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A randomized controlled evaluation of the cost effectiveness of cognitive-behavioural guided self-care versus family therapy for adolescent bulimia nervosa in a catchment area-based population

Submission date	Recruitment status
12/09/2002	No longer recruiting
Registration date	**Overall study status**
12/09/2002	Completed
Last Edited	**Condition category**
09/05/2007	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1206/88

Study information

Scientific Title

Study objectives
1. In adolescents with bulimia nervosa or eating disorder not otherwise specified (EDNOS), family therapy (FT) will produce higher rates of abstinence from bingeing and vomiting, both post-treatment (6 months) and at follow-up (12 months) than individual cognitive behavioural guided self-care (CBT-GSC).
2. CBT-GSC will be less costly to implement than FT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institute of Psychiatry Research and South London and Maudsley NHS Trust Research Ethics Committee. Date of approval 17/09/1999, reference number 163/99.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Bulimia nervosa

Interventions

Patients randomly assigned to one of two groups: family therapy or guided-self care.
1. Family Therapy: 15 conjoint family therapy sessions over 6 months
2. Guided-self Care: 10 individual weekly sessions, up to two additional sessions with a close other, then three follow-up sessions over the next 3 months

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Abstinence rates from binging and vomiting over the previous month, assessed at 6 and 12 months on an observer-rated interview measure.

Secondary outcome measures
1. Abstinence rates from bingeing and vomiting over the previous month, assessed at 6 and 12 months on a questionnaire measure
2. Longitudinal assessment of bingeing and vomiting by interview
3. Other eating disorder symptoms
4. Cost of care

Overall study start date
20/09/1999

Completion date
31/07/2004

Eligibility

Key inclusion criteria
1. Aged 20 years or under, referred to one of the following study centres: Maudsley Eating Disorders Services, Surrey-Hampshire Borders Child and Adolescent Eating Disorders Services, Royal Free Eating Disorders Services, Phoenix Eating Disorders Service at St Ann's Hospital
2. Fulfil criteria for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) bulimia nervosa or eating disorders not otherwise specified

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
42 per group; 84 in total

Key exclusion criteria
1. A body mass index below the 10th centile for age and sex
2. Insufficient knowledge of English to understand the treatment manual
3. Learning disability, severe mental illness or alcohol/substance dependence

Date of first enrolment
20/09/1999

Date of final enrolment
31/07/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Eating Disorder Research Unit
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
The Health Foundation (UK)

Sponsor details
90 Long Acre
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WC2E 9RA
+44 (0)20 7257 8000
info@health.org.uk

Sponsor type
Charity

Website
http://www.pppfoundation.org.uk/

ROR
https://ror.org/02bzj4420

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation

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	01/04/2007		Yes	No