

Equilibrium: an intervention for young people who self-harm and attempt suicide

Submission date 18/02/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/03/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/08/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The UK has one of the highest rates of self-harm in Europe and suicide is the second most common cause of death for female adolescents aged 15-19 years old. It is estimated that 25% of young people self-harm on one occasion and that recurring self-harm is less common, with 9.5% of young people self-harming on more than four occasions. Self-harm increases the likelihood that the person will eventually die by suicide by between 50 and 120 fold above the rest of the population in a 12-month period. Researchers have found a wide range of psychiatric disorders associated with self-harm, such as borderline personality disorder, depression, bipolar disorder, schizophrenia, and drug and alcohol disorders. The aims of this study are as follows:

1. To capture the real-world transactions of therapist, client and family in the context of a treatment programme entitled Equilibrium
2. To develop an Equilibrium Manual for practitioners based upon the real-world transactions of therapist, client and family

Who can participate?

Young people aged 13–17 who have harmed themselves in the previous 2-4 weeks

What does the study involve?

The treatment model is a short-term intervention of 12 sessions with the first two sessions given over to therapeutically engaging and working with the young person and their family (parent /parents/caregivers) followed by nine individual sessions of psychotherapy. The final session is with the young person and their family bringing the treatment full circle with the purpose of sustaining psychological and systemic change. It is proposed that upon completion of the intervention, the treatment model will demonstrate a reduction in actual self-harm as reported by the young person and their family with a further reduction in those young people who commonly repeat self-harm either through self-injury or self-poisoning. Family sessions will last 60 minutes and individual sessions will last for 50 minutes.

What are the possible benefits and risks of participating?

The information collected will be used to tell the researchers more about self-harm and attempted suicide in young people. This will help provide better services and treatments for young people. There are no risks present, but with any psychological treatments there is always

the risk of feeling upset or distressed. Naturally, the researchers would ensure that participants are supported and looked after if this was the case. There are no medications offered as part of this treatment.

Where is the study run from?
Orchard House (UK)

When is the study starting and how long is it expected to run for?
May 2015 to March 2020

Who is funding the study?
United Kingdom Council for Psychotherapy (UKCP)

Who is the main contact?
Dr Terence Nice
T.A.Nice@kent.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Terence Nice

ORCID ID
<http://orcid.org/0000-0002-3081-4094>

Contact details
Orchard House
17 Church Street
Broadstairs
United Kingdom
CT10 2TT
+44 (0)300 300 1983
T.A.Nice@kent.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
173231

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 173231

Study information

Scientific Title

Equilibrium: an intervention for young people who self-harm and attempt suicide in the context of a child and adolescent mental health service

Study objectives

To capture the lived experiences of young people who self-harm and attempt suicide in the context of a treatment intervention - Equilibrium.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/05/2018, London - Bromley Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8057; nrescommittee.london-bromley@nhs.net), REC ref: 18/LO/0298

Study design

Mixed methods: thematic analysis & statistical analysis

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Self-harm and attempted suicide in young people

Interventions

The treatment model is a short-term intervention of 12 sessions with the first 2 sessions given over to therapeutically engaging and working with the young person and their family (parent /parents/caregivers) followed by 9 individual sessions of psychotherapy. The final session is with the young person and their family bringing the treatment full circle with the purpose of sustaining psychological and systemic change. It is proposed that upon completion of the intervention, the treatment model will demonstrate a reduction in actual self-harm as reported by the young person and their family with a further reduction in those young people who commonly repeat self-harm either through self-injury or self-poisoning. Family sessions will last 60 minutes and individual sessions will last for 50 minutes. The treatment model is based upon therapeutic principles, which have an evidence base in contemporary research and literature:

1. Therapeutic engagement of the young person and primary caregivers (Ougrin et al, 2009)
2. Continuity of care from point of entry to discharge (NICE guidelines, 2011)
3. A treatment model that responds to risk and need that encompasses the young person, their families and wider community ties
4. Young person participation in shaping the body of the research
5. The utilisation of a self-harm pathway that is ethical, age-appropriate, respectful, non-judgemental and that works for young people and their families
6. The importance of interior mind-sets and exterior systems and subsystems to provide a scaffold to the young person in their time of most need
7. A treatment model that effectively meets the needs of young people and reduces the risk of further self-harm or completed suicide.

Equilibrium has three major domains of engagement and treatment: (1) the young person; (2) the young person's family or current caregivers; (3) the major and minor interactive systems (family/school/peers/mates/associates) that affect the young person's perceptual, cognitive and behavioural patterns. The treatment model has its roots in psychodynamic, systemic and a psycho-educational approach to the phenomena of self-harm with the aim of reducing self-harm behaviours and attempts at suicide. It has an over-arching therapeutic aim of providing a scaffold around the young person as they negotiate the developmental and contemporary tasks of adolescence. Therapeutic focus is towards working through both unconscious and conscious problematic issues within the frame of an emerging sense of self, discontinuities or perturbations in primary relationships and the disequilibrium in primary and secondary systems. In very simple terms the aim of the treatment model is to:

1. Create the capacity to be attuned to one's own feeling states
2. To have an intimate and positive regard for one's body
3. To reduce self-harming behaviours and suicide attempts
4. To encourage affective regulation
5. To challenge negative perceptual frames
6. The ability to transform negative affects, cognitions and behaviours to positive affects, cognitions and behaviours
7. To develop a coherent and functional sense of self adapted to reality
8. To repair relational discontinuities in primary relational systems and units (parents/siblings /mates/peers/school friends)

Intervention Type

Behavioural

Primary outcome measure

1. Goal-Based Outcomes (GBOs) measured at every session (12 sessions)
2. Family functioning measured using SCORE 15 at sessions 1, 4, 8, 12

Secondary outcome measures

Live feedback collected from family at final session and set of feedback questions sent by post after completion of Equilibrium

Overall study start date

12/05/2015

Completion date

30/03/2020

Eligibility

Key inclusion criteria

1. Young people aged 13–17 who have a history of self-harm and attempted suicide
2. Those young people, their parents and caregivers who are able to give informed consent to treatment
3. Young people who are not suffering from a severe mental disorder or who are severely learning disabled
4. Young people, their families and caregivers who have a basic fluency in English

Participant type(s)

Patient

Age group

Child

Lower age limit

13 Years

Upper age limit

17 Years

Sex

Both

Target number of participants

6

Key exclusion criteria

1. Those young people who are undergoing in-patient treatment
2. Those young people who are unable to give informed consent or fully understand the requirements of the study
3. Those who have a cognitive impairment
4. Those young people who are not fluent in English

Date of first enrolment

01/09/2019

Date of final enrolment

03/03/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Orchard House
17 Church Street, St. Peters
Broadstairs
United Kingdom
CT10 2TT

Sponsor information

Organisation

North East London NHS Foundation Trust

Sponsor details

CEME, Marsh Way
Rainham
London
England
United Kingdom
RM13 8EU
+44 (0)300 555 1200 Ext: 64485
admin@nelft.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.nelft.nhs.uk/>

ROR

<https://ror.org/023e5m798>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

North East London NHS Foundation Trust

Funder Name

United Kingdom Council for Psychotherapy

Results and Publications

Publication and dissemination plan

Equilibrium as an intervention and research study has captured the support of the United Kingdom Council for Psychotherapy and once data analysis has been completed and the study written up, findings, conclusions and implications for practice will be disseminated through articles, conferences and workshops.

Intention to publish date

01/06/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as informed consent was not sought from participants to publish this data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	03/05/2018	01/04/2020	No	Yes
Protocol file		06/04/2018	01/04/2020	No	No
HRA research summary			28/06/2023	No	No