Anorexia Nervosa
A test of three new study treatments

This is a research project, and you do not have to be involved

What is the study about?
Anorexia nervosa is where a person starves her- or him-self to a low weight and yet strongly fears getting fat. There is still a lot we do not know about how to effectively treat anorexia nervosa. You are invited to take part in a study that is investigating the relative effectiveness of three promising new outpatient treatments for anorexia nervosa and related eating disorders.

What does participating in the study involve?
It involves receiving one of three psychological outpatient treatments. Before treatment commences, there will be two assessment sessions – one of which will involve neuropsychological assessment. All of the treatments involve attending around 25 to 40 individual, face-to-face sessions with a psychologist over a period of 10 months. We will try to schedule the first 6 or so sessions twice a week, then sessions will be weekly, but later on in treatment, sessions may be more spread out. As this is a research study, we will be evaluating the treatments using a face-to-face interview about your eating as well as self-report questionnaires for you to fill in. The self-report questionnaires ask about your attitudes toward eating, weight and shape, motivational issues, personality, depression, anxiety, relationships and coping strategies. The interview takes about 40 minutes and filling out the self-report questionnaires takes about 20 minutes. You will be asked to do this on 5 occasions with a research assistant: immediately before treatment starts, half way through treatment, immediately after treatment finishes, and then 6- and 12-months after treatment has been completed. The assessments will all take place on site at Flinders University.

What are the treatments?
You will be allocated at random (that means by chance, as in the toss of a coin) to one of three treatments (A, B or C). In other words, you will have a one-in-three chance of receiving any particular one of the three treatments. Currently there are no guidelines regarding the best treatment options for adults with anorexia nervosa, but all of these three treatment options have been found to produce promising results in regard to helping people recover from an eating disorder. The three treatments are as follows:

- **Treatment A** was designed for the treatment of all forms of eating disorders, including anorexia nervosa. This treatment challenges dysfunctional beliefs and thoughts maintaining the eating disorder and focuses on making changes to key eating disorder symptoms, such as extreme dieting, low weight and, in some people, the use of other extreme methods of weight control such as self-induced vomiting, over-exercising or laxative misuse.

- **Treatment B** was designed specifically to treat anorexia nervosa. This treatment aims to tackle maintaining factors related to perfectionism, anxiety and beliefs about the usefulness of self-starvation for managing difficult emotions. It also focuses on the responses of close others to the person with anorexia nervosa (e.g., partners, family, spouse). Treatment B places special emphasis on motivation and makes use of therapeutic writing strategies.
Treatment C aims to help people make the necessary changes to their eating by providing high quality education, information, reassurance and advice about anorexia nervosa, eating and weight, as well as by addressing other personal issues that may be relevant to the eating disorder as identified by the patient within a supportive therapeutic relationship.

Weight regain and recovery of nutritional health is a major goal of all three treatments.

We do not know which of these three treatments is best at producing change in people with anorexia nervosa. The purpose of this study is to find out.

All treatment sessions will be audiotaped. These tapes will be used to ensure that quality of treatment is uniformly high. They will only be listened to by members of the research team. You will not be identified on these tapes. They will be securely stored and their contents will be kept confidential. When the study is over the tapes will be destroyed.

Who will be offering the treatments and where?
Registered psychologists with clinical postgraduate qualifications will be offering the treatment at the School of Psychology at Flinders University.

Am I eligible for the treatment?
You are eligible for this study if you:
1. Are 18 years or over
2. Have anorexia nervosa or a variant of anorexia nervosa
3. Can supply a letter from you medical practitioner that tells us that you are not medically unstable
4. Are willing to have regular physical check-ups with your medical practitioner throughout the treatment study
5. Have no other acute issues requiring urgent attention
6. You are not on the medication olanzapine.

What are the benefits and risks of participating?
The results of the study will help us to make decisions about the type of therapy that is best suited to patients with anorexia nervosa. Participants may not receive any benefit at all from participating in the study. Anyone who becomes medically unstable during treatment, or loses weight consecutively over several appointments, will be withdrawn from the study in order that he/she can get more appropriate treatment. If this occurs, we will ask his/her permission to continue following him/her up with the assessments, and these people can take up the opportunity to rejoin the study once they are medically stable. If you suffer 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.

Cost of participation in the treatment
There are no associated costs with participation in the study. The treatment sessions are free and parking permits can be provided.
Participation is voluntary

Your participation in the outpatient treatment is entirely voluntary and you are free at any time to withdraw consent to further participation. You do not have to give a reason or justification for a decision to withdraw from the study. Your decision whether or not to participate in the study will not affect your eligibility for current or future treatment. If you decide not to participate, you will be offered treatment as usual. All records containing personal information will remain confidential and no information that could lead to your identification will be released. A letter will be sent to your GP and/or psychiatrist informing them of your involvement in the treatment.

In accordance with usual practice, study results become the property of the researchers and will be published in scientific journals at a later date. If you decide to withdraw from the study at any time your records will be destroyed unless agreed otherwise.

What happens now?

If you would like more information on this study or are interested in participating please contact Ms Anne O'Shea on 08-8201-2416 or 08-8201-2192 or anne.oshea@flinders.edu.au

One of our research assistants will then speak with you about whether you wish to participate. If you do, we will give you an assessment appointment and send you a questionnaire pack and consent form to complete. When you come to your assessment appointment, you will need to bring your consent form, and your completed questionnaire pack. If it turns out that you are not eligible for the treatments, we will discuss alternative treatment options with you and write a referral letter if you would like us to.

Questions about this project

Should you have any questions about the project, either before, during or after the study, you may contact Professor Tracey Wade or Ms Anne O'Shea on (08) 8201-2416 or 8201-2192.

Thank you very much for taking the time to consider participation in this research which is funded by the National Health and Medical Research Council. We look forward to working with you.

This study has been reviewed by the Flinders Clinical Research Ethics Committee. If you wish to discuss the study with someone not directly involved, in particular in relation to policies, your rights as a participant, or should you wish to make a confidential complaint, you may contact the executive officer on 8204 4507 or email research.ethics@health.sa.gov.au