

## **Participant Information Sheet/Consent Form**

### **Social Science Research - Adult providing own consent**

#### **FUSED**

<b>Title</b>	<b>Intensive Cognitive Behavioural Therapy (CBT): Comparison to Guided Self-help CBT for the treatment of eating disorders.</b>
<b>Short Title</b>	Treatment of eating disorders
<b>Protocol Number</b>	204.15
<b>Principal Investigator</b>	Professor Tracey Wade
<b>Associate Investigator(s)</b>	Professor Glenn Waller
<b>Location</b>	Flinders University

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## **Part 1 What does my participation involve?**

### **1 Introduction**

You are invited to take part in this research project because you have been referred for treatment at the Flinders University Services for Eating Disorders (FUSED).

This form tells you about the research project. It explains the processes involved with taking part. 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 local health worker.

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 be involved in the research described

You will be given a copy of this Participant Information and Consent Form to keep.

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

The aim of this research is to compare a new treatment for eating disorders, intensive Cognitive Behavioural Therapy, formulated by Professor Glenn Waller in the United Kingdom, to guided self-help CBT for eating disorders. Because intensive Cognitive Behavioural Therapy is new we hope to learn more about how well it works, how it works and who it works best for.

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

Participation in this research will begin only once you have read this information sheet and signed the consent form. Participation involves being assessed on five occasions. On the first occasion this will involve an assessment appointment as well as completing an interview and a self-report questionnaire. You will then be given information to read discussing getting ready for change. Following this assessment you will be randomly (i.e., like in the throwing of a dice) allocated to begin treatment in either intensive Cognitive Behavioural Therapy or the guided self-help (GSH) CBT. Both treatments will involve attending weekly face-to-face sessions of

one hour duration for ten weeks, and experimenting with changing the way that you manage eating and mood. After the fourth session of treatment you will be assessed for a second time with the questionnaire, and then again after the last session of treatment with the questionnaire and interview. You will be assessed a fourth time 4 weeks after the treatment has finished, and again for a fifth and final time after another 8 weeks. Each assessment will take approximately 1.5 hours of your time. Therapists are provisional psychologists (postgraduate clinical psychology students), supervised by Professors Tracey Wade and Glenn Waller.

You will also be asked to complete brief assessments of how you are going each week over therapy, for discussion in the therapy session. This will take about 15 minutes on each occasion.

All treatment sessions will be held in a private therapy room in the Flinders University School of Psychology.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids researchers or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid. Reply paid envelopes will be provided for return of all questionnaires.

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

Approximately 150 people will be participating in this project at Flinders University. Results from other researchers around the world show both intensive Cognitive Behavioural Therapy and GSH CBT to have promising results, and we want to find out which approach suits what types of people best.

#### **5 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 care, your relationship with professional staff or your relationship with Flinders University. You will still receive treatment from FUSED for your eating disorder if you wish.

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

We cannot guarantee or promise that you will receive any benefits from this research; however, other people doing this treatment have reported improvements in their eating disorder and quality of life.

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

If the therapy is ineffective or unsuitable for you, the research team will be able to arrange for counselling or other appropriate support from outside the research team.

## **8 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.

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

The 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 7 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 suffer any distress or psychological injury 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.

In the event of loss or injury as a result of participation in this treatment, compensation might be paid without litigation. However, such compensation is not automatic and you may have to take legal action to determine whether you should be paid.

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

This research project is being conducted by Professor Tracey Wade and Professor Glenn Waller.

## 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 HREC of the Southern Adelaide Local Health Network and Flinders 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.

## 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 researcher on 8201 7920 (Mia Pellizzer) or any of the following people:

### Research contact person

Name	Professor Tracey Wade
Position	Dean of Psychology
Telephone	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:

### Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Southern Adelaide Clinical Human Research Ethics Committee
Position	Executive Officer
Telephone	8204 6453
Email	Health:SALHNoofficeforresearch@sa.gov.au