ISRCTN75661422 https://doi.org/10.1186/ISRCTN75661422

Can a brief relational talking therapy help adults who self-harm?

Submission date
18/10/2022

Recruitment status
No longer recruiting

Registration date
21/10/2022

Overall study status
Completed

Last Edited
11/12/2024

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
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. Research suggests that in the UK rates of self-harm have increased. It is a major health concern because self-harm is associated with a greater risk of suicide and emotional distress. Evidence of which therapies are most helpful for people who self-harm is limited. Some therapies that are currently used are also very intensive (e.g. Dialectical Behaviour Therapy), can be difficult to access, and do not suit everybody. Cognitive Analytic Therapy (CAT) is a talking therapy that has the potential to help people who self-harm. It may provide a helpful alternative for people struggling with self-harm that may not be eligible for or able to access other therapies. Before a large-scale clinical trial of CAT for self-harm 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 study of CAT for adults who self-harm. Data will be collected to help answer important feasibility uncertainties (e.g. can we recruit an adequate sample).

Who can participate?
Adults with experiences of self-harm from NHS mental health services, including IAPT (Improving Access to Psychological Therapy) services and other community-based mental health services

What does the study involve?
Participants will first be asked to complete a baseline assessment with a researcher, answering questions about their thoughts, feelings, and recent difficulties. Participants will then be randomly put into one of two groups. One group will receive the therapy, CAT, plus the usual treatment. The other group will just have access to their usual treatment. There will be further meetings with the researcher to do more assessments at 12 and 18 weeks after being put into the group. Some participants will also be invited to take part in a more in-depth interview or complete additional questionnaires online, but these parts of the study are optional. We are hoping to recruit 60 people to take part overall.

What are the possible benefits and risks of participating?
We do not yet know how helpful CAT will be for people who self-harm, which is why we are

doing this research. Taking part in research can be an interesting and rewarding experience though. Taking part in this study will help us better understand which treatments might help people who self-harm. Taking part may therefore feel like a positive experience for some people and a way to help others. The study will involve being asked questions about difficult experiences like self-harm, and this may be uncomfortable to distressing for some people. Participants will not have to answer any questions they do not wish to and will be able to leave the study at any time. The researchers will be trained to respond to distress and will be able to offer breaks during meetings and provide advice on further sources of support.

Where is the study run from?
The lead site is the study is Greater Manchester Mental Health and Social Care NHS Foundation Trust. The second site is at Rotherham, Doncaster, and South Humber NHS Foundation Trust

When is the study starting and how long is it expected to run for?
December 2022 to December 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Peter Taylor (Project lead), peter.taylor-2@manchester.ac.uk
Dr Stephen Kellett, Stephen.kellett@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Peter Taylor

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

Contact details
University of Manchester
Division of Psychology & Mental Health
Zochonis building
Room 2.28
Brunswick Park
Manchester
United Kingdom
M13 9PL
+44 (0)1613060425
Peter.taylor-2@manchester.ac.uk

Type(s)
Scientific

Contact name
Dr Stephen Kellett

Contact details
Grounded Research
2 St Catherine's Close
Tickhill Road Hospital site
Balby
Doncaster
United Kingdom
DN4 8QN
-
Stephen.kellett@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
318068

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 54183, IRAS 318068

Study information

Scientific Title
Relational Approach to Treating Self-Harm (RelATe): a feasibility study of cognitive analytic therapy for people who self-harm

Acronym
RelATe

Study objectives
As this is a feasibility trial we have 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 (completion of end-of-treatment follow-up assessments). Green: ≥80%. Amber 60-79%. Red ≤59%.
3. Missing data on primary outcomes at assessment. Green: <15%. Amber: 16-25%. Red >25%.
4. Adherence to treatment: Percentage of participants receiving the minimum dose of therapy (≥4 sessions) within a 10-week treatment window. Green: ≥80%. Amber: 60-79%. Red: ≤59%.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 07/11/2022, Greater Manchester West Research Ethics Committee (Barlow House, 3rd Floor, HRA NRES Centre Manchester, M1 3DZ, UK; +44 (0)207 104 8379; gmwest.rec@hra.nhs.uk), ref: 22/NW/0317

Study design
Randomized interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Mental health

Interventions
Cognitive Analytic Therapy (CAT) will be delivered by a qualified band 7 or 8 practitioner with appropriate core professional training (e.g., clinical psychologist) who has undertaken additional training in CAT (completing at least the first year of post-qualification CAT practitioner training). Therapists will be supervised by an accredited CAT therapist on a fortnightly basis. The therapy will follow a standard eight-session CAT model, with a specific focus on self-harm as the presenting problem. Sessions 1-3 would typically focus on developing a shared understanding of difficulties and identifying unhelpful patterns that maintain problems, using visual (drawn) mapping of experiences and therapeutic letters to assist in this process. Sessions 4-8 would typically focus on the recognition of unhelpful patterns identified so far, and the use of alternative, more helpful ways of responding to experiences and challenges, referred to as “exits”. A further follow-up session will take place up to 8 weeks after the end of therapy, based on recommendations from Patient and Public Involvement (PPI) meetings. Therapy sessions will last 50 to 60 minutes and typically occur weekly. Based on recommendations from PPI contributors, sessions could be undertaken either in person or remotely via a video call.

Intervention Type
Other

Primary outcome measure
Measured 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 18 weeks (the length of time in the study)
3. Participant missing data on the primary outcomes (self-harm behaviour and urges) at assessment will be recorded over 18 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 10-week treatment window.

Secondary outcome measures
1. Self-harm measured with the Self-Injurious Thoughts and Behaviours Interview-Short Form (SITBI) at baseline, 12 weeks, and 18 weeks
2. Self-harm urges measured with the Alexian Brothers Urges to Self-Injure Scale (ABUSI) at baseline, 12 weeks, and 18 weeks
3. Dependence on self-ham measured with the experiences of Self-Injury Questionnaire Positive Beliefs subscale at baseline, 12 weeks, and 18 weeks
4. Personality structure measured with the Personality Structure Questionnaire at baseline, 12 weeks, and 18 weeks
5. Emotional distress measured with the Kessler Distress Scale at baseline, 12 weeks, and 18 weeks
6. Interpersonal problems measured with the Inventory of Interpersonal Problems-32 at baseline, 12 weeks, and18 weeks
7. Health status measured with the EQ-5D-5L at baseline, 12 weeks, and 18 weeks
8. Adverse experiences from therapy measured with the Adverse Experiences in Psychotherapy scale (AEP) at12 weeks

Overall study start date
12/12/2022

Completion date
11/12/2024

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Three or more episodes of self-harm in the past year, confirmed via the Self-Injurious Thoughts and Behaviours Interview
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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
60

Key exclusion criteria
1. Participants will be excluded if they have a moderate-to-severe intellectual disability (IQ:< 70) affecting their eligibility for community mental health services as judged by their clinical team or referrer
2. Organic cerebral disease/injury affecting receptive and expressive language comprehension as judged by their clinical team
3. Non-English speaking to the degree that the participant is unable to answer questions and give written informed consent
4. Imminent and immediate risk to self or others, operationalised as the presence of active suicidal intent or planning to end one's life in the near future (e.g. next week). Where individuals are excluded on this basis, with the person’s consent, the researcher will aim to recontact them and the referrer in approximately one month’s time (or a time period agreed upon in collaboration with the individual) to determine if the risk has subsided to a point where they are now eligible.
5. Currently an inpatient
6. Experiencing a current, active episode of psychosis or mania
7. Currently receiving another active one-to-one psychological therapy

Date of first enrolment
13/02/2023

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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
Greater Manchester Mental Health NHS Foundation Trust

Sponsor details
C/o: Sarah Leo
R & I Office
Rawnsley building
Manchester
England
United Kingdom
M13 9WL
+44 (0)161 271 0084
researchoffice@gmmh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.gmmh.nhs.uk//

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research Central Commissioning Facility (CCF); Grant Codes: NIHR203515

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

Publication and dissemination plan
Project results will be made available to academics and clinicians, through presentations at internationally recognised conferences and at local suicide and self-harm-related conferences and events. The project will result in a series of papers in well-regarded peer-reviewed journals. A press release will be issued concerning the main trial results, to facilitate engagement with the media. We intend to submit the main trial paper for publication by March 2025.

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. The decision on which repository to use has not yet been made but will be reviewed as the trial progresses. Qualitative data will not be shared due to the greater challenges in fully anonymising such data. Data will be made available to other researchers to access once the main trial results have been published. Participants will be informed that data may be shared in this way.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		18/07/2024	19/07/2024	Yes	No
Other unpublished results		11/12/2024	11/12/2024	No	No