

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

<b>Submission date</b> 26/01/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 26/01/2009	<b>Overall study status</b> Completed	
<b>Last Edited</b> 28/04/2020	<b>Condition category</b> Mental and Behavioural Disorders	

## 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 CAMHS 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 additional 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

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## 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

## 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?
<a href="#">Protocol article</a>	protocol	04/11/2015		Yes	No
<a href="#">Results article</a>	results	01/03/2018		Yes	No
<a href="#">Results article</a>	results	01/03/2018		Yes	No
<a href="#">Results article</a>	results	10/01/2020	21/01/2020	Yes	No
<a href="#">Results article</a>	results	01/04/2019	28/04/2020	Yes	No