PARTICIPANT INFORMATION SHEET

The Acceptability and Effectiveness of an Online Self-help Programme for the Management of Eating Disorders

INVITATION

My name is Eleanor Filgate and I am required to undertake a project as part of my course and invite you to take part in the following study. However, before you decide to do so, I need to be sure that you understand firstly why I am doing it, and secondly what it would involve if you agreed. I am therefore providing you with the following information. Please read it carefully and be sure to ask any questions you might have and, if you want, discuss it with others including friends and family. I will do my best to explain the project to you and provide you with any further information you may ask for now or later.

Please note that you do not have to make an immediate decision about participating in the study, and that you can take the information away before you decide.

Background to the study

"Smart Eating" is an online self-help programme for the management of eating disorders that has been designed on Cognitive Behavioural Therapy principles. It has been found to improve motivation for change, eating disorder symptoms and quality of life in Asian and Australian patients. The programme is in the piloting stage so is under ongoing evaluation. To date, there has been no UK study of the benefits to be gained in using the "Smart Eating" programme as part of standard eating disorder outpatient treatment.

Purpose of the study

The purpose of this study is to evaluate the acceptability and effectiveness of "Smart Eating" when used as part of treatment for adult patients under the care of NHS Tayside Eating Disorders Service. If the "Smart Eating" programme is found to be helpful, the study may help to inform future treatment developments within eating disorders services.

Why have I been asked to participate in the study?

You have been asked to participate in the study as an adult patient under the care of NHS Tayside Eating Disorders Service.

Do I have to participate in the study?

No, you do not have to participate in the study. We will provide you with information, and do our best to answer any questions you may have, but it is entirely your decision as to whether to participate. **You are free to decline to participate in the study, or to withdraw from it at any time without reason and without this affecting your medical care or legal rights.**

What will participation in the study involve?

If, having read this Participant Information sheet you are interested in participating in the study, you will be asked to complete an Initial Consent for Contact Form with basic contact information (name, telephone number, email address), which you should hand back to your therapist in the NHS Tayside Eating Disorders Service. Following this (24+hours later), you will be contacted by the

Chief Investigator (Eleanor Filgate) via email or telephone (whichever you prefer), offering you an opportunity to ask any further questions you may have relating to the study. If at this point you are still interested in study involvement, you will be asked to complete a full consent form – this will be given in your next session with the NHS Tayside Eating Disorders Service. Following this, you will emailed step-by-step instructions of what to do next.

At this stage, you will be assigned to a group in a randomised fashion; where you have equal chance of being in either group 1 (treatment as usual only) or group 2 (treatment as usual + "Smart Eating" self-help programme). Further group details are below.

Group 1: Treatment as usual (TAU) from NHS Tayside Eating Disorders Service
If you are allocated to this group you will receive TAU (i.e., whatever treatment deemed appropriate by your clinician as part of your routine care). You will be asked to complete a small number of questionnaires on four occasions over an approximately six-month period via the "Smart Eating" programme website. Once the study is finished, you will be able to access the entire "Smart Eating" programme.

Group 2: Treatment as usual (TAU) plus the "Smart Eating" programme
If you are allocated to this group you will receive TAU, (i.e., whatever treatment deemed appropriate by your clinician as part of your routine care), **and** you will be given access to the full "Smart Eating" programme. The programme comprises several components and can be completed in approximately three months. You will also be asked to complete a small number of questionnaires on four occasions over an approximately six-month period.

To note: Your NHS Tayside Eating Disorders clinician will know you are involved in this study, but they will not know which group you are in.

Do I need much experience of using a computer to participate in the study?
Completion of the "Smart Eating" programme requires basic computer skills, and you will need regular access to a computer, in a quiet/private environment, for the duration of the study.

What will happen if I decide to withdraw from the study?
Participation in the study is entirely voluntary, and you are free to withdraw from it at any time without reason and without this affecting your medical care/legal rights.

Will my participation in the study be confidential?
Yes, all the details you provide as part of the study will be confidential, and any personal information given in questionnaires will be anonymised. You will be asked to indicate on a form whether you consent to your GP being informed of your participation. The Chief Investigator will access your NHS medical records to update that you are involved in this study so that people involved in your care are aware. The Chief Investigator will also gain basic information on input you have from the NHS Tayside Eating Disorders Service (e.g. how long you have been receiving treatment as usual).

If, during the study, you indicate that you or another person are/is at risk of harm (e.g., you feel suicidal), confidentiality will have to be broken, and your clinician will have to be informed so that appropriate support can be provided.

Who has organised the research?
The study is written for the Chief Investigator's submission as part fulfilment of her Doctorate in Clinical Psychology qualification at the University of Edinburgh. The study is sponsored by the University of Edinburgh, who in this role are responsible for the overall management of the study and providing insurance and indemnity.

Who has reviewed the study?
The East of Scotland Research Ethics Service REC 2, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the Sponsor (University of Edinburgh) and NHS Tayside, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected. NHS management approval has also been obtained.

Are there any benefits associated with participating in the study?
Participants in the study who receive standard outpatient treatment **plus** "Smart Eating" may benefit from improved motivation for change, eating disorder symptoms and quality of life, as demonstrated in previous studies of the "Smart Eating" programme. If the study demonstrates such improvements then it is hoped that others may benefit from receiving the full "Smart Eating" programme alongside individual NHS Tayside Eating Disorders Service input as routine treatment.

Are there any risks associated with participating in the study?
Due to the nature of the study, the potential risks to participants are minimal. None of the published studies of "Smart Eating" has documented any risks or adverse effects associated with the programme. Similarly, all of the questionnaires completed as part of the study have been used extensively in eating disorder research and clinical practice without any documented risks or adverse effects.

What should I do if I encounter any difficulties while participating in the study or if you would like to withdraw from the study?
If you encounter any difficulties while participating in the study or if you wish to withdraw from the study, you should contact the Chief Investigator (see "Contact details" below).

If you have concerns about any aspect of the study, or the way you have been treated, you may wish to speak to an independent clinician for advice (details below):

Dr Ailie Castle, Clinical Psychologist & Local NHS Psychology Tutor, NHS Tayside
ailie.castle@nhs.net

If you wish to make a formal complaint, you should contact the following:

Complaints and Feedback Team Lead
Complaints and Feedback Team
Level 7
Ninewells Hospital
Dundee DD1 9SY
Freephone: 0800 027 5507
Email: feedback.Tayside@nhs.net

What will happen when the study ends?
During and on completion of the study, you will receive treatment as usual, i.e., whatever treatment deemed appropriate by your clinician as part of your routine care. You will continue to have access to the "Smart Eating" programme if you wish. You will be advised by a member of the research team of any changes in your symptoms over the course of the study, as measured by the questionnaires you complete.

What will happen to the results of the study?
The study will be written up as a thesis project, along with a systematic review of relevant literature as part fulfilment of the Chief Investigator's Doctorate in Clinical Psychology qualification at the University of Edinburgh. If you would like to receive a copy of the published study results please select the option on the full consent form.

The study results will be submitted to a peer-reviewed journal for consideration regarding publication. The study results may inform a conference presentation to share findings with other health professionals.

To note, you will **not** be identifiable in any published results.

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION

CONTACT DETAILS

Should you wish to discuss any aspect of the study, please contact either:

Eleanor (Nell) Filgate (Chief Investigator) eleanor.filgate@nhs.net

Paula Collin (Consultant Clinical Psychologist)
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