

Maudsley Model of Anorexia Nervosa Treatment for Adults

Submission date 01/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/10/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/05/2013	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
29 Eating Disorders (79)

Study information

Scientific Title

A preliminary randomised controlled trial of the efficacy and acceptability of a new cognitive-interpersonal treatment of anorexia nervosa versus non-specific supportive clinical management

Acronym

MANTRA

Study objectives

A specific, empirically-based treatment model focusing on four core maintenance factors (Maudsley model of Anorexia Nervosa Treatment for Adults [MANTRA]) will be superior to non-specific supportive clinical management (SSCM) in producing greater weight gain and greater improvement in eating-disorder related psychopathology in adults with anorexia nervosa (AN) at end of treatment (6 months) and follow-up (12 months).

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Institute of Psychiatry/South London and Maudsley NHS Foundation Trust Research Ethics Committee approved on the 20th November 2006 (ref: 06/Q0706/105)

Study design

Two-armed single-blind 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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Anorexia nervosa

Interventions

Two different psychological interventions of 20 individual sessions each plus four follow-up meetings, two sessions with close others and two sessions with a dietician:

1. Maudsley Model of Anorexia Nervosa Treatment for Adults (MANTRA): This is a manualised cognitive-interpersonal treatment which focuses on addressing four key maintaining factors of

anorexia nervosa

2. Specialist Supportive Clinical Management (SSCM): This manualised treatment is designed to be delivered by health professionals trained in the treatment of eating disorders and aims "to mimic outpatient treatment that could be offered to individuals with AN in usual clinical practice"

Total duration of treatment is 6 months and total duration of follow-up is also 6 months (after the end of treatment). This is the same for both treatments.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Measured at pre-treatment (baseline), 6 months and 12 months post-randomisation:

1. Body mass index
2. Eating Disorders Examination Global Score

Secondary outcome measures

Measured at pre-treatment (baseline), 6 months and 12 months post-randomisation:

1. Eating Disorders Examination Subscales
2. Clinical Impairment Assessment (CIA) questionnaire
3. Hospital Anxiety and Depression Scale (HADS)
4. Embedded Figures Task
5. Brixton Spatial Anticipation Task
6. Wisconsin Card Sorting Task
7. Trail making task

Overall study start date

01/03/2007

Completion date

01/06/2010

Eligibility

Key inclusion criteria

1. Outpatients aged 18 or over, either sex
2. Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) anorexia nervosa or Eating Disorder Not Otherwise Specified
3. Body mass index of 18.5 kg/m² or below

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

66

Key exclusion criteria

1. Life-threatening AN requiring immediate in-patient treatment as defined in the UK National Institute for Health and Clinical Excellence (NICE) guidelines for eating disorders
2. Insufficient knowledge of English to understand the treatment
3. Learning disability, severe mental or physical illness
4. Needing treatment in its own right (e.g. psychosis or diabetes mellitus)
5. Substance dependency
6. Pregnancy

Date of first enrolment

01/03/2007

Date of final enrolment

01/06/2010

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

PO Box 59

London

United Kingdom

SE5 8AF

Sponsor information**Organisation**

King's College London (UK)

Sponsor details

c/o Jenny Liebscher

R&D Governance and Delivery Manager

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Sponsor type

University/education

Website

<http://www.iop.kcl.ac.uk>

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Charity

Funder Name

Psychiatry Research Trust (UK) - <http://www.psychiatryresearch.org.uk> (ref: 29 Eating Disorders (79))

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	01/11/2012		Yes	No