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

Submission date	Recruitment status	[ ] Prospectively registered
03/07/2009	No longer recruiting	[ ] 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

Study website
http://www.help4bulimia.co.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

Participant information sheet
Can be found at http://www.help4bulimia.co.uk

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 measure
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

Secondary outcome measures
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

Overall study start date
01/08/2009

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/m^2 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

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
250 participants

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
Scotland

United Kingdom

Study participating centre
University of Glasgow
Glasgow
United Kingdom
G12 0XH

Sponsor information

Organisation
University of Glasgow (UK)

Sponsor details
Finance and Purchasing Office
Gilbert Scott Building
Glasgow
Scotland
United Kingdom
G12 8QQ

Sponsor type
University/education

Website
http://www.gla.ac.uk/

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
Charity

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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