ISRCTN95266816 https://doi.org/10.1186/ISRCTN95266816

The emergence of personality disorder traits in adolescents who deliberately self harm and the potential for using a mentalisation based treatment approach as an early intervention for such individuals: a randomised controlled trial

Submission date
29/10/2007

Recruitment status
No longer recruiting

Registration date
13/12/2007

Overall study status
Completed

Last Edited
09/01/2014

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Trudie Rossouw

Contact details
Brookside
107a Barley Lane
Ilford
United Kingdom
IG3 8XQ
trudie.rossouw@googlemail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
The proposed sample group will be adolescents who harm themselves either through cutting or self poisoning and our hypotheses, which we aim to test in this study, is that the sample group will have a higher incidence of deficit in their capacity to mentalise (the ability to observe and understand invisible mental states of the self and the others, such as intentions, thoughts, desires, expectations, memories). Our hypothesis further is that the self harm group is likely to have a higher incidence of personality dysfunction, in particular of the borderline kind.

Secondly, we aim to compare Mentalisation Based Treatment (MBT) for the clinical sample group against Treatment As Usual (TAU) to test whether MBT will lead to a reduction in self harm behaviour; a reduction in sense of hopelessness and improved interpersonal relationships in comparison to TAU.

Lastly we hope to examine the mentalisation capacity and personality profiles in the parents of the clinical and the non-clinical groups, with the hypothesis being that the clinical group will present with a higher incidence of mentalisation deficit in the parents. We also hope to measure whether mentalisation based family therapy (Short Term Mentalisation and Relational Therapy [SMART]) improves the mentalisation capacity in the parents and in family functioning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Redbridge and Waltham Forest Ethics Committee in February 2006.

Study design
Blinded randomised controlled trial with two treatment groups: mentalisation based treatment versus treatment as usual. Pretest-post test design.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Self harm/borderline personality traits

Interventions
Two treatments: mentalisation based treatment measured against treatment as usual.

MBT Treatment programme:
The treatment will take three forms:
1. Individual once weekly psychotherapy sessions using the MBT approach
2. Family therapy using the SMART technique, fortnightly moving to once monthly after 4 sessions
3. Group therapy fortnightly beginning 6 months into treatment when sufficient participants have been recruited to comprise the groups

Treatment is planned to continue for an 18-month period. At the end of this period, further treatment/monitoring shall be offered to those individuals who still display severe psychopathology and/or risk to themselves or others where it is judged by the clinicians involved that further support may be beneficial. If this applies to a number of individuals this continued treatment may take to form of a group.

Qualified professionals in mental health who have additional training in MBT and in SMART treatment will provide treatment. The clinicians in the study will receive weekly supervision on their clinical work. Some of the individual and family sessions will be randomly selected to be recorded or observed in order that they can be independently rated. This will ensure that the therapy is consistent with the model and that the measure of the therapies effect is valid.

Risk will be managed by a detailed risk assessment at the outset of the study, as well as an ongoing monitoring of risk by the clinicians. Dr T Rossouw will provide psychiatric input. Emergencies after hours will be managed via the routine emergency procedures in North East London Mental Health Trust (NELMHT), which is that the young people are seen in Accident and Emergency (A & E) where they are medically examined and managed by the A & E staff and then seen for a mental state examination and risk assessment by the on call psychiatrist, who will liaise telephonically with Dr Rossouw.

Treatment as Usual:
This treatment will be provided by the tier 3 clinicians as they routinely do. Tier 3 clinicians are trained professionals working in child and adolescent psychiatry. For this group we shall be recording the number of times they were seen, the professions of the clinicians they saw and the clinicians definition of the sessions format and purpose, i.e. assessment or intervention, type of assessment and type of intervention.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The assessment battery will consist of the following assessments for the identified adolescent:
1. Mood and Feelings Questionnaire
2. Millon Adolescent Clinical Inventory (MACI)
3. Childhood Inventory of Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) Borderline Personality Disorder (CI-BPD)
4. The Reading the Mind in the Eyes Test
5. Trust game and questionnaire
7. Intelligence Quotient (IQ)
8. Self Harming Inventory

Every 3 months the self harm inventory and the mood and feelings questionnaire will be re-adminstered.

Outcome/Post-treatment measures:
1. Mood and Feelings Questionnaire
2. Millon Adolescent Clinical Inventory (MACI)
3. Childhood Inventory of DSM-IV Borderline Personality Disorder (CI-BPD)
4. The Reading the Mind in the Eyes Test
5. Social Functioning
6. Self-harming Inventory

Secondary outcome measures
In addition the following assessments will be given to the adolescents parent or guardian:
1. Millon Clinical Multiaxial Inventory-III (MCMI-III)
2. Family assessment tool (Systemic Inventory of Change [STIC])
3. The Reading the mind in the Eyes Test

At the end of the study the following measures will be given to the parents. In addition the following assessments will be given to the adolescents parent or guardian:
1. MCMI-III
2. Family assessment tool
3. The Reading the mind in the Eyes Test

Overall study start date
14/01/2008

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Young people between the ages of 13 - 18 years with a history of self harm
2. Self harm will be defined as any act performed with the intention to harm themselves, e.g. cutting, burning, overdose
3. Eating disorders will only be included if accompanied by another form of self harm as well

Participant type(s)
Patient

Age group
Child

Lower age limit
13 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
60 for the RCT

Key exclusion criteria
1. Learning disability
2. Autism and Asperger's
3. Psychosis

Date of first enrolment
14/01/2008

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brookside
Ilford
United Kingdom
IG3 8XQ

Sponsor information

Organisation
North East London Mental Health Trust (NELMHT) (UK)

Sponsor details

c/o Dr Alex Horne
Goodmayes Hospital
Barley Lane
Ilford
England
United Kingdom
IG3 8XQ
alex.horne@nelmht.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nelmht.nhs.uk/loc-goodmayes.html

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
North East London Mental Health Trust (NELMHT) (UK)

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	01/12/2012		Yes	No