SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
		SMS SOS: Effectiveness of SMS text messages in improving survival and rehabilitation rates of deliberate self harm patients and reducing re-presentation of DSH patients to hospital.
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
		This trial has been registered with The Australian Clinical Trials Registry (ACTR): ACTRN12617000607370
	2b	All items from the World Health Organization Trial Registration Data Set
		The full WHO Trial Registration Data Set will be included with materials for the ACTR registration.
Protocol version	3	Date and version identifier
		13 July 2018, Version 6
Funding	4	Sources and types of financial, material, and other support
		Translational Research Grants Scheme (TRGS Application Number: 155), New South Wales Ministry of Health The NSW Ministry of Health provided full funding for this project.
Roles and	5a	Names, affiliations, and roles of protocol contributors

responsibilities		**Professor Alison Jones** Blacktown / Mt Druitt Hospital (WSLHD) & University of Wollongong Roles: Chief Investigator. To ensure appropriate planning and ongoing clinical and research governance of the current project. Prof Jones will also be actively involved in the review and interpretation of results, and the development of detailed research dissemination and translation plans. **Clinical Associate Professor Naren Gunja** Westmead/Blacktown Hospitals (WSLHD) / University of Sydney Roles: Study development and oversight, and delivery of SMS text messaging follow-up at the BMDH and Westmead sites. Oversight of clinical response and study follow-up when participants re-present to Westmead and BMD Hospitals, including liaison/co-ordination between Toxicology and Psychiatry. **Clinical Associate Professor Christopher Ryan** Westmead Hospital / University of Sydney Study development and oversight, and delivery of SMS text messaging follow-up at the Westmead site. Oversight of clinical response and study processes when participants re-present to Westmead Hospital. **Professor Gregory Carter** Calvary Mater Newcastle Hospital / Newcastle University Roles: Study oversight, and interpretation of results. Note: key author of the Postcards from the EDge study (Carter et al, 2005, 2007) **Professor Ian Whyte** Calvary Mater Newcastle Hospital / Newcastle University Roles: Study oversight, and interpretation of results. Note: key author of the Postcards from the EDge study (Carter et al, 2005, 2007) **Professor Andrew Page** Western Sydney University Study development, co-ordination of Data Management Committee, statistical analysis and interpretation of results. **Dr Garry Stevens** Western Sydney University Study development, statistical analysis and interpretation of results. **Mr Graham Gould** Lifeline South Coast Study development and oversight. Liaison with community groups and consumer project representatives. Interpretation of study results.

	5b	Name and contact information for the trial sponsor
		Dr Kerry Chant Chief Health Officer New South Wales Ministry of Health 73 Miller St North Sydney NSW 2060 Locked Mail Bag 961 North Sydney NSW 2059 Tel. (02) 9391 9000 Fax. (02) 9391 9101
	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
		The study sponsor has no role in any of the study activities noted above, nor do they have ultimate authority over any of these activities.
	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)
		The Governance structure of the project consists of the Project Steering Committee and Data Management Committee.
Introduction		
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

		Previous studies have demonstrated that brief contact interventions, such as a simple follow-up postcard intervention, significantly reduce deliberate self-poisoning (DSP) hospital re-presentation rates, the time to first re-admission, and associated hospital costs (particularly in women).[1-5] Self-harm injury is a National Health Priority accounting for 4 billion dollars in health care expenditure each year. Deliberate self-harm (DSH), which includes self poisoning and other forms of physical self-injury, is a potentially preventable form of injury and accounts for 27% of the health burden associated with injury in Australia.[5] Deliberate self-poisoning (DSP) constitutes the bulk of self-harm injury and is defined as "the deliberate ingestion of more than the prescribed amount of medicinal substances, or ingestion of substances never intended for human consumption, irrespective of whether harm was intended". This definition takes an epidemiological stance, defining attempted suicide on the basis of behaviour alone, rather than by an inference about intention to die.[6] DSP constitutes around 90% of all DSH and hospital treated self-poisoning is very common in Australia, representing up to 5% of all hospital admissions.[7] Repetition of self-harm within 12 months of an index episode occurs at a median rate of 15% (interquartile range 12-25%).[8] This has a strong association with subsequent completed suicide, and has significant resource implications for the health system. Completed suicide is 60 fold higher among people who have engaged in DSH compared to the general population. Importantly, the repetition rate of self-harm is reduced when patients feel connected and cared for. [9] However, SMS text messaging provides more immediate communication and may be a more effective intervention than postcards. Teenagers and young adults prefer texting to talking on their mobile phones for most forms of peer contact.[10] SMS messaging has also been used successfully in health settings, and found to be beneficial in changing health behaviours.[11] A recent meta-analysis (Milner et al, 2015) of brief follow-up interventions for reducing DSH (letters, telephone calls and crisis 'Green Cards') found lower odds of any episode of self-harm or attempted suicide among those receiving the intervention compared with controls, although this result was not significant. [12] These studies were generally underpowered, varied considerably in timeframes and methods, and SMS-text studies were not included in this analysis. The authors highlighted the need for further assessment of possible benefits in well-designed trials in clinical populations. Should an SMS follow-up intervention prove to be effective in reducing DSH re-presentations, it would allow for a significantly more flexible, low-cost and deliverable medical follow-up system.

	6b	Explanation for choice of comparators
		Among those who have presented to study hospitals following DSH, two groups will be compared in this study: (1) a follow-up SMS plus treatment as usual (TAU) group, and (2) a follow-up TAU group. As noted above, SMS text messaging provides more immediate communication and may be a more effective follow-up intervention than postcards (or treatment as usual), and has been beneficial in changing health behaviours in health settings.[13]
Objectives	7	Specific objectives or hypotheses
		To determine whether an SMS-text message follow-up intervention for deliberate self-harm (DSH) plus treatment-as-usual hospital follow-up (SMS+TAU) is more effective in reducing DSH re-presentation to hospital, than treatment-as-usual hospital follow-up alone. Study Hypotheses: 1. Following a DSH hospital presentation, SMS + treatment as usual (TAU) will be associated with a significantly lower event rate of DSH re-presentation (repetition) than TAU alone. 2. Following a DSH hospital presentation, SMS+TAU will be associated with a significantly longer median time to first repetition than TAU alone
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, noninferiority, exploratory)
		This study will be conducted as a multi-centre (Blacktown/Mt Druitt (BMDH), Westmead and Nepean Hospitals) Randomised Controlled Trial (RCT), with eligible study participants being randomly assigned within each site (allocation ration of 1:1) to either hospital follow-up treatment-as-usual (TAU) or SMS-text follow-up plus TAU (SMS+TAU).
Methods: Participants, interventions, and outcomes		
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

		The study will be conducted in the Emergency Departments of the three participating hospitals (Blacktown/Mt Druitt (BMDH), Westmead and Nepean Hospitals), including clinical consultation rooms within or adjacent to the Emergency Departments used for Psychiatry and Clinical Toxicology patient consultations. Details of these study sites can be obtained at: http://www.wslhd.health.nsw.gov.au/
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)
		Individuals will be eligible for study inclusion if they present with DSH during the recruitment period, have access to a mobile phone for personal use and are aged 16 years and over. We will include individuals who present with either a first or subsequent episode of DSH. Patients who are incapable of or unwilling to give informed consent, those of no fixed address, those with insufficient English to read an SMS, and those without a mobile phone, will be excluded from the study.
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

		The control group with receive hospital follow-up treatment as usual (TAU) which consists of hospital and/or community mental health contact with the presenting individual, typically within 24 hours of their presentation, and a follow-up program of care including clinical re-assessment and individual or family-based psychological therapies, as indicated. The intervention group will receive TAU as well as an automated series of supportive text messages (TAU+SMS) received at 1,2,3,4,5,6,8,10 and 12 months after their index admission; the same schedule used in the previous 'Postcards' study (Carter et al, 2005, 2007). The messages provide a supportive expression of care and an opportunity to make contact with clinical services if the individual feels this may be necessary. The SMS message will be sent in three versions: **Text Message 1** Dear [name]. We hope that things have been going well for you since we last had contact. Just a reminder that the 24-hour contact line (131 114) is there if you'd like to connect with someone and Helpline staff (1800 011 511) can put you in touch with your local health service if needed. Best wishes. [Return SMS messages are unavailable from this service.] **Text Message 2** Hi [name]. We hope that you've been ok since our last contact. We're just checking in with you. A 24-hour phone line is there for you in case you'd like to connect with someone (131 114) or to contact your local health service (1800 011 511). Best wishes. **Text Message 3** Dear [name] Just checking in with you. A reminder that help is there if you need it. Just call (131 114) or (1800 011 511) for support. Best wishes.
	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)
		Participant request would constitute criteria for discontinuing the SMS text messaging schedule with a given participant.

	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
		The intervention involves sending an SMS message to participants and, as such, all participants in the intervention arm of the trial will receive the intervention. It will not be possible to determine whether the participant receives the message (except in instances where participants have changed phone numbers, and investigators receive notification that the message could not be delivered), or opens the message to read its content. The strategy to maximise likely participant receipt of the SMS message will be to ensure that mobile phone contact information (and other demographic information) is up to date prior to hospital discharge.
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
		Not applicable. Participants will have been discharged, and usual follow-up practices (i.e. treatment as usual) will be followed.
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
		Primary outcomes: (i) number of DSH re-presentations in each group (repetition event rate) (ii) median time to first re-presentation in each group, both within the 12 months following recruitment Secondary outcome: (i) Mortality
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)
		See 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
		Our study is powered to detect a clinically important difference in outcomes for all patients. Subgroup analysis of females for secondary analyses will likely be under-powered for comparisons of event rates over the 24-month recruitment period, but be sufficiently powered to compare median time to first repetition (see 'Feasibility' below). Assuming an incidence rate ratio (based on event rates) of RR=0.66 [4] for the intervention group compared to the control group, with a 5% significance level and 80% power and 10% adjustment for correlation of individuals within centres, a total sample size of 796 participants is required (398 in the intervention group and 398 in the control group). This assumes a median survival time (time to first repetition) in the control group of 4.3 years. Currently ~15% in the usual care group who present for DSH re-present within the following 12-months, or a probability of survival of 0.85. Median survival (m) after 1 year (t) in the usual care group = t*loge(1/2)loge(p) = 4.3 years. For assessing differences in median time to first repetition, assuming a median survival time in the usual care group of 73.5 days[14] and a similar relative difference in event rates between intervention and controls groups as above (RR=0.66) [4] , the estimated median survival time in the intervention group is 121.8 days, which requires a total sample size of 138 participants (69 participants in the intervention group and 69 participants in the control group), with 5% significance and 80% power, and 10% adjustment for correlation of individuals within centres. The number of patients likely to die within the study period is very small. A previous longitudinal study in our centre found a 1% suicide rate after 24 months and nearly a 2% suicide rate after 5 years. [15] These are lower than the 12-month 1.8% rate reported in a recent meta-analysis of psychosocial interventions after self-harm. We believe the magnitude of effect on re-presentations is possible because of previous studies showing a 5% reduction in non attendance rates in a primary care setting amongst young adults receiving text messaging. Because of the underpinning theory of social connectivity to reduce self-harm, [9] the immediacy of SMS text messaging, the greater “hit” rate of delivery using more sophisticated technology than postcards, and its greater attractiveness to young people [16] who are our target for intervention it is extremely likely that SMS text messaging will be more effective than postcards.

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
		Participants for this study will be recruited through the Emergency Departments of the three participating hospitals. The three hospitals have total combined deliberate self-poisoning and self-harm separations of approximately 900 per year (Naren Gunja, Christopher Ryan and Anita Kotak – personal communication). Hospital protocol requires all patients with self poisoning/harm to be admitted for full medical and psychiatric assessment – patients are not sent home directly from the Emergency Department. All patients presenting with deliberate self-poisoning (DSP) to emergency departments of the three hospitals are admitted to the toxicology service or notified to this service and entered prospectively into the clinical toxicology database (with an estimated 95% capture rate). The psychiatry department sees all patients with DSP and all other forms of deliberate self-harm (DSH) for assessment and diagnosis and to determine discharge destination and follow up (DSP and DSH referred collectively as DSH hereafter, unless otherwise specified). Patient data from these latter assessments is collected in the purpose-designed Ciel (Mental Health) databases and also has a very high capture rate.
Methods: Assignment of interventions (for controlled trials)		
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
		Study participants will be stratified by first DSH presentation or subsequent DSH presentation. Participants will then be randomised within strata, using random permuted blocks of size 6, to either the intervention (SMS+TAU) group or the control (TAU) group using a computer-generated randomisation program.
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

		Study participants will be stratified by first DSH presentation or subsequent DSH presentation. Participants will then be randomised within strata, using random permuted blocks of size 6, to either the intervention (SMS+TAU) group or the control (TAU) group using a computer-generated randomisation program. To ensure participants are not enrolled more than once, the treating doctor and other treating health professionals will search the study database for existing participants. For those not enrolled, group allocation will then occur via numbered sealed envelopes. The treating doctor and other treating health professionals will attach a patient ID sticker [name, gender, DOB, MRN] to the allocation information card inside the envelope and, thereafter, request written consent only from participants allocated to the intervention group (Zelen single consent process detailed below).. Participants will remain blinded to group allocation during recruitment. The envelope containing the patient identifying information, and study information and consent form will be collected by the Project Officer who will complete participant enrolment where the consent form has been signed. Clinical Toxicologists also see the majority of attending patients with DSH (i.e. those with DSP, which account for approx. 65% of presentations) and this (in addition to monitoring by research staff) will provide a further check of whether eligible participants have been allocated. In such instances the Toxicology staff will contact the patient, make the allocation, request consent and make this information available to research staff using the same procedure detailed above.
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions

		The allocation sequence will be generated by the Study Co-ordinator under the direction of the Chief Investigator and Data Monitoring Committee (DMC). As all patients with DSH and DSP receive a mental health assessment, the Doctor/Mental Health clinician/Research Officer (under clinical oversight) will be primarily responsible for allocating participants to interventions. The Doctor/Mental Health clinician/Research Officer will attach a patient ID sticker [name, gender, DOB, MRN] to the allocation information card inside the envelope and, thereafter, request written consent only from participants allocated to the intervention group (Zelen single consent process detailed below). The envelope containing the patient ID information and consent form will be collected by the Project Officer who will complete participant enrolment where the consent form has been signed. Clinical Toxicologists also see the majority of attending patients with DSH (i.e. those with DSP, which account for approx. 65% of presentations) and this (in addition to monitoring by research staff) will provide a further check of whether eligible participants have been allocated. In such instances the Toxicology staff will contact the patient, make the allocation, request consent and make this information available to research staff using the same procedure detailed above. A randomised consent design (Zelen: single consent version) will be used (Zelen, 1979, 1990). This was successfully employed in our previous study (Carter et al, 2005,2007).This design is a variation on the standard randomised controlled experimental design, in which participants are randomised to control or intervention before consent is sought. In the single consent version, written informed consent to receive the intervention (nine scheduled SMS text messages) is sought only from participants randomised to the intervention. In the event of double enrolment of patients: i) Patients' data are included in study data analyses based on the first condition to which they are allocated (control or intervention). ii) Patients enrolled in the control condition before the intervention condition will receive text messages but their data will not be included in future data analyses. Patients will not need to be contacted as they are not approached when they are enrolled in the control condition. These patients will receive text messages for ethical reasons. ii) Patients first enrolled into the intervention condition and then later enrolled into the control condition will continue to receive text messages. Data connected with their enrolment in the control condition will be excluded from data analyses.

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
		The primary requirement for blinding in the current study relates to data analysts i.e. those involved in the measurement of outcomes from hospital data. The study will employ two databases. First, a "master list" of study participants, labelled by medical record number (to maintain observer blinding), documenting their age, address, mobile phone number and allocated study group will be generated. A second electronic system will involve an abbreviated database of study participants for access by clinicians, again with each patient only identified by their record number. This second database is used to identify existing enrolees and provide a back-up to the primary database. The master database will be used to complete the analysis and contains only de-identified data ensuring that those completing the analysis remain blinded to study group membership.
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
		Not applicable. The current study does not occasion circumstances that require unblinding.
Methods: Data collection, management, and analysis		
Data collection methods	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
		Baseline socio-demographic and other clinical data will be obtained from routinely collected hospital admissions data (no additional study questionnaires or laboratory tests will be employed). Outcome data will be collected via data linkage, by individually linking participants with the study cohort with all subsequent hospital admissions over the study period (at 12, 24 and 36 months). This will identify those participants who were, or were not, re-admitted due to DSH over the follow-up period. Data linkage will be conducted by the NSW Centre for Health Record Linkage (CHeReL), to ensure that all participants, including those who re-present in other hospital catchments or Local Health Districts, are enumerated.

	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
		All participants will be retained in the study, as participant enumeration and allocation will occur using routinely collected hospital admissions data, and DSH outcome information will be obtained via periodic linkage of the study cohort with all subsequent hospital admissions data.
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
		Data will be obtained from routinely collected hospital admissions databases, as such will be entered by hospital staff. However, data quality, including range and consistency checks and assessment of missing data items will be conducted by the Study Coordinator under the direction of the Chief Investigator and Data Monitoring Committee (DMC). Data sources will be retained within the hospital sites on password secured computer networks, and will be accessed according to Local Health District data access and management protocols.
Statistical methods	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

		Characteristics of participants will be compared between intervention groups using the t-test or a non-parametric equivalent for continuous variables and the $\chi 2$ or Fisher's exact for categorical variables. The primary analysis will involve comparing the number of participant re-presentations, or deaths, related to DSH in each group in the12 months following recruitment. The number of re-admissions per patient (within 12 months following recruitment) in the intervention and control group will be compared using negative binomial regression, and differences between median time to first repetition between intervention and control group will be compared using survival analysis. Based on the Postcards from the EDge study the negative binomial is the most likely distribution for the number of DSH episodes per individual. If any baseline characteristics known to be associated with DSH readmission differ between the two intervention groups, these variables will be included in a secondary analysis which involves including imbalanced variables and other important covariates in a logistic (for any DSH readmission) or negative binomial (for the number of DSH readmissions) regression model. All analyses will be intention to treat, with all patients being analysed according to their intervention group.
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
		Secondary analyses will repeat the models above, restricted to females, given that stronger effects have previously been reported using a similar brief intervention method and stratified by first and subsequent DSH presentation.
	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)
		Loss-to follow-up in this study will be minimal, as all incident DSH events will be enumerated through routinely collected hospital admissions data, based on individual data linkage by the Centre for Health Record linkage (ensuring enumeration of any DSH events that may occur outside the immediate geographic catchments of the three hospital sites). The intervention relates to receipt of an SMS message to consenting participants' mobile phones, as such non-adherence to the intervention is not an issue. If data items are missing or incomplete in participant hospital admissions data, the pattern of missingness will be examined and multiple imputation methods will be employed to assess the potential impact of any selection bias due to missingness.
Methods: Monitoring		

Data monitoring	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
		The DMC will comprise the Project Co-ordinator, Project Officers at each hospital site, Prof. Alison Jones, and Prof. Andrew Page. The DMC will be independent from the study sponsor (Chief Health Officer, NSW Health) and competing interests. The DMC will oversee the process of data extraction, allocation and facilitation of individual linkage of baseline data with follow-up data in liaison with CHeReL. Periods of follow-up will occur at 12, 24, and 36 months.
	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
		Interim analyses will be conducted following periodic linkage of baseline data with follow-up data (at 12, 24, and 36 months). These results will be collated by the DMC and reported to the Project Steering Committee. It is not anticipated that the SMS follow-up intervention will result in adverse events. However, should interim results identify adverse effects of the intervention, the decision to terminate the trial will be made by the Project Steering Committee.
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
		All solicited and spontaneously reported adverse events or other unintended effects associated with the SMS intervention will be monitored by the Study Coordinator in liaison with hospital site Project Officers and clinical staff. Reports of adverse event and unintended effects will be reported to the Project Steering Committee.
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
		Quarterly Project Steering Committee meetings will be conducted. Trial conduct reports from each hospital site will be reviewed at these meetings. Trial conduct reports will provide information on process outcome measures including participant recruitment and preliminary data analyses, SMS texting activity and discussion of technical issues or unintended consequences of project implementation, and assessment of solicited or spontaneously reported adverse events.

Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
		This study protocol forms part of a current submission to the Western Sydney Local Health District (WSLHD) Human Research Ethics Committee.
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)
		Any protocol modifications will be conducted in consultation with the study RECs, and communication of any modifications to relevant parties will be made in accordance with the recommendations and advice of the study RECs.
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
		Informed consent will be obtained by the attending clinician at the time of the hospital admission.
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
		Patients enrolled to the study will also be invited to participate in either a telephone or face-to-face audio-recorded interview of approximately one hour duration. The interview questions will focus on SMS text messaging as a supportive mechanism in reducing self-harm, from patients' perspectives. The qualitative data will be transcribed verbatim and analysed descriptively and thematically. Socio-demographic data will also be collected and analysed descriptively for first and subsequent presentation, gender and age.
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

		As noted above, participant information will be obtained via routinely collected hospital admission records. Personal information will be stored in a "master list" database, stored on the corresponding hospital site in a password protected computer network. This database will only be accessible to project staff, including the Study Coordinator, Project Officers, and study investigators. Identifying information will also be provided to CHeReL to conduct the data linkage, which will be conducted via the Secured Unified Research Environment (SURE) system. This is the statewide secure data curation system that CHeReL uses to conduct third-party linkages with routinely collected data sources held under the NSW Master Linkage Key (including hospital admissions data and mortality data). Interim and final de-identified datasets, combining baseline and follow-up information will be held on at hospital sites on password protected computer networks and will be accessible by the Study Coordinator, Project Officers, and study investigators.
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
		Not applicable.
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
		Project staff, including the Study Coordinator, Project Officers, and study investigators will have access to the final de-identified dataset. There are no contractual agreements relating to data access.
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
		Not applicable.
Dissemination policy	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
		Study results will be disseminated via peer-review publications, conferences, and through consumer and professional stakeholder networks.
	31b	Authorship eligibility guidelines and any intended use of professional writers
		There are no plans to use professional writers. Authorship eligibility will be according to the peer-reviewed journal selected for dissemination.

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
		There are no plans for granting public access to the full protocol, participant level dataset, or statistical code.
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
		The Master Patient Information and Consent Form (for a multi-centre study) is included among documents that form the current submission to the Western Sydney Local Health District (WSLHD) Human Research Ethics Committee.
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
		Not applicable.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Figure 1 The RCT design for this study