PEER REVIEW HISTORY

This paper was submitted to a another journal from BMJ but declined for publication following peer review. The authors addressed the reviewers' comments and submitted the revised paper to BMJ Open. The paper was subsequently accepted for publication at BMJ Open.

(This paper received three reviews from its previous journal but only two reviewers agreed to published their review.)

ARTICLE DETAILS

TITLE (PROVISIONAL)	Study Protocol for the SAFETEL randomised controlled feasibility trial of a Safety Planning Intervention with Follow-up Telephone Contact to Reduce Suicidal Behaviour
AUTHORS	O'Connor, Rory; Lundy, Jenna-Marie; Stewart, Corinna; Smillie, Susie; McClelland, Heather; Syrett, Suzy; Gavigan, Marcela; McConnachie, Alex; Smith, Michael; Smith, Daniel J; Brown, Gregory K; Stanley, Barbara; Simpson, Sharon

VERSION 1 – REVIEW

REVIEWER	Fiona Shand University of New South Wales, Australia
REVIEW RETURNED	19-Aug-2018

GENERAL COMMENTS	This protocol paper is a thorough description of a 3-phase study to develop and test the feasibility of a safety planning intervention + brief intervention. The paper is appropriately detailed and well structured. I have minor comments below. I look forward to seeing the results of this study as they emerge. Abstract, first para – it's probably enough to say that 'there are no evidence based interventions' rather than 'no evidence-based effective interventions'. We don't know if any are effective yet. Intro, p4, line 32 – could you broaden out the delivery mode to more than telephone? I know that this is the mode of delivery for this intervention, but effective treatment can be delivered via other means and you probably don't need to be so specific at this point in the manuscript. Study design, p8 – could you provide a rationale for the 80/40 allocation to intervention and control conditions? Settings, p8 – the sentence about telephone-based support sessions being conducted up to four weeks later could be clearer. Is this a measurement point or part of the intervention? Could you separate out (1) intervention timing and (2) measurement points? p9, Exclusion criteria – At what time point is 'no suicidal intent' an exclusion criterion. As it relates to the index episode? Also could you please describe what happens if a participant expresses suicidal intent at baseline?

	p13, lines 26-28 - it might be clearer to specify that the first phone call will be attempted up to 72 hours following discharge and then subsequent calls will be weekly. p15, lines 30-33 - could you specify that working through each step entails beginning with using one's internal resources, through to external resources such as calling a support person or professional service? p21, para 3 - will self-reported self-harm/suicidal behaviour be captured? In case there are episodes that are not hospital-treated? I understand that these data will be incomplete because of participants lost-to-follow up but it could nevertheless provide a more complete picture of repeat self-harm/SA for this population. P26, para 1 - It would be good to see a bit more about the composition of the trial steering committee (e.g. their skills and experience) and to be clear that they are capable of also operating as an independent data safety monitoring board. p26, para 2 - will the summary paper be distributed to other participants, e.g. hospital staff, and other stakeholders?

REVIEWER	Jeff Bridge The Research Institute at Nationwide Children's Hospital and The Ohio State University, USA
REVIEW RETURNED	19-Aug-2018

GENERAL COMMENTS	This manuscript describes the study protocol for the SAFETEL RCT feasibility study of a safety planning intervention with follow-up telephone contact. The study is timely and should be of interest to reader of the Journal. The manuscript is very well-written and the authors clearly describe the rationale for the study and each study component, including progression criteria from feasibility to a full trial.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Fiona Shand

COMMENT: This protocol paper is a thorough description of a 3-phase study to develop and test the feasibility of a safety planning intervention + brief intervention. The paper is appropriately detailed and well structured. I have minor comments below. I look forward to seeing the results of this study as they emerge.

RESPONSE: Thank-you

COMMENT: Abstract, first para – it's probably enough to say that 'there are no evidence based interventions' rather than 'no evidence-based effective interventions'. We don't know if any are effective yet.

RESPONSE: Good point. We've now removed 'effective'.

COMMENT: Intro, p4, line 32 – could you broaden out the delivery mode to more than telephone? I know that this is the mode of delivery for this intervention, but effective treatment can be delivered via other means and you probably don't need to be so specific at this point in the manuscript.

RESPONSE: We have now changed 'by telephone' to 'by other means'.

COMMENT: Study design, p8 – could you provide a rationale for the 80/40 allocation to intervention and control conditions?

RESPONSE: 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. Most of our questions and progression criteria relate to intervention feasibility and acceptability and that is what our main outcomes of the trial are. Therefore it makes more sense to have this randomisation ratio.

We have added the following to the 2.4.2 Randomisation and Blinding (Phase 3 only) section: "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."

COMMENT: Settings, p8 – the sentence about telephone-based support sessions being conducted up to four weeks later could be clearer. Is this a measurement point or part of the intervention? Could you separate out (1) intervention timing and (2) measurement points?

RESPONSE: We have removed 'baseline data collection" from this sentence. We also refer the reader to the Follow-up Telephone Support section which provides full details of the intervention timings: "(see Follow-up Telephone Support section for more details)."

COMMENT: p9, Exclusion criteria – At what time point is 'no suicidal intent' an exclusion criterion. As it relates to the index episode? Also could you please describe what happens if a participant expresses suicidal intent at baseline?
RESPONSE: In the Recruitment section under Phase 2, we have now modified the text to highlight that the presence or absence of suicidal intent is made by the liaison psychiatry team initially:

"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)."

And later in that paragraph: "Research staff will confirm that participants meet inclusion criteria."

Based on our previous research, we anticipate that most participants will express suicidal intent. This will be taken into consideration when the Liaison Psychiatry team is conducting their psychosocial assessment – which all self-harm patients receive routinely.

COMMENT: p13, lines 26-28 - it might be clearer to specify that the first phone call will be attempted up to 72 hours following discharge and then subsequent calls will be weekly.

RESPONSE: Thanks. We have now made this clarification in the text.

COMMENT: p15, lines 30-33 - could you specify that working through each step entails beginning with using one's internal resources, through to external resources such as calling a support person or professional service?

RESPONSE: We have now modified this section such that it now reads: "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."

COMMENT: p21, para 3 - will self-reported self-harm/suicidal behaviour be captured? In case there are episodes that are not hospital-treated? I understand that these data will be incomplete because of participants lost-to-follow up but it could nevertheless provide a more complete picture of repeat self-harm/SA for this population.

RESPONSE: No, we are not collecting these data. Although we agree that the self-reported data could give a more complete picture, given the problems with follow-up in this population, we made a decision at the ethics application stage not to collect these data.

COMMENT: P26, para 1 - It would be good to see a bit more about the composition of the trial steering committee (e.g. their skills and experience) and to be clear that they are capable of also operating as an independent data safety monitoring board.

RESPONSE: We have now added the following additional information: "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."

COMMENT: p26, para 2 - will the summary paper be distributed to other participants, e.g. hospital staff, and other stakeholders?

RESPONSE: We have now clarified that the summary sheet will only be distributed to those who wish to receive it:

"A participant summary paper will also be disseminated to patients and policy makers who wish to receive it alongside the main publication."

Reviewer: 2
Reviewer Name: Jeff Bridge

COMMENT: This manuscript describes the study protocol for the SAFETEL RCT feasibility study of a safety planning intervention with follow-up telephone contact. The study is timely and should be of interest to reader of the Journal. The manuscript is very well-written and the authors clearly describe the rationale for the study and each study component, including progression criteria from feasibility to a full trial.

RESPONSE: Thank-you.

FORMATTING AMENDMENTS (if any)
Required amendments will be listed here; please include these changes in your revised version:

COMMENT: Please remove all your figures in your main document and upload each of them separately under file designation 'Image' (except tables and please ensure that Figures are of better quality or not pix-elated when zoomed in). NOTE: They can be in TIFF or JPG format and make sure that they have a resolution of at least 300 dpi and at least 90mm x 90mm of width. Figures in PDF, DOCUMENT, EXCEL and POWER POINT format are not acceptable.

RESPONSE: We have now done so.

COMMENT: Please remove Appendices embedded in your main document and upload it separately as supplementary file in PDF format.

RESPONSE: We have now done so.

COMMENT: Please provide a detailed contributorship statement. It needs to mention all the names/initials of authors along with their specific contribution/participation for the article.

RESPONSE: We have done so. See p.31.

COMMENT: Patient and Public Involvement:
Authors must include a statement in the METHODS section of the manuscript under the sub-heading 'Patient and Public Involvement'.

This should provide a brief response to the following questions:

How was the development of the research question and outcome measures informed by patients' priorities, experience, and preferences?
How did you involve patients in the design of this study?
Were patients involved in the recruitment to and conduct of the study?
How will the results be disseminated to study participants?
For randomised controlled trials, was the burden of the intervention assessed by patients themselves?
Patient advisers should also be thanked in the contributorship statement/acknowledgements.

RESPONSE: We have now added a Patient and Public Involvement statement on p.8:

"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."

VERSION 2 – REVIEW

REVIEWER	Fiona Shand Black Dog Institute, University of New South Wales, Australia
REVIEW RETURNED	09-Nov-2018

GENERAL COMMENTS	Thank you for your edits. All the best with the trial - I look forward to seeing results as they become available.