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A Maudsley outpatient study of treatments for anorexia nervosa and related conditions

Submission date	Recruitment status
22/02/2010	No longer recruiting
Registration date	**Overall study status**
15/04/2010	Completed
Last Edited	**Condition category**
12/09/2017	Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.eatingresearch.com

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 the Maudsley Model of Treatment for Adults with Anorexia Nervosa (MANTRA) compared to specialist supportive clinical management (SSCM) in outpatients with anorexia nervosa or eating disorder not otherwise specified (ED-NOS)

Acronym
MOSAIC

Study objectives
The Maudsley Model of therapy (MANTRA) will be superior to specialist supportive clinical management (SSCM) in producing greater weight-gain and greater improvement in eating-disorders related psychopathology in adults with anorexia nervosa (AN). Also it is hypothesised that MANTRA will be less costly than SSCM, specifically it will be associated with fewer hospitalisations during treatment compared to SSCM. Also, MANTRA will be more cost-effective than SSCM showing greater reduction in symptoms at lower costs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UCLH Research Ethics Committee A, 27/04/2010, ref: 10/H0714/9

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Anorexia nervosa (AN)/eating disorder not otherwise specified (EDNOS).

Interventions

MANTRA:
A cognitive interpersonal therapy which aims to target factors involved in the development and maintenance of AN, including:
1. Thinking styles
2. Social-emotional factors
3. Pro-anorexia beliefs
4. Responses of close others to the illness
It employs a motivational interviewing style following a manual that can be tailored to meet individual patient needs.

SSCM:
A treatment designed to mimic outpatient treatment that could be offered to individuals with AN in usual clinical practice, combining aspects of clinical management and supportive psychotherapy. The focus is on resumption of normal eating and weight restoration.

Both treatments will involve 20 once-weekly hour-long sessions of therapy followed by 4-monthly follow-up sessions. Participants with very low weight (BMI less than 15 kg/m^2) will be offered 30 once-weekly sessions. Clinicians in both treatment conditions will be responsible for the monitoring of physical risk to patients throughout treatment and follow-up. Patients will also have access to a dietetic assessment and follow-up sessions as needed throughout the trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 26/10/2012:
Body mass index (BMI; kg/m^2), and Eating Disorders Examination (EDE) Global Score to assess eating disorder symptomology.
Outcomes will be measured at baseline, 6 months, 12 months and 24 months. Potential mediators and moderators will be examined at 3 months.

Previous primary outcome measures until 26/10/2012:
Body mass index (BMI; kg/m^2), and Eating Disorders Examination (EDE) Global Score to assess eating disorder symptomology.
Outcomes will be measured at baseline, 6 months, and 12 months. Potential mediators and moderators will be examined at 3 months. Some long term outcomes will be measured at 24 months - BMI, Eating Disorders Examination, Client Services Reciept Interview and Clinical Impairment Assessment.

Secondary outcome measures
Current secondary outcome measures as of 26/10/2012:
1. EDE subscale scores
2. Depression, Anxiety and Stress Scale (DASS-21)
3. Obsessive Compulsive Inventory (OCI)
4. The Cognitive Flexibility Scale
5. Beliefs about Emotions Scale
6. Emotion Regulation Questionnaire
7. Motivational and Social Visual Analogue Scales

8. Client Services Receipt Interview (CSRI)
9. The Clinical Impairment Assessment (CIA)
10. Treatment credibility and acceptability Visual Analogue Scales
11. Neurocognitive measures:
11.1. Brixton Spatial Anticipation Task
11.2. Wisconsin Card Sorting Task
11.3. Rey-Osterreith Complex Figure Test
12. Social Cognitive Measures:
12.1 Reading the Mind in the Film
Outcomes will be measured at baseline, 6 months, 12 months and 24 months. Potential mediators and moderators will be examined at 3 months.

Previous secondary outcome measures until 26/10/2012:
1. EDE subscale scores
2. Depression, Anxiety and Stress Scale (DASS-21)
3. Obsessive Compulsive Inventory (OCI)
4. Cognitive Behavioural Transprocesses Questionnaire
5. Social Comparison Rating Scale
6. The Vulnerable Attachment Style Questionnaire (VASQ)
7. The Cognitive Flexibility Scale
8. Beliefs about Emotions Scale
9. Emotion Regulation Questionnaire
10. Motivational and Social Visual Analogue Scales
11. Client Services Receipt Interview (CSRI)
12. The Clinical Impairment Assessment (CIA)
13. Treatment credibility and acceptability Visual Analogue Scales
14. Neurocognitive measures:
14.1. Brixton Spatial Anticipation Task
14.2. Trail Making Task
14.3. Rey-Osterreith Complex Figure Test
15. Social Cognitive Measures: Reading the Mind in the Film and Interpersonal Perception Task
16. Genetic measures: Cheek swab for genotyping
Outcomes will be measured at baseline, 6 months, and 12 months. Potential mediators and moderators will be examined at 3 months. Some long term outcomes will be measured at 24 months - BMI, Eating Disorders Examination, Client Services Reciept Interview and Clinical Impairment Assessment.

Overall study start date
01/04/2010

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Aged 18 years and above, either sex
2. Meet Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria for anorexia nervosa or AN-type eating disorder not otherwise specified (EDNOS)
3. Body mass index (BMI) below 18.5 kg/m^2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
140

Key exclusion criteria
1. Life-threatening AN requiring immediate hospitalisation or in-patient treatment
2. Insufficient knowledge of English to understand treatment and assessments
3. Learning difficulty
4. Mental or physical illness requiring treatment in its own right
5. Substance dependence
6. Pregnancy

Date of first enrolment
01/04/2010

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry
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Sponsor information

Organisation

Institute of Psychiatry (UK)

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Sponsor type
Research organisation

Website
http://www.iop.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) (ref: RP-PG-0606-1043)

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?

Protocol article	protocol	30/05/2013	Yes	No
Results article	results	01/08/2017	Yes	No