ISRCTN20496110 https://doi.org/10.1186/ISRCTN20496110

Group therapy for adolescents who repeatedly harm themselves

Submission date	Recruitment status
16/06/2009	No longer recruiting
Registration date	**Overall study status**
19/08/2009	Completed
Last Edited	**Condition category**
06/04/2011	Mental and Behavioural Disorders

[ ] 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
Prof Jonathan Green

Contact details
Jean McFarlane Building
Room 4.321
University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PL
+44 (0)161 275 2000
Jonathan.green@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1727/1072

Study information

Scientific Title
A two arm single blinded randomised allocation trial of a manualised group therapy in addition to usual care compared with usual care alone for adolescents who repeatedly harm themselves

Acronym
ASSIST

Study objectives
1. To test the effect of the addition of a manualised group therapy intervention to usual care when treating adolescent repeated self harm
2. To explore the costs and cost-effectiveness of usual care plus group therapy compared to usual care alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multi-centre Research Ethics Committee (MREC) approved in March 2002 (ref: 01-8-8)

Study design
Two arm single-blinded randomised allocation 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
Self-harm (deliberate overdoses, cutting, burning, banging head, ligatures)

Interventions
Intervention:
The experimental group therapy intervention is a manualised treatment specifically designed for adolescents who harmed themselves. The group treatment is based on cognitive behaviour and problem solving techniques. Techniques used in the group integrated empirically based conceptual approaches in common clinical practice within the NHS and advocated by several

opinion leaders in the field of deliberate self harm. Participants were asked to attend four group therapy sessions. After this, they can access the group for as long as they are open to CAMHS.

Comparator - Routine Care:
Clinical centres provide routine care that they would normally provide to these patients. Treatment as usual is undertaken by the local CAMHS Team using established protocols and clinical practice. Centres agree that routine care will not include any group intervention.

For both arms of the trial, treatment was given for as long as the Care Manager though it was clinically needed. Some participants were in treatment for over a year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Frequency and severity of episodes of self harm assessed using an adapted self harm interview schedule. Steps will be taken with the interview schedule to minimise a recall bias towards more recent events and to get a clear picture of the pattern of self harm over the previous year. The self harm interview will be conducted by research assessors (blinded to treatment allocation) and additionally (to allow for reporting bias from young people) clinicians involved with the young person will also undertake the same interview.

Secondary outcome measures
1. Time to first and second repetition, number of severe suicidal acts (defined by medical risk of death)
2. Depression measured using the Moods and Feelings Questionnaire (MFQ)
3. Suicidality measured using the Suicidale Ideation Questionnaire
4. Global outcome assessed by the health of the nation outcome scales for children and adolescents (HoNOSCA)
5. Psychosocial stress assessed using the Kiddie Schedule for Affective Disorders and Scizophrenia (K-SADS)
6. Cost benefit analysis measured using the Service Use Inventory

All the above administered at baseline, 6 and 12 months. At 3 months an assessment to measure emerging personality problems was undertaken (SCID II).

Overall study start date
01/08/2002

Completion date
01/06/2007

Eligibility

Key inclusion criteria

1. Aged 12 - 17 years, either sex
2. Referred to mental health services in Greater Manchester following self-harm
3. The adolescent reports that in the last year he or she has harmed themselves on at least one other occasion

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
156 cases in each group, we need to randomise 372 cases

Key exclusion criteria
1. The adolescent cannot attend groups (e.g., in secure care)
2. Has a psychotic or eating disorder
3. Unlikely to benefit from groups (e.g., learning problems)
4. Non-English speakers

Date of first enrolment
01/08/2002

Date of final enrolment
01/06/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Jean McFarlane Building
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
Oxford Road
Manchester
England
United Kingdom
M13 9PL
+44 (0)161 275 2000
david.walkden@manchester.ac.uk

Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
Mental Health Foundation (UK) - PPP Healthcare Trust (ref: 1727/1072)

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	01/04/2011		Yes	No