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FReSH START feasibility study

Submission date
09/12/2019

Recruitment status
No longer recruiting

Registration date
20/12/2019

Overall study status
Completed

Last Edited
19/05/2025

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 is a major public health challenge with an estimated lifetime prevalence of 5-6% and some 220,000 hospital attendances annually in England and Wales. Repetition of self-harm is common with 70% of hospital attenders reporting previous episodes. 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 of those who attend hospital each year. A recent Cochrane review showed little evidence for the benefit of existing therapies for the problem of repeated self-harm. Therapies are intensive, of long duration, and require specialist therapists; there is no published evidence of cost-effectiveness. The latest Cochrane review, NICE guidelines and expert commentaries all point to the need for new research to test the effectiveness of interventions in this population. Despite the importance of reducing repetition, it is known 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 reduction of the act itself. The researchers' approach involves modifying three existing therapies specifically for use with people who self-harm. They have selected therapies that can be easily adapted to deliver a new therapeutic approach for self-harm, have an evidence-base, and are accessible to the large numbers of people who repeatedly self-harm and are seen in mainstream NHS practice. Where the therapy is not already available in certain centres, each can easily be taught and learned by mental health professionals. This feasibility study with 30 participants forms part of a National Institute for Health Research (NIHR) funded research programme. Assuming the feasibility study is successful and the therapy acceptable to participants, the next phase will be a large scale randomized controlled trial.

Who can participate?
Adults aged 18 or over 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

What does the study involve?
Participants are randomly allocated to one of the three psychological therapies modified specifically for use with people who multiply self-harm: Behavioural Therapy/Cognitive Behaviour Therapy (BT/CBT), Psychodynamic Interpersonal Therapy (PIT), and Acceptance and Commitment Therapy (ACT). The intervention is delivered by a therapist trained in the psychological therapy for the feasibility trial. Participants are offered 12 face-to-face 45-minute

therapy sessions with the option of up to two telephone booster sessions if required. The therapy takes place on the participant's local NHS Trust's premises. Sessions are recorded for purposes of clinical supervision and to ensure the intervention is delivered as intended. Recordings are encrypted and transferred securely. Any transcriptions are made by persons authorized by the University of Leeds. Within each research site it is anticipated that at least two of the three psychological therapies will be available, and at least two therapists will be trained and recruited for each therapy. Participants are followed-up for 6 months from registration. Patient reported outcome data are collected after 6 months by post (or telephone if appropriate) and by monthly text alerts for self-reported self-harm episodes. Repetition of self-harm is also collected directly from hospital electronic records by the researcher during the follow-up phase. Details on participant intervention provision and adherence are recorded. Therapist level data is collected, including demographics, experience and competencies, training, and ongoing supervision attendance. Fidelity to each of the intervention is measured, including fidelity to the self-harm adapted approach, and to each of the three psychological therapies (BT/CBT, IPT and ACT). Inclusion of the key ingredients of the self-harm adaptation is further recorded for the first assessment session of each therapy. A sample of therapists and participants are also approached to take part in interviews to explore acceptability of the therapy, and to refine the intervention and logic model ahead of the definitive multi-centre RCT. Participants are asked at time of enrolment to the feasibility study if they are willing to be approached to take part in this study. A sample of participants who consent is then approached by a study researcher to take part in this study. Separate written informed consent is given. Interviews are performed face to face on NHS Trust property, or via the telephone.

What are the possible benefits and risks of participating?
It is hoped that participants will benefit from the therapy sessions, although this cannot be guaranteed. As usual care in most NHS Trusts offers very little therapy, or only after a considerable waiting time, it is expected that participants may find participation beneficial. However, as the modified therapy is unproven, the main benefits should be stated to be helping the researchers learn more about how to help people who self-harm, and helping the researchers to find out if they can run a larger study, to find whether a new approach to therapy is an effective approach for people following self-harm.

Where is the study run from?
1. Pennine Care NHS Foundation Trust (UK)
2. Leeds And York Partnership NHS Foundation Trust (UK)
3. Humber Teaching NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2019 to September 2025

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

Who is the main contact?
1. Aaron Dowse, FReSHSTART@leeds.ac.uk
2. Prof. Else Guthrie, e.a.guthrie@leeds.ac.uk

Contact information

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Public

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
269176

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 44039, IRAS 269176

Study information

Scientific Title
Function REplacement in repeated Self-Harm: Standardising Therapeutic Assessment and the Related Therapy - WP3 - Feasibility

Acronym
FReSH START Feasibility Study

Study objectives
The aim of the study is to assess the feasibility and acceptability to both patients and therapists, of running a larger definitive randomised controlled clinical trial (RCT) using modified therapies for people who self-harm. The objectives, therefore, relate to the feasibility of implementing a full-scale RCT and can be divided into the following points:

Intervention delivery and acceptability:
1. Measure intervention delivery (number of sessions delivered/attended)
2. Measure researcher and therapist rated therapist fidelity to the intervention
3. Finalise therapist rated fidelity checklists for use in Work Package 4 (WP4) which will consist of the RCT.
4. Measure acceptability of therapy to patients
5. Measure acceptability of therapy to therapists
6. Produce an updated version of the intervention and its delivery for use in WP4
7. Undertake a qualitative study of experience of, and acceptability of interventions

Recruitment methods, uptake and follow-up:
1. Measure rates of identification, eligibility and consent, recruitment
2. Measure participant follow up rates

Follow-up data collection:
1. Assess the feasibility of obtaining the full trial's primary outcome measure 'Quality of life using Clinical Outcomes in Routine Evaluation - Outcome Measure (CORE-OM)' and secondary outcome data (hopelessness; depression; social connectedness; Quality-adjusted life years and healthcare resource use) via postal or online administration (or telephone or face to face interviews if appropriate) at 6 months.
2. Assess the acceptability and feasibility of obtaining the full trial's secondary outcome 'repetition of self-harm' via monthly text message data collection,
3. Measure self-harm follow-up rates for text, postal/online (or face to face interviews if appropriate) administration and telephone interviews at 6 months, and through hospital records via researcher data collection.
4. Assess through qualitative interviews the experience of, acceptability of, and the burden of, collecting participant-reported outcomes.

Statistical outcomes:
1. Summarise outcome data and assess variability of outcomes
2. Refine the sample size calculation for the main trial, including an estimate of clustering due to therapist effects

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/02/2020, Yorkshire & The Humber - Leeds East Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK), ref: 19/YH /0409

Study design

Non-randomized; Interventional; Design type: Treatment, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The FReSH START feasibility study is a single-arm trial, taking place across three sites, aiming to recruit 30 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 their intervention is compatible with NHS practice the researchers will recruit through mechanisms which mirror NHS pathways. Thus they will recruit participants who present to health services – most commonly hospital Emergency Departments (ED), but also adult mental health teams and primary care.

Eligible, consenting participants will be registered and allocated to the intervention comprising one of the three psychological therapies modified specifically for use with people who multiply self-harm: Behavioural Therapy/Cognitive Behaviour Therapy (BT/CBT), Psychodynamic Interpersonal Therapy (PIT), and Acceptance and Commitment Therapy (ACT). Delivery of the intervention will be by a therapist trained in the psychological therapy for the feasibility trial. Allocation of participants to one of the three psychological therapies and to a therapist will be randomised (via minimisation and stratified permuted block randomisation respectively).

Participants will be offered 12 face to face 45-minute therapy sessions with the option of up to two telephone booster sessions if required. The therapy will take place on the participant's local NHS Trust's premises. Sessions will be recorded for purposes of clinical supervision and to ensure the intervention is delivered as intended. Recordings will be encrypted and transferred securely. Any transcriptions will be made by persons authorized by the University of Leeds. Within each research site it is anticipated that at least two of the three psychological therapies will be available, and at least two therapists will be trained and recruited for each therapy.

Participants will be followed-up for 6 months from registration. Patient-reported outcome data will be collected at 6 months post-registration via postal administration (or telephone if appropriate) and via monthly text alerts for self-reported self-harm episodes. Repetition of self-harm will also be collected directly from hospital electronic records by the researcher during the follow-up phase. Details on participant intervention provision and adherence will be recorded. Therapist level data will be collected, including demographics, experience and competencies, training, and ongoing supervision attendance. Fidelity to each of the intervention will be measured, including fidelity to the self-harm adapted approach, and to each of the three psychological therapies (BT/CBT, IPT and ACT). Inclusion of the key ingredients of the self-harm adaptation will be further recorded for the first assessment session of each therapy.

A parallel study will approach a sample of therapists and participants to take part in interviews to explore the acceptability of the therapy, and to refine the intervention and logic model ahead

of the definitive multi-centre RCT. Participants will be asked at the time of enrolment to the feasibility study if they are willing to be approached to take part in this qualitative study. A sample of participants who consent (n=18) will then be approached by a study researcher to take part in this study. Separate written informed consent will be given. Interviews will be performed face to face on NHS Trust property, or via the telephone.

Intervention Type
Other

Primary outcome(s)
The outcomes relate to intervention delivery and acceptability, feasibility of recruitment, follow-up and outcome data collection, as follows:

Intervention delivery and acceptability:
1. Number and proportion of therapists undergoing training and deemed competent
2. Therapy delivery by randomly allocated therapist, cross over of patients to therapists
3. 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 (BA, ACT, PIT)
4. Availability and uptake of other treatments and services accessed by participants
5. Proportion of participants taking up telephone “top up” contact at end of therapy
6. Proportion of participants and therapists delivering key intervention components, overall and by therapy type (BA, ACT, PIT) as recorded by the therapist
7. Participant and therapist fidelity to the intervention including fidelity to the self-harm modifications and to the individual psychological therapeutic approach overall and by therapy type (BA, ACT, PIT) as recorded by the researcher rated audio-recordings
8. Number and attendance of therapy-specific supervision sessions

Recruitment methods, uptake and follow-up:
1. Number of patients screened for eligibility
2. Number of study cards given out and proportion completed
3. Method of referral e.g. Emergency Department, self-harm team, clinical staff, general practice
4. Proportion of patients that could be followed-up by the Researcher and proportion of those found eligible for the study
5. Proportion of patients that consent and are registered to the study out of those found eligible
6. Reasons for non-participation
7. Proportion of patients completing the study out of those registered, number of withdrawals from follow-up data collection, reasons for withdrawal
8. Number of losses to follow-up and characteristics of participants lost to follow-up

Follow-up data collection:
1. Proportion of participants with available monthly self-reported repetition of self-harm data
2. Proportion of participants with 6-month self-reported outcome data, proportion obtained through postal, online, telephone or face to face administration
3. Proportion of participants with self-harm follow-up obtained through hospital records, text, and 6-month self-report
4. Overall and item completion rates, and time spent on self-reported questionnaires
5. Proportion of participants reporting questionnaires as acceptable

Statistical outcomes:
Estimates and variability of self-reported outcomes at baseline and 6 months post-

randomisation with 95% Confidence Intervals, including:
1. Psychological global distress as measured by the CORE-OM
2. Hopelessness as measured by the Beck Hopelessness Scale (BHS)
3. Depression as measured by the Patient Health Questionnaire- 9 (PHQ-9)
4. Social connectedness as measured by the Social Connectedness Scale – revised (SCS-R)

1. Proportion of participants with reliable and clinically significant improvement (RCSI) defined as defined on the CORE-OM as: change in CORE-OM of 5 or more points (reliable) and movement from the clinical range (≥10/40) to the non-clinical range (<10/40) (clinically significant)
2. Clustering effect (ICC) of the CORE-OM by therapist and by therapy modality

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Adults 18 years or over
2. Presenting at ED, adult mental health services or general practice as a consequence of self-harm within the last 8 weeks, 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
3. Self-harm episode in the preceding 3 months that is at least their 3rd episode in the preceding 12 months and their lifetime 4th.
4. Has mental capacity and provides fully informed written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
30

Key exclusion criteria

1. Receiving a specific psychological intervention or where a specific intervention is indicated for a related condition (e.g. anorexia or drug addiction)
2. Refuses to provide fully informed written consent
3. Lacks capacity to comply with study requirements
4. Insufficient proficiency in English to contribute to the data collection
5. Known risk of violence
6. Researcher unable to contact participant within 8 weeks following self-harm event

Date of first enrolment
01/03/2020

Date of final enrolment
18/03/2021

Locations

Countries of recruitment
United Kingdom

England

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

Study participating centre
Leeds And York Partnership NHS Foundation Trust
Twenty One Fifty
Thorpe Park
Leeds
United Kingdom
LS15 8ZB

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

Sponsor information

Organisation
University of Leeds

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-1016-20005

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 15/08/2022:
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 IPD sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from 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 of 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?
Results article		15/05/2025	19/05/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 5.0	22/04/2021	15/08/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes