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Study Protocol for the SAFETEL randomised controlled feasibility trial of a Safety Planning Intervention with Follow-up Telephone Contact to Reduce Suicidal Behaviour

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Title: Study Protocol for the SAFETEL randomised controlled feasibility trial of a Safety Planning Intervention with Follow-up Telephone Contact to Reduce Suicidal Behaviour

Running Head: SAFETEL Study Protocol

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Abstract

Introduction: There are no evidence-based effective interventions that can be administered in hospital settings following a general hospital admission after a suicide attempt.

Aim: To determine whether a safety planning intervention (SPI) with follow-up telephone Support (SAFETEL) is feasible and acceptable to patients admitted to UK hospitals following a suicide attempt.

Methods and analysis: Three-phase development and feasibility study with embedded process evaluation. Phase 1 is comprised of tailoring a SPI with telephone follow-up originally designed for veterans in the US, for use in the UK. Phase 2 involves piloting the intervention with patients (*n* = 30) who have been hospitalised following a suicide attempt; and Phase 3 is a feasibility randomised controlled trial of 120 patients who have been hospitalised following a suicide attempt with a six month follow-up. Phase 3 participants will be recruited from across four NHS hospitals in Scotland and randomised to receive either the SPI with telephone follow-up + Treatment as Usual (*n* = 80) or Treatment as Usual only (*n* = 40). The primary outcomes are feasibility outcomes and include the acceptability of the intervention to participants and intervention staff, the feasibility of delivery in this setting, recruitment, retention and intervention adherence, as well as the feasibility of collecting the self-harm re-admission to hospital outcome data. Statistical analyses will include description of recruitment rates, intervention adherence/use, response rates and estimates of the primary outcome event rates and intervention effect size (Phase 3). Thematic analyses will be conducted on interview and focus group data.

Ethics and Dissemination: The East of Scotland Research Ethics Service (EoSRES) approved this study in March 2017 (GN17MH101 Ref: 17/ES/0036). The study results will be disseminated via peer-reviewed publication and conference presentations. A participant summary paper will also be disseminated to patients, service providers, and policy makers alongside the main publication.

Trial Registration Number: ISRCTN62181241

Article Summary

Strengths and limitations of this study

- Importance of the study: SAFETEL will test the feasibility of a safety planning intervention (SPI) with follow-up telephone support and its acceptability to patients admitted to UK hospitals following a suicide attempt. This work will inform the value and design of a potential full-scale effectiveness trial.
- Robust intervention development: The study team has used a collaborative person-centred approach to ensure that the resulting intervention is based on insights from those with lived experience as well as academics and clinicians.
- Theory-based intervention: SAFETEL incorporates evidence-based behaviour change theory. A key innovation of SAFETEL is that the individual will complete a personalised emergency plan that aims to mobilise help-seeking behaviour and protective strategies.
- Data collection methods: The study uses a mixed-methods approach (interviews, questionnaires, focus groups, medical records and hospital admission data) to address the research questions.
- Generalisability: This study will be undertaken in four hospitals across two health board areas. These feasibility findings will inform the development of a larger effectiveness trial.

1. Introduction

Suicide and self-harm are major public health problems. According to the World Health Organisation, 804,000 people die by suicide each year across the globe (WHO, 2014) with approximately 6,000 people dying by suicide each year in the UK. Those with a history of self-harm are at markedly increased risk of suicide (Chan et al., 2016); indeed 16% of those who are treated in hospital will have self-harmed again within 1 year and 1 in 25 patients will die by suicide within 5 years (Carroll, Metcalfe, & Gunnell, 2014). Despite the increased risk of suicide, there is a lack of evidence-based interventions within general hospital settings for those who have attempted suicide specifically. Although there are challenges in determining suicidal intent and debate about definitions of self-harm (Kapur, Cooper, O'Connor, & Hawton, 2013), the majority of patients admitted to hospital following self-harm are cases of attempted suicide (e.g., O'Connor, O'Carroll, Ryan, & Smyth, 2012). Therefore, delivering effective treatment in hospital and by telephone in the weeks following a suicide attempt represents a vitally important opportunity to mitigate future suicide risk.

Despite the fact that individuals who self-harm or attempt suicide represent a high risk group for suicide, there is little research evidence about what works to reduce risk of future self-harm or suicide in this population (Armitage, Abdul Rahim, Rowe, & O'Connor, 2016; Gysin-Maillart, Schwab, Soravia, Megert, & Michel, 2016; Mann et al., 2005; NICE, 2011; O'Connor et al., 2017; O'Connor & Kirtley, 2018; O'Connor & Nock, 2014; Turecki & Brent, 2016). To date, there are no evidence-based effective interventions that can be administered in hospital following an emergency admission to reduce the risk of future suicidal behaviour in those who have attempted suicide. Existing interventions tend to be

intensive and not delivered in acute settings (Brown et al., 2005; Brown & Jager-Hyman, 2014; Gysin-Maillart et al., 2016; Linehan et al., 2006). In general, patients in emergency department (ED) settings are 'assessed and referred on' for further care (Stanley & Brown, 2012), although there is considerable variability.

This study addresses this evidence gap by seeking to answer the following research question: Can a new, innovative, theory-driven Safety Planning Intervention (SPI) with follow-up telephone support (SAFETEL), originally developed for use in veterans' hospitals in the US, be tailored, and made feasible for use with patients admitted to UK general hospitals following a suicide attempt?

The SAFETEL Intervention

SAFETEL is an innovative and theoretically driven Safety Planning Intervention (SPI) with follow-up telephone support which was developed in the US and aims to reduce suicide attempts. The SPI is a collaborative emergency safety plan developed by the patient in collaboration with a trained practitioner. The SPI is then supplemented with up to five structured follow-up telephone calls over four weeks.

A cohort comparison trial of suicidal ED patients in US veteran's hospitals (Stanley, Brown, Brenner, Galfalvy, Currier, Knox, Chaudhury, Bush, & Green, 2018) found that SPI and phone follow-up reduced suicidal behaviours and increased treatment engagement in the intervention condition. Thus, the intervention is very promising, pointing to the potential positive impacts of the SAFETEL intervention. Although developments in the US are encouraging, it is important to determine whether this intervention can be tailored to and is feasible and acceptable in a UK, non-veteran, ED/acute care setting. Then, if shown to be

feasible and acceptable, it should be rigorously assessed in a future definitive randomised controlled trial (RCT).

In addition to the personal distress, suicide attempts and suicide incur high economic costs therefore; any intervention that reduces their occurrence will yield considerable economic benefits. Each death by suicide in the UK is estimated to cost in excess of £1,370,000 (McDaid, 2016) and direct costs of self-harm range from £1,500 per annum to £3,524 for 6 months (McDaid, 2016; Sinclair, Gray, Rivero-Arias, Saunders, & Hawton, 2011). Indeed, the overall annual cost of general hospital management of self-harm (for England) is estimated to be £162 million per year (Tsiachristas et al., 2017). The SAFETEL intervention has the potential, therefore, to fill an important gap in service provision with clear clinical impact and to reduce NHS/societal costs. Although the focus will be on feasibility, we will also record readmission to hospital following self-harm[1] in the subsequent 6 months following the index suicide attempt to inform effect size estimates for a full trial.

Aim

To determine whether SAFETEL is feasible and acceptable in a UK NHS context. The study has the following objectives:

Specific Objectives

1. To adapt/tailor an innovative SPI with follow-up telephone support for use within UK NHS hospital settings.
2. To investigate how participants engage with the intervention.
3. To assess feasibility and acceptability of the intervention.

[1] Self-harm is defined, consistent with the NICE guidance, as intentional self-poisoning or self-injury, irrespective of type of motive or the extent of suicidal intent.

4. To investigate trial recruitment, retention and other trial processes including data collection.
5. To explore the barriers and facilitators to intervention implementation.
6. To collect data on readmission to hospital following self-harm in the 6 months following the index suicide attempt to inform the sample size required for a full trial.
7. To further develop and test the logic model and theoretical basis of the intervention (see Appendix 1 for the proposed study logic model).
8. To assess whether an effectiveness trial is warranted.

2. Methods and Analysis

2.1 Study Design

This study follows the Medical Research Council (MRC) guidance for the development and evaluation of complex interventions (Craig et al., 2013; Moore et al., 2015). The SAFETEL study is a three-phase development and feasibility trial of a SPI with follow-up telephone support (see Figure 1) with embedded process evaluation.

Phase 1: In consultation with key stakeholders (patients and NHS staff), the existing SAFETEL intervention will be adapted for administration within a UK NHS context.

Phase 2: Piloting of the intervention with approximately 30 patients who have been admitted to hospital following a suicide attempt.

Phase 3: A feasibility RCT with 120 patients who have been admitted to hospital following a suicide attempt. Participants will be randomised to either the SPI with follow-up telephone support + treatment as usual (*n* = 80) or treatment as usual only (*n* = 40).

We are adhering to protocol version 4 dated 26th April 2018. Any additional changes to the protocol will be reported to the Study Sponsor and receive appropriate approvals, as required.

FIGURE 1 HERE

2.2 Settings

Participants will be recruited from four NHS hospitals across two health boards in Scotland. SAFETEL will be delivered to intervention arm participants (in addition to treatment as usual) in these hospitals. The safety planning component of the intervention, and baseline quantitative data collection, will be conducted face-to-face in these hospitals with telephone-based support sessions conducted up to four weeks later. The follow-up phone calls will typically begin when the participant has been discharged from hospital. Qualitative interviews and focus groups will be conducted at NHS or University of Glasgow sites, and in Phase 3 study participants will be given the option of being interviewed over the phone or in their own homes. Staff participating in this phase will be interviewed at their place of work or by telephone.

2.3 Participants

To potentially receive the SAFETEL intervention, participants are eligible for the study if they meet the following criteria:

Inclusion Criteria

1. Are aged 18 years or over.
2. Have been admitted to hospital presenting with a self-harm episode where there was evidence of suicidal intent (i.e., a suicide attempt).
3. Have been assessed by the Liaison Psychiatry team.
4. Are proficient in English so that they can provide informed consent and complete written records in English.

Exclusion Criteria

1. Indicate no suicidal intent.
2. Are medically unfit for interview.
3. Are unable to provide informed consent.
4. Have a level of English that is not sufficient to complete the assessment measures or SPI with follow-up telephone support.
5. Are participating in another psychological intervention study in the hospital.
6. Do not have access to a telephone.

The researcher will conduct a further assessment of the participant's eligibility in regards to presence of suicidal intent at the baseline assessment.

2.4 Study Procedures

2.4.1 Recruitment

Phase 1. Individuals with lived experience of suicide (i.e., been suicidal in the past) will be recruited by advertising via mental health organisations, websites and social media. Information about the study will be circulated at the hospital sites and clinical leads at the

sites will be approached to be interviewed or to provide contact details of relevant staff to approach for interview.

Phase 2. Psychiatry Liaison team staff at each hospital will be informed of the study and the participant inclusion and exclusion criteria. All team members will be asked to identify patients who are eligible for inclusion in the study. The hospital staff will inform potential participants about the study and invite them to meet with the study researcher following their psychosocial assessment with the Psychiatric Liaison team. If the patient agrees, the researcher will approach the patient and provide them with the Participant Information Sheet, answer any questions and give them time to consider taking part. If the patient agrees, informed consent will be taken by the researcher and by consenting to take part, participants will agree to the research team accessing their medical notes. We will also seek consent to audio-record the SPI for the purposes of fidelity monitoring of intervention delivery, but participation will not be contingent on consenting to this element. Similarly, information on the process evaluation interviews will be given and consent to future contact for this purpose will be sought, with participation in the intervention/study unaffected by opting not to consent to this element.

Phase 3. Recruitment for Phase 3 will be the same as per Phase 2 (i.e., referral following assessment by hospital Liaison Psychiatry teams) unless feedback from Phase 2 suggests modifications. For Phase 3, however, participants will be informed that they will be randomised to receive either the SPI with follow-up telephone support + treatment as usual or treatment as usual only.

Process Evaluation. Participants who consented to be contacted for this element of the study will be invited to participate in a one-to-one interview about their experiences of

taking part. In Phase 2, participants will be contacted after they have finished the telephone support component of the intervention (approx. 1-2 months after baseline), and in Phase 3 participants (both control and intervention arms) will be contacted approximately 6 months after baseline and once they have completed their involvement with the telephone follow up component of the study. In Phase 2, the interview will be face-to-face at an NHS or University of Glasgow site, and in Phase 3, participants will be given the additional options of telephone interview or home visit. A process evaluation-specific Participant Information Sheet and Consent Form will be sent to all participants in advance of the interviews and reviewed at the interview to ensure it is understood and then the consent form will be completed. In the case of telephone interviews, verbal consent will be audio-recorded at the outset of the interview.

At Phases 2 and 3, NHS staff from the hospital sites and those directly involved in participants' care (e.g. psychiatry liaison team members) will be invited to take part in interviews or focus groups using the same recruitment method as per Phase 1. The study research team will also be invited to participate in focus groups after the completion of Phases 2 and 3 to discuss their experiences of delivering the intervention.

2.4.2 Randomisation and Blinding (Phase 3 only)

For Phase 3, participants will be randomised with a 2:1 ratio to receive either one of two study allocations: (i) the SPI with follow-up telephone support + treatment as usual or (ii) treatment as usual only. Following consent and completion of the initial study measures, participants will be randomised using a telephone randomisation service provided by the Robertson Centre for Biostatistics (RCB), University of Glasgow (within the Glasgow Clinical

Trials Unit). Neither the participant nor the researcher will know the allocation while initial study measures are being recorded. After randomisation, both the participant and the researcher will be unblinded to the participant's allocation, which is unavoidable given the nature of the trial. No changes in assignment will be possible. Randomisation will be performed using a mixed minimisation/randomisation method. Within each hospital site, 3 out of every 15 participants will be allocated at random (in a 2:1 ratio), and 12 will be allocated according to a minimisation algorithm, designed to minimise imbalance with respect to hospital site, gender (as indicated by their current health record at date of consent), and history of self-harm (0-1 previous episodes versus 2 or more episodes). Whether participants are to be allocated at random, or by minimisation, will be determined by a computer-generated, block randomisation schedule, to be stored in a secure area of the RCB network, with access restricted to those responsible for the maintenance of the randomisation system.

Figure 2 shows the flow of participants through Phase 3 of the study.

FIGURE 2 HERE

2.4.3 Withdrawal, Loss to Follow-up and Retention strategies

Participants may fall into three categories relating to ceasing their participation in the study, these are:

(i) Lost to completion of the Safety Planning intervention

(ii) Lost to follow up data collection (i.e. telephone follow up calls)

(iii) Withdrawn from the study

Participants will be withdrawn from the study based on the following circumstances:

1. If the participant requests to be withdrawn from the study
2. If it becomes known (e.g., through telephone contact during the intervention or by other means) that the participant has lost capacity[2]

If a participant is withdrawn from the study, we will still use the assessment and other data collected (including follow-up clinical data regarding hospital readmission for self-harm) unless the participant explicitly states that they wish to have their data removed from the study.

2.4.3.1 Study engagement, retention strategies and adverse events

The study will use the following retention strategies to support participants to continue their engagement in the study alongside their treatment as usual commitments. Telephone follow-up calls will be offered up to 72 hours following discharge from hospital, and weekly thereafter at a time and date agreed with the participant. Call slots will be flexible and pragmatic as the study time elapses. In the event that a participant cannot be reached across three calls over two calendar days, the next call made will be to the participant's provided emergency contact to establish the patient is safe and well. In the event that a follow up call informs the research team directly or via a third party that the participant has been re-admitted to hospital for self-harm/suicide attempt (i.e. the occurrence of an adverse event); or the call itself requires the study team to support the participant to seek help or to stay safe (i.e. experiencing suicidal ideation), a further follow-up call will be offered. This additional call will act to provide adequate support to the participant and facilitate ongoing follow-up engagement. The researcher will follow the study Standard

[2] A person lacks capacity in relation to a matter if at the material time they are unable to make a decision for themselves in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind. This impairment may be permanent or temporary in nature.

Operating Procedures (SOPs) to take appropriate action to maintain participant safety, which may include contacting existing care providers, referral to the ED, or calling the emergency services. Data on the number, type, and context of all adverse events will be routinely recorded in line with NHS and Good Clinical Practice regulations and reported to the Trial Steering Committee and study senior management. The Trial Steering Committee will thereafter report to the study sponsor and governance management team as agreed in the initial stages of the ethical approval process. Given the nature of this study, we anticipate adverse events will occur.

2.4.4 Control and Intervention groups

All participants will be invited to complete the study measures and to participate in the interviews for the process evaluation component of the study (regardless of the condition that they are allocated to).

Control group

Following randomisation, participants in the control group (i.e., treatment as usual only) will be fully debriefed and will receive treatment as usual. Treatment as usual is variable but it may include referral to one of the following: (i) a primary care; (ii) community psychiatric service; (iii) third sector service; (iv) specialist mental health service; (v) intensive home treatment; (vi) outpatient services; (vii) transfer to inpatient care; (viii) other services follow up (i.e. crisis card, social work input); or (ix) no further treatment plan. Treatment as usual will be characterised at each site as part of the process evaluation.

Intervention group

SATETEL will either be delivered by researchers trained by the intervention developers (Barbara Stanley and Gregory Brown), or by study investigators. This training will be cascaded down to new team members and researchers who support participant recruitment (i.e. Mental Health Research Network researchers). The SPI element of the intervention will be delivered in the hospital before the patient is discharged. Within the SPI, patients are supported to complete a written, personalised safety plan in collaboration with the researcher. The safety plan is comprised of six steps outlined below. The purpose of the SPI is to help patients identify warning signs indicative of an approaching suicidal crisis and to develop a list of internal coping strategies. In addition, patients also identify individuals in their social network, who could provide distraction or support, and professional agencies who patients can contact during or preceding suicidal crises to reduce the risk of engaging in further suicidal behaviour. Although the order of completion of the safety plan is not completely fixed, participants will be encouraged to work through each step. This includes advising them to contact professional services immediately if they are in crisis and unable to keep themselves safe. They are also invited to take steps to make their environment safe by reducing access to lethal means (e.g., restricting access to medication).

Developing the Safety Plan

At the outset of the SPI collaboration, the researcher conducts a further risk assessment to ensure the participant is not at imminent risk. The patient is offered regular breaks during the assessment to mitigate fatigue and anticipated distress. Indeed, participants can become emotionally upset during Safety Plan completion, which is handled sensitively by the researcher (e.g., offering to stop, take breaks, etc.). The participant is also supported to

complete the safety plan at a pace that suits their needs. The researcher explores the recent suicide attempt as a means to explain the purpose of the safety plan; and how to utilise it to support the participant to keep themselves safe during a suicidal crisis. This process aims to improve identification of warning signs that alert the participant that they may be approaching a crisis; explore the use of distraction techniques; encourage the idea of seeking social or professional support and restricting access to lethal means. When completing each step of the safety plan, the researcher explores the suitability and likelihood of employing these strategies during a suicidal crisis as well as providing examples of such strategies.

Follow-up Telephone Support

This component of the intervention consists of five structured telephone contacts with the participant over a period of four weeks. The first contact is typically delivered as soon as possible after discharge from hospital following the index suicide attempt (between 24 and 72 hours) followed by four weekly telephone contacts. The follow-up telephone calls are comprised of three components: 1. Suicide risk assessment and mood check; 2. Review of the participant's safety plan, with revisions made if required; and 3. Supporting treatment engagement through exploration of barriers to engagement, motivational enhancement, problem-solving and support. The duration of follow-up calls will vary but it is expected that they will last around 15 minutes on average. At the end of each follow-up call (apart from the final one), the participant is asked if they consent to another follow-up call. Follow-up telephone support is discontinued after five phone calls, if the participant no longer wishes to be contacted, or if the participant can no longer be contacted. The researcher will attempt to contact the participant up to three times per scheduled contact point. They will

send a text or leave a voicemail message if the participant cannot be reached by telephone and if the participant has consented to this. The researcher may also attempt to contact the participant by letter. In the event where a participant cannot be reached and there is concern regarding their safety, the researcher may contact the participant's emergency contact (recorded at the initial assessment with the participant's consent) or professional services involved in the patient's care (e.g., their GP). On the final follow-up call, in addition to the standard procedure, the participant is asked if they are still happy to be contacted for information regarding the process evaluation element of the study.

2.4.5 Process Evaluation Measures

The process evaluation will seek to assess feasibility and acceptability and explore the ways in which the SAFETEL may operate to produce outcomes. Specifically it will focus on intervention fidelity, exposure, reach, context, recruitment, retention, and contamination, as well as the acceptability of study procedures. Figure 3 presents the process evaluation framework and shows the various time points at which data collection and analysis are intended.

FIGURE 3 HERE

Intervention Fidelity Checking

With participants' consent, all SPI sessions in Phases 2 and 3 will be audio-recorded. Fidelity of intervention delivery is being checked in different ways for the face-to-face sessions and telephone sessions. For the face-to-face sessions, 20% of the recordings will be randomly selected to check fidelity against a standardised measure of fidelity for the SPI (Safety Planning Intervention Rating Scale; Brown & Stanley, 2013). These will be double coded by another team member and tested using Cronbach's alpha to test inter-rater reliability. A

standardised checklist for the follow-up telephone support calls will be completed by the research team to enhance intervention fidelity and the results will be reported descriptively.

Qualitative Interviews with Study Participants

We will conduct semi-structured interviews with intervention participants at Phase 2 (n = up to 10) and Phase 3 (n = up to 30). Actual numbers will depend on data saturation. Participants will be purposively sampled based on a number of criteria (i.e. gender, age, hospital site of recruitment, engagement with the intervention, and history of self-harm). Semi-structured interview topic guides will be used and interviews will seek to explore participants' experience of the study and intervention including contextual factors, acceptability of study and intervention procedures, barriers and facilitators to engagement with the intervention, and potential mediators of change. We will also seek to interview participants in the control arm at Phase 3 (n = up to 10) to explore their experiences of their treatment as usual, potential contamination, and the acceptability of study procedures.

Qualitative Interviews/Focus Groups with Staff

We will conduct semi-structured interviews with NHS clinical staff involved in the care of patients who have been admitted to hospital following a suicide attempt at Phase 2 (n = up to 6) and Phase 3 (n = up to 10). The interviews will focus on current context, procedures and services available to patients, feasibility of the intervention, and acceptability of the study and intervention procedures, including experienced or perceived barriers and facilitators, intervention 'fit' within the setting and suggestions for improvement. In addition we will conduct focus groups at Phase 2 and 3 with researchers responsible for study

recruitment, data collection and intervention delivery (all researchers will be included where possible). Focus groups will explore experiences of recruitment, data collection, and intervention delivery, as well as perception of participants' experiences.

Data on Recruitment, Retention and Adherence

Data on the number of potential participants approached, who declined, were ineligible, and those who consented and were retained will be recorded and presented in the CONSORT diagram for the study. Concerning adherence to the intervention, we will record details of all intervention-related contacts, including number/length of sessions of support completed and contact attempts made, in order to build a comprehensive picture of how participants engage with the study and the intervention. Data on the rate of safety plan completion and the use of safety plans between telephone contacts are recorded as well as the amount/and type of changes made to safety plans over the course of the (up to) five follow-up calls.

2.4.6 Outcome Measure Feasibility

Baseline

For Phases 2 and 3, all participants will be asked to complete a number of measures during the initial assessment at baseline with a trained researcher (see below). The purpose of collecting these will be to assess feasibility and acceptability of using these questionnaires in a full trial, as well as to characterise the sample and explore potential moderators. We will also record participant demographics, information on treatment as usual received by participants and other relevant information regarding the sample (e.g., suicidal history),

which may be considered potential moderators or mediators in a full trial. The schedule of baseline measure completion for Phases 2 and 3 is outlined in Figure 2 and detailed below:

- *The Columbia Suicide Severity Rating Scale* (Posner et al., 2011) is a 20-item semi-structured brief, valid and reliable tool used to assess suicide risk and suicidal ideation and behaviours, such as previous suicide attempts as well as interrupted and aborted attempts and preparatory behaviours.
- *The Entrapment Scale* (Gilbert & Allan, 1998) is a 16-item scale that examines feelings of entrapment and defeat using a 5-point Likert-type scale (ranging from 0 "Not at all like me" to 4 "Extremely like me"). It is comprised of two subscales: internal (10 items) and external entrapment (6 items).
- *The Interpersonal Needs Questionnaire* (Van Orden, Cukrowicz, Witte, & Joiner, 2012) is a 12-item measure of perceived burdensomeness (7 items) and thwarted belongingness (5 items), with items rated on a 7-point Likert-type scale (ranging from 1 "Not at all true for me" to 7 "Very true for me").
- *The ENRICHD Social Support Instrument* (Vaglio et al., 2004) is a 7-item measure that assesses four attributes of social support: emotional, instrumental, informational, and appraisal on a 5-point Likert-type scale (ranging from 1 "None of the time" to 5 "All of the time").

The following measure will also be completed at Phase 3 only:

- *The Suicide-Related Coping Scale* (Stanley et al., 2017; Phase 3 only) is a 17-item measure that assesses suicide-related coping. It is comprised of two subscales: external coping, with items relating to recognising and utilising social support and professional resources during suicidal crisis and lethal means restriction, and internal

coping, with items pertaining to self-administered coping strategies and confidence in relation to coping with suicidal feelings. Responses are rated on a 5-point Likert-type scale (ranging from 0 “Strongly disagree” to 4 “Strongly agree”).

Follow-up telephone calls

Measures completed at follow up calls include; (i) the contact inventory (i.e. call duration, time between calls and number and means of participant contact); (ii) a mood and suicidal thoughts and behaviours assessment; (iii) a review of the safety plans and use; (iv) treatment engagement and (v) participant agreement to receive the next follow-up call.

6-month post index data capture

Follow-up data on hospital readmissions for self-harm after baseline will be collected at Phase 2 (1-2 months post index suicide attempt) and Phase 3 (6 months post index suicide attempt) using NHS clinical databases in order to assess the viability of collecting these data in a full trial.

2.5 Data Analysis

The Robertson Centre for Biostatistics (RCB) within the University of Glasgow will provide statistical services in support of Phase 3 of the trial. The RCB is part of the Glasgow Clinical Trials Unit, and has extensive experience of the design, analysis and reporting of clinical trials and epidemiological studies.

2.5.1 Sample size

It is estimated that Psychiatry Liaison teams across the four hospitals annually see at least 3,700 patients who self-harm, and we estimate that 75% report suicidal intent (O'Connor et al., 2012, 2015). Therefore, across 6 months of recruitment for Phase 3, there will be approximately 1,388 eligible participants; so we are aiming to recruit 20 participants per month. A sample of 120 participants is sufficient to explore the feasibility and acceptability of the intervention and allow estimation of the outcome event rates for a full trial.

2.5.2 Quantitative Data

Statistical analysis will include descriptive summaries of recruitment rates, attrition and retention, and intervention adherence. The baseline characteristics of the sample will be summarised. The primary outcome (readmission to hospital following self-harm within 6 months of the index suicide attempt) will be summarised by randomised group, and the intervention effect estimated using logistic regression, adjusting for minimisation factors (i.e. hospital site, gender and history of self-harm). Associations between baseline characteristics and the primary outcome will also be assessed to explore potential moderators for a full RCT.

2.5.3 Qualitative Data

Qualitative data from the interviews and focus groups conducted with study participants, NHS staff and the researchers who will deliver the intervention will be analysed via thematic analysis (Phases 2 and 3) using Braun and Clark's approach (Braun & Clarke, 2008). Thematic analysis is a systematic approach in which the data are initially coded and then collated into themes, which are then analysed in more detail to map out the overall data and examine

relationships between them. Finally, themes are refined to produce an overall story of participants' views and experiences. Data collection and analysis of interview data will be conducted simultaneously and the analyses will inform data collection in terms of changes to the interview schedule (e.g., adding new questions to probe particular areas of interest). Data collection will continue until data saturation is reached and variables coded using Nvivo v11.4.1. Due to the primary focus of the semi-structured interviews and focus groups, the identified themes are likely to be on areas of interest to the study evaluation (e.g., recruitment, retention, acceptability, adherence, etc.) but this method also allows unexpected themes to emerge and to be added to the coding framework. The coding framework will be discussed and refined with the other members of the study team. Twenty per cent of the interviews will be double coded to ensure reliability. Disagreements will be resolved by discussion.

Qualitative data will also be triangulated with quantitative data. We will draw upon qualitative and quantitative data to test the logic model (see Appendix 1) and investigate mechanisms through which the intervention may operate in order to further develop the intervention theory (Phase 3). All analyses will be specified in a detailed Qualitative Analyses Plan and Process Evaluation Framework.

2.6 Progression Criteria from Feasibility to Full Trial

The feasibility and acceptability of both the trial methods and the SAFETEL intervention, and the potential for these to be developed and delivered in a full-randomised controlled trial are the key outcomes of this trial. These will be assessed using the progression criteria

outlined in Appendix 2. These criteria have been developed by our Trial Management Group and approved by our Trial Steering Committee; who will also undertake final assessment of these following analyses of the findings of the study.

3. Data Management and Access

The Robertson Centre for Biostatistics (RCB, part of the Glasgow Clinical Trials Unit), within the University of Glasgow, will provide data management services in support of Phase 3 of the trial. The RCB will create the database for Phase 3 data, and provide the online electronic Case Record Form (e-CRF), as well as training in the use of the system. Data will be entered locally with data validation checks built in. RCB will also run routine data validation checks and alert the study management team to general issues or specific data queries.

All personal information will be encrypted and visible only to the research team; all personally identifiable information will be held separately from research data. The RCB statisticians will develop analysis programmes during the trial and communicate any data anomalies to RCB data managers. At the end of the trial, final data validation checks will be carried out prior to database lock. The study database will be held by RCB for the duration of the study and for a minimum of 5 years after study completion.

3.1 Data Sharing

At baseline, potential participants are asked to consent to the following in order to participate in the study:

- Permission for the research team to access routinely collected medical data (including CHI numbers) to determine what contact the participant has had with clinical services within 5 years of taking part in this study, where it is relevant to their taking part in the research.
- Permission for authorised representatives of the study Sponsor, NHS Greater Glasgow and Clyde/NHS Lothian, and regulatory authorities to have access to their personal information and research data for the purposes of audit.
- In addition, participants are given the option of consenting to the research team sharing their data in the following circumstances:
    - Anonymous storage of data in the UK data archive where other researchers can have access to this data only if they have scientific and ethical approval, and agree to preserve the confidentiality of this information as set out in the study consent form.
    - Informing the participant's own General Practitioner and other relevant mental health professionals involved in their care, of their participation in the study and sending them a copy of the participant's safety plan.

3.2 Serious Adverse Events (SAE/AEs)

As discussed in section 2.4.3.1 in detail; in the event of serious adverse events occurring within the study, standard operating procedures, robust recording and reporting measures to detail these occurrences will be employed. Any complaints made by participants or relevant adverse events will be recorded and reported to Trial Steering Committee. The Trial Steering Committee will thereafter report to the study sponsor and governance

management team as agreed in the initial stages of the approval process. The Trial Steering Committee will take on the role of Data Monitoring Committee for oversight of adverse events.

4. Ethics and Dissemination

The East of Scotland Research Ethics Service approved the SAFETEL study in March 2017 (EoSRES; REC Reference: GN17MH101). The study will be conducted in accordance with the recommendations for physicians involved in research on human participants adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. The study results will be disseminated via peer-reviewed publication and conference presentations. A participant summary paper will also be disseminated to patients and policy makers alongside the main publication.

5. Trial Status

This trial and recruitment are ongoing.

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Footnotes

Author Statement: ROC is principal investigator who together with SAS developed the study protocol alongside the other co-investigators (BS, GB, MS, DS, AM, SS), and has overall responsibility for the management of the trial. MG is the trial manager and is responsible for coordinating the trial. The Research Associate JML also coordinates the trial and provides day-to-day management of the research team and oversees recruitment at hospital sites as well as data capture, supported by MG. SSM is the process evaluation researcher. MG, JML, CS and SSM were involved in finalising the study protocol, implementing study processes and drafting the manuscript. HMcC and CS are research assistants on the trial and have responsibility for participant recruitment, data capture, contributing to the study design, reviewing the manuscript. AM was involved in finalising the study protocol, in particular the statistical analyses, and reviewing the manuscript. BS and GB had responsibility for training the research staff in delivering the intervention. SS is the SAFETEL study peer researcher who is also responsible for representing patient views and focus group activity and reviewed the manuscript. All authors commented on and approved the final version of the manuscript.

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Role of Sponsor and funder: The Sponsor and funder had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had nal responsibility for the decision to submit for publication.

Competing interests: None declared.

Ethical Approval: The East of Scotland Research Ethics Service (EoSRES) approved this study in March 2017 (Research Ethics Committee Reference: GN17MH101 Ref: 17/ES/0036). Trial Registration Number: ISRCTN62181241.

Data access: subject to ethical approvals, the final trial dataset will be made available.

Provenance and peer review: Not commissioned; externally peer reviewed.

Figures

Figure 1. SAFETEL Study Flow Chart v 4.0

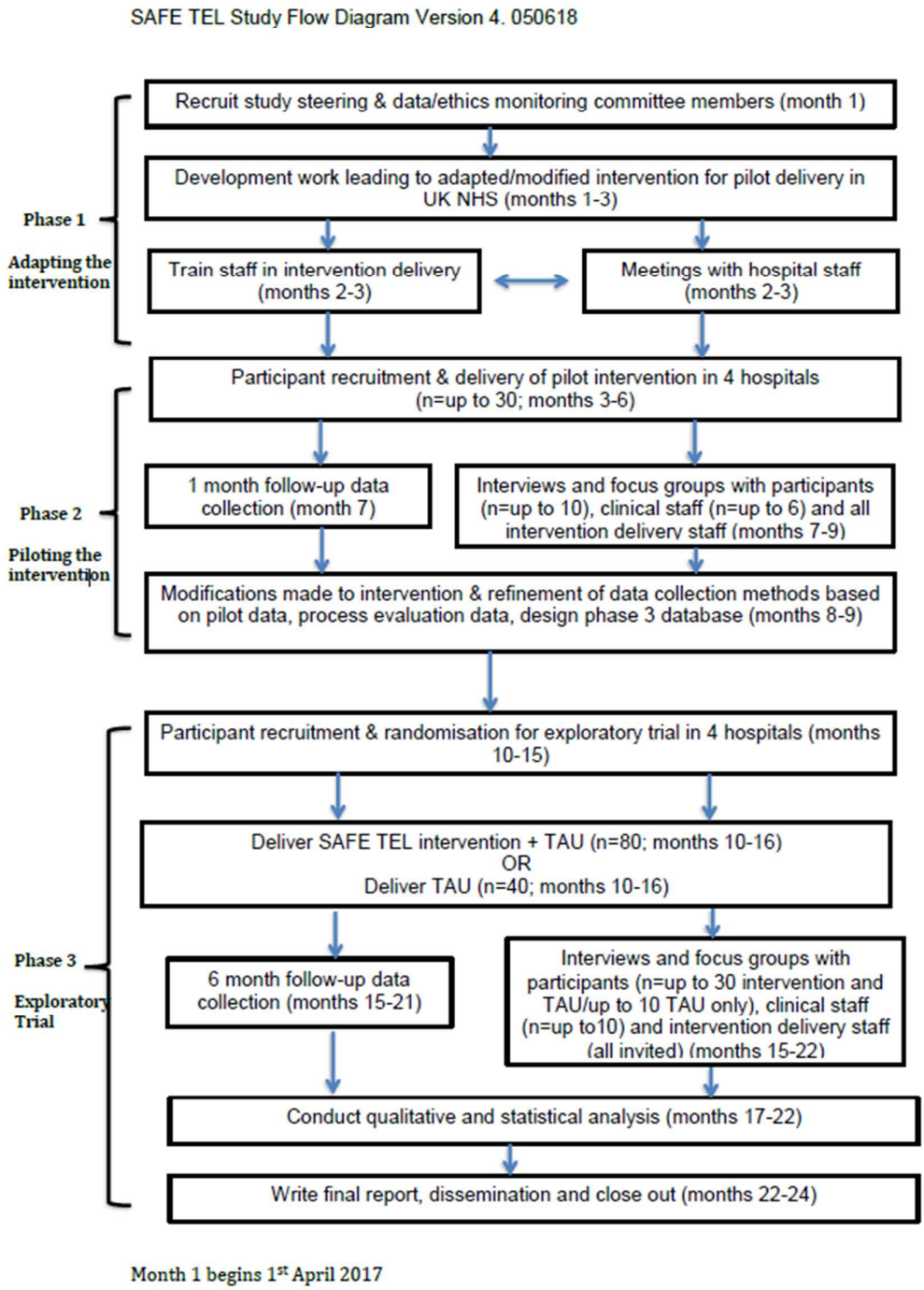
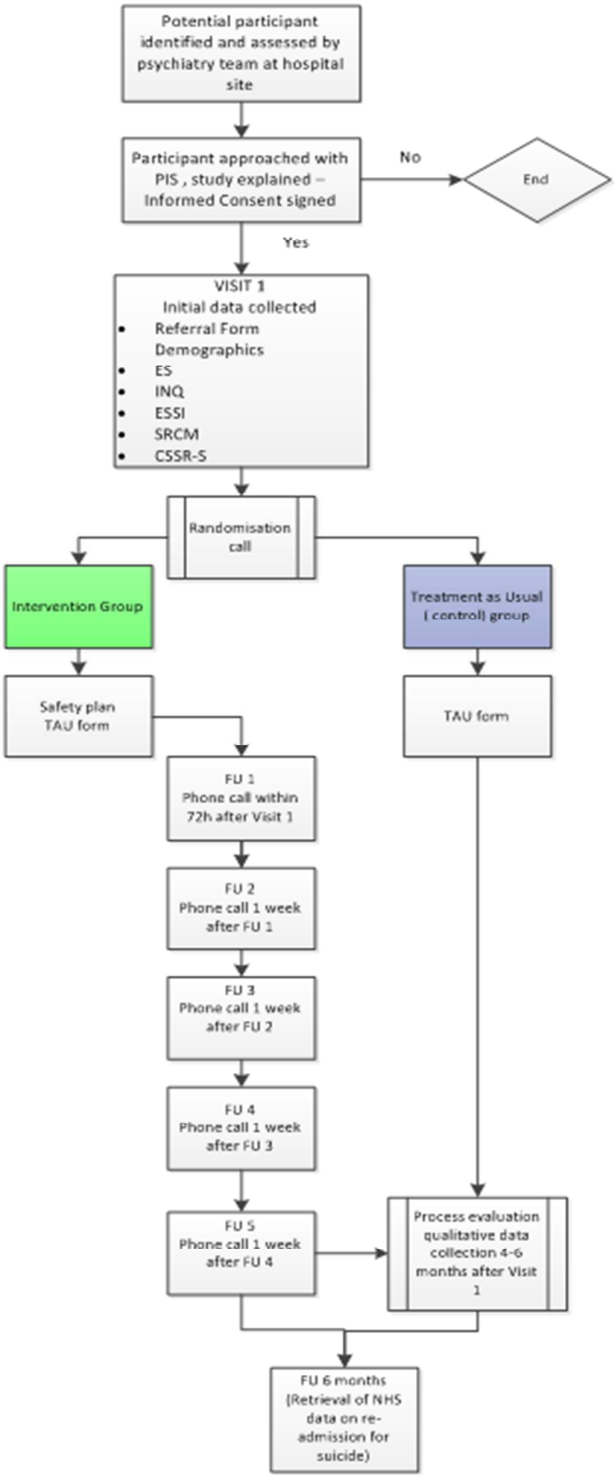


Figure 2. Planned flow of participants through the Phase 3 randomised controlled trial of the SAFETEL study.

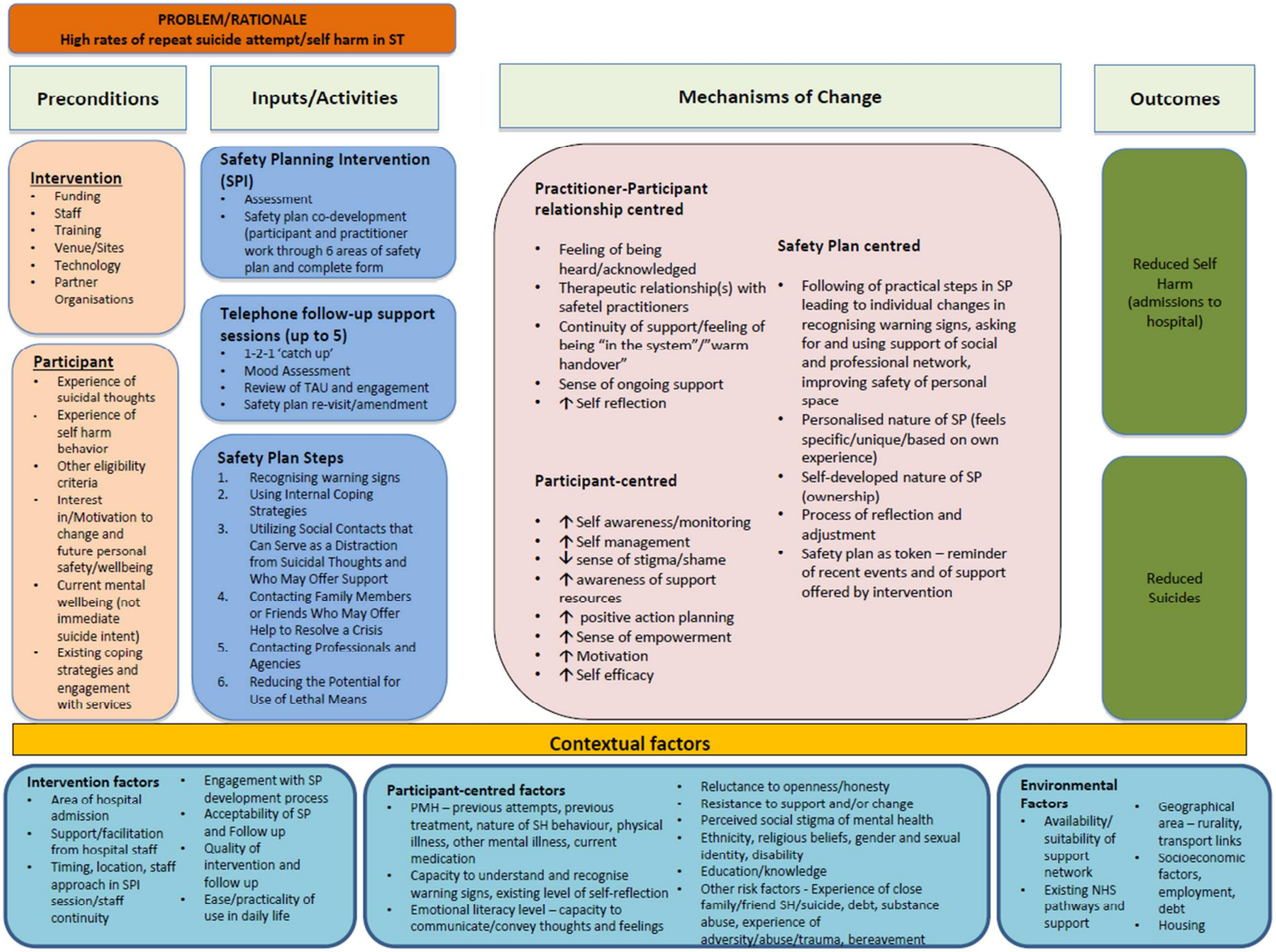


Note: PIS = Participant Information Sheet; ES = Entrapment Scale; INQ = Interpersonal Needs Questionnaire; ESSI = ENRICHD Social Support Instrument; SRCM = Suicide-Related Coping Scale; CSSR-S = Columbia Suicide Severity Rating Scale; TAU = Treatment as usual; FU = Follow-up.

Figure 3. Process Evaluation Framework for Analysis (v3.0 27.06.2018)

Evaluation Area	Questions
Fidelity (The degree to which the intervention was delivered as intended.)	• What is the intervention? • Was the intervention (safety plan and follow up telephone calls) delivered as intended? • Was there consistency in terms of how the intervention was delivered? • What, if any, adaptations were needed to the planned intervention? And were they needed? • What barriers, if any, were there to delivering the intervention in a consistent way? (safety plan and follow up telephone calls)
Exposure (The extent to which participants received and understood the different elements of the intervention and whether they implemented these as intended. Their satisfaction with the intervention and barriers to receipt and implementation were also considered.)	• To what extent did participants take up all potential elements of the full programme of intervention (safety plan and 5 follow up telephone calls)? • To what degree did participants receive the minimum dose (safety plan and 1 follow up phone call)? • To what extent was the safety plan completed as intended by the participant? If it wasn't what were the reasons for that? • How did participants use the Safety Plan they had developed? (e.g. frequency of use, practicality - where did they keep it, did they share with others) • To what extent did participants alter or amend their safety plans throughout the course of the intervention? • What elements of the intervention did participants find helpful/unhelpful and why? What elements of the intervention would participants change and why? • What changes, if any, did participants feel that they implemented as a result of taking part in the intervention? • What factors were involved in ongoing engagement with the intervention? • What do participants report were barriers and facilitators to developing the safety plan, engaging with telephone support and using the safety plan in practice? • What feedback do participants have regarding feasibility and acceptability of the safety plan and follow up telephone calls?
Reach (The extent to which the target audience is reached by the intervention, as well as any 'spill over' effects on people not recruited)	• How well does the study sample represent the population of interest? • Did participants report sharing their SP with family or friends? • To what extent did the intervention reach and influence people other than recruited participants?
Context (Includes information relating to aspects of the context in which the intervention was delivered, as well as the broader context that both the practitioner and client were operating within that may influence intervention effectiveness.)	• What participant-centred contextual factors influenced engagement with the intervention (safety planning and follow up calls) and use of the safety plan in practice? • What contextual factors within participants' day to day environment influenced engagement with the intervention (safety planning and follow up calls) and use of the safety plan in practice? • How did the context in which the intervention was delivered influence engagement with the intervention and use of the safety plan in practice? • Was the safety plan useful in certain circumstances and not in others? • How does the intervention fit in with what is delivered in hospital (how easy was is it to deliver in this setting and does it conflict with anything)? • What were the particular context-related difficulties/issues that arose during the study in delivering the intervention?
Recruitment and Retention	• How did participants feel about being approached/recruited in hospital setting? • How acceptable were study and intervention procedures to participants? • What motivated study participants to agree to take part? (And what kept them engaged?) • Were there any difficulties in recruitment? • What is the attrition rate overall and by subgroup? i.e. intervention groups and control • What were the reasons for withdrawal?
Contamination	• What are the characteristics of other groups or services people are attending or resources they are using - do these provide any elements of the intervention? • Have participants used a safety plan or similar in the past? • Did participants in the TAU (treatment as usual) arm investigate 'Safety Plan' strategy on their own? • Have any of the TAU arm participants seen intervention content from other participants? • How did randomisation to the TAU arm affect participants?

Appendix 1: Proposed logic model SAFETEL study (v5.0 07.06.2018)



Appendix 2: Proposed Progression Criteria SAFETEL study (v1.0 11.06.2018)

CRITERIA	INDICATOR GREEN=Very strong indication to proceed AMBER=Medium indication to proceed. Discuss with TSC and proceed with identified plan to improve performance on indicator in Phase III trial RED=Indication of doubt as to whether to proceed. Discuss with TSC, and only proceed if other indicators are amber/green and there is a clear mitigating strategy	METHOD OF ASSESSMENT
1. Were hospital-based study procedures feasible to deliver and acceptable to staff involved (hospital staff onsite and study staff delivering)? *(e.g. referral, recruitment, assessment, SP session delivery)*	Progression to be agreed in conjunction with Trial Steering Committee (TSC) [1] based on qualitative data captured around experienced and potential barriers to delivery. • No current barriers, or those emerging have been minor, planned for and overcome in the past during the course of the feasibility study • Some barriers but for which plans have been made/alternatives prepared • Barriers for which no feasible plan or alternative can be offered/developed	Qualitative data collected in SAFETEL intervention provider focus groups, and clinical staff interviews, analysed as part of the process evaluation and reported on to the TSC. Barriers identified and changes made to Study Protocol as a result will be reported to TSC. Given the small number of participants offering qualitative feedback, value will be placed on individual reports of barriers, not simply those barriers that are frequently reported by different participants.
2. Were study procedures feasible to deliver and acceptable to participants (including control arm)? *(e.g. recruitment, consent/information given, assessment, safety planning session, follow up phone calls)*	Progression to be agreed in conjunction with Trial Steering Committee (TSC) based on qualitative data captured around experienced and potential barriers to delivery. • No current barriers, or those emerging have been minor, planned for and overcome in the past during the course of the feasibility study • Some barriers but for which plans have been made/alternatives prepared • Barriers for which no feasible plan or alternative can be offered/developed	Qualitative data collected in SAFETEL study participant interviews (intervention and control arms) analysed as part of the process evaluation and reported on to the TSC. Complaints made by participants or relevant Adverse Events will be recorded and reported on to TSC. Given the small number of participants offering qualitative feedback, value will be placed on individual reports of barriers, not simply those barriers that are frequently reported by different participants.
3. Was it feasible to deliver Safety Plan in the	**Feasibility of intervention delivery**:	% of safety plans delivered

hospital?	• Green: > 90% of SAFETY PLANS delivered at hospital • Amber: 60-90% • Red: <60%	
4. Was it feasible to deliver 1st follow up phone call attempt within 72 hours?	**Was the progression criteria met?** • Green: >90% of first calls made within 72 hours of discharge • Amber: 60-90% • Red: <60%	**Feasibility of intervention delivery**: % Call attempts made at 1st follow up phone call time point **Was the progression criteria met?** % of 1st Follow up call delivered within 72 hours. Additional qualitative data from SAFETEL intervention provider focus groups, risk log, changes to study protocol identifying barriers and facilitators to implementation reported to TSC.
5. Was the target rate of recruitment and retention achieved? *(Are appropriate and effective routes of recruitment available to achieve a powered sample size in a full trial?)*	**Actual Recruitment rate vs. Target Recruitment rate:** • Green: >80% of participants • Amber: 60-80% • Red: <60%	**Actual Recruitment rate vs. Target Recruitment rate:** Actual participant recruitment rate and target recruitment rate will be measured to support projection of a powered sample for a full trial.
6. Was it feasible to attain a minimum dose target required to justify a full trial?	**Adherence rates:** • Green: Over 80% • Amber: 60% - 80% inclusive • Red: Less than 60%	**Feasibility of attaining minimum dose:** % of participants who completed minimum dose participation (i.e. SP+1 Follow up call).
7. Was a target rate of completed baseline measures achieved?	**Completion of core measures:** • Green: More than 90% data completion • Amber: 70%- 90% inclusive • Red: less than 70%	**Completion of core measures:** % of participants completed the core questionnaires. % of missing data from completed core questionnaires.
8. Are identified barriers and challenges to implementation of and adherence to the intervention planned for and surmountable?	Progression to be agreed in conjunction with Trial Steering Committee based on qualitative data captured around experienced and potential barriers to implementation of and adherence to the intervention beyond those already captured in Criteria 1 and 2.	Process Evaluation report SWOT analysis.

[1] *Trial Steering Committee (TSC)*

[2] *The Community Health Index (CHI) is a population register, which is used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index.*

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	8
Funding	#4	Sources and types of financial, material, and other support	1
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 30
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	30

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	30
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	14, 24
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	7-9, 14-15
Objectives	#7	Specific objectives or hypotheses	6-7
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7,11, 12
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8-9
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5, 9-17

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	25
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	14-19
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	14
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	See note 1
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	22
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	9, 16
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11-12
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	11-12

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11-12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11-12
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11-12
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	17-23
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	17-23
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	24-25
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	21-25
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	22
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	21-23

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	25-26
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	25-26
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	26
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	8
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9-11, 24
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	9-11, 24
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	24
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	31
Data access	#29	Statement of who will have access to the final trial dataset,	31

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/A
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Author notes

1. 2, 19, 22, 23

BMJ Open

Study Protocol for the SAFETEL randomised controlled feasibility trial of a Safety Planning Intervention with Follow-up Telephone Contact to Reduce Suicidal Behaviour

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Title: Study Protocol for the SAFETEL randomised controlled feasibility trial of a Safety Planning Intervention with Follow-up Telephone Contact to Reduce Suicidal Behaviour

Running Head: SAFETEL Study Protocol

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Abstract

Introduction: There are no evidence-based interventions that can be administered in hospital settings following a general hospital admission after a suicide attempt.

Aim: To determine whether a safety planning intervention (SPI) with follow-up telephone Support (SAFETEL) is feasible and acceptable to patients admitted to UK hospitals following a suicide attempt.

Methods and analysis: Three-phase development and feasibility study with embedded process evaluation. Phase 1 is comprised of tailoring a SPI with telephone follow-up originally designed for veterans in the US, for use in the UK. Phase 2 involves piloting the intervention with patients (*n* = 30) who have been hospitalised following a suicide attempt; and Phase 3 is a feasibility randomised controlled trial of 120 patients who have been hospitalised following a suicide attempt with a six month follow-up. Phase 3 participants will be recruited from across four NHS hospitals in Scotland and randomised to receive either the SPI with telephone follow-up + Treatment as Usual (*n* = 80) or Treatment as Usual only (*n* = 40). The primary outcomes are feasibility outcomes and include the acceptability of the intervention to participants and intervention staff, the feasibility of delivery in this setting, recruitment, retention and intervention adherence, as well as the feasibility of collecting the self-harm re-admission to hospital outcome data. Statistical analyses will include description of recruitment rates, intervention adherence/use, response rates and estimates of the primary outcome event rates and intervention effect size (Phase 3). Thematic analyses will be conducted on interview and focus group data.

Ethics and Dissemination: The East of Scotland Research Ethics Service (EoSRES) approved this study in March 2017 (GN17MH101 Ref: 17/ES/0036). The study results will be disseminated via peer-reviewed publication and conference presentations. A participant summary paper will also be disseminated to patients, service providers, and policy makers alongside the main publication.

Trial Registration Number: ISRCTN62181241

Article Summary

Strengths and limitations of this study

- SAFETEL will test the feasibility and acceptability of a safety planning intervention (SPI) with follow-up telephone support to patients admitted to UK hospitals following a suicide attempt.
- We have employed a collaborative person-centred approach to support the development of the SPI by involving those with lived experience as well as academics and clinicians.
- A process evaluation is embedded within the study.
- We have employed a mixed-methods approach (interviews, questionnaires, focus groups, medical records and hospital admission data).
- To enhance generalisability, this study is conducted in four hospitals.

1. Introduction

Suicide and self-harm are major public health problems. According to the World Health Organisation, 804,000 people die by suicide each year across the globe[1] with approximately 6,000 people dying by suicide each year in the UK. Those with a history of self-harm are at markedly increased risk of suicide;[2] indeed 16% of those who are treated in hospital will have self-harmed again within 1 year and 1 in 25 patients will die by suicide within 5 years.[3] Despite the increased risk of suicide, there is a lack of evidence-based interventions within general hospital settings for those who have attempted suicide specifically. Although there are challenges in determining suicidal intent and debate about definitions of self-harm,[4] the majority of patients admitted to hospital following self-harm are cases of attempted suicide.[5] Therefore, delivering effective treatment in hospital and by other means in the weeks following a suicide attempt represents a vitally important opportunity to mitigate future suicide risk.

Despite the fact that individuals who self-harm or attempt suicide represent a high risk group for suicide, there is little research evidence about what works to reduce risk of future self-harm or suicide in this population.[6-12] To date, there are no evidence-based interventions that can be administered in hospital following an emergency admission to reduce the risk of future suicidal behaviour in those who have attempted suicide. Existing interventions tend to be intensive and not delivered in acute settings.[7 13-15] In general, patients in emergency department (ED) settings are 'assessed and referred on' for further care,[16] although there is considerable variability.

This study addresses this evidence gap by seeking to answer the following research question: Can a new, innovative, theory-driven Safety Planning Intervention (SPI) with follow-up

telephone support (SAFETEL), originally developed for use in veterans' hospitals in the US, be tailored, and made feasible for use with patients admitted to UK general hospitals following a suicide attempt?

The SAFETEL Intervention

SAFETEL is an innovative and theoretically driven Safety Planning Intervention (SPI) with follow-up telephone support which was developed in the US and aims to reduce suicide attempts. The SPI is a collaborative emergency safety plan developed by the patient in collaboration with a trained practitioner. The SPI is then supplemented with up to five structured follow-up telephone calls over four weeks.

A cohort comparison trial of suicidal ED patients in US veteran's hospitals[17] found that SPI and phone follow-up reduced suicidal behaviours and increased treatment engagement in the intervention condition. Thus, the intervention is very promising, pointing to the potential positive impacts of the SAFETEL intervention. Although developments in the US are encouraging, it is important to determine whether this intervention can be tailored to and is feasible and acceptable in a UK, non-veteran, ED/acute care setting. Then, if shown to be feasible and acceptable, it should be rigorously assessed in a future definitive randomised controlled trial (RCT).

In addition to the personal distress, suicide attempts and suicide incur high economic costs therefore, any intervention that reduces their occurrence will yield considerable economic benefits. Each death by suicide in the UK is estimated to cost in excess of £1,370,000[18] and

direct costs of self-harm range from £1,500 per annum to £3,524 for 6 months.[18 19] Indeed, the overall annual cost of general hospital management of self-harm (for England) is estimated to be £162 million per year.[20] The SAFETEL intervention has the potential, therefore, to fill an important gap in service provision with clear clinical impact and to reduce NHS/societal costs. Although the focus will be on feasibility, we will also record readmission to hospital following self-harm[a] in the subsequent 6 months following the index suicide attempt to inform effect size estimates for a full trial.

Aim

To determine whether SAFETEL is feasible and acceptable in a UK NHS context. The study has the following objectives:

Specific Objectives

1. To adapt/tailor an innovative SPI with follow-up telephone support for use within UK NHS hospital settings.
2. To investigate how participants engage with the intervention.
3. To assess feasibility and acceptability of the intervention.
4. To investigate trial recruitment, retention and other trial processes including data collection.
5. To explore the barriers and facilitators to intervention implementation.

[a] Self-harm is defined, consistent with the NICE guidance, as intentional self-poisoning or self-injury, irrespective of type of motive or the extent of suicidal intent.

6. To collect data on readmission to hospital following self-harm in the 6 months following the index suicide attempt to inform the sample size required for a full trial.
7. To further develop and test the logic model and theoretical basis of the intervention (see Appendix 1 for the proposed study logic model).
8. To assess whether an effectiveness trial is warranted.

2. Methods and Analysis

2.1 Study Design

This study follows the Medical Research Council (MRC) guidance for the development and evaluation of complex interventions.[21 22] The SAFETEL study is a three-phase development and feasibility trial of a SPI with follow-up telephone support (see Figure 1) with embedded process evaluation.

Phase 1: In consultation with key stakeholders (patients and NHS staff), the existing SAFETEL intervention will be adapted for administration within a UK NHS context.

Phase 2: Piloting of the intervention with approximately 30 patients who have been admitted to hospital following a suicide attempt.

Phase 3: A feasibility RCT with 120 patients who have been admitted to hospital following a suicide attempt. Participants will be randomised to either the SPI with follow-up telephone support + treatment as usual (n = 80) or treatment as usual only (n = 40).

We are adhering to protocol version 4 dated 26th April 2018. Any additional changes to the protocol will be reported to the Study Sponsor and receive appropriate approvals, as required.

Patient and Public Involvement

One of the study co-investigators (and co-author) is a service user and was involved in the development of the research questions, the measures used and all aspects of study design and dissemination. As this is a feasibility study, we are seeking views from patients and others with experience of suicidal thoughts and attempts throughout.

FIGURE 1 HERE

2.2 Settings

Participants will be recruited from four NHS hospitals across two health boards in Scotland. SAFETEL will be delivered to intervention arm participants (in addition to treatment as usual) in these hospitals. The safety planning component of the intervention will be conducted face-to-face in these hospitals with telephone-based support sessions conducted up to four weeks later. The follow-up phone calls will typically begin when the participant has been discharged from hospital (see Follow-up Telephone Support section for more details). Baseline data collection will also be conducted in the hospitals. Qualitative interviews and focus groups will be conducted at NHS or University of Glasgow sites, and in Phase 3 study participants will be given the option of being interviewed over the phone or in their own homes. Staff participating in this phase will be interviewed at their place of work or by telephone.

2.3 Participants

To potentially receive the SAFETEL intervention, participants are eligible for the study if they meet the following criteria:

Inclusion Criteria

1. Are aged 18 years or over.
2. Have been admitted to hospital presenting with a self-harm episode where there was evidence of suicidal intent (i.e., a suicide attempt).
3. Have been assessed by the Liaison Psychiatry team.
4. Are proficient in English so that they can provide informed consent and complete written records in English.

Exclusion Criteria

1. Indicate no suicidal intent.
2. Are medically unfit for interview.
3. Are unable to provide informed consent.
4. Have a level of English that is not sufficient to complete the assessment measures or SPI with follow-up telephone support.
5. Are participating in another psychological intervention study in the hospital.
6. Do not have access to a telephone.

The researcher will conduct a further assessment of the participant's eligibility in regards to presence of suicidal intent at the baseline assessment.

2.4 Study Procedures

2.4.1 Recruitment

Phase 1. Individuals with lived experience of suicide (i.e., been suicidal in the past) will be recruited by advertising via mental health organisations, websites and social media. Information about the study will be circulated at the hospital sites and clinical leads at the sites will be approached to be interviewed or to provide contact details of relevant staff to approach for interview.

Phase 2. Psychiatry Liaison team staff at each hospital will be informed of the study and the participant inclusion and exclusion criteria. All team members will be asked to identify patients who are eligible for inclusion in the study (e.g., present following self-harm episode where there was evidence of suicidal intent). The hospital staff will inform potential participants about the study and invite them to meet with the study researcher following their psychosocial assessment with the Psychiatric Liaison team. If the patient agrees, the researcher will approach the patient and provide them with the Participant Information Sheet, answer any questions and give them time to consider taking part. If the patient agrees, informed consent will be taken by the researcher and by consenting to take part, participants will agree to the research team accessing their medical notes. Research staff will confirm that participants meet inclusion criteria. We will also seek consent to audio-record the SPI for the purposes of fidelity monitoring of intervention delivery, but participation will not be contingent on consenting to this element. Similarly, information on the process evaluation interviews will be given and

consent to future contact for this purpose will be sought, with participation in the intervention/study unaffected by opting not to consent to this element.

Phase 3. Recruitment for Phase 3 will be the same as per Phase 2 (i.e., referral following assessment by hospital Liaison Psychiatry teams) unless feedback from Phase 2 suggests modifications. For Phase 3, however, participants will be informed that they will be randomised to receive either the SPI with follow-up telephone support + treatment as usual or treatment as usual only.

Process Evaluation. Participants who consented to be contacted for this element of the study will be invited to participate in a one-to-one interview about their experiences of taking part. In Phase 2, participants will be contacted after they have finished the telephone support component of the intervention (approx. 1-2 months after baseline), and in Phase 3 participants (both control and intervention arms) will be contacted approximately 6 months after baseline and once they have completed their involvement with the telephone follow up component of the study. In Phase 2, the interview will be face-to-face at an NHS or University of Glasgow site, and in Phase 3, participants will be given the additional options of telephone interview or home visit. A process evaluation-specific Participant Information Sheet and Consent Form will be sent to all participants in advance of the interviews and reviewed at the interview to ensure it is understood and then the consent form will be completed. In the case of telephone interviews, verbal consent will be audio-recorded at the outset of the interview.

At Phases 2 and 3, NHS staff from the hospital sites and those directly involved in participants' care (e.g. psychiatry liaison team members) will be invited to take part in interviews or focus

groups using the same recruitment method as per Phase 1. The study research team will also be invited to participate in focus groups after the completion of Phases 2 and 3 to discuss their experiences of delivering the intervention.

2.4.2 Randomisation and Blinding (Phase 3 only)

For Phase 3, participants will be randomised with a 2:1 ratio to receive either one of two study allocations: (i) the SPI with follow-up telephone support + treatment as usual or (ii) treatment as usual only. As we are most interested in exploring the feasibility of the intervention, we randomised 2:1 to extract the maximum information out of the data. Following consent and completion of the initial study measures, participants will be randomised using a telephone randomisation service provided by the Robertson Centre for Biostatistics (RCB), University of Glasgow (within the Glasgow Clinical Trials Unit). Neither the participant nor the researcher will know the allocation while initial study measures are being recorded. After randomisation, both the participant and the researcher will be unblinded to the participant's allocation, which is unavoidable given the nature of the trial. No changes in assignment will be possible. Randomisation will be performed using a mixed minimisation/randomisation method. Within each hospital site, 3 out of every 15 participants will be allocated at random (in a 2:1 ratio), and 12 will be allocated according to a minimisation algorithm, designed to minimise imbalance with respect to hospital site, gender (as indicated by their current health record at date of consent), and history of self-harm (0-1 previous episodes versus 2 or more episodes). Whether participants are to be allocated at random, or by minimisation, will be determined by a computer-generated, block randomisation schedule, to be stored in a secure area of the RCB

network, with access restricted to those responsible for the maintenance of the randomisation system.

Figure 2 shows the flow of participants through Phase 3 of the study.

FIGURE 2 HERE

2.4.3 Withdrawal, Loss to Follow-up and Retention strategies

Participants may fall into three categories relating to ceasing their participation in the study, these are:

(i) Lost to completion of the Safety Planning intervention

(ii) Lost to follow up data collection (i.e. telephone follow up calls)

(iii) Withdrawn from the study

Participants will be withdrawn from the study based on the following circumstances:

1. If the participant requests to be withdrawn from the study
2. If it becomes known (e.g., through telephone contact during the intervention or by other means) that the participant has lost capacity[b]

If a participant is withdrawn from the study, we will still use the assessment and other data collected (including follow-up clinical data regarding hospital readmission for self-harm) unless the participant explicitly states that they wish to have their data removed from the study.

[b] A person lacks capacity in relation to a matter if at the material time they are unable to make a decision for themselves in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind. This impairment may be permanent or temporary in nature.

2.4.3.1 Study engagement, retention strategies and adverse events

The study will use the following retention strategies to support participants to continue their engagement in the study alongside their treatment as usual commitments. The first telephone follow-up calls will be attempted up to 72 hours following discharge from hospital, and weekly thereafter at a time and date agreed with the participant. Call slots will be flexible and pragmatic as the study time elapses. In the event that a participant cannot be reached across three calls over two calendar days, the next call made will be to the participant's provided emergency contact to establish the patient is safe and well. In the event that a follow up call informs the research team directly or via a third party that the participant has been re-admitted to hospital for self-harm/suicide attempt (i.e. the occurrence of an adverse event); or the call itself requires the study team to support the participant to seek help or to stay safe (i.e. experiencing suicidal ideation), a further follow-up call will be offered. This additional call will act to provide adequate support to the participant and facilitate ongoing follow-up engagement. The researcher will follow the study Standard Operating Procedures (SOPs) to take appropriate action to maintain participant safety, which may include contacting existing care providers, referral to the ED, or calling the emergency services. Data on the number, type, and context of all adverse events will be routinely recorded in line with NHS and Good Clinical Practice regulations and reported to the Trial Steering Committee and study senior management. The Trial Steering Committee will thereafter report to the study sponsor and governance management team as agreed in the initial stages of the ethical approval process. Given the nature of this study, we anticipate adverse events will occur.

2.4.4 Control and Intervention groups

All participants will be invited to complete the study measures and to participate in the interviews for the process evaluation component of the study (regardless of the condition that they are allocated to).

Control group

Following randomisation, participants in the control group (i.e., treatment as usual only) will be fully debriefed and will receive treatment as usual. Treatment as usual is variable but it may include referral to one of the following: (i) primary care; (ii) community psychiatric service; (iii) third sector service; (iv) specialist mental health service; (v) intensive home treatment; (vi) outpatient services; (vii) transfer to inpatient care; (viii) other services follow up (i.e. crisis card, social work input); or (ix) no further treatment plan. Treatment as usual will be characterised at each site as part of the process evaluation.

Intervention group

SATETEL will either be delivered by researchers trained by the intervention developers (Barbara Stanley and Gregory Brown), or by study investigators. This training will be cascaded down to new team members and researchers who support participant recruitment (i.e. Mental Health Research Network researchers). The SPI element of the intervention will be delivered in the hospital before the patient is discharged. Within the SPI, patients are supported to complete a

written, personalised safety plan in collaboration with the researcher. The safety plan is comprised of six steps outlined below. The purpose of the SPI is to help patients identify warning signs indicative of an approaching suicidal crisis and to develop a list of internal coping strategies. In addition, patients also identify individuals in their social network, who could provide distraction or support, and professional agencies who patients can contact during or preceding suicidal crises to reduce the risk of engaging in further suicidal behaviour. Although the order of completion of the safety plan is not completely fixed, participants will be encouraged to work through each step. Working through each step entails beginning with using one's internal resources, through to considering external resources such as calling a support person or professional service if they are in crisis and unable to keep themselves safe. They are also invited to take steps to make their environment safe by reducing access to lethal means (e.g., restricting access to medication).

Developing the Safety Plan

At the outset of the SPI collaboration, the researcher conducts a further risk assessment to ensure the participant is not at imminent risk. The patient is offered regular breaks during the assessment to mitigate fatigue and anticipated distress. Indeed, participants can become emotionally upset during Safety Plan completion, which is handled sensitively by the researcher (e.g., offering to stop, take breaks, etc.). The participant is also supported to complete the safety plan at a pace that suits their needs. The researcher explores the recent suicide attempt as a means to explain the purpose of the safety plan; and how to utilise it to support the participant to keep themselves safe during a suicidal crisis. This process aims to improve

identification of warning signs that alert the participant that they may be approaching a crisis; explore the use of distraction techniques; encourage the idea of seeking social or professional support and restricting access to lethal means. When completing each step of the safety plan, the researcher explores the suitability and likelihood of employing these strategies during a suicidal crisis as well as providing examples of such strategies.

Follow-up Telephone Support

This component of the intervention consists of five structured telephone contacts with the participant over a period of four weeks. The first contact is typically delivered as soon as possible after discharge from hospital following the index suicide attempt (between 24 and 72 hours) followed by four weekly telephone contacts. The follow-up telephone calls are comprised of three components: 1. Suicide risk assessment and mood check; 2. Review of the participant's safety plan, with revisions made if required; and 3. Supporting treatment engagement through exploration of barriers to engagement, motivational enhancement, problem-solving and support. The duration of follow-up calls will vary but it is expected that they will last around 15 minutes on average. At the end of each follow-up call (apart from the final one), the participant is asked if they consent to another follow-up call. Follow-up telephone support is discontinued after five phone calls, if the participant no longer wishes to be contacted, or if the participant can no longer be contacted. The researcher will attempt to contact the participant up to three times per scheduled contact point. They will send a text or leave a voicemail message if the participant cannot be reached by telephone and if the participant has consented to this. The researcher may also attempt to contact the participant

by letter. In the event where a participant cannot be reached and there is concern regarding their safety, the researcher may contact the participant's emergency contact (recorded at the initial assessment with the participant's consent) or professional services involved in the patient's care (e.g., their GP). On the final follow-up call, in addition to the standard procedure, the participant is asked if they are still happy to be contacted for information regarding the process evaluation element of the study.

2.4.5 Process Evaluation Measures

The process evaluation will seek to assess feasibility and acceptability and explore the ways in which SAFETEL may operate to produce outcomes. Specifically it will focus on intervention fidelity, exposure, reach, context, recruitment, retention, and contamination, as well as the acceptability of study procedures. Table 1 presents the process evaluation framework and shows the various time points at which data collection and analysis are intended.

Table 1. Process Evaluation Framework for Analysis (v3.0 27.06.2018)

Evaluation Area	Questions
Fidelity (The degree to which the intervention was delivered as intended)	• What is the intervention? • Was the intervention (safety plan and follow up telephone calls) delivered as intended? • Was there consistency in terms of how the intervention was delivered? • What, if any, adaptations were needed to the planned intervention? And were they needed? • What barriers, if any, were there to delivering the intervention in a consistent way? (safety plan and follow up telephone calls)
Exposure (The extent to which participants received and understood the different	• To what extent did participants take up all potential elements of the full programme of intervention (safety plan and 5 follow up telephone calls)? • To what degree did participants receive the minimum dose (safety plan and 1 follow up phone call)? • To what extent was the safety plan completed as intended by the participant? If

elements of the intervention and whether they implemented these as intended. Their satisfaction with the intervention and barriers to receipt and implementation were also considered)	it wasn't what were the reasons for that? • How did participants use the Safety Plan they had developed? (e.g. frequency of use, practicality - where did they keep it, did they share with others) • To what extent did participants alter or amend their safety plans throughout the course of the intervention? • What elements of the intervention did participants find helpful/unhelpful and why? What elements of the intervention would participants change and why? • What changes, if any, did participants feel that they implemented as a result of taking part in the intervention? • What factors were involved in ongoing engagement with the intervention? • What do participants report were barriers and facilitators to developing the safety plan, engaging with telephone support and using the safety plan in practice? • What feedback do participants have regarding feasibility and acceptability of the safety plan and follow up telephone calls?
Reach (The extent to which the target audience is reached by the intervention, as well as any 'spill over' effects on people not recruited)	• How well does the study sample represent the population of interest? • Did participants report sharing their SP with family or friends? • To what extent did the intervention reach and influence people other than recruited participants?
Context (Includes information relating to aspects of the context in which the intervention was delivered, as well as broader context that both practitioner and client were operating within that may influence intervention effectiveness)	• What participant-centred contextual factors influenced engagement with the intervention (safety planning and follow up calls) and use of the safety plan in practice? • What contextual factors within participants' day to day environment influenced engagement with the intervention (safety planning and follow up calls) and use of the safety plan in practice? • How did the context in which the intervention was delivered influence engagement with the intervention and use of the safety plan in practice? • Was the safety plan useful in certain circumstances and not in others? • How does the intervention fit in with what is delivered in hospital (how easy was is it to deliver in this setting and does it conflict with anything)? • What were the particular context-related difficulties/issues that arose during the study in delivering the intervention?
Recruitment and Retention	• How did participants feel about being approached/recruited in hospital setting? • How acceptable were study and intervention procedures to participants? • What motivated study participants to agree to take part? (And what kept them engaged?) • Were there any difficulties in recruitment? • What is the attrition rate overall and by subgroup? i.e. intervention groups and control • What were the reasons for withdrawal?
Contamination	• What are the characteristics of other groups or services people are attending or resources they are using - do these provide any elements of the intervention? • Have participants used a safety plan or similar in the past? • Did participants in the TAU (treatment as usual) arm investigate 'Safety Plan'

	strategy on their own? • Have any of the TAU arm participants seen intervention content from other participants? • How did randomisation to the TAU arm affect participants?

Intervention Fidelity Checking

With participants' consent, all SPI sessions in Phases 2 and 3 will be audio-recorded. Fidelity of intervention delivery is being checked in different ways for the face-to-face sessions and telephone sessions. For the face-to-face sessions, 20% of the recordings will be randomly selected to check fidelity against a standardised measure of fidelity for the SPI (Safety Planning Intervention Rating Scale; Brown, G. K., & Stanley, B. Safety Plan Intervention Rating Scale (SPIRS)). These will be double coded by another team member and tested using Cronbach's alpha to test inter-rater reliability. A standardised checklist for the follow-up telephone support calls will be completed by the research team to enhance intervention fidelity and the results will be reported descriptively.

Qualitative Interviews with Study Participants

We will conduct semi-structured interviews with intervention participants at Phase 2 (n = up to 10) and Phase 3 (n = up to 30). Actual numbers will depend on data saturation. Participants will be purposively sampled based on a number of criteria (i.e. gender, age, hospital site of recruitment, engagement with the intervention, and history of self-harm). Semi-structured interview topic guides will be used and interviews will seek to explore participants' experience of the study and intervention including contextual factors, acceptability of study and

intervention procedures, barriers and facilitators to engagement with the intervention, and potential mediators of change. We will also seek to interview participants in the control arm at Phase 3 (n = up to 10) to explore their experiences of their treatment as usual, potential contamination, and the acceptability of study procedures.

Qualitative Interviews/Focus Groups with Staff

We will conduct semi-structured interviews with NHS clinical staff involved in the care of patients who have been admitted to hospital following a suicide attempt at Phase 2 (n = up to 6) and Phase 3 (n = up to 10). The interviews will focus on current context, procedures and services available to patients, feasibility of the intervention, and acceptability of the study and intervention procedures, including experienced or perceived barriers and facilitators, intervention 'fit' within the setting and suggestions for improvement. In addition we will conduct focus groups at Phase 2 and 3 with researchers responsible for study recruitment, data collection and intervention delivery (all researchers will be included where possible). Focus groups will explore experiences of recruitment, data collection, and intervention delivery, as well as perception of participants' experiences.

Data on Recruitment, Retention and Adherence

Data on the number of potential participants approached, who declined, were ineligible, and those who consented and were retained will be recorded and presented in the CONSORT diagram for the study. Concerning adherence to the intervention, we will record details of all intervention-related contacts, including number/length of sessions of support completed and

contact attempts made, in order to build a comprehensive picture of how participants engage with the study and the intervention. Data on the rate of safety plan completion and the use of safety plans between telephone contacts are recorded as well as the amount/and type of changes made to safety plans over the course of the (up to) five follow-up calls.

2.4.6 Outcome Measure Feasibility

Baseline

For Phases 2 and 3, all participants will be asked to complete a number of measures during the initial assessment at baseline with a trained researcher (see below). The purpose of collecting these will be to assess feasibility and acceptability of using these questionnaires in a full trial, as well as to characterise the sample and explore potential moderators. We will also record participant demographics, information on treatment as usual received by participants and other relevant information regarding the sample (e.g., suicidal history), which may be considered potential moderators or mediators in a full trial. The schedule of baseline measure completion for Phases 2 and 3 is outlined in Figure 2 and detailed below:

- *The Columbia Suicide Severity Rating Scale*[23] is a 20-item semi-structured brief, valid and reliable tool used to assess suicide risk and suicidal ideation and behaviours, such as previous suicide attempts as well as interrupted and aborted attempts and preparatory behaviours.
- *The Entrapment Scale*[24] is a 16-item scale that examines feelings of entrapment and defeat using a 5-point Likert-type scale (ranging from 0 “Not at all like me” to 4

"Extremely like me"). It is comprised of two subscales: internal (10 items) and external entrapment (6 items).

- *The Interpersonal Needs Questionnaire*[25] is a 12-item measure of perceived burdensomeness (7 items) and thwarted belongingness (5 items), with items rated on a 7-point Likert-type scale (ranging from 1 "Not at all true for me" to 7 "Very true for me").
- *The ENRICHD Social Support Instrument*[26] is a 7-item measure that assesses four attributes of social support: emotional, instrumental, informational, and appraisal on a 5-point Likert-type scale (ranging from 1 "None of the time" to 5 "All of the time").

The following measure will also be completed at Phase 3 only:

- *The Suicide-Related Coping Scale*[27] (Phase 3 only) is a 17-item measure that assesses suicide-related coping. It is comprised of two subscales: external coping, with items relating to recognising and utilising social support and professional resources during suicidal crisis and lethal means restriction, and internal coping, with items pertaining to self-administered coping strategies and confidence in relation to coping with suicidal feelings. Responses are rated on a 5-point Likert-type scale (ranging from 0 "Strongly disagree" to 4 "Strongly agree").

Follow-up telephone calls

Measures completed at follow up calls include; (i) the contact inventory (i.e. call duration, time between calls and number and means of participant contact); (ii) a mood and suicidal thoughts

and behaviours assessment; (iii) a review of the safety plans and use; (iv) treatment engagement and (v) participant agreement to receive the next follow-up call.

6-month post index data capture

Follow-up data on hospital readmissions for self-harm after baseline will be collected at Phase 2 (1-2 months post index suicide attempt) and Phase 3 (6 months post index suicide attempt) using NHS clinical databases in order to assess the viability of collecting these data in a full trial.

2.5 Data Analysis

The Robertson Centre for Biostatistics (RCB) within the University of Glasgow will provide statistical services in support of Phase 3 of the trial. The RCB is part of the Glasgow Clinical Trials Unit, and has extensive experience of the design, analysis and reporting of clinical trials and epidemiological studies.

2.5.1 Sample size

It is estimated that Psychiatry Liaison teams across the four hospitals annually see at least 3,700 patients who self-harm, and we estimate that 75% report suicidal intent.[5 28] Therefore, across 6 months of recruitment for Phase 3, there will be approximately 1,388 eligible participants; so we are aiming to recruit 20 participants per month. A sample of 120 participants is sufficient to explore the feasibility and acceptability of the intervention and allow estimation of the outcome event rates for a full trial.

2.5.2 Quantitative Data

Statistical analysis will include descriptive summaries of recruitment rates, attrition and retention, and intervention adherence. The baseline characteristics of the sample will be summarised. The primary outcome (readmission to hospital following self-harm within 6 months of the index suicide attempt) will be summarised by randomised group, and the intervention effect estimated using logistic regression, adjusting for minimisation factors (i.e. hospital site, gender and history of self-harm). Associations between baseline characteristics and the primary outcome will also be assessed to explore potential moderators for a full RCT.

2.5.3 Qualitative Data

Qualitative data from the interviews and focus groups conducted with study participants, NHS staff and the researchers who will deliver the intervention will be analysed via thematic analysis (Phases 2 and 3) using Braun and Clark's approach.[29] Thematic analysis is a systematic approach in which the data are initially coded and then collated into themes, which are then analysed in more detail to map out the overall data and examine relationships between them. Finally, themes are refined to produce an overall story of participants' views and experiences. Data collection and analysis of interview data will be conducted simultaneously and the analyses will inform data collection in terms of changes to the interview schedule (e.g., adding new questions to probe particular areas of interest). Data collection will continue until data saturation is reached and variables coded using Nvivo v11.4.1. Due to the primary focus of the semi-structured interviews and focus groups, the identified themes are likely to be on areas of

interest to the study evaluation (e.g., recruitment, retention, acceptability, adherence, etc.) but this method also allows unexpected themes to emerge and to be added to the coding framework. The coding framework will be discussed and refined with the other members of the study team. Twenty per cent of the interviews will be double coded to ensure reliability. Disagreements will be resolved by discussion.

Qualitative data will also be triangulated with quantitative data. We will draw upon qualitative and quantitative data to test the logic model (see Appendix 1) and investigate mechanisms through which the intervention may operate in order to further develop the intervention theory (Phase 3). All analyses will be specified in a detailed Qualitative Analyses Plan and Process Evaluation Framework.

2.6 Progression Criteria from Feasibility to Full Trial

The feasibility and acceptability of both the trial methods and the SAFETEL intervention, and the potential for these to be developed and delivered in a full-randomised controlled trial are the key outcomes of this trial. These will be assessed using the progression criteria outlined in Appendix 2. These criteria have been developed by our Trial Management Group and approved by our Trial Steering Committee; who will also undertake final assessment of these following analyses of the findings of the study.

3. Data Management and Access

The Robertson Centre for Biostatistics (RCB, part of the Glasgow Clinical Trials Unit), within the University of Glasgow, will provide data management services in support of Phase 3 of the trial. The RCB will create the database for Phase 3 data, and provide the online electronic Case Record Form (e-CRF), as well as training in the use of the system. Data will be entered locally with data validation checks built in. RCB will also run routine data validation checks and alert the study management team to general issues or specific data queries.

All personal information will be encrypted and visible only to the research team; all personally identifiable information will be held separately from research data. The RCB statisticians will develop analysis programmes during the trial and communicate any data anomalies to RCB data managers. At the end of the trial, final data validation checks will be carried out prior to database lock. The study database will be held by RCB for the duration of the study and for a minimum of 5 years after study completion.

3.1 Data Sharing

At baseline, potential participants are asked to consent to the following in order to participate in the study:

- Permission for the research team to access routinely collected medical data (including CHI numbers) to determine what contact the participant has had with clinical services

within 5 years of taking part in this study, where it is relevant to their taking part in the research.

- Permission for authorised representatives of the study Sponsor, NHS Greater Glasgow and Clyde/NHS Lothian, and regulatory authorities to have access to their personal information and research data for the purposes of audit.
- In addition, participants are given the option of consenting to the research team sharing their data in the following circumstances:
    - Anonymous storage of data in the UK data archive where other researchers can have access to this data only if they have scientific and ethical approval, and agree to preserve the confidentiality of this information as set out in the study consent form.
    - Informing the participant's own General Practitioner and other relevant mental health professionals involved in their care, of their participation in the study and sending them a copy of the participant's safety plan.

3.2 Serious Adverse Events (SAE/AEs)

As discussed in section 2.4.3.1 in detail; in the event of serious adverse events occurring within the study, standard operating procedures, robust recording and reporting measures to detail these occurrences will be employed. Any complaints made by participants or relevant adverse events will be recorded and reported to Trial Steering Committee (TSC). The TSC will thereafter report to the study sponsor and governance management team as agreed in the initial stages of

the approval process. The TSC will take on the role of Data Monitoring Committee for oversight of adverse events. The TSC will be comprised of individuals with extensive expertise in clinical trials, suicide prevention research, biostatistics and clinical practice as well as lived experience.

4. Ethics and Dissemination

The East of Scotland Research Ethics Service approved the SAFETEL study in March 2017 (EoSRES; REC Reference: GN17MH101). The study will be conducted in accordance with the recommendations for physicians involved in research on human participants adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. The study results will be disseminated via peer-reviewed publication and conference presentations. A participant summary paper will also be disseminated to patients and policy makers who wish to receive it alongside the main publication.

5. Trial Status

This trial is ongoing but all participants have now been randomised.

Footnotes

Author Statement: Rory O'Connor is principal investigator who together with Sharon A Simpson developed the study protocol alongside the other co-investigators (Barbara Stanley, Gregory Brown, Michael Smith, Daniel Smith, Alex McConnachie & Suzy Syrett), and has overall responsibility for the management of the trial. Marcela Gavigan is the trial manager and is responsible for coordinating the trial. The Research Associate Jenna-Marie Lundy also coordinates the trial and provides day-to-day management of the research team and oversees recruitment at hospital sites as well as data capture, supported by Marcela Gavigan. Susie

Smillie is the process evaluation researcher. Marcela Gavigan, Jenna-Marie Lundy, Corinna Stewart and Susie Smillie were involved in finalising the study protocol, implementing study processes and drafting the manuscript. Heather McClelland and Corinna Stewart are research assistants on the trial and have responsibility for participant recruitment, data capture, contributing to the study design, reviewing the manuscript. Alex McConnachie was involved in finalising the study protocol, in particular the statistical analyses, and reviewing the manuscript. Barbara Stanley and Gregory Brown had responsibility for training the research staff in delivering the intervention. Suzy Syrett is the SAFETEL study peer researcher who is also responsible for representing patient views and focus group activity and reviewed the manuscript. All authors commented on and approved the final version of the manuscript.

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Role of Sponsor and funder: The Sponsor and funder had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had overall responsibility for the decision to submit for publication.

Competing interests: None declared.

Ethical Approval: The East of Scotland Research Ethics Service (EoSRES) approved this study in March 2017 (Research Ethics Committee Reference: GN17MH101 Ref: 17/ES/0036). Trial Registration Number: ISRCTN62181241.

Data access: subject to ethical approvals, the final trial dataset will be made available.

Provenance and peer review: Not commissioned; externally peer reviewed.

Figure Legends

Figure 1. SAFETEL Study Flow Diagram Version v5.0

Figure 2. SAFETEL Phase 3 Participant flow diagram v3

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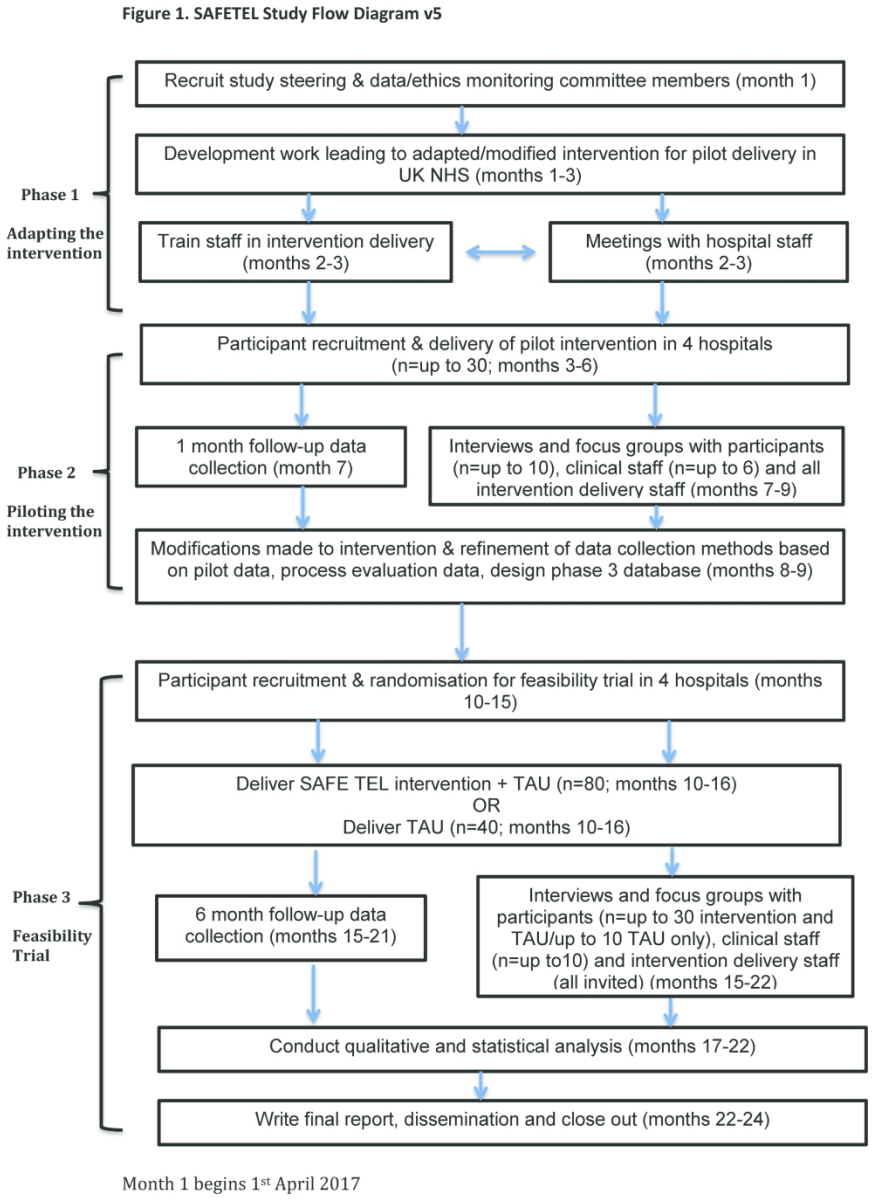


Figure 1. SAFETEL Study Flow Chart v 5.0

197x268mm (300 x 300 DPI)

Figure 2. SAFETEL Phase 3 Participant Flow Diagram v3

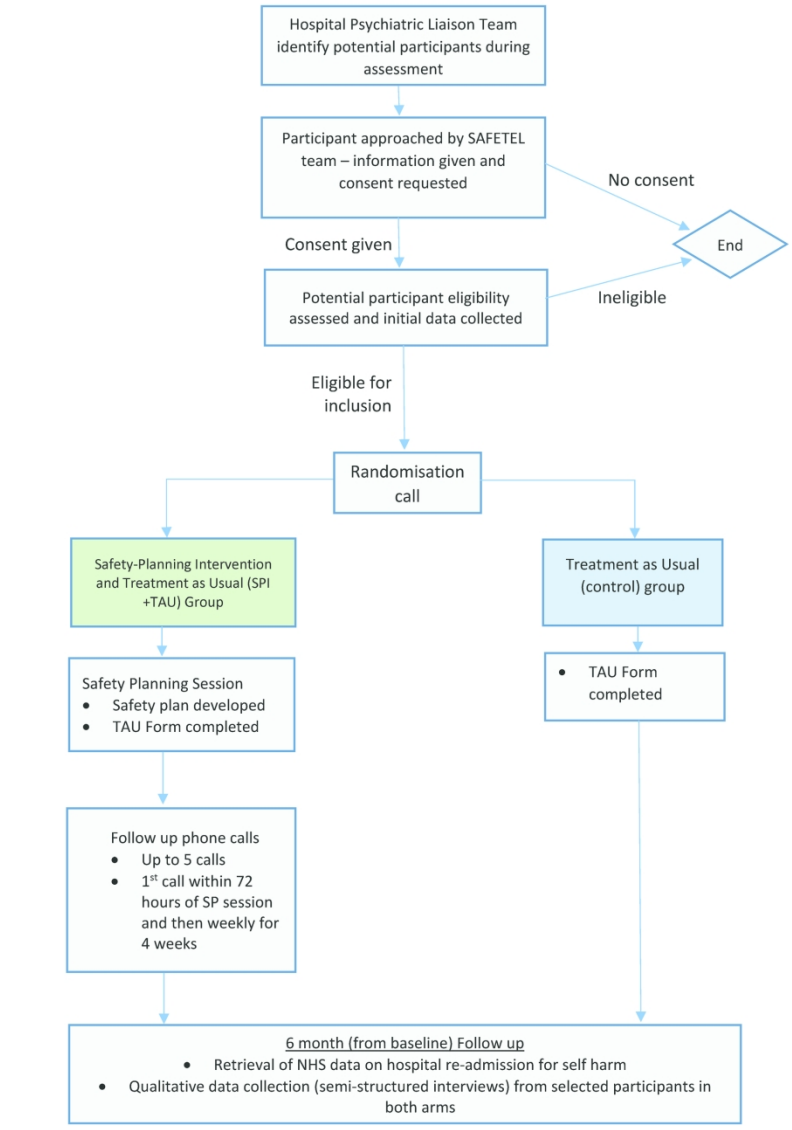
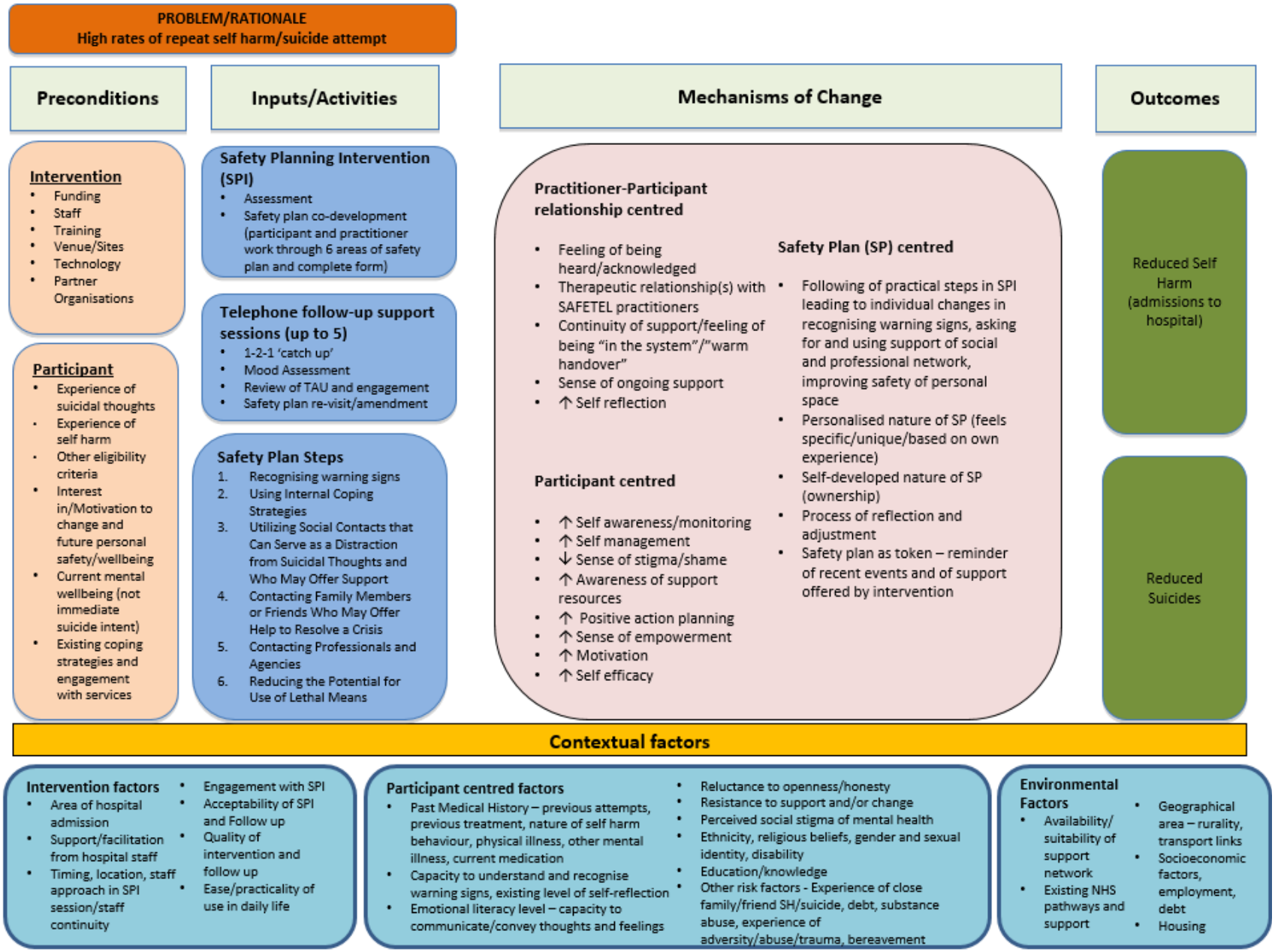


Figure 2. SAFETEL Phase 3 Participant Flow Diagram v.3.0

165x248mm (300 x 300 DPI)

Appendix 1: Proposed logic model SAFETEL study (v5.0 07.06.2018)



Appendix 2: Proposed Progression Criteria SAFETEL study (v1.0 11.06.2018)

CRITERIA	INDICATOR GREEN=Very strong indication to proceed AMBER=Medium indication to proceed. Discuss with TSC and proceed with identified plan to improve performance on indicator in Phase III trial RED=Indication of doubt as to whether to proceed. Discuss with TSC, and only proceed if other indicators are amber/green and there is a clear mitigating strategy	METHOD OF ASSESSMENT
1. Were hospital-based study procedures feasible to deliver and acceptable to staff involved (hospital staff onsite and study staff delivering)? *(e.g. referral, recruitment, assessment, SP session delivery)*	Progression to be agreed in conjunction with Trial Steering Committee (TSC) [1] based on qualitative data captured around experienced and potential barriers to delivery. • No current barriers, or those emerging have been minor, planned for and overcome in the past during the course of the feasibility study • Some barriers but for which plans have been made/alternatives prepared • Barriers for which no feasible plan or alternative can be offered/developed	Qualitative data collected in SAFETEL intervention provider focus groups, and clinical staff interviews, analysed as part of the process evaluation and reported on to the TSC. Barriers identified and changes made to Study Protocol as a result will be reported to TSC. Given the small number of participants offering qualitative feedback, value will be placed on individual reports of barriers, not simply those barriers that are frequently reported by different participants.
2. Were study procedures feasible to deliver and acceptable to participants (including control arm)? *(e.g. recruitment, consent/information given, assessment, safety planning session, follow up phone calls)*	Progression to be agreed in conjunction with Trial Steering Committee (TSC) based on qualitative data captured around experienced and potential barriers to delivery. • No current barriers, or those emerging have been minor, planned for and overcome in the past during the course of the feasibility study • Some barriers but for which plans have been made/alternatives prepared • Barriers for which no feasible plan or alternative can be offered/developed	Qualitative data collected in SAFETEL study participant interviews (intervention and control arms) analysed as part of the process evaluation and reported on to the TSC. Complaints made by participants or relevant Adverse Events will be recorded and reported on to TSC. Given the small number of participants offering qualitative feedback, value will be placed on individual reports of barriers, not simply those barriers that are frequently reported by different

3. Was it feasible to deliver Safety Plan in the hospital?	**Feasibility of intervention delivery**: • Green: > 90% of SAFETY PLANS delivered at hospital • Amber: 60-90% • Red: <60%	% of safety plans delivered.
4. Was it feasible to deliver 1st follow up phone call attempt within 72 hours?	**Was the progression criterion met?** • Green: >90% of first calls made within 72 hours of discharge • Amber: 60-90% • Red: <60%	**Feasibility of intervention delivery**: % Call attempts made at 1st follow up phone call time point **Was the progression criterion met?** % of 1st Follow up call delivered within 72 hours. Additional qualitative data from SAFETEL intervention provider focus groups, risk log, changes to study protocol identifying barriers and facilitators to implementation reported to TSC.
5. Was the target rate of recruitment and retention achieved? *(Are appropriate and effective routes of recruitment available to achieve a powered sample size in a full trial?)*	**Actual Recruitment rate vs. Target Recruitment rate:** • Green: >80% of participants • Amber: 60-80% • Red: <60%	**Actual Recruitment rate vs. Target Recruitment rate:** Actual participant recruitment rate and target recruitment rate will be measured to support projection of a powered sample for a full trial.
6. Was it feasible to attain a minimum dose target required to justify a full trial?	**Adherence rates:** • Green: >80% • Amber: 60% - 80% • Red: <60%	**Feasibility of attaining minimum dose:** % of participants who completed minimum dose participation (i.e. SP+1 Follow up call).
7. Was a target rate of completed baseline measures achieved?	**Completion of core measures:** • Green: >90% data completion • Amber: 70%- 90% • Red: <70%	**Completion of core measures:** % of participants completed the core questionnaires. % of missing data from completed core questionnaires.
8. Are identified barriers and challenges to implementation of and adherence to the intervention planned for and surmountable?	Progression to be agreed in conjunction with Trial Steering Committee based on qualitative data captured around experienced and potential barriers to implementation of and adherence to the intervention beyond those already captured in Criteria 1 and 2.	Process Evaluation report. SWOT analysis.

[1] Trial Steering Committee (TSC)

[2]The Community Health Index (CHI) is a population register which is used in Scotland for healthcare purposes. The CHI number uniquely identifies a person on the index.

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	8
Funding	#4	Sources and types of financial, material, and other support	1
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 30
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	30

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	30
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	14, 24
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	7-9, 14-15
Objectives	#7	Specific objectives or hypotheses	6-7
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7,11, 12
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8-9
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5, 9-17

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	25
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	14-19
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	14
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	See note 1
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	22
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	9, 16
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11-12
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	11-12

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11-12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11-12
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11-12
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	17-23
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	17-23
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	24-25
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	21-25
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	22
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	21-23

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	25-26
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	25-26
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	26
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	8
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9-11, 24
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	9-11, 24
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	24
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	31
Data access	#29	Statement of who will have access to the final trial dataset,	31

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/A
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Author notes

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