**PARTICIPANT INFORMATION SHEET AND CONSENT FORM**

**Title:** Helping people make a better start on Cognitive Behaviour Therapy for non-underweight eating disorders

**Chief Investigator:**

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**Co-Investigator:**

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**Description of the Study**

We are evaluating the best way to provide therapy to people with eating disorders.

**Purpose of the study**

The aim of this study is to see if we can help people with eating disorders get more out of therapy by supporting them with useful information before they start therapy.

**Benefits of the study?**

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

**Participant involvement and potential risks**

If you agree to participate in the research study, you will be asked to:

* Attend an initial assessment at the Flinders University Service for Eating Disorders (FUSED) to discuss whether this study would suit you - you must be at least 15 years old, have a body mass index of 18.5 or above, have an eating disorder, and be willing for the therapist to communicate with your general practitioner. You won’t be able to do the treatment if you have a severe psychiatric condition that would interfere with treatment (e.g., high suicidality, psychosis), if you are already receiving therapy for an eating disorder, if you have difficulty speaking or understanding English, or if you have binge eating disorder (in this case you will be directed to self-help material).
* Decide if the treatment would suit you, and if so, you will be randomly allocated to a short intervention (50 minutes online) that will help you think about (i) how you can act differently to form new connections between neurons in your brain, (ii) how you can increase pleasurable activity in your life, or (iii) how you can decrease the impact of self-criticism in your life.
* Try to provide your body with the nutrition it needs for the 2 weeks after the initial assessment.
* Do either an 10-session online cognitive behaviour therapy (CBT) with a therapist guide or a 10-session face-to-face CBT held in a private therapy room at FUSED, depending on your progress with providing yourself with adequate nutrition. Both are provided by post-graduate trainee psychologists supervised by Professors Wade and Waller. There are no costs associated with participating in this research and you will not be paid. If at any point you decide that you do not want to receive the CBT, this is absolutely not a problem. Sometimes you need to try different approaches before you find the one that works for you. We will write to you and your GP to provide a list of alternative options. Throughout the study, you can request any support person to be present, and you can also ask for special additional sessions for a significant other and yourself.
* Complete questionnaires on six occasions over a 24-week period up to 30 minutes on each occasion, a total of 3 hours of assessment. Questionnaires will be completed online and will include questions/statements relating to disordered eating, self-harm, self-criticism, cognitive impairment, depression, anxiety, and stress. We ask about sensitive issues such as self-harm, abuse, whether life is meaningless, feeling disgust about one-self. The assessments occur before your initial assessment, after 2 weeks, then 4-weeks after that, at the end of therapy, and then four and twelve weeks after therapy has finished.

Although we believe this research poses no risk for participants, it does deal with some sensitive personal issues. If you need, you may also contact the following free services:

* the Flinders University Health, Counselling, and Disability Services (Level 3, Student Services Centre, open 8.45am to 5pm Monday to Friday) on (08) 8201 2118
* Lifeline on 13 11 14,
* the Statewide Eating Disorder Service (open 9am to 4.30pm Monday to Friday) on (08) 8198 0800,
* Beyond Blue (open 24/7) on 1300 224 636,
* Suicide Call Back on 1300 659 467
* the Butterfly National Helpline for eating disorders (available 8am to midnight, 7 days a week) on 1800 33 4673.

**Withdrawal rights**

You may decline to take part in this research study. If you decide to take part and later change your mind, you may, withdraw at any time without providing an explanation. Let your therapist know if you want any data collected up to the point of your withdrawal to be securely destroyed.

**Confidentiality and Privacy**

Only researchers listed on this form have access to the individual information provided by you. Privacy and confidentiality will be assured at all times. The research outcomes may be presented at conferences, written up for publication or used for other research purposes as described in this information form. However, the privacy and confidentiality of individuals will be protected at all times. You will not be named, and your individual information will not be identifiable in any research products. No data, including identifiable, non-identifiable and de-identified datasets, will be shared or used in future research projects without your explicit consent.

**Data Storage**

The information collected will be stored securely on a password protected computer and Flinders University server for 5 years. Any identifiable data will be de-identified for data storage purposes. With your consent, these data will also made available permanently on the Open Science Framework where other researchers around the world can request permission to analyse the data for the purposes of replicability or meta-analysis.

**How will I receive feedback?**

Following project completion, a brief report of the outcomes of the project will be provided on Professor Tracey Wade’s web page and can also be emailed to you on request.

**Ethics Committee Approval**

The project has been approved by Flinders University’s Human Research Ethics Committee (5857).

**Queries and Concerns**

Queries or concerns regarding the research can be directed to the research team. If you have any complaints or reservations about the ethical conduct of this study, you may contact the Flinders University’s Research Ethics & Compliance Office team via telephone 08 8201 2543 or email [human.researchethics@flinders.edu.au](mailto:human.researchethics@flinders.edu.au).

Thank you for taking the time to read this information sheet which is yours to keep. If you accept our invitation to be involved, please sign the enclosed Consent Form.

**CONSENT FORM**

**Consent Statement**

I have read and understood the information about the research, and I understand I am being asked to provide informed consent to participate in this research study. I understand that I can contact the research team if I have further questions about this research study.

I am not aware of any condition that would prevent my participation, and I agree to participate in this project.

I understand that I am free to withdraw at any time during the study.

I understand that I can contact Flinders University’s Research Ethics & Compliance Office if I have any complaints or reservations about the ethical conduct of this study.

I understand that my involvement is confidential, and that the information collected will be published. I understand that I will not be identified in any research products.

I further consent to:

completing questionnaires

sharing my de-identified data with other researchers on the Open Science Framework

my de-identified data being used in this project and other related projects for an extended period of time

**Signed:**

**Name:**

**Date:**