

PARTICIPANT INFORMATION SHEET

IRAS Project ID: 285922

REC No: 22/LO/0655



Study title: Shortening Duration of Untreated Illness in First Episode Eating Disorders: A Randomised Controlled Feasibility Trial of a Smart-Phone Friendly Multi-Modal Decision-Making Tool (FREED-M) to Improve Help-Seeking

Short title: **FREED-Mobile**

Please read the Information Sheet below and click next when you have finished. You will be able to download a copy of the Information Sheet to keep.

If you have any questions about the study, please contact one of our researchers at FREEDMobile@kcl.ac.uk before you decide whether to join in.

What is the study about?

We want to understand the impact that online resources may make on young people's help-seeking behaviours and motivation to make changes to their eating and/or other aspects of their life. We are testing two different ways of delivering resources. In each of the two conditions, participants will be sign-posted to or given access to further information or downloadable resources that they may find useful. The difference between the two conditions is the ways in which the information is presented and how much information participants are given.

Who is being asked to take part?

Young people aged 16-25, living in England or Wales, who are concerned about their eating or weight and have not yet received specialised eating disorder treatment. If you are on the waiting list for treatment but have not yet started, then you are still able to take part.

Do I have to take part?

You do not have to take part if you do not want to and not taking part in this study will not disadvantage you in anyway. If you decide to take part, you can withdraw from the study at any time without giving a reason.

What will happen if I take part?

To take part in the study, it is important that you read this participant information sheet and the consent form carefully and complete the consent form. The consent form serves as your permission to take part in the project, and you don't have to complete it if you don't want to take part.

This study will take place online, via the FREED-M website. After signing the consent form, you will be asked a few questions to check if this study is right for you. If the study isn't right for you, we would like to keep your anonymised responses to the screening questions to explore who showed interest in the study. If the study is right for you, you will be asked to provide your contact information and complete some questionnaires.

After that you will be allocated by a computer to one of two conditions.

In both conditions you will be given access to online resources that may help you to seek help for your eating difficulties. This may include things such as written information about different types of

eating problems, short videos and personal accounts of recovery. You will have access to the online content of the intervention until the end of the study. There will be no direct contact with members of the research team, although we may send you electronic reminders from time to time to continue with parts of the study. Once the study is finished, you will be offered access to the other condition if you wish.

Throughout the study you will complete three main surveys: one at the beginning of the study, one after 4 weeks and one after 12 weeks (end of the study). These surveys will ask about your eating and weight, how you are feeling in general, your supports and your social media use. Each survey takes about 35 minutes to complete. After you complete the first survey, we will share the online resources with you to look through in your own time. You will be invited to access these resources at least once per week for 4 weeks. We recommend spending 15-20 minutes each week on the resources. In addition to the main surveys, we will send you a few questions about your eating once a week for 3 weeks. Web platform data will also be collected throughout the course of your participation in the study.

There will also be an opportunity to take part in an interview about what you thought about the resources after you complete the study. You can still take part in the main study if you don't want to do an interview. These interviews will take place online, on the phone, or in person. The interviews will be recorded for transcription purposes and deleted once this has been completed.

Will I be paid for taking part?

You will be paid with a £20 Love2Shop voucher for completing the study. The voucher will be sent in the post and you will be asked to provide your postal address via email at the end of the study. The voucher will be sent in a discreet envelope, and your postal address will not be stored as data.

What are the benefits of taking part?

We hope that you will find the study interesting and might learn something new from it. The study will help us to find out how best to support young people with eating problems.

What are the risks of taking part?

We do not think that taking part has any major risks. The surveys and resources are not designed to make you feel distressed. However, some questions or topics might be sensitive for you. If you feel upset, please speak to a friend or family member, your GP or another source of support.

Will my responses be kept confidential?

We will keep your responses to the surveys and free-text entries confidential and safe. We may use your responses in any free-text boxes or interviews as quotes in our publications and reports, but these will be anonymous and stripped of any personal details that could identify you. Your privacy is of the utmost importance. In rare circumstances, if you disclose information that indicates there is an urgent risk of harm to yourself/others, the research team may have to contact the relevant external agencies without your permission to ensure your safety and the safety of those around you.

We will follow the data protection law (known as the General Data Protection Regulation, 2018) when we collect, use and store the data in this study. This means that we will keep any information about you confidential (private) and store it safely. Information collected on the website will be downloaded and stored on our secure servers at King's College London in password-protected files. Your identifiable information will then be removed and stored separately, and we will use a participant number to identify you rather than your name in the study database. Identifiable information will be deleted on completion of the study. For participants who consented to being contacted about the follow up studies to this project, contact details (not linked to their study data)

will be stored for 5 years after the study completion. For participants who did not consent to being contacted about the follow up studies to this project, their contact details will not be stored after the study completion. After the study has ended anonymised data will be stored indefinitely at King's College London's data repository (KORDS – King's Open Research Data System). Anonymised data may be used by other researchers for future work.

How is the project funded?

This research is funded by the National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB) scheme.

Who has reviewed this study?

This study has been reviewed by an independent group of experts, called a Research Ethics Committee. This study has been reviewed and approved by Camden and King's Cross Research Ethics Committee (reference number 22/LO/0655).

What will happen to the results of the study?

We hope to share the results of the study in academic journals, at conferences, through our newsletters, on websites, publications in collaboration with Beat, and in other reports. We will not use your name or any other identifiable information in any reports or publications. If you would like to receive a summary of the study findings, please indicate this on the consent form and we will share it with you when it is ready. You will also be able to receive information about peer-reviewed publications if you wish to.

What if something goes wrong?

If you have any concerns about the study, you can let one of the researchers in the team know by emailing FREEDMobile@kcl.ac.uk. We will do our best to address the problem.

If you remain unhappy and wish to formally complain, please contact the South London and Maudsley NHS Foundation Trust's Patient Advice and Liaison (PALS) service on freephone 0800 731 2864 (Option 2) or by email at pals@slam.nhs.uk. The PALS service is open Monday to Friday, 9am to 5pm.

Who should I contact for further information?

If you have any questions or would like any further information about this study, please contact one of our researchers at FREEDMobile@kcl.ac.uk. If you need to update your contact details after the study is completed, please email us with your new information.

Will my GP be informed of my participation?

We won't tell your GP. However, if you want to let your GP know that you are going to take part in this study, you can download a letter we have written for GPs that tells them more about the study.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name and contact details. We will use this information to do the research (e.g. to send you reminder emails and/or text messages) or to check your research records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. We will save data from this study in the King's Open Research Data System.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from

<https://www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research>.

- by asking one of the research team at FREEDMobile@kcl.ac.uk
- by sending an email to the Data Protection Officer, Albert Chan, info-compliance@kcl.ac.uk