

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

Submission date 22/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 15/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 12/09/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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/m²) 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/m²), 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/m²), 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 Receipt 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 Receipt 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/m²

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

London

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Sponsor information**Organisation**

Institute of Psychiatry (UK)

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Sponsor type

Research organisation

Website

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