

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

Submission date 31/01/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/04/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/11/2016	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.nourished-project.co.uk/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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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+44 (0)20 8442 6000

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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