51299025
Email	yamuna.rajoo@rmit.edu.au

### Complaints

Should you have any concerns or questions about this research project, which you do not wish to discuss with the researchers listed in this document, then you may contact:

Reviewing HREC name	RMIT University
HREC Secretary	Peter Burke
Telephone	03 9925 2251
Email	<a href="mailto:human.ethics@rmit.edu.au">human.ethics@rmit.edu.au</a>
Mailing address	Research Ethics Co-ordinator Research Integrity Governance and Systems RMIT University GPO Box 2476 MELBOURNE VIC 3001