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Synopsis

Brief psychodynamic-interpersonal therapy for adults with a history of self-harm: the SafePIT RCT

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Abstract

Background: There are over 200,000 hospital attendances for self-harm per annum in the United Kingdom at an estimated annual cost of £133–162M. Systematic reviews prior to commencing the study suggested that brief psychological interventions are effective in reducing psychological distress after self-harm and reduce repetition of self-harm.
Objective: The SafePIT trial was designed to evaluate the effectiveness and cost-effectiveness of self-harm-focused psychological therapy plus standard care versus standard care alone.
Design: Pragmatic, multicentre individually randomised controlled trial of brief psychodynamic-interpersonal therapy compared with standard care with internal pilot, cost-effectiveness and process evaluation.
Setting and participants: People aged over 18 years who attend hospital after intentional self-harm with a history of ≤ 3 episodes in the last 12 months.
Intervention: Individual psychodynamic-interpersonal therapy, delivered face to face or by video conferencing by liaison mental health nurses, over four (or fewer by mutual agreement) 50-minute weekly sessions with two optional boosters.
Main outcome measures: The primary outcome was time from randomisation to first repetition of self-harm leading to hospital attendance. Secondary outcomes (at 6 and 12 months) included rate of repetition of self-harm leading to hospital attendance; self-reported self-harm using questionnaires and Short Message Service; psychological distress and clinically significant improvement (Clinical Outcomes in Routine Evaluation – Outcome Measure); anxiety (Generalised Anxiety Disorder-7); hopelessness (Beck Hopelessness Scale); interpersonal function (Inventory of Interpersonal Problems-32) and quality of life (EuroQol-5 Dimensions, five-level version; Recovering Quality of Life; Clinical Outcomes in Routine Evaluation-6D).
Results: The planned sample size was 770 participants. The trial closed to recruitment early in January 2023 at the end of the 12-month internal pilot, with 22 randomised participants, 12 allocated to psychodynamic-interpersonal therapy and 10 to standard care. Due to the early trial closure, trial follow-up was curtailed to 6 months, and analyses are restricted to descriptive statistics.
Seven of 12 participants allocated to psychodynamic-interpersonal therapy started therapy, and four completed therapy. Participant-reported secondary outcomes were completed for nine (40.9%) participants at 6 months. Repetition of self-harm leading to hospital presentation could be assessed for 18 participants and occurred in two

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participants in the psychodynamic-interpersonal therapy arm (18.2%) and no participants in the standard care arm within 6 months of randomisation. Economic findings indicated no substantive changes in health-related quality of life, or primary and secondary care resource usage across arms or over time. Intervention costs were highly sensitive to assumptions regarding the number of patients that would be treated per therapist in real-world role out of intervention.

Limitations: The study was unable to recruit the necessary sample size, preventing the trial from progressing. The trial met with several challenges.

Conclusions: Trial timelines coincided with the start of the second wave of the COVID-19 pandemic, causing substantial delays, difficulties with recruitment and, ultimately, its early closure.

Although the trial closed early and with insufficient participants to proceed with full statistical analysis, our experiences and recommendations can inform future trial design and delivery.

Future work: Self-harm remains a major risk factor for suicide, and provision of cost-effective interventions for people who self-harm is a key part of the government's Suicide Prevention Strategy.

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A plain language summary of this synopsis is available on the NIHR Journals Library Website https://doi.org/10.3310/TNGF8545.

Introduction

This section summarises Self-harm, Assessment, Formulation, Engagement Trial of Psychodynamic-Interpersonal Therapy (SafePIT) protocol version 6.0 and the outcome of the 1-year internal pilot. The full protocol is available at: https://fundingawards.nihr.ac.uk/award/NIHR131334.

The SafePIT trial was designed prior to the COVID-19 pandemic to evaluate one-to-one, face-to-face therapy delivered by liaison mental health practitioners, based in emergency departments (EDs), for people attending EDs following self-harm (SH). The intervention was a brief intervention for people with a first-time presentation of SH or a minimal history of SH. At the time the study was designed, liaison mental health services in EDs in England had undergone a dramatic expansion with a £120M central investment from NHS England, so that 70% of all hospitals in England had a fully resourced service with capacity to deliver limited brief interventions for the purposes of the trial.[1] The trial opened in February 2022 at the height of the Omicron wave of the COVID-19 pandemic.[2] Before starting the trial, the intervention (four sessions of individual therapy) was modified so it could be delivered either remotely or face to face (with appropriate social distancing measures) with all training provided so it could be delivered remotely, as was therapy supervision. By the time the trial opened, the NHS had been dealing with COVID for nearly 2 years. During this time, mental health teams based in the EDs underwent considerable disruption; many were relocated away from the ED departments, and staff turnover and sickness absence were high. COVID-19 impacted on Research and Governance infrastructure, so site set-up was challenging. The trial included an internal pilot, which concluded in December 2022. It was agreed with the funder, in January 2023, to close the trial due to poor recruitment and an unlikelihood that any future mitigations would significantly improve recruitment to make the trial viable.

Rationale and background

The National Suicide Prevention Strategy in England was first introduced over 20 years ago. The most recently updated strategy, published in November 2023,[3] has three central aims: to halve the national suicide rate over the next 5 years, improve support for people who have self-harmed and improve support for people bereaved by suicide. SH remains the strongest factor associated with subsequent suicide.[4] There are over 200,000 hospital attendances for SH per annum in the UK[4] and approximately 100,000 acute hospital admissions,[5] at an estimated annual cost of £133–162M.[6,7]

The recent Adult Psychiatric Morbidity Study reported that 62% of people following SH received no treatment,[8] and the most socially disadvantaged people are least likely to receive help following SH. Six-year follow-up of people who presented to ED with SH show that, for many, problems persist with high levels of mortality and psychological morbidity, further SH, and low quality of life (QoL).[9] Effective treatment has the potential to improve mental health and QoL and reduce risk of further SH.[10]

Over 8% of people who SH have a recognised mental disorder,[11] with depression and anxiety disorders being the most common. One in 25 people who present to hospital following SH will end their own life within the next 5 years, and approximately half of all people who die by suicide have previously self-harmed.[9] In the UK, 30% repeat SH within 6 months and 50–60% in the next 5–6 years.[9] In terms of treatment approach, we distinguished (1) people

who present with acts of SH that are a response to recent stressors and are associated with acute distress and (2) people who present with multiple (repeated) acts that are associated with longer-term individual psychological problems. Those people in the first group, who present with acute distress, require an acute solution to their current distress.

Two recent systematic reviews prior to commencing the study suggested that brief psychological interventions are effective in reducing psychological distress after SH and reduce repetition of SH.[12,13] The two best candidate interventions are cognitive–behavioural therapy and psychodynamic-interpersonal therapy (PIT). Both are supported by trial evidence and have been used routinely to treat SH in the NHS. Barriers to providing treatment for SH include difficulties therapists have in delivering therapy to high-risk groups, the resources required to treat so many people and the lack of definitive evidence to inform National Guidelines.

The SafePIT trial was designed to evaluate brief PIT delivered by liaison mental health nurses (who are familiar with risk) in people who present to EDs in England with SH and acute distress. The intensity of the treatment intervention was chosen to match the population of patients and in keeping with relevant National Institute for Health and Care Excellence (NICE) guidance.[14]

Trial design

The trial was designed as a multicentre, parallel-group, two-arm, individually randomised controlled trial (RCT) of PIT plus standard care (SC) versus SC alone for people who attend hospital EDs, following an episode of SH with a history of three or fewer episodes of SH in the last 12 months. The trial included an internal pilot with clear progression criteria for recruitment and retention to therapy; a comprehensive cost-effectiveness analysis; a nested process evaluation to explore qualitative participants and therapists' experiences of participating in the trial and receiving or delivering treatment, and implementation in existing services. A study within a trial, 'SWAT', was included to explore the effect of a letter from the patient and public involvement (PPI) group at baseline and/or at follow-up on trial engagement and questionnaire return rates.

Objectives

Primary objective

To assess the effectiveness of PIT plus SC compared to SC alone as measured by repetition of SH, defined as the time (in months) from randomisation to the date of hospital episode of SH.

Secondary objective

To assess the effect of PIT plus SC versus SC alone on:

- repetition of SH leading to hospital attendance at 6 and 12 months
- overall recurrence of SH leading to hospital attendance
- self-reported SH repetition at 6 and 12 months
- psychological global distress, measured by the Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM) at 6 and 12 months[15]
- reliable and clinically significant improvement (RCSI) in QoL/psychological global distress, measured by the CORE-OM at 6 and 12 months[16–18]
- anxiety, measured by the Generalised Anxiety Disorder-7 (GAD-7) at 6 and 12 months[19]
- hopelessness, measured by the Beck Hopelessness Scale (BHS) at 6 and 12 months[20]
- interpersonal function, measure by the Inventory of Interpersonal Problems (IIP-32) at 6 and 12 months.[21]

Cost-effectiveness objectives

To determine:

- The effect of PIT plus SC compared to SC alone on QoL (CORE-OM) at 6 and 12 months.
- The effect of PIT plus SC compared to SC alone on self-reported resource use.
- The cost-effectiveness of PIT plus SC compared to SC alone at 6 months and 12 months.

Exploratory objectives

To determine whether psychological measures at baseline moderate outcome, including:

- personality disorder, measured by the Standardised Assessment of Severity of Personality Disorder (SASPD)[22]
- interpersonal needs, measured by the Interpersonal Needs Questionnaire (INQ)[23]
- defeat and entrapment, measured by the Short Defeat and Entrapment Scale (SDES)[24]
- life events, measured by the List of Threatening Experiences (LTE).[25]

Embedded qualitative evaluation objectives

The trial included a qualitative component to determine participants' and therapists' experiences of therapy and how the intervention could be embedded in future service delivery. Due to the low recruitment rate, this part of the trial was not undertaken as planned.

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Internal pilot objective

To ensure the efficient use of resources in the trial by assessing trial recruitment and intervention delivery rates against clear progression criteria.

Trial methods, data collection and analysis

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Trial setting

The trial was based in acute hospitals in England with an ED and an active liaison mental team who regularly assessed patients presenting to the hospital with SH.

Participant recruitment process

Potential participants attending hospital following an episode of SH initially received an ED consultation and any required physical treatment. They were subsequently offered a psychosocial assessment with a member of the liaison mental health team. Liaison mental health staff approached potential participants to introduce the study and obtain consent (written or verbal) for researcher contact.

Prior to any approach by the research team, the principal investigator at the site reviewed the electronic case notes of any potential participant identified by the liaison teams as being suitable and who expressed an interest in being contacted by the research team. The review focused on the presence of certain patterns of behaviour that may impact on the ability of someone to participate in the trial in a meaningful way and whether the potential participant had been referred to, or offered psychological treatment, which was likely to start within the immediate future (i.e. the next 6 months) and could interfere with the therapy offered as part of the trial.

If the clinical check was acceptable, a local study researcher contacted the potential participant to explain the study in more detail and, if the potential participant was still interested, established initial eligibility over the phone. Full copies of the participant information sheet were provided either at initial attendance or were provided by the site research team after contact was made and before full consent was provided.

Eligibility criteria

Inclusion criteria

- Aged 18 years or over.
- Registered with a general practitioner (GP) in the catchment area of the mental health trust for the duration of the therapy.
- Presenting at ED as a consequence of SH, 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 also includes self-poisoning, such as taking overdoses of drugs.[14]
- Attended hospital as a result of SH ≤ 3 times in their lifetime.
- Mental capacity to provide fully informed written consent.

Exclusion criteria

- 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.
- Lacking capacity to comply with study requirements.
- Assessed by clinician as currently unsuitable for therapy (e.g. known risk of violence).
- Insufficient proficiency in English to contribute to the data collection.
- Known risk of violence (e.g. reported by ED or liaison psychiatry staff).
- Researcher unable to contact potential participant within 6 weeks following SH event.

A summary of changes to inclusion criteria, and all other protocol changes in the trial, can be found in *Appendix 3*, *Table 20*.

Baseline data collection, randomisation and blinding

Baseline data collection

Where potential participants were eligible and willing to consider participation, the researcher arranged a baseline assessment to establish full eligibility, obtain consent and complete study measures. All baseline assessments were performed by telephone or video call.

All participants in the trial gave fully informed written or electronic consent. Following confirmation of informed consent and eligibility, patients were e-mailed a link to

complete participant-reported baseline questionnaires directly into Research Electronic Data Capture (REDCap).

Randomisation

Following completion of baseline measures, participants were randomised by the study researcher via the Clinical Trials Research Unit's (CTRU's) automated 24-hour randomisation system. Participants were randomised on a 1 : 1 basis to SC plus intervention or SC alone using computer-generated adaptive minimisation algorithm that incorporates a random element stratified using site, gender and number of prior SH episodes.

Following randomisation, the local researcher contacted participants to inform them of their allocation. Appropriate information about national and local support networks were provided to all participants, regardless of their randomisation allocation. If randomised to SC plus intervention, the participant was allocated to a trained therapist within their site, and the local researcher liaised with the allocated therapist and service lead to initiate the intervention. Where possible, participants randomised to intervention were randomly allocated to therapist using simple randomisation between all available therapists at the corresponding sites.

Blinding

Due to the nature of the intervention, participants, therapists and local researchers were aware of treatment allocation. Central researchers involved in supporting follow-up outcome data collection were masked to enable unbiased follow-up.

Intervention

Participants randomised to receive the intervention were offered four therapy sessions, or fewer by mutual agreement between the participant and therapist, over a maximum of 12 weeks from randomisation, with an option of one to two additional booster sessions (typically by telephone) within 3 months of the completion of therapy. The intervention was delivered in accordance with the manual developed for the therapy and was undertaken at appropriate trust premises. Sessions delivered face to face, or remotely via video call, were 45–50 minutes in duration and, where possible, occurred on a weekly basis. All sessions were audio-recorded for use in supervision and independent fidelity assessment. Face-to-face, appropriate social distancing measures were used, if required.

Psychodynamic-interpersonal therapy is a psychodynamic form of therapy which aims to manage feelings in the context of interpersonal relationships. It focuses upon interpersonal problems or ways of relating which may underpin symptomatic or problem scenarios.[26] There is a strong focus on developing a strong therapeutic alliance from which interpersonal problems can be identified and solved. The different components of the model are as follows: (1) focus on feelings which precipitate SH, (2) encourage the client to stay with feelings, (3) explore what associated thoughts, images, memories come to mind, (4) explore links or patterns in interpersonal relating that are problematic, (5) acknowledge these problematic patterns and (6) test out new ways of behaving both in the session with the client and in personal relationships outside and help contain distressing emotions and feelings. A goodbye letter is given to the client at the end of the therapy to summarise the work.

Therapist training

The intervention was delivered by health professionals (mental health nurses, psychologists, occupational therapists, psychiatrists, counsellors) who had prior experience of working with people who SH and managing risk. Potential therapists were identified at each site following discussion with the relevant service managers. All therapists had a recognised mental health professional background (e.g. nursing, occupational therapy, clinical psychology, psychiatry, therapist, counsellor), good interpersonal skills and experience of managing risk.

All therapists underwent therapy-specific training in a group format. Online training was delivered by the chief investigator, together with a therapy manual and additional online materials. The training consisted of 72-hour sessions spread over 2 weeks to enable consolidation of skills between training episodes. The aim of the training was to equip therapists with sufficient skills that they could start therapy on the premise that they would then be offered ongoing supervision from an experienced PIT practitioner, utilising the audio-recordings in supervision, to complete the therapy. Group or individual supervision sessions were scheduled every 2 weeks. Supervision was delivered virtually using secure NHS-approved systems.

Standard care

Both arms received SC. NICE guidance states that the person who SHs should receive a comprehensive assessment of needs and risks. Information should be provided about possible strategies to help reduce SH, and consideration should be given to offering a psychological intervention.

All service users who became participants in the study were offered an integrated and comprehensive psychosocial assessment from a mental health practitioner of their

needs and risks.[14] This took place prior to enrolment in the study. The psychosocial assessment took place either in the ED on the hospital ward, if the participant had been admitted to an acute hospital bed, or in the mental health unit, if the liaison team had been displaced from the ED because of COVID.

Safety reporting procedures

All sites had a designated clinician who was available for consultation regarding any risk issues or other questions related to wider clinical management. Therapists managed and escalated risk as per routine clinical practice and through discussion with their psychotherapy supervisor and designated site clinician.

If a participant became upset/distressed during or immediately after research data collection, or phoned the researcher and indicated they were in distress, the researcher followed a written protocol to help manage this distress and, if concerned about the welfare of the participant, immediately contacted a senior clinician at the appropriate site.

Trial assessments and data collection

Participant-reported outcome data

Participant-reported outcome data were collected at 3, 6, 9 and 12 months after randomisation via online REDCap administration (or telephone/post if appropriate) and monthly text alerts for self-reported SH episodes up to 6 months post randomisation. Follow-up at 3 and 9 months was for self-reported usage of services only, which was also collected at the other time points. Text message and e-mail reminders were sent to non-responders to the questionnaires to prompt completion, followed by up to four further reminders by the blinded researcher (using text, phone or e-mail).

To maximise follow-up, participants were issued with £20 vouchers at the completion of final assessments at 12 months, revised to 6 months at study closure.

Participant-reported outcome measures collected at baseline, 6 and 12 months included:

- Self-reported SH, including any report of SH, regardless of whether it led to hospital attendance or not (trial-specific).
- CORE-OM, psychological distress CORE-OM score ranges from 0 to 40, with a higher score indicating higher levels of distress.
- GAD-7 (anxiety). The GAD-7 total score ranges from 0 to 21, with a higher score indicating higher levels of anxiety.
- BHS (hopelessness). BHS total score ranges from 0 and 20, with a higher score indicating higher levels of hopelessness.
- Inventory of Interpersonal Problems (IIP-32, interpersonal function). IIP-32 total score ranges from 0 to 128. A higher score indicates more interpersonal problems.
- Recovering Quality of Life questionnaire (ReQoL-10, QoL). ReQoL total score ranges from 0 to 40, where 0 indicates poorest QoL and 40 indicates highest QoL.
- EuroQol-5 Dimensions, five-level version (EQ-5D-5L).

Participant-reported outcome measures collected at baseline, 3, 6, 9 and 12 months:

- Self-reported resource use – primary and community care and medications and private financial burden due to SH (trial-specific).

Participant-reported measures collected at baseline only included:

- The SASPD (personality disorder).
- INQ (interpersonal needs). INQ: the total score ranges from 15 to 105, where a higher score indicates greater perceived burdensomeness.
- SDES (short defeat and entrapment scale).
- The LTEs, life events.

Full details of each measure and end-point derivation can be found in *Appendix 2*.

Fidelity assessment

Participant adherence to the intervention was measured by the number of sessions offered and attended. Fidelity assessments of the individual psychological therapeutic approach were measured using items from the PIT subscale of the Sheffield Psychotherapy Rating Scale.[27] Assessment was undertaken by a therapist with expertise in PIT.

It was originally planned to take a random sample of 20% of the sessions during the internal pilot, and 10% of the sessions during the remainder of the trial, stratified by therapist and centre, to be reviewed and scored using the fidelity measure. Due to the low recruitment, a random sample of 10 sessions was rated, including at least 1 therapy session from each participant.

Routinely collected healthcare data

It was intended that routine healthcare data would be used to collect resource use and hospital attendances for SH (and other reasons) via Hospital Episode Statistics

(HES), the Mental Health Services data set and Office for National Statistics mortality statistics through linkage of participants through NHS Digital (Leeds, UK).

Due to the early closure of the trial and small number of participants, follow-up was restricted to 3 and 6 months' time points only, and routine healthcare data were not obtained via NHS Digital. Hospital record data (including safety events and SH-related attendances) were instead collected from electronic hospital records directly by the trial researchers.

Sample size

The target sample size was 770 participants. Across approximately 12 sites, we estimated that sites would recruit between 40 and 80 participants, depending on the size of the site and length of time open to recruitment. We allowed time for recruitment processes to establish and anticipated the recruitment would stabilise at four patients per month at each site. Across all open sites, we estimated recruitment of 24 patients per month by the end of the internal pilot.

Three hundred and eighty-five participants per arm (total 770 participants, 262 events) were required to provide 90% power (5% two-sided alpha) to detect a hazard ratio (HR) of 0.637,[12] indicating the relative likelihood of a hospital episode of SH in PIT versus control participants at any given point in time. The sample size accounted for clustering of participants by therapist, assuming that 35 therapists treated ≈11 participants each (range 3–15) with an intracluster correlation coefficient of 0.02[28] for participants randomised to PIT and an equivalent design effect within SC.

Internal pilot

An internal pilot assessed recruitment after 12 months and intervention delivery for patients recruited during the first 8 months of the pilot. The internal pilot informed a decision to close the study which was agreed with the funder and Trial Steering Committee (TSC).

Statistical analysis

Due to early trial closure, formal hypothesis testing was not conducted, and descriptive analyses were performed on an intention-to-treat basis.

The trial is reported in line with the Consolidated Standards of Reporting Trials (CONSORT) statement,[29] and summary statistics are reported for screening and recruitment, participant characteristics, therapeutic delivery and adherence, retention in treatment and follow-up rates. Outcomes are reported using summary statistics alongside 95% confidence intervals (CIs). Missing data were not imputed, other than for imputing missing items when calculating questionnaire scores. There are no subgroup analyses.

Health economic analysis

As per the statistical analysis, formal health economic analyses were not conducted as either a Within-Trial Analysis or via a decision-analytic model. Incremental costs and quality-adjusted life-years (QALYs) between treatments were not calculated nor presented in conventional ratio comparison. Descriptive statistics of costs and health-related QoL instruments are reported as summaries. Missing data were not imputed.

Embedded qualitative study analysis

Due to the slow recruitment, we delayed the recruitment of the research fellow who would undertake the interviews and analysis of the embedded qualitative study. We wanted to ensure an adequate participant pool from which to sample, this had not yet been reached when the trial was closed to recruitment. We focused our qualitative work on understanding the difficulties in recruitment at sites to inform and support our efforts to maximise recruitment.

Trial oversight

The TSC, with an independent chair, provided overall supervision of the trial.

The Data Monitoring and Ethics Committee (DMEC) reviewed the safety and ethics of the trial through accumulating data on recruitment and treatment. The DMEC planned to meet or communicate via teleconference approximately annually as well as reviewing unblinded safety data at least 6-monthly. It was planned to present data from NHS England on all-cause hospitalisations; however, this was not obtained due to the early study closure.

The Trial Management Group (TMG), comprising the chief investigator, CTRU team and coinvestigators were responsible for the clinical set-up, ongoing management and promotion of the trial, as well as the interpretation of results.

Results summary

Progression criteria

The trial met the green criteria for the number of sites open and the proportion recruited of eligible subjects. However, the trial was in the 'red' criteria for the total number of participants recruited, monthly recruitment rate per site and intervention session attendance (*Table 1*).

TABLE 1 Progression criteria

	Red	Amber	Green	End of pilot	End of trial
Intervention delivery	< 50% complete 2 sessions < 40% complete 4 sessions	50–80% complete 2 sessions ≥ 40% complete 4 sessions	> 80% complete 2 sessions > 50% complete 4 sessions	2/5 (40%) completed 2 sessions 1/5 (20%) completed 4 sessions	5/12 (42%) completed 2 sessions 4/12 (33%) completed 4 sessions
Trial recruitment					
Proportion recruited of eligible subjects	< 35%	35–45%	> 45%	16 (52% of eligible)	22 (63% of eligible)
Recruitment rate – per site, per month	< 2 pts	2–3 pts	≥ 4 pts	0.37	0.41
Number of sites open and recruiting	2	3–4	5–6	7 opened (1 had since closed, 1 paused)	8
Total number of participants recruited	< 80	80–180	> 180	16	22

Screening and recruitment

During a 12-month recruitment period, from February 2022 to January 2023, 378 patients were screened, 152 (40.2%) patients were introduced to the trial, 35 (9.3%) were eligible for recruitment to the trial and 22 participants were randomised across eight sites. Of the 226 participants not introduced to the trial, the most common reasons were that participants were not interested (*n* = 27, 11.9%), did not satisfy SH eligibility criteria (*n* = 27, 11.9%) or were already receiving therapy (*n* = 25, 11.1%) (*Figure 1*).

Of the 22 randomised participants, 12 were allocated to the SafePIT therapy, and 10 were allocated to usual care (UC) (see *Figure 1*). Baseline assessments were conducted face to face for seven participants (33.3%) and over the telephone for 14 participants (66.7%) (data missing for one participant). Screening and recruitment varied across sites (see *Appendix 1*, *Figure 2*).

Baseline characteristics

The mean age for randomised participants was 40 years old (ranging from 19 to 73). Sixteen participants were women (72.7%), five participants were men (22.7%) and one participant identified as non-binary (4.5%). The majority of participants were White British (20, 90.9%), one was White Irish (4.5%) and one was Pakistani (Asian or Asian British) (4.5%) (*Table 2*). Baseline differences between the two arms should be interpreted cautiously due to the small sample size.

The screened population were slightly younger than the eligible and randomised populations on average (see *Appendix 1*, *Table 8*). This could be due to high student populations in selected sites who receive care, such as counselling through university services. Around one-third of patients screened were male, which is representative of the clinical population.[6] The proportion of males in the randomised population dropped to 22.7%, which is similar to other trials evaluating psychological interventions for mental health problems.[30]

The majority of randomised participants presented to emergency services with self-poisoning (19, 86.4%), with the remaining three participants presenting with self-injury (13.6%). Self-injury was more common in the screened population (106/378, 28%). Participants had high levels of previous abuse: 11 had previously been physically abused (50%), 16 had been emotionally abused (73%) and 8 had been sexually abused (36%). The majority of participants had long-standing illness or disability (12/22, 55%). Most participants had treatment for mental health problems (17/22, 77%), with 16 participants having taken medication for mental health (*n* = 16, 73%).

A total of 15 participants (68%) had at least moderate risk of harm from alcohol intake according to the alcohol use disorders identification test-consumption (AUDIT-C) score, and these 15 participants had a mean AUDIT-C score 5.1 (ranging from 0 to 11). Six participants reported drinking more than 10 units on a typical day (27%). Eight participants (36%) reported recent or current substance abuse.

Almost all participants had at least one threatening experience (21, 95%), with an average 3.3 threatening events per participant (see *Appendix 1*, *Table 9*).

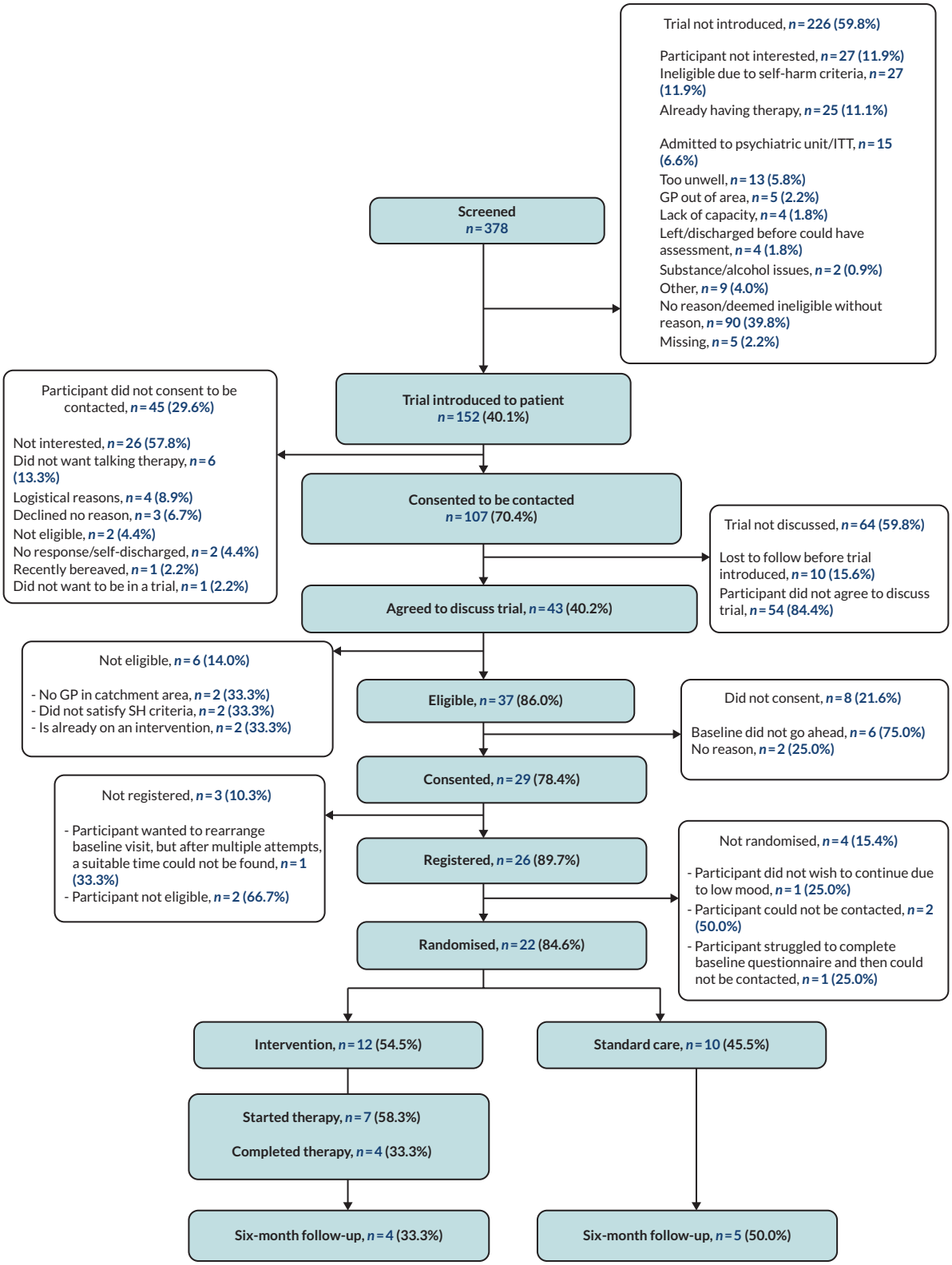

FIGURE 1 The CONSORT diagram.

TABLE 2 Baseline characteristics

	SafePIT intervention *N* = 12	SC *N* = 10	Total *N* = 22
Age			
Mean (SD)	33.3 (17.33)	48.0 (17.11)	40.0 (18.40)
Median (range)	24.5 (19–73)	54.5 (21–64)	35.0 (19–73)
Gender			
Man	2 (16.7%)	3 (30.0%)	5 (22.7%)
Woman	9 (75.0%)	7 (70.0%)	16 (72.7%)
Non-binary	1 (8.3%)	0 (0.0%)	1 (4.5%)
Ethnicity			
White British	10 (83.3%)	10 (100.0%)	20 (90.9%)
White Irish	1 (8.3%)	0 (0.0%)	1 (4.5%)
Asian or Asian British – Pakistani	1 (8.3%)	0 (0.0%)	1 (4.5%)
Education			
O level/GCSE/NVQ2/equivalent	1 (9.1%)	5 (50.0%)	6 (28.6%)
A level/NVQ3/equivalent	6 (54.5%)	3 (30.0%)	9 (42.9%)
Advanced diploma/bachelor degree/equivalent	2 (18.2%)	2 (20.0%)	4 (19.0%)
Post-graduation certificate, diploma or master's degree/equivalent	1 (9.1%)	0 (0.0%)	1 (4.8%)
Other	1 (9.1%)	0 (0.0%)	1 (4.8%)
Missing	1	0	1
Prior SH	7 (63.6%)	8 (80.0%)	15 (71.4%)
Mental health diagnosis (past or current)	4 (36.4%)	6 (60.0%)	10 (47.6%)
On mental health medication	8 (72.7%)	8 (80.0%)	16 (76.2%)
Experienced physical abuse	7 (63.6%)	4 (40.0%)	11 (52.4%)
Experienced emotional abuse	9 (81.8%)	7 (70.0%)	16 (76.2%)
Experienced sexual abuse	6 (54.5%)	2 (20.0%)	8 (38.1%)
Drink ≥ 10 units on a typical day	2 (18.2%)	4 (40.0%)	6 (28.6%)
AUDIT-C score categorised as risky drinking	6 (54.5%)	9 (90.0%)	15 (71.4%)
AUDIT-C total score			
Mean (SD)	4.3 (4.34)	6.0 (2.91)	5.1 (3.74)
Median (range)	3.0 (0.0–11.0)	6.0 (1.0–11.0)	6.0 (0.0–11.0)

SD, standard deviation.

Therapy

Intervention delivery

Seven (58.3%) of 12 participants randomised to the SafePIT therapy arm started therapy, of whom four (57.1%) (*Table 3*) completed therapy with their first four treatment sessions occurring within 10 weeks (see *Appendix 1*, *Figure 3*). One participant received two additional booster sessions. No participants changed therapist during their treatment. Two participants were referred to other services (trauma and Improving Access to Psychological Therapies (IAPT)

TABLE 3 Treatment summary

	SafePIT intervention *N* = 12
Treatment summary	
Completed therapy	4 (33.3%)
Started but discontinued therapy	2 (16.7%)
Started but unsure if completed therapy	1 (8.3%)
Did not start therapy	4 (33.3%)
Missing	1 (8.3%)
Number of sessions attended (in those started therapy)	
1	2 (33.3%)
4	3 (50.0%)
6 (including 2 booster sessions)	1 (16.7%)
Missing—audio recordings returned suggested they attended at least three sessions	1
Total	7

services). Treatment data were missing for one participant who had an eligibility violation.

Across the seven participants who began therapy, 10 sessions were assessed for fidelity to the intervention using audio-recordings. Fidelity to the intervention was achieved in all 10 sessions; scores ranged from 4 to 5 out of a possible 7 (average 4.6), with a higher score indicating greater fidelity (see *Appendix 1*, *Tables 12* and *13*).

Therapist training and supervision

A total of 38 therapists started training; 34 of 38 (89.5%) were assessed as ready to deliver therapy. Therapist and supervisor characteristics are presented in *Appendix 1*, *Tables 14* and *15*. Five of the 34 therapists treated at least one participant, and therapists treated a maximum of two patients.

Four of the 34 therapists assessed as ready to deliver therapy withdrew during the trial (11.8%). Reasons for withdrawal were moving post (*n* = 1); parental leave (*n* = 1); sick leave (*n* = 1); and inability to attend supervision times (*n* = 1). The time to the therapist withdrawal ranged from 38 to 263 days from being assessed as ready to deliver therapy (mean 128 days). None of the therapists who withdrew treated a participant.

There were 43 supervision sessions in total, with between one and five therapists attending each session. The main focus of the session was most commonly reviewing practice (*n* = 14, 32.6%) and therapy approaches (*n* = 12, 27.9%) (see *Appendix 1*, *Table 16*).

Eligibility violation and withdrawal

An eligibility violation occurred for one randomised participant who was assessed as unsuitable for therapy since they had a diagnosis of autism spectrum disorder (breaching the exclusion criteria). After the violation was identified post randomisation, it was felt unethical to remove the offer of treatment, but no record was received to confirm whether they attended any therapy sessions.

Two (9.1%) participants formally withdrew from all elements of the trial: questionnaires, medical notes, interview, two-way Short Message Service (SMS) and future research; one in the intervention arm 42 days after randomisation, and one in the control arm 145 days after randomisation.

Data collection

Three- and 6-month questionnaire completion was achieved for 11 (50%) and 9 (41%) participants, respectively. A comparison of the baseline characteristics of participants by 6-month questionnaire return can be found in

Appendix 1, *Table 10*. All but one participant completed the questionnaires online via REDCap, with one completing a paper questionnaire returned by post.

Fifteen participants (68%) responded to at least 1 monthly SMS message asking about their number of SH episodes, and five participants responded to all monthly SMS messages during the 6-month follow-up period (23%).

Hospital record checks were completed for 18 (82%) participants. Non-completion was due to access issues for two participants in one site (the site researcher reported being unable to complete the check since they only had access to the mental health trust records and could not access the acute trust hospital records), and participant withdrawal of consent to access medical notes for two participants. The time from randomisation to the medical record check ranged from 222 to 466 days. The median time to checking was 358 days after randomisation.

Descriptive analysis of outcomes

Primary outcome

Two participants, both allocated to the SafePIT intervention arm, were hospitalised due to SH during the follow-up period (2/18, 11%). Both were due to self-poisoning events using paracetamol and/or ibuprofen, treatment was required and occurred within 6 months of hospital attendance (2.4 and 5.9 months after randomisation). No participants were hospitalised more than once due to SH.

Secondary outcomes

According to participant-reported questionnaires, two of eight participants reported SH during the 6-month follow-up period: one of four in the SafePIT therapy arm (25%) and one of four in the SC arm (25%). The mean number of times self-harmed over 6 months was 0.6 (SD 1.19, $n = 8$) overall: 0.5 (SD 1.00, $n = 4$) in the SafePIT therapy arm and 0.8 (SD 1.50, $n = 4$; see *Appendix 1*, *Table 11*).

Based on monthly SMS responses from participants who responded for all 6 months, the mean number of times participants had self-harmed was 0.6 (SD 0.89, $n = 5$) overall: 0.8 (SD 0.96, $n = 4$) in the SafePIT therapy arm and 0.0 (SD 0.00, $n = 1$) in the SC arm (see *Appendix 1*, *Table 11*).

Descriptive summaries for further secondary outcomes are presented in *Table 4*. On the CORE-OM, RCSI was observed for four (4/9, 44.4%) participants, and deterioration in one participant. Similar levels of hopelessness, anxiety, interpersonal problems and QoL were observed at baseline and 6-month follow-up; however, interpretation is limited by the low follow-up rate.

Safety

No related unexpected serious adverse events were reported. There were no deaths and no risk incidents during the follow-up period. Of the 18 participants whose medical record was checked, two participants had one hospitalisation not due to SH during the 6-month follow-up period (11%). Both hospitalisations resulted in discharge from the ED, and neither of the participants was admitted to a hospital ward.

Health economic results

Health-related quality of life

Health-related quality of life was collected at baseline and 6 months. Responses were converted to a utility index using the conventional scoring algorithms.[31–33] According to current NICE guidance, the EQ-5D-5L was also converted using the three-level (3L) crosswalk.[34]

Area under the curve between baseline and 6 months was used to calculate QALYs. EQ-5D and ReQoL mean values are similar in magnitude and show little variation across treatment arms and time (*Table 5*). They are also comparable to preferred NICE values for SH states. CORE-6D values are consistently lower than index values from the other instruments. Pairwise correlations between instruments range from 0.45 to 0.91.

Intervention costs

Intervention costs are broken into two parts – the fixed costs for therapist training and supervision and the costs of therapists delivering the intervention which varied by participant depending on the number of sessions attended.

The curtailed nature of the trial means that therapist training costs are spread over far fewer therapists and patients than might be expected if the intervention were to be rolled out in the real world. We, therefore, produce costs according to what was observed and what may be expected (see *Appendix 1*, *Table 17*).

Costs are calculated by multiplying the duration of time required on each resource item by healthcare professionals' unit costs. Unit costs were obtained from the latest 'unit costs of health and social care manual'.[35]

TABLE 4 Descriptive summaries of outcomes

	Baseline			6 months		
	SafePIT intervention	UC	Total	SafePIT intervention	UC	Total
Hospitalisation due to SH				2/11 (18.2%)	0/7 (0%)	2/18 (11.1%)
Self-reported SH on 6-month questionnaire				1/4 (25.0%)	1/4 (25.0%)	2/8 (25.0%)
CORE-OM						
Mean (SD)	22.0 (8.83)	24.9 (6.68)	23.3 (7.88)	19.6 (4.36)	18.8 (10.02)	19.1 (7.58)
Median (range)	24.1 (1.5–33.5)	25.7 (13.0–32.6)	24.9 (1.5–33.5)	20.0 (13.8–24.4)	19.4 (5.3–31.2)	19.7 (5.3–31.2)
95% CI	(16.43 to 27.65)	(20.11 to 29.67)	(19.84 to 26.83)	(12.62 to 26.50)	(6.32 to 31.21)	(13.29 to 24.95)
Missing	0	0	0	8	5	13
CORE-OM categories						
Severe (25 to 40)	5 (41.7%)	6 (60.0%)	11 (50.0%)	0 (0.0%)	1 (20.0%)	1 (11.1%)
Moderate to severe (20 to < 25)	3 (25.0%)	2 (20.0%)	5 (22.7%)	2 (50.0%)	1 (20.0%)	3 (33.3%)
Moderate (15 to < 20)	2 (16.7%)	1 (10.0%)	3 (13.6%)	1 (25.0%)	1 (20.0%)	2 (22.2%)
Mild (10 to < 15)	0 (0.0%)	1 (10.0%)	1 (4.5%)	1 (25.0%)	1 (20.0%)	2 (22.2%)
Low level (6 to < 10)	1 (8.3%)	0 (0.0%)	1 (4.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Healthy (0 to < 6)	1 (8.3%)	0 (0.0%)	1 (4.5%)	0 (0.0%)	1 (20.0%)	1 (11.1%)
Missing	0	0	0	8	5	13
CORE-OM RCSI						
Not significant				3 (75.0%)	1 (20.0%)	4 (44.4%)
Significant improvement				1 (25.0%)	3 (60.0%)	4 (44.4%)
Significant deterioration				0 (0.0%)	1 (20.0%)	1 (11.1%)
Missing				8	5	13
BHS summaries						
Mean (SD)	12.4 (6.35)	16.1 (5.17)	14.0 (6.04)	11.8 (7.41)	17.9 (2.63)	15.1 (5.87)
Median (range)	14.5 (1.0–18.9)	17.0 (4.0–20.0)	17.0 (1.0–20.0)	12.5 (2.0–20.0)	19.0 (13.3–20.0)	18.0 (2.0–20.0)
95% CI	(8.32 to 16.39)	(12.11 to 20.05)	(11.20 to 16.70)	(−0.04 to 23.54)	(14.60 to 21.13)	(10.64 to 19.66)
Missing	0	1	1	8	5	13

continued

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TABLE 4 Descriptive summaries of outcomes (*continued*)

	Baseline			6 months		
	SafePIT intervention	UC	Total	SafePIT intervention	UC	Total
BHS categories						
Normal range (0–3)	1 (8.3%)	0 (0.0%)	1 (4.8%)	1 (25.0%)	0 (0.0%)	1 (11.1%)
Mild (4–8)	3 (25.0%)	1 (11.1%)	4 (19.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Moderate (9–14)	2 (16.7%)	1 (11.1%)	3 (14.3%)	2 (50.0%)	1 (20.0%)	3 (33.3%)
Severe (> 14)	6 (50.0%)	7 (77.8%)	13 (61.9%)	1 (25.0%)	4 (80.0%)	5 (55.6%)
Missing	0	1	1	8	5	13
GAD-7						
Mean (SD)	13.6 (7.19)	15.6 (4.27)	14.5 (5.99)	14.5 (2.08)	9.8 (7.66)	11.9 (6.09)
Median (range)	14.5 (1.0–21.0)	15.0 (10.0–21.0)	14.5 (1.0–21.0)	14.5 (12.0–17.0)	9.0 (0.0–21.0)	12.0 (0.0–21.0)
95% CI	(9.07 to 18.21)	(12.54 to 18.66)	(11.87 to 17.19)	(11.19 to 17.81)	(0.29 to 19.31)	(7.21 to 16.57)
Missing	0	0	0	8	5	13
GAD-7 category						
No anxiety (0–4)	1 (9.1%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	1 (20.0%)	1 (12.5%)
Mild (5–9)	3 (27.3%)	0 (0.0%)	3 (14.3%)	0 (0.0%)	2 (40.0%)	2 (25.0%)
Moderate (10–14)	2 (18.2%)	5 (50.0%)	7 (33.3%)	2 (66.7%)	1 (20.0%)	3 (37.5%)
Severe (15–21)	5 (45.5%)	5 (50.0%)	10 (47.6%)	1 (33.3%)	1 (20.0%)	2 (25.0%)
Missing	1	0	1	9	5	14
IIP-32 total score						
Mean (SD)	49.8 (24.67)	56.0 (14.93)	52.6 (20.60)	68.3 (20.55)	63.6 (28.78)	65.7 (24.05)
Median (range)	55.0 (10.0–87.0)	54.5 (39.0–79.0)	55.0 (10.0–87.0)	68.0 (45.0–92.0)	51.0 (32.0–98.0)	59.0 (32.0–98.0)
95% CI	(34.08 to 65.42)	(45.32 to 66.68)	(43.46 to 61.72)	(35.55 to 100.95)	(27.86 to 99.34)	(47.18 to 84.15)
Missing	0	0	0	8	5	13
IIP-32 T-score category						
Low	4 (33.3%)	4 (40.0%)	8 (36.4%)	0 (0.0%)	1 (20.0%)	1 (11.1%)
T > 60–70 – Above average	4 (33.3%)	3 (30.0%)	7 (31.8%)	2 (50.0%)	2 (40.0%)	4 (44.4%)
T > 70 – Significant difficulty	4 (33.3%)	3 (30.0%)	7 (31.8%)	2 (50.0%)	2 (40.0%)	4 (44.4%)
Missing	0	0	0	8	5	13

TABLE 4 Descriptive summaries of outcomes (*continued*)

	Baseline			6 months		
	SafePIT intervention	UC	Total	SafePIT intervention	UC	Total
ReQoL						
Mean (SD)	27.50 (2.91)	27.50 (2.32)	27.50 (2.60)	28.25 (3.59)	25.40 (3.36)	26.67 (3.57)
Median (range)	28.00 (20–31)	27.00 (23–32)	27.50 (20–32)	29.50 (23–31)	26.00 (20–29)	27.00 (20–31)
95% CI	(25.65 to 29.35)	(25.84 to 29.16)	(26.35 to 28.65)	(22.53 to 33.97)	(21.23 to 29.57)	(23.92 to 29.41)
Missing	0	0	0	8	5	13

TABLE 5 Descriptive summaries of HRQoL and QALYs

	Baseline			6 months		
	SafePIT intervention (*n* = 10)	UC (*n* = 12)	Total (*n* = 22)	SafePIT intervention (*n* = 4)	UC (*n* = 5)	Total (*n* = 9)
HRQoL						
EQ-5D-5L	0.73	0.62	0.68	0.68	0.71	0.70
EQ-5D-5L (mapped to 3L)	0.63	0.52	0.58	0.59	0.65	0.62
CORE-6D	0.56	0.49	0.53	0.56	0.60	0.58
ReQoL	0.69	0.68	0.68	0.69	0.63	0.66
QALYs						
EQ-5D-5L	N/A	N/A	N/A	0.35	0.34	0.35
EQ-5D-5L (mapped to 3L)	N/A	N/A	N/A	0.30	0.31	0.31
CORE-6D	N/A	N/A	N/A	0.29	0.26	0.27
ReQoL	N/A	N/A	N/A	0.34	0.34	0.34

N/A, not applicable.

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Professional-specific costs were assigned based on therapists self-reported job title and band. Trainers were assumed to be Agenda for Change band 7.

Two methods were used when applying unit costs to fixed cost items (training and supervision), by either regarding them as investments in human capital which is consumed over time (adjusted costs), or as direct costs into intervention delivery (unadjusted costs).

Adjusted unit costs are calculated as per,[35] following methods described by Netten and colleagues, 1998.[36] The fixed costs per therapist are added to annual qualification and training costs in the unit cost calculation. To incorporate fixed costs into unit costs, we assume 1553 hours of work per week in line with estimates for qualified nurses.[35] We have assumed the additional training costs are ongoing annuitised costs. This results in additional unit costs of £1 per hour of healthcare professionals' time.

Unadjusted unit costs include the standard unit costs reported by[35] and include therapist fixed costs directly in the intervention costs. The variable costs for intervention delivery are reported in *Appendix 1*, *Table 18*.

Total intervention costs (fixed and variable costs) are reported in *Table 6*. We present three costing scenarios, which differ according to the use of unadjusted or adjusted unit costs and how fixed costs are distributed across patients and therapists. The base case assumes that all therapist training costs are considered human capital costs that is depreciated slowly over time (and unrelated to the number of patients seen). Scenarios 1 and 2 consider training as fixed costs to be divided over the numbers of patients seen. Scenario 2 considers the number of patients with interventions seen during the trial, whereas scenario 1 considers the planned number of patients as in the original RCT design, where each therapist was expected to treat 11 participants.

Resource use

Resource use costs were determined from self-reported resource over the previous 3 months multiplied by unit costs taken from standard sources.[35] A full description of primary and community care resource usage is provided in *Appendix 1*, *Table 19*. Societal costs were obtained from self-reported work absenteeism and private expenditure related to SH over the previous 3 months (*Table 7*).

Discussion and interpretation

Study closure

The SafePIT trial was closed in agreement with the funder (NIHR-HTA) in January 2023 because of a failure to recruit sufficient numbers of participants during the 12-month internal pilot. SafePIT recruitment commenced on 21 February 2022 when the first site was opened, and a total of 16 participants were recruited during the internal pilot phase (between 1 January 2022 and 31 December 2022) and 22 in total prior to closure. Assessment of the pilot phase criteria showed that the trial had met the green criteria for the number of sites open and recruiting, and the proportion of recruited eligible subjects, but met the red criteria for the total number of participants recruited and number of participants recruited monthly per site.

Summary of challenges

Even prior to the COVID-19 pandemic, it was not unusual for large-scale trials to struggle with recruitment;[37] one report identified that out of 114 MRC- or HTA-funded trials, less than one-third had recruited to target.[38] Since the COVID-19 pandemic, many non-COVID-related

TABLE 6 Intervention costs (per participant)

	Base case: adjusted unit costs	Scenario 1	Scenario 2
Fixed costs			
Training	N/A	£90	£823
Supervision	N/A	£47	£431
Variable costs			
Attended sessions	£110	£109	£109
Unattended sessions	£3	£2	£2
Total intervention costs	£113	£248	£1365

TABLE 7 Descriptive summary of resource use and societal costs

Item	Baseline			3 months			6 months		
	SafePIT (*n* = 12)	UC (*n* = 10)	Total (*n* = 22)	SafePIT (*n* = 4)	UC (*n* = 6)	Total (*n* = 10)	SafePIT (*n* = 4)	UC (*n* = 5)	Total (*n* = 9)
Primary and community care	£115	£100	£108	£21	£53	£40	£67	£111	£91
Pharmaceuticals	£18	£3	£11	NA	NA	NA	£29	£2	£14
Hospital	N/A	N/A	N/A	N/A	N/A	N/A	£195	£73	£139
Total health care	£133	£103	£118	£21	£53	£40	£291	£186	£244
Work absenteeism	£0	£0	£0	£0	£0	£0	£0	£0	£0
Personal costs	£24	£54	£38	£22	£1	£8	£16	£19	£18
Total wider societal costs	£24	£54	£38	£22	£1	£8	£16	£19	£18

clinical trials have struggled, particularly with site set-up and participant recruitment.[39]

Many of the trial team involved in SafePIT had previously conducted a similarly designed earlier-phase feasibility trial Multi-centre Intervention Designed for Self-harm using Interpersonal Problem-solving and a definitive trial Self-harm Intervention: Family Therapy to evaluate the effectiveness of a psychological intervention for adults and young people, respectively, who SH. Both studies were conducted prior to the COVID-19 pandemic and successfully recruited to target of 60 and 832 participants, respectively.[40,41] The recruitment methods employed by the SafePIT trial team drew upon the expertise gained from delivery of these trials, in addition, to published research about maximising recruitment[37,42] and included plans to work closely with trial sites to engage clinical and research staff, deliver training and maintain regular review.

Although there were several challenges which affected the ability to deliver the SafePIT trial, undoubtedly, the major impediment to delivery was the impact of the COVID-19 pandemic and its aftermath.[43] The trial was adversely impacted by COVID-19 in four key areas: (1) disruption to clinical liaison mental health teams which affected recruitment to the trial and delivery of the intervention; (2) pressure on research and development (R&D) teams which delayed site set-up and impaired recruitment; (3) enforced changes to training and delivery of the intervention to reduce risk of infection; and (4) a reduction in the number of eligible patients attending ED departments with SH during the pandemic and subsequently.

1. Disruption to clinical liaison mental health teams

During the COVID-19 pandemic, liaison mental health teams, who are normally based in EDs, were relocated from EDs to other parts of the hospital. Many staff in these teams were also redeployed to other mental health teams to help cope with staff sickness and absence. Although by the start of the SafePIT trial, most liaison mental health teams had been reconstituted and had returned to having a physical presence in ED, many suffered from a high turnover of staff and frequent sickness absence. Teams also reported a sense of demoralisation and difficulties in coping with an increased workload because of staff shortages. In the planning stage of the funding application for SafePIT, the team had informal dialogues with several liaison mental health services, which suggested there was capacity in teams at that time, due to a recent national investment in liaison services, and enthusiasm for the project. Although we were able to mitigate some of the effects of high staff turnover by training many more potential therapists than we had originally planned, we were not able to prevent delays to the opening of sites, site closure in one case and what was planned to be a temporary closure at another site developed into ultimately indefinite closure.

2. Pressure on R&D teams

There were a variety of problems and delays in site set-up and recruitment due to pressure on R&D teams. R&D teams had worked throughout the pandemic to deliver COVID-related research and many teams, when approached, asked for delays in site set-up to help accommodate their workload and targets. The trial provided monies for local researchers from R&D teams to manage recruitment.

However, there was a high turnover of research staff at sites, which led to gaps in availability of research staff, and problems with recruitment. Some research staff were not able to physically visit EDs and liaise with clinical staff face to face due to the Omicron wave and subsequent concerns regarding infection risks, which limited their ability to work closely with clinical teams. Other teams had set up requirements above and beyond what would typically be expected which led to considerable delays. Such requirements included extensive reviews of database security and the requirement of honorary contracts for liaison team members working on the trial.

3. Enforced changes to the intervention

In the funding application, it was planned to deliver all therapist training and the intervention itself face to face. Because of COVID-19, the team adapted the training so it could be delivered online, and the therapy was changed so it could be delivered either online or face to face or a blended form of both delivery modes. Two previous meta-analyses have reported that there is no major difference in outcome between face-to-face and remote therapy;[44,45] however, it is possible that remote therapy is not suitable for all clients. A recent analysis of the impact of switching from face-to-face therapy to video therapy as a consequence of the COVID-19 pandemic has suggested that although overall outcome is similar, patients who have been more negatively affected by COVID-19 may benefit less from remote therapy.[46]

4. Possible reduction in SH attendances at ED

Presentations of SH to ED fell during the first wave of COVID-19,[47] as did presentations to ED overall. Although overall attendances at ED bounced back in the latter half of 2020, recent attendance figures from NHS England suggest attendance rates for SH have remained low. Attendances for SH to hospitals in England for 2020–1, 2021–2 and 2022–3 were 71,634, 89,211 and 60,464, respectively.[48] These figures are likely to be underestimates due to a lack of mandatory reporting of intent in the Emergency Care Data Set but are still well below pre-COVID estimates of 220,000 presentations per annum.[5] Clinical staff at local trial sites also reported anecdotal drops in SH presentations and our PPI group reported that some people they knew were more reluctant to attend ED following SH because of a fear of contracting COVID-19 and long waits. It has been estimated that HES data underestimate SH attendances at ED by as much as 60%,[49] so it is not possible to determine whether there has been an actual fall in SH attendances post COVID-19 or a perceived fall by staff.

In addition to barriers arising from the COVID-19 pandemic, we also encountered other challenges that were unrelated to COVID-19. These included: (1) non-COVID-related delays to site set-up; (2) mental health staff attitudes to randomisation; and (3) the eligibility criteria we specified for the study.

1 Non-COVID-related delays to site set-up

Delays with the time taken to set-up sites for multicentre clinical trials is a recognised problem.[50] Proposals by the HRA to streamline the process by introducing targets and incentivising trusts do not work, as sites ask for delays before allowing applications to be submitted to them, 'so the clock does not start'. While we recognise that R&D departments have been working under enormous pressure to deliver both COVID-19-related and non-COVID-19-related research, there are non-COVID-19-related issues that contribute to considerable delays. Individual research sites do not behave in a uniform way and there are unacceptable variations in the levels of documentation required; the degree of scrutiny undertaken; the classification of Participant Identification Centres; sites not having correct contractual arrangements in place across Participant Identification Centres; the interpretation of Health Research Authority (HRA) guidelines; and the attribution and resourcing of excess treatment costs. There is also an unnecessary amount of duplication, and we encountered lengthy delays because sites did not have correct contractual arrangements in place across Participant Identification Centres. Although the HRA process recommends local R&D offices only address local capacity and capability issues, sites often create new local processes.[50] In our experience 9 months was the minimum time it took to set up a site with many sites taking over 12 months. In a recent study, which examined trial processes in 13 multisite RCTs, the mean time to site approval varied from 4.8 months to 24.9 months.[51]

2. Staff attitudes to approaching patients for consent to contact

Clinical research is essential to improve the outcomes for patients and there have been several recent initiatives, such as the joint statement by the Royal College of Physicians and NIHR, 'Making research everybody's business'[52] to try to embed a research culture in the NHS. Our experience suggests that there is not a strong research culture in mental health services, and this needs to be addressed.

Discussions with site teams suggested that ED staff were reluctant to approach patients because they felt uncomfortable about offering patients the opportunity to

participate in the trial when they could be allocated to the UC and receive no further treatment or support.

3. Eligibility criteria

Our original eligibility criteria were developed to identify patients with a relatively brief history of self-harming behaviour; people who were attending for the first time for SH or who had few prior SH episodes. At the same time as SafePIT, we were also running a parallel trial, the FReSH START trial,[53] to evaluate a more intensive intervention in people with multiple episodes of SH. We therefore ensured that the SafePIT and FReSH START eligibility criteria did not overlap, in order to differentiate clearly between eligibility for the two studies should they both to be hosted at the same site.

We found, however, it was not possible to run the two studies at the same site due to site capacity issues and the increased numbers and distinct liaison staff therapists required to deliver both trials. Data from some of the FReSH START study sites suggested that if we simplified the SafePIT eligibility criteria, there may be more patients who would be eligible for the SafePIT trial, without compromising the intention of recruiting people with a brief history of SH. After discussion with and support from our oversight committees, we implemented the new criteria concerned with the number of hospital attendances rather than number of SH events. We were unable to determine whether these changes impacted on recruitment due to the closure of the trial shortly after implementation.

Mitigation strategies

The trial opened in February 2022 at the height of the Omicron wave of the COVID-19 pandemic. We anticipated that site recruitment would be slow, given the circumstances, but after 4 months into the study, we recognised that recruitment was even more challenging than anticipated. As a routine, we had already implemented many of the recommendations to optimise recruitment to the trial,[54] which included mapping of eligibility and recruitment pathways and understanding the recruitment process. In discussion with the trial sites and the trial team, we implemented the following changes to address recruitment concerns: we reviewed patient and study-specific documentation and resources that provided information about SafePIT and simplified trial documentation that mental health staff had to complete reducing any burden on the teams as much as possible; we enabled patients to provide verbal rather than written consent for researcher contact (with approval from ethics) which eliminated the need for mental health staff to ask patients to sign a consent to contact form; we highlighted the recruitment issues on the intervention training so members of the liaison team who had trained as therapists would encourage their co-workers to approach patients for recruitment; we consulted with our PPI group and developed further patient facing literature to explain the study; we consulted frequently with site researchers and clinical staff and met frequently with teams to address concerns about randomisation and equipoise. We regularly reviewed recruitment screening logs and encouraged teams to approach all patients who had self-harmed and not try to judge themselves who may or may not be eligible for the study.

We considered whether the process of recruitment could be changed so that ED staff could also introduce the study to potential participants, so we did not have to rely on the overstretched liaison mental health teams. However, this would have meant that participants would not have received a structured psychosocial assessment from a mental health professional, prior to entering the study, which would compromise their safety and the integrity of the provision of SC as recommended by NICE.[55] After much consideration we decided not to implement this change.

To ensure that as many patients could be reached as possible, we gained approval for patients seen in diversionary services to be screened for the trial as well as those who attended ED. The diversionary services were often mental health decisions units where patients could attend after a SH event without needing to go through the ED. It became clear early in the trial that more and more diversionary services were being set up in many different trusts to reduce the number of patients seen by the ED. By including patients from these services too, we ensured that our reach of participant screening was as broad as possible, though ultimately no participants were screened or recruited from mental health decisions units due to the early study closure.

A key mitigation strategy employed was the change to the inclusion criteria of the trial, shifting this away from the numbers of times a patient had self-harmed in their lifetime to the number of ED attendances due to SH in their lifetime. Data from the FReSH START trial suggested such a change would result in a greater number of eligible patients, with around 50% of those screened for FReSH START who would be eligible for SafePIT under this criterion. Importantly, the change would still ensure the trial focused on patients with lower amounts of SH overall than targets in the FReSH START trial, ensuring that each trial targeted distinct populations as appropriate to the trial intervention intensity. SafePIT was originally designed to run in tandem with FReSH START, hence the distinct numbers in the inclusion criteria. Due to capacity

issues and the increased numbers and distinct liaison staff therapists required to deliver both trials only one site ever ran both trials and closed SafePIT to recruitment after only a few months due to a lack of support for the trial and very low numbers of patients meeting the SH criteria. The data available suggested that the change made would result in greater recruitment for the trial; unfortunately, the decision was made to close SafePIT to recruitment shortly after the implementation of this change.

Trial closure

Despite having support from both the TSC and the DMEC to continue recruitment, the SafePIT team was asked by the funder to consider whether continuation of the trial was feasible considering the ongoing COVID-19 climate where impact on already strained R&D/other NHS capacity could not be justified. Consequently, with approval of the TMG and the funder, the decision was made that the trial was not feasible to deliver under the current circumstances and the trial was closed to recruitment.

As part of the closedown plan, all sites were instructed to stop approaching patients, and participants who had been randomised but not yet started or completed their intervention were permitted to complete their intervention. A substantial amendment was submitted to inform the Research Ethics Committee (REC) about the early trial closure together with materials to inform participants about the reasons for the early closure, the reduction of follow-up to 6 months and the need to collect primary end-point data via medical notes review instead of through NHS England. The PPI lived experience group reviewed and contributed to the creation of the end of trial closure letters sent to participants undergoing follow-up and those who had already completed follow-up. Once REC approval was obtained for the substantial amendment, participants were phoned by sites researchers to verbally explain the reasons for the early trial closure, after which participants were sent the closedown letter.

Interpretation of study results

We have presented the trial results in the form of descriptive statistics due to the small number of participants. As expected, the baseline mean scores on the psychological measures we employed suggested that participants had high levels of psychological distress, hopelessness, anxiety and depression in keeping with a SH population.[9] The follow-up data we obtained are limited to 6-month post-randomisation questionnaire responses and as we informed all participants that the trial was closing, the response rate should be interpreted in this context.

Our primary outcome was time from randomisation to presentation at ED with a further SH episode which we planned to obtain via HES data supplemented with local searches. Collection of these data were not possible, but we obtained information from individual sites about attendances at local EDs within 6 months of randomisation by participants. The re-attendance rates were lower than we anticipated even allowing for the reduced follow-up period as most repeated SH occurs within the first 3 months of the index episode.[41] For example, in a feasibility study in a similar trial population, repetition of SH leading to hospital presentation within 6 months of randomisation occurred in 19 of the 62 participants (30.6%, 95% CI 19.2% to 42.1%).[41] We were unable, however, to capture attendances for SH beyond the trial site hospitals which may partially account for the lower rates, as participants could have attended other hospitals without our knowledge.

There were no suicides or major adverse events during the internal pilot and the truncated follow-up period. The safety measures which we employed during the study appeared to work well.

HRQoL as measured by the conventional generic EQ-5D instrument and the more mental health-orientated instruments of CORE-6D and ReQoL remained fairly stable across treatment arms, time point and choice of instrument.

The costs of the intervention are difficult to calculate under a curtailed trial as they consist of fixed costs such as training therapists (estimated at £1505 per therapist) and the variable costs of intervention delivery (estimated at £133 per participant). As fixed costs are spread across the numbers treated then an artificially low number of patients leads to artificially high fixed costs per delivery. Thus, the cost of the intervention ranges from £248 per patient to £1365 depending on whether we use the planned ratio of therapists to patients or the observed ratio.

Primary and secondary care use was variable across patients with no obvious differences between arms. Hospital costs represented the largest component and wider societal costs such as personal costs and work absenteeism close to zero.

There were too few subjects who were randomised to the intervention to be able to assess its acceptability. However, and of *interpretation of study results* of those who started the treatment 57% completed. Four participants agreed to take part in the study and were randomised

to the intervention but did not attend for treatment. We are unable to assess whether this was related to the intervention, but it is unlikely, as participants had been given information about the study and intervention and consented to take part.

Reflections on study design

Prior to submitting the SafePIT funding application to HTA, we considered several different trial designs, including cluster randomised, platform and Zelen designs.[56] We revisited this discussion with both of our oversight committees in view of the poor recruitment to SafePIT. While randomisation of sites rather than individuals to treatment allocation in a cluster randomised design may have resolved some of the concerns that clinical staff had about individual randomisation and helped with recruitment at intervention sites, it would not have been possible to recruit participants prior to randomisation of sites. It is likely then that recruitment at control sites would have remained challenging and potentially open to selection bias. Platform trials, including multiple intervention arms, could also be considered as an alternative that could make recruitment more appealing to patients and researchers due to a higher chance of receiving an active treatment; however, this may not address the key challenges faced in SafePIT.[57] A Zelen design, in which random assignment of treatment takes place prior to patient or participant consent, with consent to the assigned treatment, has been used in previous trials of SH.[58] However, this design has not been used within this population within the UK as far as we are aware and may be unlikely to be approved by a REC due to the autonomy interests of potential participants. A further alternative design to facilitate further work in this area is a trial within a cohort study, in which, unlike the traditional Zelen post-randomisation consent design, the cohort participants are informed about future research within the cohort.[59] Cohort studies generate and collect longitudinal data, and RCTs are increasingly using such studies as data infrastructures to help identify and recruit trial participants. It is possible that this approach in SH could lead to more efficient recruitment, more representative samples, and lessen disappointment bias in patients and reduce mental health staff's concerns about approaching patients to participate in trials.[60]

Patient and public involvement

The aim of the PPI was to ensure we considered the experience and needs of people who SH in the design and conduct of the study and help ensure the trial was conducted in a participant-friendly and ethically acceptable way.

We had PPI input from the initial stages of development of the trial protocol through involvement of a co-applicant, with personal experience of SH and considerable experience of raising awareness and advocating for better mental health care. When the study began, we established a lived experience panel of 14 people, with either personal experience of SH or experience of caring for someone who self-harmed. We established with individual members a personal plan of how best to involve them and what support they needed. The panel met online eight times over the study period with between 5 and 14 members present at each meeting. Panel members not in attendance had the option of submitting comments by e-mail. Initial meetings focused on providing input to the development of study procedures and materials – all patient-facing documentation was written in collaboration with our panel. As recruitment started and the trial progressed, the meetings focused on exploring recruitment difficulties and identifying strategies to support recruitment. At study closure, we discussed with our panel how to manage this with participants and developed patient-facing documents to explain the closure. A final panel meeting in March 2024 discussed the implications of the early closure and strategies to disseminate the study findings and implications.

Our lived experience panel have been actively involved in important discussions about the study. There was much disappointment in the decision to close the study, there was worry that this signalled a disinvestment in mental health research. Our PPI panel have been keen to stress throughout the importance of the study area; there are few evidence-based interventions available for people who SH and the panel were very keen that funding be available for further studies in this area. Reflecting on our PPI input, we had good engagement form the panel and received a lot of useful advice and feedback. We had to be extremely proactive to ensure we recruited a diverse panel; we enlisted help from organisations that provided services to ethnically diverse populations to help us recruit panel members. Our panel had diversity across gender and ethnicity. This time investment was important as there was a lot of discussion about inclusive and appropriate language for our participant facing materials.

Equality, diversity and inclusion

Although the number of participants recruited to the trial was small, they were broadly reflective of the population of people who attend EDs in England following SH. There

was a slight over representation of females in the trial and people with a White British ethnic background.

Gender

Men account for approximately one-third of all presentations to the ED for SH[6] however, the proportion of men who were recruited to the study was lower (22.9%). This was not entirely unexpected as men are less likely than women to seek help for mental health problems[61] and they are under-represented in trials of psychotherapy. A recent scoping review of male involvement in randomised trials testing psychotherapy or behavioural interventions for depression determined that men's representation was low across all intervention characteristics; out of 110 eligible articles 26% of participants were male and 73% were female;[30] similar to the proportions of males and females recruited to SafePIT.

Reasons for lower participation of men in trials of psychological treatment and their lower likelihood of receiving psychological help from the NHS[62] include: perceptions that mental health problems and help seeking are signs of weakness;[63] views of psychotherapy as unappealing and not-masculine;[64] and discomfort with certain aspects of personal disclosure, emotional expression and vulnerability.[65]

Men who recover from self–harming behaviour report that they do so when the 'time feels right for them' so they may or may not engage with mental health professionals if they are not ready to address their behaviour and want help.[66] Qualitative work suggests a tendency for men to only seek help after exhausting all other perceived avenues for support and to struggle to engage in the therapeutic process.[67] Encountering non-judgemental professionals when they are ready to engage is important in their recovery. Psychotherapy may therefore be helpful and appropriate, but only when certain preconditions to recovery align in a person's life (e.g. being able to ask for help, accepting setbacks, trusting others). Non-psychological approaches to helping males who SH have been suggested in certain circumstances, but these were beyond the scope of this study.

Ethnicity

Ninety-one per cent of those screened for SafePIT and 90.9% of those randomised were classified as White British. The proportion of people from ethnic minorities who present to ED with SH varies across the country, with relatively higher rates in urban areas, particularly London.[68] Data collected from three English cities (Manchester, Oxford and Derby) using established monitoring systems reported rates of hospital presentations of SH for people with a White British background of 77%, 87% and 77%, respectively, from each of the three cities.[6] However, only 6%, 7% and 3% (Manchester, Oxford and Derby, respectively) of people in the study were classed as having a Black or Asian ethnicity, although there were quite a lot of missing data (17% of the data were missing in Derby and 10% were missing in Manchester).

It is likely that there is a slightly higher than expected proportion of people with a White British background who were screened and recruited to the trial.

Impact and learning

As the trial was closed early, there are no results from the study that can be used to inform current policy or service delivery. The main findings concern the barriers to the delivery of the trial we encountered as a consequence of factors related to the COVID-19 pandemic and factors unrelated to the pandemic.

Implications for practice/decision-maker

There are no implications for practice or decision-makers as the trial could not be completed.

Importance of the research question

The need for a definitive trial of psychological treatment for SH remains important. The recently updated National Suicide Prevention Strategy which, was published in November 2023,[3] includes the improvement of support for people who have self-harmed as one of its three central aims. SH remains the strongest factor associated with subsequent suicide[4] and in those people who attend hospital following SH, the risk is greatest in the first month following attendance.[69]

The provision of appropriate and timely psychological aftercare for people who SH remains substandard. Recent research suggests staff in liaison mental health services report ongoing challenges in finding appropriate aftercare for people as patients may be considered 'too well' for hospital care but too high a suicide risk for primary care.[70] This leaves liaison mental health staff feeling they are 'between a rock and a hard place' as they are not able to access any meaningful treatment for patients.

Despite increased investment in mental health services in the ED and community, many people presenting to hospital with SH report they are offered very little follow-up care[71,72] and remain at high risk of suicide. Narrow referral criteria mean that people are excluded either because they are not ill enough or too risky, or because they have alcohol-related problems.[73]

The SafePIT intervention was designed to provide a timely and tailored intervention for patients following SH presentations at ED, delivered by well-resourced mental health teams. Despite the failure to deliver the trial (due in a large part to COVID-19), this kind of intervention delivery remains a priority for patients. A recent study which explored patient experiences of accessing psychological therapies following SH, recruited 128 patients and 23 carers from 16 English mental health trusts.[74] Participants reported long waiting times, multiple failed promises and rejection when trying to access therapies following SH. Other barriers included a lack of tailored interventions, stigmatising response by staff and use of exclusionary thresholds to access services. Participants recommended the importance of timely access to aftercare from well –funded teams, continuity of care and greater choice over interventions. This suggests the intervention model used in SafePIT accords with patient concerns, but its delivery is challenging in the current post COVID-19 environment.

Research recommendations

As the trial was closed early, our recommendations are limited and focus upon areas that could help successful trial delivery in the future.

- The time taken to set up research trial sites in multicentre studies needs to be reduced by further streamlining and standardising the processes involved and reform of the system using learning acquired from the successful pragmatic approach to the regulation of COVID-19 research.
- Delivery of therapist training via online methods is less costly than face-to-face training, less disruptive to staff and mental health services, and enables training to be delivered more frequently. We were not able to assess whether it results in the same level of fidelity to the intervention, due to the small number of therapies delivered during the trial.
- Future trials of SH should consider additional support to improve participants' engagement in therapy to reduce the proportion of those randomised to the intervention who do not attend for any therapy sessions.
- Alternate approaches to recruiting people who have self-harmed need to be developed and tested. These include recruiting people in the ED before they have had a psychosocial assessment,[75] or recruiting people in the period after they have self-harmed through primary care or third sector services.[76] Cohort studies generate and collect longitudinal data and RCTs are increasingly using such studies as data infrastructures to help identify and recruit trial participants. It is possible that this approach in SH research could lead to more efficient recruitment, more representative samples, and lessen disappointment bias in patients and reduce mental health staff's concerns about approaching patients to participate in trials.[60]
- Acute mental health services should be further encouraged and resourced to participate in research.

Conclusions

The SafePIT study was closed early due to severe difficulties with recruitment. We identified several reasons for the failure of the study, including those related to the COVID-19 pandemic and those non-related. The greatest impediment to the delivery of the trial was the impact of the pandemic and its aftermath on the disruption and collapse in some cases of the clinical services within which we had embedded the study and the local research teams who were charged with recruitment.

Pre-COVID, clinical liaison mental health teams had experienced an uplift in funding and had the necessary skills and capacity at that time to deliver the intervention. Many of the trial team had experience of successfully delivering both a previous multicentre feasibility study of a psychological intervention for adults who self-harmed and a large multicentre study for young people who self-harmed and were confident a similar study could be delivered.

Further research in this area is imperative as SH remains the biggest single risk factor for suicide, and psychological services for people who SH are limited. A definitive trial is still required. However, the design, methods of recruitment, and delivery of the intervention need to be revised as EDs and mental health services associated with EDs and R&D departments remain under severe pressure.

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Additional information

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Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it is important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

Data-sharing statement

Data supporting this work are available on reasonable request. All requests will be reviewed by relevant stakeholders, based on the principles of a controlled access approach. Requests to access data should be made to CTRU-DataAccess@leeds.ac.uk in the first instance.

Ethics statement

Research Ethics Committee approval was obtained from the East of England – Cambridgeshire and Hertfordshire Research Ethics Committee on 1 October 2021 (ref.: 21/EE/0204).

Information governance statement

The University of Leeds is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679.

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Florence Day is involved with the grant funding paid to collaborating institutions for this trial.

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

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List of abbreviations

AUDIT-C	alcohol use disorders identification test-consumption
BHS	Beck Hopelessness Scale
CORE-OM	Clinical Outcomes in Routine Evaluation – Outcome Measure
CTRU	Clinical Trials Research Unit
DMEC	Data Monitoring and Ethics Committee
ED	emergency department
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
GAD-7	Generalised Anxiety Disorder-7
GP	general practitioner
HES	Hospital Episode Statistics
IIP-32	Inventory of Interpersonal Problems-32
INQ	Interpersonal Needs Questionnaire
LTE	List of Threatening Experiences
NICE	National Institute for Health and Clinical Excellence
PIT	psychodynamic-interpersonal therapy
PPI	patient and public involvement
QALY	quality-adjusted life-year
R&D	research and development
RCSI	reliable and clinically significant improvement
RCT	randomised controlled trial
REC	Research Ethics Committee
REDCAP	Research Electronic Data Capture
REQOL	recovering quality of life
SAFEPIT	Self-harm, Assessment, Formulation, Engagement Trial of Psychodynamic Interpersonal-Therapy
SASPD	Standardised Assessment of Severity of Personality Disorder
SC	standard care
SH	self-harm
SDES	Short Defeat and Entrapment Scale
SMS	Short Message Service
TMG	Trial Management Group
TSC	Trial Steering Committee
UC	usual care

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Guthrie E, Copsey B, Wright-Hughes A, Dowse A, Bojke C, Mattock R, *et al*. Brief psychodynamic-interpersonal therapy for adults with a history of self-harm: the SafePIT RCT [published online ahead of print November 26 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/TNGF8545

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Appendix 1 Additional tables and figures

TABLE 8 Comparison of characteristics of screened, eligible and randomised patients

	Screened *N* = 378	Eligible *N* = 35	Randomised *N* = 22
Age (years)			
Mean (SD)	34.7 (15.36)	39.1 (16.29)	40.0 (18.40)
Median (range)	30.0 (17–91)	34.0 (19–73)	35.0 (19–73)
Missing	10	0	0
Gender			
Male	121 (33.1%)	8 (22.9%)	5 (22.7%)
Female	239 (65.3%)	26 (74.3%)	16 (72.7%)
Non-binary	6 (1.6%)	1 (2.9%)	1 (4.5%)
Missing	12	0	0
Type of SH			
Self-injury	84 (24.0%)	5 (14.3%)	3 (13.6%)
Self-poisoning	244 (69.7%)	30 (85.7%)	19 (86.4%)
Both	22 (6.3%)	0	0
Missing	28	0	0
Ethnicity			
White British	342 (91.2%)	31 (88.6%)	20 (90.9%)
White Irish	1 (0.3%)	1 (2.9%)	1 (4.5%)
White Gypsy or Irish Traveller	2 (0.5%)	0	0
Any other White background	8 (2.1%)	0	0
Mixed – White and Black Caribbean	6 (1.6%)	1 (2.9%)	0
Mixed – White and Black African	1 (0.3%)	0	0
Other mixed background	1 (0.3%)	0	0
Asian or Asian British – Pakistani	2 (0.5%)	1 (2.9%)	1 (4.5%)
Other Asian background	3 (0.8%)	1 (2.9%)	0
Black or Black British – African	1 (0.3%)	0	0
Black or Black British – Caribbean	1 (0.3%)	0	0
Other Black background	1 (0.3%)	0	0
Not stated/prefer not to say	6 (1.6%)	0	0
Missing	3	0	0

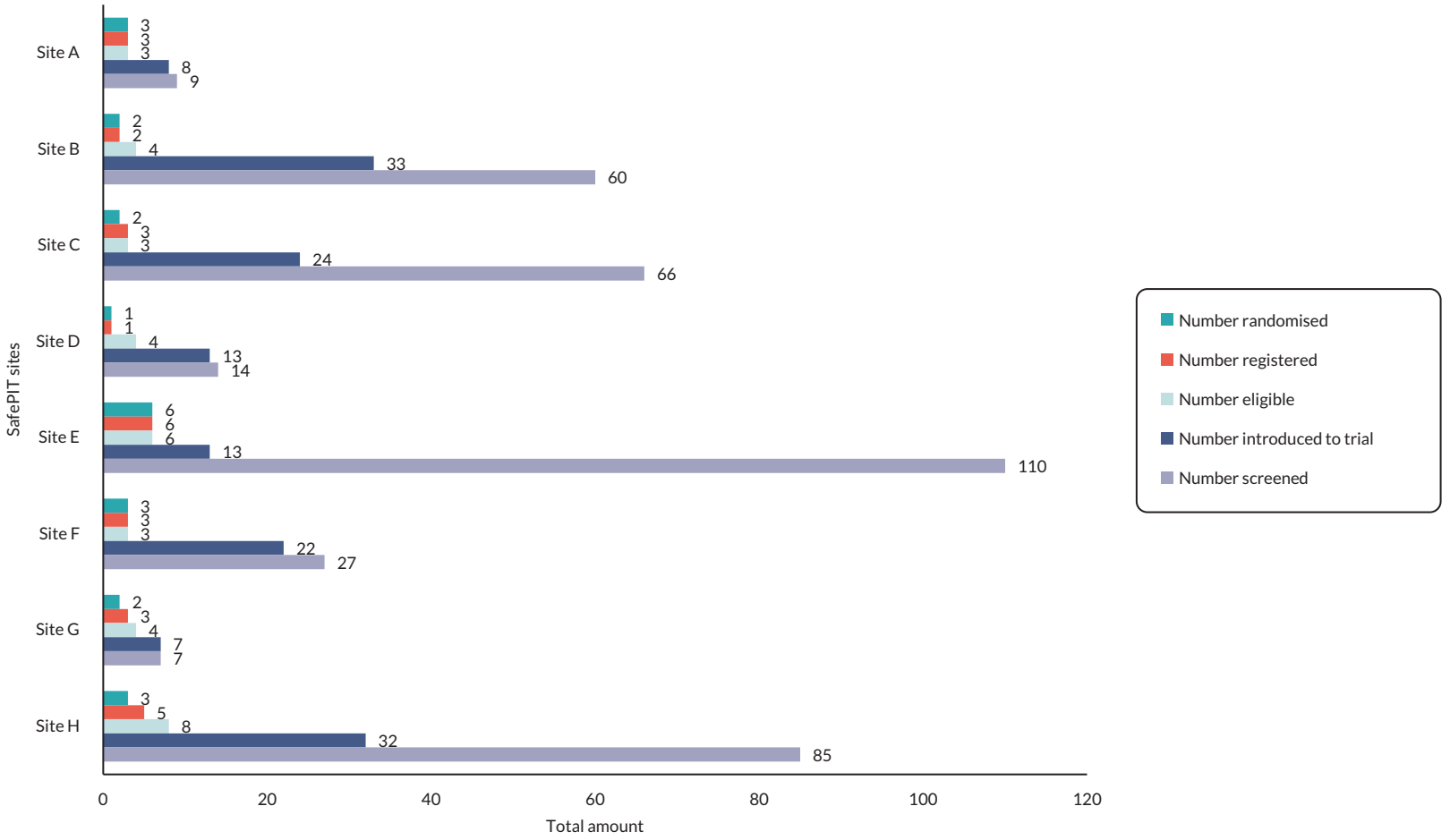

FIGURE 2 Screening and recruitment by site.

This synopsis should be referenced as follows: Guthrie E, Copsey B, Wright-Hughes A, Dowse A, Bojke C, Mattock R, *et al*. Brief psychodynamic-interpersonal therapy for adults with a history of self-harm: the SafePIT RCT [published online ahead of print November 26 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/TNGF8545

TABLE 9 Additional baseline questionnaires

	SafePIT intervention *N* = 12	SC *N* = 10	Total *N* = 22
SASPD score			
Mean (SD)	8.8 (3.77)	11.5 (5.28)	10.0 (4.62)
Median (range)	8.0 (3.0–13.0)	10.5 (2.0–20.0)	9.5 (2.0–20.0)
Missing	0	0	0
SASPD score – categorised			
Less than mild: < 8	6 (50.0%)	1 (10.0%)	7 (31.8%)
Mild: 8 to < 10	1 (8.3%)	3 (30.0%)	4 (18.2%)
Moderate: 10 or more	5 (41.7%)	6 (60.0%)	11 (50.0%)
INQ score			
Mean (SD)	56.2 (19.53)	62.3 (18.60)	59.0 (18.91)
Median (range)	60.0 (19.0–78.0)	61.5 (39.0–96.0)	61.0 (19.0–96.0)
Missing	0	0	0
INQ perceived burden subscale score			
Mean (SD)	21.8 (12.84)	21.9 (11.22)	21.9 (11.85)
Median (range)	23.0 (6.0–42.0)	19.5 (7.0–42.0)	21.0 (6.0–42.0)
Missing	0	0	0
INQ perceived burden subscale category			
Clinically significant social disconnection: 12 or more	9 (75.0%)	8 (80.0%)	17 (77.3%)
Not significant social disconnection: < 12	3 (25.0%)	2 (20.0%)	5 (22.7%)
INQ thwarted belonging subscale score			
Mean (SD)	34.5 (10.44)	40.4 (8.86)	37.2 (9.98)
Median (range)	36.5 (13.0–50.0)	39.0 (31.0–54.0)	37.0 (13.0–54.0)
Missing	0	0	0
INQ thwarted belonging subscale category			
Clinically significant social disconnection: 36 or more	8 (66.7%)	6 (60.0%)	14 (63.6%)
Not significant social disconnection: < 36	4 (33.3%)	4 (40.0%)	8 (36.4%)
LTE score			
Mean (SD)	3.3 (1.67)	3.2 (2.15)	3.3 (1.86)
Median (range)	3.5 (1.0–6.0)	2.5 (0.0–7.0)	3.0 (0.0–7.0)
Missing	0	0	0
LTE score – categorised			
No events	0 (0.0%)	1 (10.0%)	1 (4.5%)
1 or more events	12 (100.0%)	9 (90.0%)	21 (95.5%)

TABLE 9 Additional baseline questionnaires (*continued*)

	SafePIT intervention *N* = 12	SC *N* = 10	Total *N* = 22
SDES score			
Mean (SD)	2.4 (1.41)	2.9 (0.66)	2.6 (1.14)
Median (range)	2.8 (0.0–4.0)	3.0 (1.9–4.0)	3.0 (0.0–4.0)
Missing	0	0	0
SDES defeat subscale score			
Mean (SD)	2.4 (1.43)	2.9 (0.87)	2.6 (1.21)
Median (range)	2.6 (0.0–4.0)	3.0 (1.5–4.0)	3.0 (0.0–4.0)
Missing	0	0	0
SDES entrapment subscale score			
Mean (SD)	2.4 (1.41)	2.9 (0.67)	2.6 (1.14)
Median (range)	2.8 (0.0–4.0)	3.1 (1.8–4.0)	2.9 (0.0–4.0)
Missing	0	0	0

TABLE 10 Baseline characteristics by whether participant returned 6-month questionnaire

	Returned *N* = 9	Did not return *N* = 13	Total randomised *N* = 22
Age			
Mean (SD)	43.6 (20.30)	37.5 (17.37)	40.0 (18.40)
Median (range)	53.0 (20–64)	29.0 (19–73)	35.0 (19–73)
Gender			
Man	2 (22.2%)	3 (23.1%)	5 (22.7%)
Woman	7 (77.8%)	9 (69.2%)	16 (72.7%)
Non-binary	0 (0.0%)	1 (7.7%)	1 (4.5%)
Ethnicity			
White British	7 (77.8%)	13 (100.0%)	20 (90.9%)
White Irish	1 (11.1%)	0 (0.0%)	1 (4.5%)
Asian or Asian British – Pakistani	1 (11.1%)	0 (0.0%)	1 (4.5%)
Education			
O Level/GCSE/NVQ2	4 (44.4%)	2 (15.4%)	6 (27.3%)
A Level/NVQ3	3 (33.3%)	6 (46.2%)	9 (40.9%)
Advanced diploma/bachelor degree	2 (22.2%)	2 (15.4%)	4 (18.2%)
Post-graduation certificate, diploma or master's degree	0 (0.0%)	1 (7.7%)	1 (4.5%)
Other	0 (0.0%)	1 (7.7%)	1 (4.5%)
Missing	0 (0.0%)	1 (7.7%)	1 (4.5%)

continued

TABLE 10 Baseline characteristics by whether participant returned 6-month questionnaire (*continued*)

	Returned *N* = 9	Did not return *N* = 13	Total randomised *N* = 22
SH before			
Yes	7 (77.8%)	8 (61.5%)	15 (68.2%)
No	2 (22.2%)	4 (30.8%)	6 (27.3%)
Missing	0 (0.0%)	1 (7.7%)	1 (4.5%)
CORE-OM categories (severity) at baseline			
Severe (25–40)	4 (44.4%)	7 (53.8%)	11 (50.0%)
Moderate to severe (20 to < 25)	3 (33.3%)	2 (15.4%)	5 (22.7%)
Moderate (15 to < 20)	2 (22.2%)	1 (7.7%)	3 (13.6%)
Mild (10 to < 15)	0 (0.0%)	1 (7.7%)	1 (4.5%)
Low level (6 to < 10)	0 (0.0%)	1 (7.7%)	1 (4.5%)
Healthy (0 to < 6)	0 (0.0%)	1 (7.7%)	1 (4.5%)
CORE-OM baseline score[a]			
Mean (SD)	24.2 (5.09)	22.7 (9.50)	23.3 (7.88)
Median (range)	24.1 (17–33)	25.9 (1–34)	24.9 (1–34)

a CORE-OM score ranges from 0 to 40 with a higher score indicating higher levels of distress.

TABLE 11 Participant-reported SH outcomes at 6 months

	SafePIT intervention	SC	Total
Number of times self-harmed in 6 months – questionnaire			
Mean (SD)	0.5 (1.00)	0.8 (1.50)	0.6 (1.19)
Median (range)	0 (0–2)	0 (0–3)	0 (0–3)
Missing	8	6	14
N	4	4	8
SMS SH for 6 months (no missing responses)			
Mean (SD)	0.8 (0.96)	0.0 (.)	0.6 (0.89)
Median (range)	1 (0–2)	0 (0–0)	0 (0–2)
Missing	8	9	17
N	4	1	5

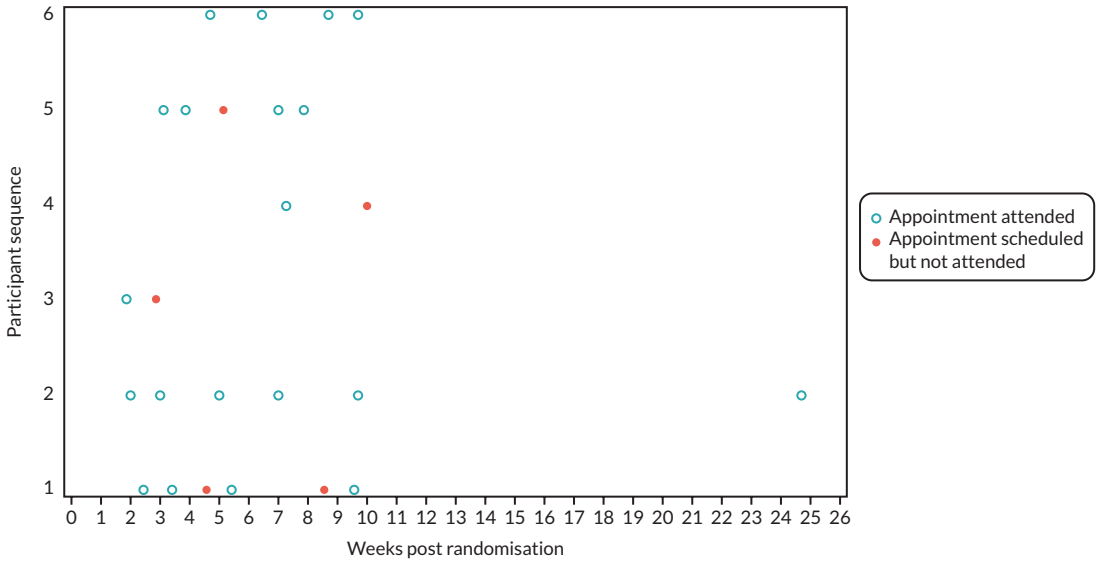

FIGURE 3 Session attendance.

TABLE 12 Fidelity overall scores

	Session assessed			
	1	2	3	Total
Fidelity achieved[a]				
Yes	5 (100.0%)	3 (100.0%)	2 (100.0%)	10 (100.0%)
No	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
PIT overall score[b]				
Mean (SD)	4.4 (0.43)	4.6 (0.44)	4.9 (0.42)	4.6 (0.42)
Median (range)	4.4 (4–5)	4.4 (4–5)	4.9 (5–5)	4.5 (4–5)
95% CI	(3.89 to 4.97)	(3.54 to 5.73)	(1.09 to 8.65)	(4.28 to 4.88)
N	5	3	2	10

a Fidelity to PIT (F36) is defined as therapists achieving a mean score of at least 4 points on all items that were employed (PIT-specific adherence, items 1–8). Items that are not employed in that particular session (i.e. items where the response is 'N/A') will not be rated and will not count towards the mean score.
b The overall fidelity score ranges from 1 to 7 with a higher score indicating greater fidelity.

TABLE 13 Fidelity item-level scores

	1. Statements	2. Understanding hypotheses	3. Negotiating style	4. Therapy rationale	5. Cue basis	6. Metaphor	7. Focusing	8. Exploration of feelings
1 Not at all	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)
3 Some	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)
4	3 (30.0%)	3 (30.0%)	7 (70.0%)	0 (0.0%)	4 (40.0%)	3 (30.0%)	3 (30.0%)	2 (20.0%)
5 Quite a lot	4 (40.0%)	7 (70.0%)	2 (20.0%)	1 (10.0%)	4 (40.0%)	0 (0.0%)	6 (60.0%)	7 (70.0%)
6	2 (20.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	2 (20.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)

continued

TABLE 13 Fidelity item-level scores (*continued*)

	1. Statements	2. Understanding hypotheses	3. Negotiating style	4. Therapy rationale	5. Cue basis	6. Metaphor	7. Focusing	8. Exploration of feelings
7 Considerably	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
N/A	0 (0.0%)	0 (0.0%)	1 (10.0%)	7 (70.0%)	0 (0.0%)	5 (50.0%)	0 (0.0%)	1 (10.0%)
Total	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)

Note
Fidelity item scores range from 1 to 7, with a higher score indicating greater fidelity.

TABLE 14 Therapist characteristics

	Total *N* = 18
Current job role	
Liaison mental health nurse	11 (68.8%)
Mental health nurse	1 (6.3%)
Psychiatrist	2 (12.5%)
Senior psychological therapist	2 (12.5%)
Missing	2
Team	
Liaison psychiatry team	13 (81.3%)
Community team	2 (12.5%)
Other	1 (6.3%)
Missing	2
Gender	
Man	2 (12.5%)
Woman	14 (87.5%)
Missing	2
Ethnicity	
White British	15 (93.8%)
Any other Asian background	1 (6.3%)
Missing	2
NHS Band	
Band 6	8 (50.0%)
Band 7	3 (18.8%)
Band 8a	3 (18.8%)
Other	2 (12.5%)
Missing	2

TABLE 14 Therapist characteristics (*continued*)

	Total *N* = 18
Age	
Mean (SD)	42.1 (7.13)
Median (range)	42.0 (32–56)
Missing	4
Undergraduate degree	
Nursing	9 (56.3%)
Occupational therapy	1 (6.3%)
Psychology	2 (12.5%)
Medicine	2 (12.5%)
No undergraduate health discipline degree	2 (12.5%)
Missing	2
Are you a registered nurse?	
Yes	13 (81.3%)
No	3 (18.8%)
Missing	2
Post-graduate qualifications in a health discipline	
Postgraduate certificate/diploma	5 (41.7%)
Masters	2 (16.7%)
Other (Membership of the Royal College of Psychiatrists	1 (8.3%)
No post-graduate qualifications	4 (33.3%)
Missing	6

Notes
Therapist characteristics are reported for 18 therapists who returned their baseline form. Forms were not returned for the remaining 20 therapists who started training.
Other bands included ST6 (*n* = 1) and medical (*n* = 1).

TABLE 15 Supervisor characteristics

	Total *N* = 5
What is your current job role?	
Psychologist	1 (20.0%)
Psychiatrist	2 (40.0%)
Psychotherapist	1 (20.0%)
Clinical supervisor	1 (20.0%)
How would you describe your gender?	
Male	4 (80.0%)
Female	1 (20.0%)

continued

TABLE 15 Supervisor characteristics (*continued*)

	Total *N* = 5
How would you describe your ethnicity?	
White British	3 (60.0%)
Any other White background	1 (20.0%)
White and Black African	1 (20.0%)
What NHS Band does your job fall in?	
Band 7	1 (20.0%)
Band 8b	1 (20.0%)
Consultant	2 (40.0%)
N/A – retired	1 (20.0%)
Please state your age in years	
Mean (SD)	48.4 (11.99)
Median (range)	49.0 (33–65)
Missing	0

TABLE 16 Supervision sessions

	Total *N* = 43 sessions
Method of supervision	
Telephone	1 (2.3%)
Video conference, for example, Microsoft Teams/Zoom call[a]	42 (97.7%)
Number of therapists attending	
1	15 (34.9%)
2	17 (39.5%)
3	8 (18.6%)
4	1 (2.3%)
5	2 (4.7%)
Topic discussed	
Fidelity monitoring	16 (37.2%)
Review of actual practice	23 (53.5%)
Therapy interventions/approaches	35 (81.4%)
Case conceptualisation/formulation	27 (62.8%)
Client relationship/alliance building	34 (79.1%)
Administrative tasks	30 (69.8%)
Crisis/risk issues	18 (41.9%)
Supervisee's professional roles	25 (58.1%)
Supervisory relationship/process	23 (53.5%)
Other topic	17 (39.5%)

TABLE 16 Supervision sessions (*continued*)

	Total *N* = 43 sessions
Main focus of the supervision session	
Fidelity monitoring	2 (4.7%)
Review of actual practice	14 (32.6%)
Therapy interventions/approaches	12 (27.9%)
Case conceptualisation/formulation	5 (11.6%)
Client relationship/alliance building	8 (18.6%)
Administrative tasks	3 (7.0%)
Crisis/risk issues	2 (4.7%)
Supervisee's professional roles	2 (4.7%)
Supervisory relationship/process	2 (4.7%)
Other topic	9 (20.9%)

a Microsoft Teams (Microsoft Corporation, Redmond, WA, USA)/Zoom (Zoom Video Communications, San Jose, CA, USA).

Note
Other topics discussed were: role play (*n* = 7); recruitment to study (*n* = 2); saying goodbye, including the use of goodbye letter (*n* = 2); contacting patients after crisis assessment (*n* = 1); exclusion criteria (*n* = 1); past mental health linking to present (*n* = 1), pre- and post-natal depression (*n* = 1); difficulties of being a novice therapist and applying learning in future (*n* = 1) and delivering therapy via Teams (*n* = 1). Other main focus areas of the session were: role play (*n* = 5); recruitment to the study (*n* = 2) and saying goodbye, including the use of goodbye letter (*n* = 2). See table above.

TABLE 17 Fixed intervention costs for training and supervision

	Full sample (*n* = 38)[a]		Artificially curtailed sample (*n* = 10)[b]		Best estimate[c]	
	Duration (hours)	Cost	Duration (hours)	Cost	Duration (hours)	Cost
Training costs[d]						
Therapists	13.1	£861	13.4	£872	13.1	£861
Trainers	1.84	£127	6.8	£469	1.84	£127
Total		£988		£1341		£988
Supervision costs[e]						
Therapists	6.6	£429	4.1	£270	4.1	£270
Supervisors	3.2	£247	3.5	£271	3.2	£247
Total		£676		£541		£517
Total training + supervision		£1664		£1882		£1505

a All therapists included in the RCT.
b Only therapists assigned to participants prior to RCT closure.
c Our best estimate of fixed costs given the stated limitations.
d Includes costs across both samples .
e Supervision costs were not applicable to all therapists in the full sample; therefore per therapists costs are calculated by dividing total costs by the total number of therapists attending supervision.

TABLE 18 Variable costs for delivery of SafePIT therapy sessions

	N = 12	Duration (hours)	Unadjusted unit costs	Adjusted unit costs[a]
Sessions attended, mean (SD)	1.83 (2.59)	1.59 (2.19)	£109 (£147)	£110 (£148)
Sessions missed, mean (SD)	0.42 (0.67)	0.03 (0.06)	£2 (£4)	£3 (£4)
Total, mean (SD)			£111 (£149)	£113 (£152)

a Adjusted unit costs add the full sample fixed costs per therapist (£1505) to ongoing annual training and qualification costs per year within unit costs calculations, assuming 1553 hours' work per year. Therefore, adjusted unit costs are increased by £0.97 per hour.

TABLE 19 Descriptive summary of primary and community care costs

	Baseline			3 months			6 months		
HCP	SafePIT intervention (*n* = 12)	UC (*n* = 10)	Total (*n* = 22)	SafePIT intervention (*n* = 4)	UC (*n* = 6)	Total (*n* = 10)	SafePIT intervention (*n* = 4)	UC (*n* = 5)	Total (*n* = 9)
GP	3.58	2.80	3.23	0.50	0.83	0.70	1.75	2.60	2.22
Practice nurse	0.58	0.10	0.36	0.00	0.17	0.10	0.00	1.00	0.56
District nurse	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Physiotherapist	0.00	0.10	0.05	0.00	0.00	0.00	0.00	0.40	0.22
Occupational therapist	0.00	0.30	0.14	0.00	0.50	0.30	0.00	0.60	0.33
Drug and alcohol worker	0.33	0.00	0.18	0.00	0.00	0.00	0.00	0.00	0.00
Mental health worker	0.92	1.20	1.05	0.00	1.33	0.80	1.75	1.00	1.33
Social worker	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Helpline	1.25	0.20	0.77	0.75	0.00	0.30	1.00	0.00	0.44
IAPT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Midwife	0.08	0.00	0.05	0.00	0.00	0.00	0.00	0.00	0.00
Total	**6.75**	**4.70**	**5.82**	**1.25**	**2.83**	**2.20**	**4.50**	**5.60**	**5.11**

Appendix 2 End-point derivation

Primary end point

Time from randomisation to first repetition of SH leading to hospital attendance.

Self-harm-related hospital attendance was collected objectively from electronic hospital records by the trial researchers. They recorded any hospital attendances that occurred from the date of randomisation to the date of the medical records check.

Secondary end points

All secondary end points were only measured at 6 months due to the early closure of the trial. In the original protocol, end points were at 12 months post randomisation.

Rate of repetition of self-harm leading to hospital attendance

Self-harm leading to hospital attendance was determined from medical records, using the same process as the primary end point. The time was calculated from the date of randomisation to the date of the medical records check.

Time from randomisation to repetition of self-harm leading to hospital attendance (all events)

Time from randomisation to repetition of SH used the same process as the primary end point; however, it includes all events and not only the first repetition of SH. This outcome was not applicable since no participant had more than one episode of SH leading to hospital attendance.

Rate of repetition of self-reported self-harm using questionnaires

Self-reported SH was measured at 6 months by questionnaire and includes any report of SH, regardless of whether it led to hospital attendance.

Rate of repetition of self-reported self-harm using Short Message Service

Self-reported SH using SMS was sent monthly for 6 months for all participants. Participants were asked, 'In the past 4 weeks, on how many occasions have you harmed yourself?'

Psychological distress as measured by Clinical Outcomes in Routine Evaluation – Outcome Measure total score

The CORE-OM is a 34-item generic measure of psychological distress scored from 0 to 4. The overall score will be calculated as the mean score of the items multiplied by 10, giving a score from 0 to 40, with a higher score indicating higher levels of distress. Where there are missing data for three items or fewer, the overall score will be calculated as the mean across the recorded items multiplied by 10. If more than three items are missing, the overall score will be assigned as missing.

The CORE-OM score was categorised into: severe (25–40), moderate to severe (20 to < 25), moderate (15 to < 20), mild (10 to < 15), low level (6 to < 10), healthy (0 to < 6). The CORE-OM score was also categorised according to clinical cut-offs of clinical (10–40) and non-clinical (0 to < 10).

The proportion of people with clinically significant improvement (and deterioration) on Clinical Outcomes in Routine Evaluation – Outcome Measure

Reliable and clinically significant improvement on the CORE-OM was defined as: change in CORE-OM of five or more points (reliable) and movement from the clinical range (≥ 10/40) to the non-clinical range (< 10/40) (clinically significant).

Anxiety as measured by the Generalised Anxiety Disorder-7 total score

The GAD-7 is a seven-item questionnaire. The total score is the sum of the items, scoring from 0 to 3. The total score ranges from 0 to 21, with a higher score indicating higher levels of anxiety.

Hopelessness as measured by the Beck Hopelessness Scale total score

The BHS is a questionnaire in which a patient answers 'true' or 'false' to a series of 20 statements that test his or her feelings about the future. Nine items are inversely scored to prevent acquiescence. After inversion of the positively worded items, a sum score is calculated between 0 and 20, with a higher score indicating higher levels of hopelessness.

Higher scores indicate higher levels of hopelessness: 0–3 normal range, 4–8 mild hopelessness, 9–14 moderate hopelessness, scores > 14 severe hopelessness.

Interpersonal function measured by the Inventory of Interpersonal Problems

Inventory of Interpersonal Problems-32 questionnaire is a 32-item questionnaire. The raw total score is the sum of all items from 0 to 4. The total score ranges from 0 to 128 and is converted to T-scores, indicating difficulty relative to a non-clinical representative U.S. sample.

This synopsis should be referenced as follows:
Guthrie E, Copsey B, Wright-Hughes A, Dowse A, Bojke C, Mattock R, *et al*. Brief psychodynamic-interpersonal therapy for adults with a history of self-harm: the SafePIT RCT [published online ahead of print November 26 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/TNGF8545

Quality of life measured by the Recovering Quality of Life questionnaire-10

The ReQoL questionnaire is a 11-item questionnaire. The total score ranges from 0 to 40, where zero indicates poorest QoL and 40 indicates highest QoL. The ReQoL-10 index score can be calculated by summing the numbers for the first 10 questions on the first page.

Appendix 3 Summary of protocol changes

TABLE 20 Changes to study protocol

Change to protocol	Date
• Removed the requirement that the ED visit must be within the last 8 weeks from the inclusion criteria as this is covered in the exclusion criteria • The local PI can be a non-medically qualified professional at the discretion of the chief investigator • Deaths are to be reported to the DMEC rather than the TSC • The ISRCTN number has been added • Completion of therapy has been defined as four sessions, or a mutually agreed ending up to four sessions • The word 'competency' (referring to therapists) has been replaced by 'trial readiness' • Safety events will be collected up to 12 months post randomisation instead of 12 months post registration • The section describing the SWAT has been moved to the appendix at the request of the funder	19 January 2022
We have clarified guidance the clinical screening section (9.3) by listing a number of examples We have corrected an error in section 15.4 by replacing 'registered' with 'randomised'	28 March 2022
Inclusion criteria of 'Self-harmed 1–2 times in the last 12 months (any amount in their lifetime) OR self-harmed exactly three times in the last 12 months but never before this year' changed to 'Attended hospital as a result of SH three or fewer times in their lifetime'. This is in response to feedback from recruiting sites who indicate that they are unable to identify suitable participants based on the original criteria, as potential participants who attend hospital have often self-harmed more frequently, although this usually has not involved them attending hospital (in other words, the SH is very minor). By modifying our criteria to specify that potential participants must have attended ED following SH, for a prior episode to count, will enable us to recruit more people to the study without significantly changing the nature of the target population Update in key contact details (section 1) Update to inclusion criteria for the trial (section 8.1) Addition of decisions unit to recruitment setting (section 9.1) Addition of clinic posters displayed in participating sites (e.g. EDs, accident and emergency waiting areas, dedicated mental health decision units and so on) (section 9.2) Addition of optional guidance notes for the liaison mental health team staff to use (section 9.2) Confirmation that suitably qualified and experienced delegate should be approved by the PI as detailed on the authorised personnel log (section 9.3) Addition of an optional potential participant unsuitability confirmation letter to be sent out to patients if they have been found to be unsuitable for the trial at the clinical screening stage (section 9.3) Addition of junior doctors as staff suitable to deliver the trial intervention (section 10.3) Reduction of the supervision session from 90 minutes to 60 minutes to reflect information in the validated Schedule of Events Cost Attribution Tool (section 10.5.1) Increase to the maximum follow-up phone calls/text/e-mail from 2 to 4 and clarity of this process, with approval from the PPI group (section 12.7.1) Amendment of the definition of the end of trial to be compliant with CTRU guidance (section 12.10) Change from HES to data sets obtained via NHS Digital (sections 6.2 and 14.2)	30 November 2022
A section (section 25) has been added to the protocol outlining the early closure of the trial and the actions that have been taken in the closedown Reasons for the early closure of the trial Communication of trial closure to participants by phone and by letter Reduction of follow-up from 12 months to 6 months after the date of randomisation Accessing primary outcome data via hospital records only rather than NHS Digital Clarification that qualitative evaluation will not be conducted Revised statistical and health economic considerations for analysis	29 March 2023

Notes
A number of corrections of minor errors and clarifications have been made to the study protocol. The full trial protocol is available at: https://fundingawards.nihr.ac.uk/award/NIHR131334