

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

Plain Language Statement

Date: August 2018 - August 2022

Full Project Title: Exploring the effectiveness of group schema therapy for persistent depression: A feasibility trial conducted in a naturalistic setting

Principal Researcher: Dr Tamara May

Student Researcher: N/A

Associate Researcher(s): Dr Rita Younan, Ms Rosemary McDonagh; Ms Rachael Torcasio

Dear Participant,

You are invited to participate in a research project being conducted by Monash University and The Schema Therapy Institute Australia. Please read this sheet carefully and be confident that you understand its contents before deciding whether to participate. If you have any questions about the project, please ask one of the investigators.

What is the purpose of this study and what methods are being used?

This intervention study is being conducted at The Schema Therapy Institute Australia. It aims to reduce the symptoms associated with persistent depression via a 20-week Group Schema Therapy intervention. There will be assessments conducted 10 weeks prior to starting the program, within the week directly before the program starts, after 10 weeks of engagement with the program, and immediately following the end of the program. Participants will attend the 20-week Group Schema Therapy intervention via face to face or telehealth format. We will compare how your symptoms of depression change across the assessment time points.

What is Group Schema Therapy?

A Schema is a pattern. It develops during childhood and adolescence and can be activated again and again - a bit like an emotional button. When this emotional button is pushed it influences how we see things around us, the decisions we make, and the emotions we experience are very painful and distressing. In Group Schema Therapy sessions focus on different group activities that help to: enhance understanding of schemas and their origin, learn about the emotional states that arise from the activation of schemas (known as modes) and work on skills for effectively managing modes.

What does participation involve?

If you consent, you will complete an initial assessment to make sure you are eligible for the study, an assessment 10 weeks prior to starting the program, an assessment directly before the program commences, an assessment 10 weeks into the program, and an assessment

directly following the end of the program. These assessments will measure your symptoms related to depression, your current quality of life, and other information related to your schemas. Each assessment will take around 30 minutes to complete and will occur via telehealth or at The Schema Therapy Institute Australia. You will also complete a questionnaire package online in your own time at each assessment point, which will take approximately 1 hour to complete. Telehealth sessions will be recorded to assess whether the program is being delivered as developed and is feasible in the telehealth format.

Following the program participants have the option of participating in an individual interview to understand participants perspectives on the program.

Group Schema Therapy Program: The Group Schema Therapy program involves attending a single 2-hour session per week, over 20 weeks either via telehealth or face to face at the Schema Therapy Institute Australia. All participants are expected to attend their group sessions, do set homework tasks and practice strategies learnt. Additionally, throughout each participant's time in the study, they will be required to keep a "Treatment Diary" briefly documenting therapy sessions attended whether that be at the Schema Therapy Institute Australia or elsewhere and any psychoactive medications taken.

What are the benefits if I agree to participate?

It is hoped that participation in the Group Schema Therapy program will result in reduced symptoms of depressive symptoms and psychological distress. We cannot guarantee that every participant will experience these positive outcomes.

Are there any risks for me if I agree to take part in the study?

Schema Therapy will involve some processing of childhood trauma. As such there is a risk that participants in the Group Schema Therapy program will experience emotional and psychological distress. Experienced psychologists will be available throughout your time in the program to provide support and care. Participation is voluntary and you can withdraw from the study at any time without disadvantage to yourself. Withdrawal from the study will not affect your relationship with The Schema Therapy Institute Australia, Dr Rita Younan, or Monash University in any way.

If you wish to access psychological support from the project you can contact Dr Tamara May.

If you wish to access external counselling you can contact your general practitioner for an appropriate referral, or find a psychologist in a location suitable to you via the Australian Psychological Society Find a psychologist service: <https://www.psychology.org.au/Find-a-Psychologist>. If you need immediate crisis support, contact Lifeline on 13 11 14.

What will happen to the information I provide?

The information collected through this project will remain strictly confidential. Research materials will be stored securely in locked filing cabinets at Monash University and on a secure Monash University research database. In line with data storage policies, this data will be stored for 7 years after the final publication, after which it will be securely destroyed. Only the research team will have access to information collected from you. Your responses

will not be disclosed to anybody else. We only report results in a group format i.e. ‘males had more symptoms than females’.

The individual results collected from assessments, interviews and questionnaires completed online will form part of the group data which will be analysed in this research. Data will be presented in published journal articles and research presentations, however, as this data is provided in a group format, your individual results will not be identifiable.

This group data will be summarised in a 1 to 2 page document. You can request this document by contacting any of the researchers with the contact details provided at the end of this document.

Your personal information may be stored to contact you for future follow up studies. However this will only be allowed if you provide specific consent for this by ticking the appropriate check box on the attached consent form.

If you request, your information will also be used to provide you with a brief summary report outlining your individual results. Should you have any concerns around these results you will be provided with the contact details of study investigators to discuss these concerns.

Expected benefits to the wider community?

Persistent depression is a prevalent condition. As such, by conducting research exploring the efficacy of Group Schema Therapy in reducing persistent depressive symptoms, it is hoped that the results of this study can provide a better understanding of effective treatment options for this condition.

Will I receive compensation?

Participants will not receive compensation for participating in this study. You will not be paid to participate in this study.

Who is funding this research project?

This research project is being funded by Monash University.

Alternatives to participation

If you do not wish to participate you can still access the Group Schema Therapy program at the Schema Therapy Institute Australia.

Do I have to take part in this research?

No. Participation in this research project is entirely voluntary and you have the right to withdraw from the project at any time without reason. Information will only be collected from participants who have provided written consent. In some cases it will not be possible to withdraw your data from the project if you decide to withdraw as it may have already been used in published research, or research presentations. However, if you do wish to withdraw your data please contact an investigator and they can assess if this is a possibility. Whether or not you participate in this research/withdraw at any point, will not affect your relationship with The Schema Therapy Institute Australia or Monash University.

Monitoring of this research project

This research project has been approved by the Monash University Human Research Ethics Committee (HREC). This means at any time this project could be randomly selected for an audit inspecting adherence to ethical procedures. Investigators involved with this project will be monitoring the project for ethical compliance at all times. This will involve providing annual reports and a report at the end of the project detailing progress, outcomes, maintenance of records and security, compliance with the approved proposal and compliance with any conditions of approval. The investigators will also immediately notify the DUHREC of any adverse events or outcomes, although this is not anticipated for this project.

Complaints

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

The Human Research Ethics Office, Monash University,

Please quote project number 19872.

Contact Details of Primary Research Investigators:

Dr Tamara May
Department of Paediatrics
Monash University
Monash Children's Hospital
Level 5, 246 Clayton Road
Clayton, Vic, 3168
Ph: (03) 8572 2837

Dr Rita Younan
The Schema Therapy Institute Australia
145 Drummond Street
Carlton VIC 3053
Ph: (03) 9539 4941

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: *Participants*

Consent Form

Date:

Full Project Title: *Exploring the effectiveness of group schema therapy for persistent depression: A feasibility trial conducted in a naturalistic setting*

Reference Number:

I have read, or have had read to me and I understand the attached Plain Language Statement.

I freely agree to participate in this project according to the conditions in the Plain Language Statement.

I have been given a copy of the Plain Language Statement and Consent Form to keep.

The researcher has agreed not to reveal my identity and personal details, including where information about this project is published, or presented in any public form.

I understand that if I participate in the telehealth group sessions these will be recorded for the purposes of assessing the fidelity of the delivered program in the telehealth format.

Additional consent:

I agree to be contacted for future follow up studies

I agree to complete an interview about my experience of the Group Schema Therapy program, which will be audio recorded.

Participant's Name (printed)

Signature Date

Please mail this form to:

Dr Tamara May
Monash University
Monash Children's Hospital
Level 5, 246 Clayton Road
Clayton, Vic, 3168

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: *Participants*

Withdrawal of Consent Form

Date:

Full Project Title: *Exploring the effectiveness of group schema therapy for persistent depression: A feasibility trial conducted in a naturalistic setting*

Reference Number:

I hereby wish to WITHDRAW my consent to participate in the above research project and understand that such withdrawal WILL NOT jeopardise my relationship with Monash University and the Schema Therapy Institute Australia

Participant's Name (printed)

Signature Date

Please mail this form to:

Dr Tamara May
Monash University
Monash Children's Hospital
Level 5, 246 Clayton Road
Clayton, Vic, 3168