

Participant Information Sheet

Title	Can the addition of metacognitive training (MCT) to treatment as usual improve treatment outcomes for adolescents with anorexia nervosa? A pilot randomised controlled trial.
Short Title	MCT for eating disorders
Protocol Number	HREC/19/WCHN/107
Principal Investigator	Dr Ryan Balzan, Flinders University
Associate Investigator	Professor Tracey Wade, Flinders University
Location	Study conducted online

Part 1: What does my participation involve?

1 Introduction

This form will explain to you what you need to know before participating in this research and what you will do in this research as a participant. 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 to take part, you might want to talk about it with your parents, caregiver, a relative, friend or local health worker.

If you decide to take part in the research project, you will be asked to sign a consent form. By signing it you are telling us that **you understand what you have read** and **consent to be involved in the research described**. You will be given a copy of this Participant Information Sheet and Consent Form.

2 What is the purpose of this research?

The aim of this research is to see whether metacognitive training (MCT) is a helpful addition to your existing treatment. Because little research has studied the use of MCT in people with eating disorders, we want to hear your feedback after you have participated in this training program. Specifically, we want to know what you think about it, what you like or do not like about it, and what is helpful or unhelpful to you. This information will help us understand whether this training program can be potentially helpful to people with an eating disorder.

3 What is Metacognitive training (MCT)?

MCT is a brief one-on-one training programme that encourages people to 'think about their thinking' (i.e., 'meta' means 'about' and 'cognition' means 'thinking'). What this means is that we will help you reflect on your thinking styles and explore ways that can help you think more flexibly. For instance, everyone can fall into some very common "thinking traps" from time to time (e.g., when we only pay attention to the things that we want to see and ignore the things that don't 'fit' with our views). When we get stuck in these "thinking traps" we might not be able to manage our emotions properly and that can sometimes lead to us to some unhelpful behaviours such as eating very little because of how we feel. Being better at detecting these "thinking traps" and getting better at thinking flexibly can help you manage your emotions better and reduce unhelpful behaviours that come from inflexible thinking.

The MCT programme for eating disorders will be conducted online and is spread over four modules (two are approximately 30-minutes long and two are approximately 60-minutes long), which will cover some common thinking errors and strategies to reduce them. The reason why we think this might be helpful to you is because some research has shown that people with an eating disorder might struggle with thinking flexibly when it comes to food rules, body shape or weight, or other areas in their lives, which might lead to difficulties in changing thoughts and behaviours that fuel disordered eating (e.g., dieting, exercising).

4 What does participation in this research involve?

Once you read the information sheet and signed the consent form, you will be able to participate in this study. There will be two groups in this study - you will be randomly (i.e., like flipping a coin) allocated to one of them. Only one of the groups contains the MCT programme, whereas the other group provides the same treatment as if the study did not take place ('Wait List group').

If you are in the 'MCT group', you will participate in four 'face-to-face' video-chat sessions conducted online with a researcher who will walk you through some PowerPoint slides where you will learn about some interesting psychology facts and complete some 'thinking exercises'. For example, you will learn about the 'confirmation bias' (i.e., which is when your mind filters things so you only 'see' things that fit with your own ideas or beliefs) and how to be a more 'flexible' thinker in everyday life.

The online MCT sessions will be delivered by a provisional psychologist, who is a psychology student in their 5th or 6th year of training to become a fully qualified psychologist. The provisional psychologist will receive supervision from two qualified psychologists who will provide regular support and guidance.

To understand whether the MCT training was helpful to you, you will also be asked to complete some questionnaires which will ask you to rate how much do you agree with some statements such as "the MCT sessions were useful and sensible". You will do these questionnaires immediately after completing the final module and at 3-months after the start of your study.

5 Other relevant information about the research project

There will not be payment made for your participation in this study, nor will there be additional costs.

6 Do I have to take part in this research project?

It is completely up to you whether or not you want to participate in this research. 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 routine care, your relationship with professional staff or your relationship with your treatment team.

7 What are the possible benefits of taking part?

We cannot guarantee that you will receive any benefits from this research. This research aims to improve researchers' understanding of whether MCT is a helpful additional treatment component for adolescents with anorexia nervosa, which may benefit other people with anorexia nervosa in the future.

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

MCT has been designed to be fun and engaging, hence we do not expect you to experience any distress participating in this study. However, if an uncomfortable situation arises during the experiment, the researcher (who is a trained provisional psychologist) will be able to assess visible signs of distress and check in with you to see if you need any additional support. With that being said, we would encourage you to notify the researcher immediately regardless during the session should you feel uncomfortable at any point. The researcher will then be able to notify your treatment team who will be able to provide the support and care you need.

9 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time, but please notify a member of the research team before you withdraw. You will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave 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.

10 What happens when the research project ends?

The anonymised results will be published in a peer reviewed journal.

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 the research team 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. Your files will be stored in a locked filing cabinet only accessible by the research team. Electronic data will be stored in a non-identifiable way on a computer only accessible by the research team. As required by our professional body, data will be retained for a period of 30 years before being destroyed. 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.

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

12 Complaints and compensation

If you experience any distress as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

Participation in this study does not impact on your basic legal right to seek compensation; however, if you do suffer harm, you may receive compensation without litigation.

13 Who is organising and funding the research?

This research project is being conducted by Dr Ryan Balzan and Professor Tracey Wade. Dr Balzan can be contacted by email at ryan.balzan@flinders.edu.au. The project is funded by the Channel 7 Children's Research Foundation scheme.

14 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 Women and Children's Hospital Research Ethics Committee. The Executive Officer of the Committee, Mr Luke Fraser, can be contacted 08 8161 6521 if you would like to discuss the approval process or have any concern or complaint. 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.

15 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 problems which may be related to your involvement in the project, you can contact the researchers as outlined in the table below:

Research contact person

Name	Dr Ryan Balzan
Position	Lecturer, College of Education, Psychology & Social Work, Flinders University
Telephone	(08) 8201 3082
Email	ryan.balzan@flinders.edu.au

Name	Professor Tracey Wade
Position	Matthew Flinders Distinguished Professor, College of Education, Psychology & Social Work, Flinders University
Telephone	(08) 8201 3736
Email	tracey.wade@flinders.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:

Complaints contact person

Name	<i>Paula Davies</i>
Position	<i>Director, Office for Research</i>
Telephone	8204 6453
Email	Health.SALHNOOfficeforResearch@sa.gov.au

Reviewing HREC approving this research and HREC Research Information Officer details

Name	<i>Luke Fraser</i>
Reviewing HREC	Women and Children's Hospital Research Ethics Committee
Position	<i>Research Information Officer</i>
Telephone	8161 6521
Email	luke.fraser2@sa.gov.au

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

Institution	<i>Southern Adelaide Local Health Network</i>
Position	<i>Research Governance Officer</i>
Telephone	8204 6453
Email	Health.SALHNOOfficeforResearch@sa.gov.au

16. Summary of Key Points

- Please read through the Participant Information Sheet thoroughly.
- If you are interested in participating in this study, please email me at ryan.balzan@flinders.edu.au with your contact details (name, phone number).
- Someone from our research team will then contact you to answer any questions you might have about the study. We can then make an assessment appointment for you, which will be conducted online via a 'video-chat'.
- At this initial online appointment, you will be sent a link to sign an electronic Consent Form to confirm that you are happy to take part in this study. After providing consent, you will complete some online survey questionnaires, which will take approximately 30 minutes. We will remain 'online' with you as you complete these questions, should you wish to clarify anything. After completing the survey questions, you will then be randomised into the 'MCT group' or the 'Wait list group' and our researcher will inform you which group you have been assigned.
- If you have been randomised into the Wait List group, we will be in contact with you another two times to complete a similar 'follow-up' assessment online. This will occur approximately one-month and three-months after commencing the study. After the final three-month follow-up, you will be emailed the full MCT programme to complete at your own pace.
- If you are randomised into the MCT group, you will complete the four MCT modules via video-chat with our researcher. These sessions will be conducted once per week across four weeks. You will have the option of completing the first MCT module (approximately 30-minutes) at the initial online appointment. The next two MCT modules will be approximately one-hour each. The fourth and final MCT module (approximately 30-minutes) can be combined with the follow-up assessment.