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Online feasibility trial for early intervention in eating disorders to improve help seeking behaviours

Submission date
01/06/2022

Recruitment status
No longer recruiting

Registration date
27/07/2022

Overall study status
Completed

Last Edited
25/03/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Early intervention (getting help quickly when a problem starts) gives young people the best chance to recover from eating disorders (EDs). An important focus of early intervention is to shorten the time between a person first developing symptoms and starting treatment (duration of untreated eating disorder; DUED). DUED has several parts. Some are patient-related (e.g., not knowing there is a problem, not asking for help) and others are services-related (e.g., waiting lists). Service-related delays can successfully be overcome by changing the way services are run (using a novel first episode rapid early intervention service for EDs, known as FREED). Researchers now want to tackle the help-seeking component of DUED.
The aim of this study is to develop and test a smartphone-friendly, online intervention for young people, who have recently developed an eating disorder (ED), called FREED-M (First Episode Rapid Early Intervention for EDs–Mobile). This intervention aims to increase young people's understanding of their illness and to raise their motivation to seek treatment. It will do this by giving them information about EDs, personalised feedback on their symptoms, and practical steps on how to seek help. Before they conduct a large evaluation, the researchers will first conduct a feasibility study to explore how young people find this new intervention, and to gather the data they would need to carry out the larger evaluation.

Who can participate?
Young people aged 16-25 years who are concerned about their eating or weight, who can understand written and spoken English, and who have access to the internet.

What does the study involve?
After reading the information sheet and electronically signing the consent form on the study website, participants will be asked a few questions to check that the study is right for that individual, and are asked to provide contact information and complete some questionnaires. After that, participants will be allocated by the King's Clinical Trial Unit to one of the two groups. In both groups, participants will be given access to online resources that may help them to seek help for their eating difficulties. This may include things such as written information about different types of eating problems, short videos and personal accounts of recovery. They 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 they may send you electronic reminders from time to time to continue with parts of the study. Once the study is finished, participants will be offered access to the other condition if they wish.
Throughout the study, participants 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 them eating and weight, how they are feeling in general, their supports and their social media use. Each survey takes about 35 minutes to complete. After the participant completes the first survey, the researchers will share the online resources with them to look through in their own time. They will be invited to access these resources at least once per week for 4 weeks. It is recommended that they spend 15-20 minutes each week on the resources. In addition to the main surveys, the researchers will send participants a few questions about their eating once a week for 3 weeks.
There will also be an opportunity to take part in an interview about what they thought about the resources after they complete the study. Participants can still take part in the main study if they don't want to do an interview.

What are the possible benefits and risks of participating?
The researchers do not think that taking part has any major risks. The surveys and resources are not designed to make participants feel distressed. However, some questions or topics might be sensitive. If participants feel upset from something in the study, they are recommended to speak to a friend or family member, their GP or another source of support.
As for the possible benefits of taking part, it is hoped that participants will find the study interesting and might learn something from it. The study will help to find out how best to support young people with eating problems.

Where is the study run from?
King's College London and South London and Maudsley NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2020 to August 2023

Who is funding the study?
The National Institute for Health Research (NIHR), Research for Patient Benefit (RfPB) (UK)

Who is the main contact?
Ulrike Schmidt, ulrike.schmidt@kcl.ac.uk

Study website
https://freedm.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

IRAS number
285922

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 285922

Study information

Scientific 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

Acronym
FREED-M

Study objectives
To assess the feasibility of the FREED-M online tool as an intervention for improving motivation for change and help-seeking as proxy measures for shortening the duration of untreated eating disorders. The main feasibility outcome is the attrition rate at follow-up (12 weeks post-randomisation).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/10/2022, London - Camden & Kings Cross REC (Temple Quay House, 2 The Square, Bristol Research Ethics Committee Centre, BS1 6PN, UK; +44 207 1048089; camdenandkingscross.rec@hra.nhs.uk), ref: 20/LO/0655

Study design
Multi-centre randomized control parallel-group feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Probable eating disorder

Interventions
Participants will be randomly allocated to either the FREED-M intervention or signposted to the resources on an eating disorders charity website. Random allocation will be conducted by the King's Clinical Trials Unit using an online system to ensure allocation concealment.

Participants allocated to the interactive FREED-M intervention will be invited to access educational animations, resource booklets, and personalised feedback (based on their baseline questionnaire responses). They will be able to access one new animation per week for 4 weeks. Following each animation, they will be invited to briefly reflect on the content and will be asked to answer questions on the personal relevance of the materials shown. They will also be able to access weekly downloadable associated information that complements the animation content with more in-depth information. Participants will be able to revisit online content over the study period.

Intervention Type
Other

Primary outcome measure
Online assessments at baseline (week 0) and week 12 (unless otherwise noted):
1. Demographic information (week 0 only; full date of birth, name, ethnicity, sex) - to capture the demographics of the participants who take part in the trial
2. Eating Disorder Diagnostic Scale (EDDS-DSM5): to measure symptoms of anorexia nervosa, bulimia nervosa, and binge-eating disorder
3. Self-reported weight and height - to calculate participant's BMI
4. Eating disorders symptom onset - to measure when eating disorder symptoms first started
5. Help-seeking questions - to know if participant's have previously sought help for their eating disorder
6. Visual Analogue Scales (VAS) - to measure motivation to change for participant's eating disorder symptoms/behaviours
7. Visual Analogue Scale (VAS) - to measure the participant's readiness to change their eating disorder symptoms/behaviours
8. Work and Social Adjustment Scale-Youth (WSAS-Y) - to measure impact of eating disorder on their work and life

9. Patient Health Questionnaire (PHQ-4) - to measure current anxiety and depression symptoms
10. Disclosure Expectations Scale (DES) - to understand how much participants are willing to share personal information with healthcare professionals
11. Motivations for Social Media Use (MSMU) - to understand participant's reasons for their social media use
12. Social media behaviours questions - to understand participant's social media behaviours
13. EuroQol measure (EQ-5D-5L) - to measure health related quality of life
14. Adult Service Use Schedule (AD-SUS) - to capture information about participant's use of health services in the past 3 months

Online Within-Intervention Questionnaires (week 1, 2, 3)
15. Short EDDS - shorter version of the EDDS-DSM-5 to measure symptoms of anorexia nervosa, bulimia nervosa, and binge-eating disorder
16. VAS scales x2 – to measure participant's motivation and readiness to change their eating disorder symptoms/behaviours

Online Post-Intervention Assessments (week 4):
17. BEAT website usage questions - asks if participants used Beat's website resources (also at week 12)
18. Intervention feedback questions - questions to capture how participants found the intervention tool
19. Same as baseline assessments, with the omission of the demographic questions, ED symptom onset questions, and self-reported height

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
10/01/2020

Completion date
31/08/2023

Eligibility

Key inclusion criteria
1. People aged 16 to 25 years
2. Probable eating disorder, defined by a score of >2 on a widely used screening instrument for eating disorders (the 'SCOFF')
3. No previous specialist eating disorder treatment

Participant type(s)
Other

Age group
Mixed

Lower age limit
16 Years

Upper age limit

25 Years

Sex
Both

Target number of participants
116

Total final enrolment
176

Key exclusion criteria
1. People with previous or current specialist eating disorder treatment
2. People outside the inclusion criteria age
3. People who cannot understand spoken or written English
4. People who do not have access to the internet

Date of first enrolment
03/07/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
ED Section, Department of Psychological Medicine, IoPPN
16 De Crespigny Park
London
United Kingdom
SE5 8AF

Study participating centre
Maudsley Hospital
South London and Maudsley NHS Foundation Trust
Denmark Hill
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United Kingdom
SE5 8AZ

Sponsor information

Organisation
King's College London

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SE5 8AF
+44 (0)20 7848 0002
slam-ioppn.research@kcl.ac.uk

Sponsor type
University/education

Website
https://www.kcl.ac.uk/ioppn

ROR
https://ror.org/0220mzb33

Organisation
South London and Maudsley NHS Foundation Trust

Sponsor details
Maudsley Hospital
Denmark Hill
London
England
United Kingdom
SE5 8AZ
+44 (0)20 3228 6000
slam-ioppn.research@kcl.ac.uk

Sponsor type
Hospital/treatment centre

Website
https://www.nhs.uk/services/hospitals/overview/defaultview.aspx?id=2775

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
It is intended that the results of this study will be disseminated through conferences, scientific papers, and media/social media, as well as patient, school and university organisations, and our early intervention network.

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan
After the study has ended, anonymised data will be stored indefinitely at King's College London's Data Repository System (KORDS).
Access to the KORDS:
The majority of the datasets in KORDS are openly accessible and are available to view and download freely by anyone (King's College London affiliate or not). However, the users must abide by the terms of the licence selected by authors for each dataset, which determine how they may be used and attributed.
Some datasets in KORDS are restricted access; marked as 'Files under embargo' on the front page of KORDS. Some may be shared on request using a Data Access Agreement which explains the conditions of access and re-use of the data obtained. External researchers who wish to access and use this data need to meet the terms of agreement, and typically would need to be signed by a legal/contracts representative of their institution. Restricted dataset records on KORDS will include a reason as to why this is restricted i.e., sensitive data.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.3	09/03/2023	18/05/2023	No	Yes
Protocol article		07/02/2025	10/02/2025	Yes	No