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Nice OUtcomes for Referrals with Impulsivity, Self Harm and Eating Disorders: The NOURISHED Study

Submission date	Recruitment status
31/01/2011	No longer recruiting
Registration date	**Overall study status**
19/04/2011	Completed
Last Edited	**Condition category**
21/11/2016	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.nourished-project.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 mentalisation based therapy against specialist supportive clinical management in patients with both eating disorders and symptoms of borderline personality disorder

Acronym
NOURISHED

Study objectives
Mentalisation based therapy is no more
1. Clinically effective
2. Cost effective
at reducing observer rated symptoms of eating disorder as measured by the global score of the Eating Disorders Examination Questionnaire (EDE-Q) in patients with combined eating and borderline personality disorder symptoms up to 18 months post-randomisation than specialist supportive clinical management.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Research Ethics Committee, 14/12/2010, ref: 10/H1102/2

Study design
Multicentre randomised single-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.nourished-project.co.uk; Please click on the link for "Participant and carer information sheet"

Health condition(s) or problem(s) studied

Eating disorders/borderline personality disorder

Interventions
1. Mentalisation Based Therapy (MBT): Intensive Outpatient program model for one year
2. Control treatment: Specialist Supportive Clinical Management (SSCM)

20 - 26 sessions over maximum one year for SSCM. Both groups receive 5 hours of dietetic advice in the year.
MBT participants receive weekly individual and group therapy for one year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Eating disorder symptoms will be measured 6-monthly using the global score of the Eating Disorder Examination (Time points: 0, 6, 12, 18 months)

Secondary outcome measures
1. Borderline Personality Disorder symptoms will be measured 6-monthly using the total score of the ZAN-BPD (Time points 0, 6, 12, 18 months)
2. The economic evaluation will examine the costs-effectiveness of Mentalization Based Therapy and Specialist Supportive Clinical Management including an analysis of incremental cost per QALY
3. Participant rated general psychiatric symptoms of Borderline Personality Disorder will be measured 6-monthly using the DASS-21 (Time points 0, 6, 12, 18 months)
4. Possible mediators of change in Borderline Personality Disorder symptoms include reflective function and object relations, measured by the Reflective Function Questionnaire, The Reading the Mind in the Eyes test and the Object Relations Inventory and personality factors (e.g. resilience, dysregulation, restriction) thought to be important in Eating Disorders (Time points 0, 6, 12, 18 months)

Overall study start date
01/04/2011

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Aged over 18 years, either sex
2. Eating disorder diagnosis
3. Borderline personality disorder (BPD) symptoms. The criteria for "BPD symptoms" are that the patient fulfils both behavioural criteria of the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV), namely:
3.1. Impulsivity in at least two areas that are potentially self-damaging (e.g., spending, sexual behaviour, substance abuse, reckless driving, binge eating)

3.2. Recurrent suicidal behaviour, or self-mutilating behaviour
4. Able and willing to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
140

Key exclusion criteria
1. Current psychosis
2. Current inpatient
3. Currently in psychological therapy
4. Received mentalisation-based treatment (MBT) less than 6 months prior to randomisation
5. Organic brain disease leading to significant cognitive impairment
6. Body mass index (BMI) less than 15 kg/m2 (normal range 19 - 25 kg/m2, anorexia nervosa less than 17.5 kg/m2)

Date of first enrolment
01/04/2011

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Ann's Hospital
London
United Kingdom
N15 3TH

Sponsor information

Organisation
Barnet Enfield and Haringey Mental Health Trust (UK)

Sponsor details
Trust HQ
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Sponsor type
Hospital/treatment centre

Website
http://www.beh-mht.nhs.uk/

ROR
https://ror.org/00d2v4e22

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB PG 0408 15183)

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	21/02/2014		Yes	No
Results article	results	17/11/2016		Yes	No