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An assessment of the effectiveness of Psychodynamic Interpersonal Therapy in reducing the repetition of self-harm in adults presenting to an emergency department with acute self-harm (history of 3 or fewer episodes in the last 12 months)

Submission date
28/10/2021

Recruitment status
No longer recruiting

Registration date
04/11/2021

Overall study status
Completed

Last Edited
15/12/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
We want to find out whether a type of brief therapy, psychodynamic interpersonal therapy (PIT), helps people who attend an emergency department (ED) after an episode of self-harm (SH). We are interested in whether PIT helps people reduce future SH and ED attendance and improve their mental health and quality of life. We will also measure costs and potential cost savings as this is important for the NHS.
PIT therapy involves 4 weekly sessions and is intended for people who have 3 or fewer SH episodes. People who SH more frequently require more intensive treatment and we have a separate study which will assess a more intensive treatment for this group. Standard care involves a full psychosocial assessment and a care plan.

Who can participate?
Adults over 18 years, who have attended the emergency department as a consequence of self-harm.

What does the study involve?
Mental health nurses who work in EDs will approach people who have attended hospital following SH to see if they are interested in taking part, assuming the study is suitable for them. Those who agree to take part will be allocated by chance to one of two groups; PIT as well as standard care or standard care only.
We have involved users with experience of SH in designing this study and have a co-applicant who has personal experience of SH and considerable experience of raising awareness and advocating for better mental health care.

What are the possible benefits and risks of participating?
Benefits: We hope that participants who are randomised to the intervention group and attend therapy sessions will benefit from the therapy sessions, though this cannot be guaranteed. As not all participants will receive the intervention therapy sessions, the benefit should be stated to be:
-helping the researchers learn more about how to help people who self-harm
-helping to researchers to find out whether this brief therapy is an effective approach for people following self-harm.

Risks: We do not envisage there being any additional risks that participants will be exposed to as a result of taking part in the study. All consenting participants will be made aware that if they are randomised to the intervention arm they will be receiving therapy, and of the number of questionnaires and SMS messages involved. Questionnaires and SMS messages could be seen as intrusive as they (by definition) ask questions of a personal nature. Questionnaires and therapy sessions may cause some inconvenience in terms of time. Participants are free to withdraw from the study at any time should they wish to. The questionnaires chosen for the SafePIT study participants are widely used and are therefore expected to be acceptable. Participants will be sent monthly SMS messages asking them to self-report any episodes of self-harm. Participants will be asked to consent to this. Participants will be able to opt out of any further messages by texting STOP. Risk escalation protocols have been built into the study protocol in case any participant experiences deterioration in their mental state, which does occur within the study population independently of participation in the study. Local PI and clinical teams are very experienced in managing risk.

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

When is the study starting and how long is it expected to run for?
March 2021 to November 2023

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

Who is the main contact?
SafePIT@leeds.ac.uk
Prof Else Guthrie, E.A.Guthrie@leeds.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Trial Manager

Contact details
Clinical Trials Research Unit
Leeds Institute of Clinical Trials Research
University of Leeds
Leeds
United Kingdom

LS2 9JT
+44 (0)113 343 7589
safepit@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)113 343 2442
E.A.Guthrie@leeds.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
301794

Protocol serial number
CPMS 50394, NIHR131334

Study information

Scientific Title
The Self-harm, Assessment, Formulation, Engagement Trial of Psychodynamic Interpersonal Therapy (SAFE-PIT)

Acronym
SAFE-PIT

Study objectives
4-6 sessions of one-to-one Psychodynamic Interpersonal Therapy (PIT) plus standard care in comparison to standard care alone for people attending the emergency department with acute self-harm (three or fewer episodes in the last 12 months) will significantly increase the length of time between randomisation and the next hospital attendance related to a self-harm episode.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/10/2021, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8241; cambsandherts.rec@hra.nhs.uk), ref: 21/EE/0204

Study design
Interventional randomized controlled trial with qualitative follow up

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The SafePIT RCT is a 1:1 randomised controlled trial of standard care plus referral to intervention vs standard care alone. A total of 770 participants will be recruited across 12 sites (Mental Health Trusts) following attendance at a hospital ED. To ensure that our intervention is compatible with NHS practice we will recruit through mechanisms which mirror NHS pathways.

Patients who potentially meet the eligibility criteria will be verbally informed of the study (by the clinical care team) and given a copy of the Participant Information Sheet, and will be asked for their permission for researcher contact. If they agree to this contact, they will be asked to provide their contact details which will be sent to the local researcher via secure email (or the local researcher will collect). They will not be asked to consent to any study procedures or study involvement at this stage. Consent to researcher contact may be given either in writing or verbally by the participant.
Verbal consent to contact will be recorded on the designated 'consent to contact' form by the clinical care team.
If the potential participant leaves hospital prior to the psychosocial assessment having taken place, and local procedure is for the clinician to contact them by telephone to arrange the assessment, they may introduce the study to the potential participant and take verbal consent to researcher contact during such a clinically indicated telephone contact. The participant information sheet with a covering invitation letter will then be sent to them via post or email.

Following consent to researcher contact (C2C) and clinical screening 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 10 short validated questionnaires (4 of these are completed at baseline only) and 2 non-validated questionnaires (1 for participant completion and 1 for researcher administration) which will be submitted for approval. The self-completed questionnaires will be sent to the participant via an on-line link (paper completion is possible if preferred). Following the baseline assessments, the participant is randomised.

If randomised to standard care plus intervention, the participant will be allocated to a trained therapist within their site to receive 4 sessions of PIT therapy (+2 optional booster sessions). If randomised to the standard care arm the participant receives 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 by the trials unit(or postal if requested by the participant)and via monthly text alerts for self-reported self-harm episodes. Participants will receive a £20 e-voucher on completion of the final questionnaire. Repetition of self-harm will also be collected using routine data obtained from NHS Digital by the CTRU, 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 PIT. 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 undergo group-training in PIT by the Chief Investigator and the central research team. Training will be delivered during live on-line sessions, equivalent to a 3 day face to face workshop. 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. Group supervision will be delivered fortnightly by supervisors at the research sites.

Fidelity to the intervention will be measured.Fidelity assessments will be made via a 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 carers/close others, the therapists and other key stakeholders (n=25), to explore key implementation issues from a service perspective. Interviews will be held by members of the central research team and will be held via telephone. 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=25) and carers/close others (n=10) 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. Therapists and other stakeholders will be purposively sampled across the participating sites and invited to take part should they so wish.

There will be an embedded study within a trial (SWAT) which aims to examine whether the addition of a letter from the PPI group would increase trial engagement and questionnaire return. Participants will be randomised to receive a letter from the PPI group detailing the importance of their participation in the trial immediately following randomisation and at the 6 and 12 months follow-up points, in addition to standard follow-up procedures.

Intervention Type
Behavioural

Primary outcome(s)
Time (in months) from randomisation to first repetition of self-harm leading to hospital attendance, obtained from HES data supplemented by clinical record check.

Key secondary outcome(s))
1. Rate of repetition of self-harm leading to hospital attendance at 6 and 12 months, obtained from HES data supplemented by clinical record check.
2. Time (in months) from randomisation to repetition of self-harm leading to hospital attendance (all events), obtained from HES data supplemented by clinical record check.
3. Rate of repetition of self-reported self-harm at 6 and 12 months, obtained via monthly text message and 6 and 12-month questionnaires.
4. Psychological distress as measured by (CORE-OM) at 6 and 12 months.
5. The proportion of people with clinically significant improvement (and deterioration) on CORE-OM at 6 and 12 months.
6. Anxiety as measured by the Generalised Anxiety Disorder-7 (GAD-7) at 6 and 12 months.
7. Hopelessness as measured by the Beck Hopelessness Scale (BHS) at 6 and 12 months.
8. Interpersonal function measured by the Inventory of Interpersonal Problems (IIP-32) at 6 and 12 months.
9. Quality of life as measured by the ReQoL-10 at 6 and 12 months (with comparison to EQ-5D-5L and CORE-6D measures).
10. Health care use, measured by a structured health-resource–use questionnaire and HES data, over 12 months post-randomisation.
11. QALYs based on ReQOL at 6 and 12 months.

Internal Pilot Outcome Measure:
1. Recruitment and intervention delivery at 12 months.

Qualitative Evaluation Outcome Measures:
1. Thematic analysis of interviews of participants and/or their supporters regarding experience of receiving the therapy.
2. Thematic analysis of interviews of the therapists' experience of participating in the trial.
3. Logic model of interviews of the service managers and therapists of how the intervention was delivered and the implications for sustaining the intervention in future.

Completion date
01/11/2023

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-harmed 1-2 times in the last 12 months (any amount in their lifetime) OR self-harmed exactly 3 times in the last 12 months but never before this year.
5. 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
22

Key exclusion criteria
1. Receiving, or having been referred to, 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. Assessed by clinician as currently unsuitable for therapy (e.g. in crisis; actively suicidal)
3. Lacking capacity to comply with study requirements
4. Insufficient proficiency in English to contribute to the data collection
5. Known risk of violence (for example reported by ED or liaison psychiatry staff)
6. Researcher unable to contact potential participant within 6 weeks following self-harm event

Date of first enrolment
21/02/2022

Date of final enrolment
26/01/2023

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

Study participating centre
Cornwall Partnership NHS Foundation Trust
Carew House
Beacon Technology Park
Dunmere Road
Bodmin
England
PL31 2QN

Study participating centre
Derbyshire Healthcare NHS Foundation Trust
Trust Headquarters
Kingsway Hospital
Kingsway
Derby
England
DE22 3LZ

Study participating centre

Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
Bracknell
England
RG12 1BQ

Study participating centre
Bradford District Care Trust
New Mill
Victoria Road
Shipley
England
BD18 3LD

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
England
NE3 3XT

Study participating centre
Central and North West London NHS Foundation Trust
Trust Headquarters
350 Euston Road
Regents PLACE
London
England
NW1 3AX

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

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?
Results article		26/11/2025	15/12/2025	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			30/10/2024	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes