ISRCTN73357210 https://doi.org/10.1186/ISRCTN73357210

# FReSH START – Looking at new approaches for people who self-harm

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 19/07/2021 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 03/08/2021 | Ongoing | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 20/01/2026 | Mental and Behavioural Disorders | [X] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Self-harm is a major public health challenge with an estimated lifetime prevalence of 5-6% and 220,000 hospital attendances annually in England and Wales. Repetition of self-harm is common with 70% of hospital attenders reporting previous episodes of self-harm. An intervention that improves the quality of life of people who repeatedly self-harm and that could be delivered without the need for expensive specialist services would be of potential benefit to many who attend hospital each year.
We know from working with people who have experience of self-harm that a therapeutic approach that works with service users to identify valued (positive) goals is a more acceptable approach than therapies focused on the reduction of the act itself. Our approach involves modifying three existing therapies specifically for use with people who self-harm.
This study is a large scale definitive individually randomised controlled trial of the therapies, recruiting 630 participants across 12 NHS sites.

Who can participate?
Adults over 18 years, who have had several episodes of self-harm behaviour in the past 12 months.

What does the study involve?
If a participant agrees to take part they will need to do the following:
-Meet a researcher who will ask them about their health and their self-harm. They will also be asked to complete 4 questionnaires about their well-being, and 1 about money they may have spent related to self-harm.
-If they are allocated to the intervention group: attend up to 12 sessions of therapy with a trained therapist over a maximum of 6 months. These sessions will each take about 45 minutes. The sessions will either take place at their local NHS Trust premises or via phone or video call.
-If they are allocated to the standard care group: they will receive the care that your Trust normally provides to people who self-harm.
-Respond to monthly secure text messages to let us know how they are doing, and whether they have self-harmed in the last month.
-Complete the same set of questionnaires they filled out at the start of the study, online (or if this is not possible by post) after 6 and 12 months. We will send them a text message or email to

let them know when and how to complete the questionnaire.
-Complete a much shorter questionnaire at 3 and 9 months, when we will ask them about hospital attendances, appointments and contact with other services.
-The researcher may invite them to take part in an optional interview after 12 months so that they can tell us about the therapy they received.

What are the possible benefits and risks of participating?
• If they are randomised to the intervention group and attend the therapy sessions, we hope that these might help them but we cannot say that the participants will definitely feel better.
• Whichever group a participant is in, even if there is no direct benefit to them, they will be helping us to learn more about how to support people who self-harm.
• Completing the questionnaires will take a little of the participant's time. We will adhere to all government and NHS guidance with regard to COVID-19. We do not expect there to be any risks in taking part, although some of these questionnaires ask about how they are feeling and may upset some people. The researcher will provide the participants with details of organisations that they can contact if the research upsets them in any way.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
January 2021 to January 2026

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

Who is the main contact?
Senior Trial Manager, freshstart@leeds.ac.uk
Professor Else Guthrie, e.a.guthrie@leeds.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr - Trial Manager

### Contact details
Clinical Trials Research Unit
University of Leeds
Leeds
United Kingdom
LS2 9JT
-
freshstart@leeds.ac.uk

### Type(s)
Scientific

### Contact name

Prof Else Guthrie

**ORCID ID**
https://orcid.org/0000-0002-5834-6616

**Contact details**
Leeds Institute of Health Sciences
University of Leeds
Leeds
United Kingdom
LS2 9JT
+44 (0)1133432442
e.a.guthrie@leeds.ac.uk

# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**Integrated Research Application System (IRAS)**
297939

**ClinicalTrials.gov (NCT)**
Nil known

**Grant Code**
RP-PG-1016-20005

**Central Portfolio Management System (CPMS)**
49617

# Study information

**Scientific Title**
Function REplacement in repeated Self-Harm: Standardising Therapeutic Assessment and the Related Therapy (WP4 - Randomised Controlled Trial)

**Acronym**
FReSH START RCT

**Study objectives**
12 sessions of one to one psychological treatment plus standard care in comparison with standard care alone for people attending the emergency department with a history of multiple self-harm will produce a greater improvement in psychological distress and quality of life as determined by the CORE-OM at 12 months post randomisation.

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**

Approved 14/07/2021, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8265; cambsandherts.rec@hra.nhs.uk), ref: 21/EE/0145

## Study design
Interventional randomized controlled trial with embedded qualitative study

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Self harm

## Interventions
The FReSH START RCT is a 1:1 randomised controlled trial of standard care plus referral to intervention (one of three adapted therapies) vs standard care alone. It will take place across 12 sites with the aim to recruit 630 participants aged 18 years or older and reporting a self-harm episode in the preceding three months that is at least their 3rd episode in the preceding 12 months and their lifetime 4th.
To ensure that our intervention is compatible with NHS practice we will recruit through mechanisms which mirror NHS pathways. Thus we will recruit participants who present to health services by presenting at hospital Emergency Departments (ED) and are seen by liaison mental health teams.

Following consent to researcher contact (C2C) the local researcher will contact the potential participant to further discuss the study. If the potential participant is interested the baseline visit will take place (this can be via phone) where eligibility is confirmed and full consent is taken. The participant is then registered. Following registration the baseline assessment will take place which includes both researcher administered and self-completed participant questionnaires. These consist of 4 validated questionnaires and 2 non-validated questionnaires which will be submitted for approval. The self-completed questionnaires will be sent to the participant via an online link (paper completion is possible if preferred). Following the baseline assessments the participant is randomised.

Standard care plus intervention arm:
If randomised to standard care plus intervention, the participant will be allocated to a trained therapist within their site to receive one of the possible psychological therapies available for delivery within the research site:
• Cognitive Behaviour Therapy (CBT),
• Psychodynamic Interpersonal Therapy (PIT),
• Acceptance and Commitment Therapy (ACT).
Within each research site at least two of the three therapies should be available for delivery, and it is anticipated that at least two therapists per therapy per site will be trained.

Where possible, participants randomised to intervention will be randomly allocated to the therapist delivering their treatment. Randomisation to the primary therapist will be stratified by

centre and include all available therapists at the corresponding sites.
Participants will be offered 12 weekly sessions delivered over maximum of 6 months, with the opportunity for 1-2 booster telephone contacts in months 6/7, if required.

Standard care arm:
Treatment that is compliant with NICE guidelines for the assessment and treatment of individuals referred to liaison mental health services because of self-harm. This consists of an integrated and comprehensive therapeutic psychosocial assessment from a mental health practitioner of the person's needs and risks, followed by appropriate signposting or referral to relevant services. All potential participants must have undergone such an assessment, before they are eligible to take part in the study. The assessor i.e. the member of the liaison mental health team who conducts the assessment in the ED, will confirm that such an assessment has taken place, when making a referral to the study.

Participants in both study arms will be followed up for 12 months from randomisation. Patient reported outcome data will be collected at 3, 6, 9 and 12 months post randomisation via on-line administration (or telephone if appropriate) and via monthly text alerts for self-reported self-harm episodes. Repetition of self-harm will also be collected using routine data, supported if required by by local researcher data collection directly from hospital electronic records during the follow up phase.
Details on participant intervention provision and adherence will be recorded.

The intervention will be delivered by health professionals (mental health nurses, psychologists, occupational therapists, psychiatrists, counsellors) who have either prior experience of working with people who self-harm and managing risk, or who are already trained in one of the three therapies. Some prior experience of delivering any form of recognised therapy is desirable but not essential. Good interpersonal skills are essential as judged by being able to form strong working alliances with clients/users.

Potential therapists will be identified at each site following discussion with the relevant service managers. All therapists will have a recognised mental health professional background (e.g. nursing, occupational therapy, clinical psychology, psychiatry, CBT therapist, counsellor).

We aim to recruit as many therapists for each type of therapy as is feasible at each site, in order to build in resilience against staff turnover and sickness, with two of the three therapies made available at each site, and at least 3 therapists per site trained in each of the two therapies.

All therapists will undergo therapy specific group-training according to the type of therapy they will deliver in the study. Training will be delivered by the co-investigator therapy leads, either face to face in a 3-day workshop or during equivalent live on-line sessions. Additional on-line materials will be provided as necessary. Therapist level data will be collected, including demographics (age, gender, ethnicity), experience and competencies, training, and ongoing supervision attendance.

Fidelity to each of the interventions will be measured, including fidelity to the self-harm adapted approach, and to each of the three psychological therapies (CBT, PIT and ACT). Inclusion of the key ingredients of the self-harm adaptation will be further recorded for the initial assessment session(s) of each therapy.Fidelity assessments will be made via therapist reported checklist for all sessions and through researcher rated assessment of audio recordings (all sessions are audio recorded).

An embedded qualitative interview study will explore the experiences of participants involved in the study and receiving the intervention, as well as the experiences of the therapists and other key stakeholders, to explore key implementation issues from a service perspective. Patient participants will be asked at time of enrolment to the trial if they are willing to be approached to take part in the qualitative study. A sample of participants who consent (n=30) will be approached to take part in this study. Consent can be taken over the telephone and the researcher will sign on behalf of the participant. Consenting participants will be interviewed at the end of therapy and the interviews will be audio recorded and transcribed.
A sample of therapist (20 to 30) will be invited to be interviewed towards the end of the study (when they have finished delivering the intervention)as well as a number of service managers. They will be given participant information and will be asked for their consent. Consent can be taken over the telephone and the researcher will sign on behalf of the participant. Interviews will be audio recorded and transcribed.
During transcription, any potentially identifying information that may be contained in the interview discussions will be removed. Only the research team and the transcriber will listen to the interview audio files. Audio files will be securely transferred in encrypted format, and securely stored at the University of Leeds accessible to only those members of the study team requiring such access.

## Intervention Type
Behavioural

## Primary outcome(s)
Global distress measured using CORE-OM at 12 months from randomisation

## Key secondary outcome(s))
1. Global distress measured using CORE-OM clinical score at 6 and 12 months
2. Time to repetition of self-harm leading to hospital attendance at a minimum of 12 months (HES data supplemented by clinical record check).
3. Response to “In the past four weeks, on how many occasions have you harmed yourself” asked via monthly text message and at 6 and 12 months
4. Hopelessness measured using the Beck Hopelessness Scale total score at 6 and 12 months
5. Depression measured using PHQ-9 total score at 6 and 12 months
6. The degree to which youth feel connected to others in their social environment measured using Social Connectedness Scale-Revised at 6 and 12 months
7. Cost-effectiveness outcome measures:
7.1. Cost of health care resource use including primary, community, and social care, emergency, admitted and outpatient hospital care, cost of prescribed psychotropic medications at 6 and 12 months.
7.2. Using utility as measured by the preference based measure CORE 6D generated from CORE-OM at 6 and 12 months
7.3. Incremental cost-effectiveness ratio expressed in terms of incremental cost per quality adjusted life year (QALY) at 6 and 12 months, and at 5 years (using decision analytic modelling).
8. Internal pilot outcome measure: Recruitment and follow-up rates at 9 months
9. Process Evaluation outcome measures:
9.1. Proportion of participants attending therapy, completing the required number of therapy sessions, number of early drop-outs from treatment, reasons for early drop outs, overall and by therapy type (CBT, ACT, PIT)
9.2. Fidelity to the safety and FReSH START components measured by therapist-reported session checklist

9.3. Fidelity to the safety and FReSH START components measured by researcher (from audio recordings of therapy sessions)
9.4. Researcher-rated fidelity to therapy-specific intervention components (from audio-recordings of therapy sessions)

### Completion date
30/04/2026

## Eligibility

### Key inclusion criteria
1. Aged 18 years or over
2. Registered with a GP in the catchment area of the mental health trust for the duration of the therapy
3. Presenting at ED as a consequence of self-harm, defined as: intentional acts that directly harm a person's own body. This includes methods like cutting, burning, scratching, banging or hitting parts of the body, or interfering with wound healing and it also includes self-poisoning, such as taking overdoses of drugs
4. Self-harm episode in the preceding three months that is at least their 3rd episode in the preceding 12 months and their lifetime 4th or more episodes
5. Has mental capacity to provide fully informed written consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
100 years

### Sex
All

### Total final enrolment
337

### Key exclusion criteria
1. Receiving, or having been referred to (and likely to receive this within the next 6 months), a specific psychological intervention that is similar to the trial intervention, or where a specific intervention is indicated for a related condition (e.g. anorexia nervosa or drug addiction) and would conflict with trial participation.
2. Taken part in the FReSH START Feasibility study
3. Assessed by clinician to currently be unsuitable for therapy (e.g. in crisis; actively suicidal,

unable to tolerate therapy - i.e. past talking treatments have resulted in severe deterioration of mental state, has a diagnosis of schizophrenia, autism, or other form of severe mental illness that would be a contraindication for the talking treatments in this study - n.b. people with schizophrenia are offered CBT but it is tailored specifically to help with psychotic experiences. The CBT in this study is not specifically tailored for the needs of people with schizophrenia)
4. Lacking capacity to comply with study requirements
5. Insufficient proficiency in English to contribute to the data collection
6. Known risk of violence (for example reported by ED or liaison psychiatry staff)
7. Researcher unable to contact potential participant within 6 weeks following self-harm event

### Date of first enrolment
25/10/2021

### Date of final enrolment
31/01/2025

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Leeds and York Partnership NHS Foundation Trust**
2150 Century Way
Thorpe Park
Leeds
England
LS15 8ZB

### Study participating centre
**Greater Manchester Mental Health NHS Foundation Trust**
Prestwich Hospital
Bury New Road
Prestwich
Manchester
England
M25 3BL

### Study participating centre
**Pennine Care NHS Foundation Trust**
225 Old Street

Ashton-under-Lyne
England
OL6 7SR

**Study participating centre**
**Sheffield Health & Social Care NHS Foundation Trust**
Fulwood House
Old Fulwood Road
Sheffield
England
S10 3TH

**Study participating centre**
**Kent and Medway NHS and Social Care Partnership Trust**
Farm Villa
Hermitage Lane
Maidstone
England
ME16 9PH

**Study participating centre**
**Lancashire & South Cumbria NHS Foundation Trust Hq**
Sceptre Point
Sceptre Way
Bamber Bridge
Preston
England
PR5 6AW

**Study participating centre**
**Tees, Esk and Wear Valleys NHS Foundation Trust**
Trust Headquarters
West Park Hospital
Edward Pease Way
Darlington
England
DL2 2TS

**Study participating centre**
**Cambridgeshire and Peterborough NHS Foundation Trust**
Elizabeth House,

Fulbourn Hospital
Fulbourn
Cambridge
England
CB21 5EF

**Study participating centre**
**Gloucestershire Health and Care NHS Foundation Trust**
Edward Jenner Court
1010 Pioneer Avenue
Gloucester Business Park
Gloucester
England
GL3 4AW

# Sponsor information

**Organisation**
University of Leeds

**ROR**
https://ror.org/024mrxd33

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Central Commissioning Facility (CCF)

**Funder Name**
National Institute for Health Research (NIHR) (UK)

**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
Current Individual participant data (IPD) sharing statement as of 27/06/2022:

De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security), and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing, and believe it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree suitable requirements for release.

Previous Individual participant data (IPD) sharing statement:

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (CTRU-DataAccess@leeds.ac.uk). Data will be shared according to a controlled-access approach. Data will only be shared for participants who have given consent to use their data for secondary research. Requests will be reviewed by relevant stakeholders. No data will be released before an appropriate agreement is in place setting out the conditions of release.

### IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 26/08/2024 | 02/09/2024 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |