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Evaluating a relational approach to working with young people who self-harm

Submission date
31/07/2025

Recruitment status
Not yet recruiting

Registration date
01/08/2025

Overall study status
Ongoing

Last Edited
01/08/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Self-harm refers to when a person intentionally harms themselves, for example, by cutting themselves or taking an overdose. Self-harm can occur both with and without suicidal intent. Self-harm is prevalent amongst young people, and rates have increased in recent years. Self-harm in young people is a major health concern because it is associated with a greater risk of suicide and emotional distress. Evidence of which therapies are most helpful for young people who self-harm is limited. Some therapies currently used are also very intensive, can be difficult to access, and may not suit everyone. Cognitive Analytic Therapy (CAT) is a talking therapy that has the potential to help young people who self-harm. An 8-session form of CAT focusing on self-harm in adults has been previously developed and evaluated. That was adapted to work for young people. Before a large-scale clinical trial of CAT for self-harm in young people can be undertaken, it is helpful to conduct a smaller-scale feasibility trial. The aim of the current study is therefore to undertake a feasibility randomised controlled trial (RCT) of CAT for young people (aged 13-17 years) who self-harm. Data will be collected to help answer important feasibility uncertainties (e.g. is it possible to recruit an adequate sample).

Who can participate?
Young people aged 13-17 years with experiences of self-harm from NHS child and adolescent mental health services (CAMHS). Young people will need to have self-harmed at least twice, with one instance in the last year.

What does the study involve?
Participants will be randomly allocated to either receive their usual treatment or receive eight sessions of CAT plus their usual treatment. Participants will be invited to complete assessments at the study start, and at 8, 16 and 20 weeks after they have been randomly allocated to a group. Assessments will capture important clinical outcomes, and data will also be collected on recruitment and attendance rates.

What are the possible benefits and risks of participating?
It is unknown if CAT will be helpful for young people who self-harm. However, taking part may still feel like a positive experience as it is a way to improve the understanding of what treatments are best for young people who self-harm and so help others in the future. The study

would involve answering questions about potentially difficult topics like self-harm, which may be uncomfortable or distressing for some people. Likewise, taking part in therapy can be challenging at times. The research team and therapists will work with participants to reduce any risk of distress and ensure they feel supported. Participants do not need to answer anything they do not want to and can leave the study at any time.

Where is the study run from?
The Pennine Care NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
March 2025 to November 2027

Who is funding the study?
The National Institute for Health and Care Research (NIHR), Research for Patient Benefit (RfPB) programme, UK

Who is the main contact?
Dr Peter Taylor, Chief Investigator, peter.taylor-2@manchester.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Peter Taylor

ORCID ID
https://orcid.org/0000-0003-1407-0985

Contact details
Division of Psychology & Mental Health| Room 4.003, Booth Street East Building, The University of Manchester, Booth Street
Manchester
United Kingdom
M13 9SS
+44 161 275 2215
Peter.taylor-2@manchester.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
344320

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 62582, NIHR208568

Study information

Scientific Title
Relational approach to working with young people who self-harm (RELATE-YP): a feasibility study of cognitive analytic therapy for self-harm in young people

Acronym
RELATE-YP

Study objectives
As this is a feasibility trial, there are progression criteria rather than hypotheses. These are outlined below.

A traffic light system (Green = progress to definitive trial; Amber = modification needed; Red = do not progress) has been adopted to guide the decision to progress:

1. Recruitment rates: Data on the ability to randomise 60 participants within 12 months (5 participants per month). Green: ≥80%. Amber: 60-79%. Red: ≤59%.
2. Retention rate: Percentage of participants attending the 16-week assessment as the potential primary outcome timepoint. Green: ≥75%. Amber 60-74%. Red ≤59%.
3. Missing data on primary outcomes at 16-week assessment. Green: <15%. Amber: 16-25%. Red >25%.
4. Adherence to treatment: Percentage of participants receiving the minimum dose of therapy (>4 sessions) within the 16-week treatment window. Green: ≥75%. Amber: 60-74%. Red: ≤59%.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 21/07/2025, Greater Manchester Central (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048023; gmcentral.rec@hra.nhs.uk), ref: 25/NW/0230

Study design
Feasibility randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cognitive analytic therapy for self-harm in young people

Interventions
The project involves a single therapeutic intervention
The study is a feasibility trial where participants will be randomised using a block design (with

random blocks of 4 or 6), stratified by Trust (SealedEnvelope.com), to either Treatment as Usual (TAU) or TAU plus Cognitive Analytic Therapy (CAT). Researchers will assess clinical outcomes, including self-harm, at baseline and after 8, 16 and 20 weeks from when participants are allocated to a group. Qualitative interviews will be conducted to understand what people thought of the trial and intervention.

CAT will be delivered over eight 60-minute sessions, following a standard 8-session protocol, with a focus on self-harm. Therapy will be delivered by a qualified band 7 or 8 practitioner with appropriate core professional training (e.g., clinical psychologist), who is either qualified in CAT or has completed the first year of CAT practitioner training (or equivalent). Therapists will be supervised by an accredited CAT therapist on a fortnightly basis. A follow-up session will take place up to 8 weeks after the end of therapy. Sessions could be undertaken either in person or remotely via a video call.

Intervention Type
Behavioural

Primary outcome(s)
The following primary outcome measures were assessed using patient records:
1. Recruitment rates will be recorded across the 12-month recruitment period
2. Participant retention rate (completion of end-of-treatment follow-up assessments) will be recorded over 20 weeks (the length of time in the study)
3. Participant missing data on the proposed primary clinical outcomes (self-harm behaviour and urges) at assessment will be recorded over 20 weeks (the length of time in the study)
4. Adherence to treatment will be recorded as the percentage of participants receiving the minimum dose of therapy (≥4 sessions) within the 16-week treatment window

Key secondary outcome(s))
The following secondary outcome measures were assessed at the baseline, 8, 16 and 20 week assessments, unless otherwise stated:
1. Self-harm behaviour frequency measured using the Self-Injurious Thoughts and Behaviours Interview-Short Form (SITBI)
2. Urges to self-harm over the past week measured using the Alexian Brothers Urges to Self-Injure Scale (ABUSI)
3. Perceived recovery from mental health difficulties over the past week measured using the Recovery Questionnaire (ReQuestYP)
4. Positive beliefs and perceived dependency on self-harm measured using the Experiences of Self-Injury Questionnaire – Positive Beliefs subscale (ESIQ)
5. Depressive symptoms over the past two weeks measured using the Patient Health Questionnaire – 9 for adolescents (PHQ9A)
6. Difficulties in young people, including internalizing, externalizing and peer problems, measured using the Strengths and Difficulties Questionnaire self-report version (SDQ)
7. Potential adverse experiences that might arise from participation in a psychotherapy trial measured using the Adverse Experiences in Psychotherapy questionnaire (AEP) at 16 weeks only

Completion date
30/11/2027

Eligibility

Key inclusion criteria

1. Aged 13 – 17 years
2. Engaged in self-harm two or more times in their lifetime, with at least one episode in the past year. This will be confirmed via the Self-Injurious Thoughts and Behaviours Interview Short Form (SITBI)
3. Can be safely seen in an outpatient clinical context in which treatment is being provided, as judged by their clinical team or referrer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 years

Upper age limit
17 years

Sex
All

Key exclusion criteria
1. Moderate-to-severe intellectual disability (IQ:< 70) affecting their eligibility for community mental health services as judged by their clinical team
2. Organic cerebral disease/injury affecting receptive and expressive language comprehension as judged by their clinical team
3. Currently an inpatient
4. Currently experiencing an active episode of mania or psychosis. The MINI International Neuropsychiatric Interview for children and adolescents (MINI-KID) will be used at baseline to screen for the presence of current mania or psychosis
5. Judged at imminent risk of harm to themselves, operationalised as the presence of intent or planning to end their lives within the near future (e.g. next two weeks). In such cases, individuals could still participate once the level of risk has declined
6. Currently receiving another active one-to-one psychological therapy. This would include structured psychological therapies such as CBT or DBT. Other forms of support, like a support group or skills group, seeing a clinician for informal support or medication advice, or engaging with self-help materials, will not exclude people.

Date of first enrolment
01/02/2026

Date of final enrolment
01/08/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Pennine Care NHS Trust
225 Old Street
Ashton-under-lyne
United Kingdom
OL6 7SR

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
Rotherham Doncaster and South Humber NHS Foundation Trust
Woodfield House
Tickhill Road
Doncaster
United Kingdom
DN4 8QN

Sponsor information

Organisation
Pennine Care NHS Foundation Trust

ROR
https://ror.org/03t59pc95

Funder(s)

Funder type

Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a data repository. The choice of repository is to be determined. The team will determine whether a public or non-publicly available repository is most appropriate, drawing on discussions with the steering committee and advisory group. Data will be made available after the publication of the main trial results. Only quantitative data will be made available for sharing due to the greater risk of patient identification with qualitative data, even when it is anonymised. Participants will be asked for their consent for data to be shared with other researchers.

IPD sharing plan summary
Stored in publicly available repository, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes