Will an online life skills package be helpful for individuals with bulimia nervosa?

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------|---|-----------------------------|--|--|
| 03/07/2009 | | ☐ Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 04/08/2009 | Completed | [X] Results | | |
| Last Edited | Condition category | Individual participant data | | |
| 03/04/2013 | Mental and Behavioural Disorders | | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Miss Carrie-Anne McClay

Contact details

University of Glasgow
Section of Psychological Medicine
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH
+44 (0)141 211 0646
c.mcclay@hotmail.co.uk

Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

A randomised controlled trial of an online life skills package for bulimia nervosa, recruiting from community settings

Study objectives

- 1. The immediate treatment group at 10 weeks:
- 1.1. Will have reduced bulimic symptoms compared to their baseline scores and controls
- 1.2. Will have reduced anxiety and depression scores along with increased social functioning compared to their baseline scores and controls
- 2. Both the immediate treatment group and delayed treatment group will show a reduction in bulimic symptoms, anxiety and depression scores and will have increased social functioning following completion of the package (however the delayed treatment group may exhibit lower levels of improvement)
- 3. Participants who complete more sessions of the package will show the highest levels of improvement in outcome measures. Therefore, we expect to see a dose-effect relationship.
- 4. Improvements in bulimic symptoms and other aspects of mental health and well being will be maintained at the 6 month follow-up due to the reusable nature of the package
- 5. The greatest improvements in condition will be seen in participants who have mild to moderate bulimic symptoms at baseline
- 6. Participants whose onset of bulimia is the most recent are expected to have the greatest improvements in outcome measures
- 7. We aim to ascertain who benefits most from using the package, i.e., mild to moderate sufferers or severe bulimics. Also whether onset of illness has an effect on the effectiveness of the package.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Glasgow Medical Faculty Ethics Committee approved on the 27th May 2009 (ref: FM03508)

Study design

Single-centre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bulimia nervosa

Interventions

Package name: 'Overcoming Bulimia Online'

Intervention: immediate access (IA) to the above package

Control: delayed access (DAC) to the above package after 10 weeks

Following entry into the randomised controlled trial (RCT) section of the study, participants will be randomly allocated to either the IA group or the DAC group. The IA group will be offered

access to 'Overcoming Bulimia Online' following completion of baseline measures. The DAC group will be offered access to the package after a 10 week delay. Participants are advised to complete one session of the package per week so the package should take 8 - 19 weeks to complete. Participants will complete outcome measures at baseline, 10 weeks, 6 months, 12 months, with consent being taken to allow for future follow up assessment at 24 months and up to 10 years post-intervention (if future funding allowed a further follow-up contact).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Eating Disorders Examination Questionnaire at baseline, 10 weeks, 6 months and 12 months. Main factors are:

- 1. Global score
- 2. Frequency or bingeing
- 3. Frequency of vomiting

Key secondary outcome(s))

- 1. Hospital anxiety and depression scale (HADS)
- 2. Work and Social Adjustment Scale
- 3. Recovery Locus of Control Scale
- 1. Hospital anxiety and depression scale (HADS), measured at baseline, 10 weeks, 6 months and 12 months
- 2. Work and Social Adjustment Scale, measured at baseline, 10 week and 12 months
- 3. Recovery Locus of Control Scale, measured at baseline, 10 week and 12 months
- 4. Significant Others Scale, measured at baseline
- 5. Mental Health Literacy Questionnaire, measured at baseline, 10 weeks, 6 months and 12 months
- 6. Economic analysis, measured at baseline, 10 weeks, 6 months and 12 months

Completion date

31/07/2011

Eligibility

Key inclusion criteria

Stage One:

- 1. Aged 16 or above, either sex
- 2. Based in the UK
- 3. Show significant symptoms of bulimia nervosa or eating disorders not otherwise specified (EDNOS), as indicated by the Eating Disorder Examination Questionnaire
- 4. Body mass index (BMI) of 18.5 kg/m² or above

Stage Two:

1. Meet the criteria for a research diagnosis of bulimia EDNOS, as indicated by the Eating Disorders Examination Interview

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

All

Key exclusion criteria

Stage One:

- 1. Under the age of 16
- 2. Do not fulfil the inclusion criteria of Stage One

Both Stages:

- 1. Currently receiving specialist mental health therapy
- 2. Currently involved in any treatment based eating disorder research
- 3. Alcohol or drug dependent
- 4. Have active suicidal thoughts
- 5. Participate in severe self-harm
- 6. Have a diagnosis of psychosis
- 7. Diabetic
- 8. Pregnant

Date of first enrolment

01/08/2009

Date of final enrolment

31/07/2011

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre University of Glasgow

Glasgow United Kingdom G12 0XH

Sponsor information

Organisation

University of Glasgow (UK)

ROR

https://ror.org/00vtgdb53

Funder(s)

Funder type

Charity

Funder Name

Helen Hay Pollock Bequest (UK) (ref: 48261)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | results | 15/03/2013 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |