ISRCTN04094806 https://doi.org/10.1186/ISRCTN04094806

The impact of systemic family therapy as an element of treatment for families following trauma

Submission date	Recruitment status	[ ] Prospectively registered
14/05/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/06/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/06/2017	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EAT/3196/05

Study information

Scientific Title
The impact of systemic family therapy as an element of treatment for families following trauma

Study objectives
A combination of systemic family therapy and trauma-focused cognitive behavioural therapy (CBT) will improve outcomes compared to trauma-focused CBT alone for families referred to a clinical service following trauma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland (ORECNI), 25/10/2006, ref: 06/nir02/106

Study design
Randomised single-blind trial

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
Trauma

Interventions
The families are randomly allocated to either of the following arms:
Arm 1: CBT and systemic family therapy
Arm 2: CBT only

The therapies are manualised and conducted by highly experienced mental health professionals including clinical psychologists, family therapists and CBT therapists. There are CBT and systemic consultants to the trial who review session checklists to ensure treatment fidelity. The family are invited to bring all who they deem relevant to the family therapy sessions. Family sessions last

up to 90 mins and occur on a three weekly cycle. Individual therapy lasts for up to 60 mins and occurs on a 2 - 3 week cycle. The total number of therapy sessions per participant is not fixed, and some sessions may be missed for other family priorities. The number of sessions attended is recorded for each participant and therefore the dose effect for individuals and families can be included in the analysis.

Intervention Type
Behavioural

Primary outcome measure
McMaster family assessment device. This tool has seven subscales as follows: problem solving, communication, roles, affective responses, affective involvement, behavioural control and general functioning. This assessment will be carried out at baseline and 6 months.

Secondary outcome measures
The following assessments will be carried out at baseline and 6 months:
1. Hospital anxiety and depression scale
2. Antonovsky's sense of coherence scale
3. Rosenberg self esteem scale

Overall study start date
15/02/2007

Completion date
31/08/2008

Eligibility

Key inclusion criteria
1. Those who live in the study area at time of referral
2. One or more members of the family have suffered a traumatic event that is the primary reason for referral to the family trauma centre
3. Both males and females are eligible to participate. Measures are completed by those aged 13 and older who attend the initial assessment session.

Family will be offered an initial assessment interview at the family trauma centre between February 2007 and August 2008.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
40 families

Key exclusion criteria
1. Not a trauma Case
2. Child sexual abuse case
3. Interpreter needed to facilitate therapy
4. Ongoing individual therapy with another service
5. New episode of treatment in an ongoing case
6. Very urgent response needed

Date of first enrolment
15/02/2007

Date of final enrolment
31/08/2008

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Institute of Child Care Research (ICCR)
Belfast
United Kingdom
BT7 1LP

Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

Sponsor details
Knockbracken Healthcare Park
Saintfield Road
Belfast
Northern Ireland
United Kingdom
BT8 8BH
+44 (0)2890 960000
info@belfasttrust.hscni.net

Sponsor type
Hospital/treatment centre

Website
http://www.belfasttrust.hscni.net

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
Department of Health, Social Services and Public Safety for Northern Ireland (UK) (ref: EAT/3196/05)

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