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SHIFT Trial - Family therapy vs treatment as usual for young people seen after second or subsequent episodes of self-harm

Submission date
26/01/2009

Recruitment status
No longer recruiting

Registration date
26/01/2009

Overall study status
Completed

Last Edited
28/04/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The main aim of this study is to assess the effectiveness of Family Therapy (FT) compared to Treatment as Usual (TAU) for adolescents aged 11-17 years who have engaged in at least one previous episode of self-harm, as measured by rates of repetition of self-harm leading to hospital attendance over an 18-month period.

Who can participate?
The study aimed to recruit 832 families (adolescents aged 11-17 years who have engaged in at least one previous episode of self-harm, and their parent/guardian) over a 3-year period from Child and Adolescent Mental Health Services (CAMHS) in Yorkshire, Greater Manchester and London.

What does the study involve?
Families who consented to participate in the trial were randomly allocated to either TAU (standard care offered by local CAHMS team) or FT (delivered by trial-specific Family Therapists). If allocated to FT, families were requested to attend about eight FT sessions over a 6-month period depending on individual requirements. All families were then followed-up at 3, 6, 12 and 18 months to complete questionnaires and assessments.

What are the possible benefits and risks of participating?
The trial team do not anticipate any addition risks in taking part in this trial. Although the trial team hope that families completing family therapy will find the treatment useful we can't say that this treatment will definitely help. The same would be true for families not taking part in the trial. The main benefit is that the research project will help us learn more about how to help people who have self-harmed in the future.

Where is the study run from?
The study is being led by a team of researchers at the University of Leeds, in collaboration with researchers at the University of Manchester and King's College London.

When is the study starting and how long is it expected to run for?
The first family was recruited to the trial in April 2010. The trial closed to recruitment in December 2013 (44 months), having recruited the full sample required for statistical analysis. The trial is now in the follow-up phase ahead of final analysis with trial results anticipated by early 2016.

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Chief Investigator - Professor David Cottrell, University of Leeds (d.j.cottrell@leeds.ac.uk)
Senior Trial Manager - Ms Liz Graham, University of Leeds (e.h.graham@leeds.ac.uk)

Contact information

Type(s)
Scientific

Contact name
Prof David Cottrell

Contact details
Level 8, Worsley Building
University of Leeds
Clarendon Way
Leeds
United Kingdom
LS2 9NL
-
d.j.cottrell@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 07/33/01

Study information

Scientific Title
SHIFT Trial. Self-Harm Intervention, Family Therapy: a randomised controlled trial of family therapy vs treatment as usual for young people seen after second or subsequent episodes of self-harm

Acronym

SHIFT

Study objectives
The primary objective is to assess the effectiveness of Family Therapy (FT) compared to Treatment as Usual (TAU) as measured by rates of repetition of self-harm leading to hospital attendance 18 months after randomisation.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/073301

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds (West) Research Ethics Committee, 23/04/2009, REC ref: 09/H1307/20

Study design
Randomised controlled multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Self-harm in adolescents

Interventions
Participants will be individually randomised to either FT or TAU arm.

FT: This will be delivered by qualified family therapists using a modified version of the Leeds Family Therapy & Research Centre Systemic Family Therapy Manual (LFTRC Manual). Adolescents and their families randomised to receive FT will receive up to 8 sessions of FT of approximately 1 h 15 min hours duration, delivered over 6 months at approximately monthly intervals but with more frequent initial appointments.

TAU: This treatment is likely to be diverse and may involve individual and/or family-orientated work, delivered by a range of practitioners with various theoretical orientations. The average duration of treatment in CAMHS is approximately 6 sessions.

Patients in both arms of the trial will be followed up for 18 months post-randomisation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Repetition of self-harm leading to hospital attendance within 18 months of randomisation. Admissions data will be collected from CAMHS notes and hospital records.

Secondary outcome measures
1. Repetition of self-harm leading to hospital attendance within 12 months of randomisation
2. The cost per self-harm event avoided due to FT, measured using a structured questionnaire designed for use in the trial
3. Characteristics of further episodes of self-harm (number of subsequent self-harm events, time to next event, severity of event [fatal, near fatal or not] and dangerousness of method used, as measured by the Suicide Attempt Self-Injury Interview
4. Suicidal ideation as measured by the Beck Scale for Suicide Ideation
5. Quality of life as measured by the Paediatric Quality of Life Enjoyment and Satisfaction measure, PQ-LES

Mediator and moderator variables which influence engagement with and benefit from treatment will also be measured.

Timepoints of assessment and other details are being finalised as of 28/01/2009.

Overall study start date
01/09/2009

Completion date
31/03/2016

Eligibility

Key inclusion criteria
1. Both males and females, aged 11-17 years (from date of 11th birthday to the day prior to 18th birthday)
2. Self-harmed prior to assessment by the Child and Adolescent Mental Health (CAMHS) team
3. Engaged in at least one previous episode of self-harm prior to current presentation by self-injury or self-poisoning (or both)
4. Assessed in hospital following current episode, or referred directly to CAMHS from primary care within a week of current episode (i.e. 7 days maximum from event to referral)
5. Assessed as requiring treatment
6. Lives with primary caregiver
7. Both child/adolescent and primary caregiver have sufficient proficiency in English to participate in therapy without an interpreter
8. Both child/adolescent and primary caregiver have given written informed consent

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
832

Total final enrolment
832

Key exclusion criteria
1. At serious risk of suicide
2. Severe major depressive disorder requiring psychiatric inpatient care
3. Undergoing a current child protection investigation
4. Would not ordinarily be treated in generic CAMHS but rather by a specific service (e.g., for teenage pregnancy, schizophrenia and other psychotic disorders, bipolar disorders, eating disorders [anorexia and bulimia nervosa], significant substance misuse where this is the primary diagnosis)
5. Has not been seen in CAMHS more than once in the last three months
6. In Local Authority or foster accommodation (often too transitory to allow FT)
7. Moderate to severe mental retardation or lacks capacity to comply with protocol
8. Involved in another research project - currently or within the last six months

Date of first enrolment
01/04/2010

Date of final enrolment
30/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Leeds
Leeds
United Kingdom
LS2 9NL

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Woodhouse Lane
Leeds
England
United Kingdom
LS2 9JT

Sponsor type
University/education

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

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/10/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. David Cottrell (d.j.cottrell@leeds.ac.uk). The data includes UK Government hospital attendance data over which there are very strict controls. Anyone wanting the data would need a data sharing agreement and possibly also approval from UK government NHS Digital.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/11/2015		Yes	No
Results article	results	01/03/2018		Yes	No
Results article	results	01/03/2018		Yes	No
Results article	results	10/01/2020	21/01/2020	Yes	No
Results article	results	01/04/2019	28/04/2020	Yes	No