The BEACON Study: Protocol for a cluster randomized controlled trial of a service to deliver smartphone-assisted problem-solving therapy compared to usual care in men who present with intentional self-harm to Emergency Departments in Ontario

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Study protocol

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Abstract

Background

Patients who present to Emergency Departments (ED) after intentional self-harm receive variable levels of care in Ontario. Many are not assessed by a mental health professional following discharge from ED and do not receive psychological services available in the community as many of these services are not covered by the provincial health insurance. Patients who present with intentional self-harm to hospital are more likely to die by suicide and premature death by other means compared to the general population. This risk is elevated in men, who represent two-thirds of those who die by suicide in Ontario. One way of potentially addressing this gap is to offer problem-solving therapy (PST) designed specifically for men, facilitated by the use of a patient facing smartphone application and a clinician facing dashboard. This attempts to blend the use of face to face therapy and technology to create an effective intervention after self-harm.

Methods

This is a pragmatic, multicentre pre- and post-design cluster randomized controlled trial (cRCT) comparing the provision of a suicide prevention intervention to usual care, in men who present to the ED with self-harm. The study intervention is composed of: 1) staff education; 2) resource materials for men who present to the ED with self-harm; and, 3) the option to refer patients to a blended PST service for the treatment of self-harm. The primary outcome to be assessed is a composite of the incidence of suicides and/or re-presentations to any ED in Ontario for self-harm in the year after presentation with self-harm. Secondary outcome measures include: total number of suicides; re-presentations to any ED in Ontario for the repetition of self-harm; re-presentations to any ED in Ontario for any reason; other health system use including use of primary care and hospital outpatient appointments; mortality not related to suicide; and, health system costs over one year. All outcomes will be measured from provincial health administrative databases available at the Institute for Clinical and Evaluative Sciences (IC/ES).

Introduction

Background and rationale {6a}

This paper describes the study protocol for a cluster randomized controlled trial (cRCT) to test the effectiveness of a new service which delivers blended problem-solving therapy (PST) compared to usual care (UC) in men 18 years or older who present to the Emergency Department (ED) with intentional self-harm. All outcomes in this cRCT will be obtained from provincial administrative health databases, with the primary outcome being a composite measure of the proportion of men who die by suicide and/or re-presenting to ED with self-harm within a year of their index presentation, defined throughout this protocol as a patient's initial presentation which renders them eligible to participate in the study. In a separate linked publication, we have described a cohort study protocol to evaluate the impact of the PST intervention on suicidality and other mental health outcomes.

Rates of Self-Harm Among Men

Self-harm has a strong association with suicide: 1.6% of people presenting to ED with self-harm will die by suicide within one year (95% confidence interval 1.2 to 2.1%), with the incidence rate being almost double in men compared to women (2.7% vs 1.2%) (1). After five years, approximately 3.9% of individuals who have presented to the ED for the treatment of self-harm die by suicide (1). This risk is more than 50 times greater than the general population rate and is associated with a 40-year reduction in average life expectancy (1). A recent retrospective study of individuals who died by suicide in Southwestern Ontario identified a history of self-harm in over a third of decedents (2). As presentation to the ED with self-harm is a major identifiable risk factor for suicide (3,4), it is likely that any reduction in the repetition of self-harm will be mirrored by a decline in subsequent deaths by suicide. The Canadian Association for Suicide Prevention (CASP) Blueprint for a Canadian National Suicide Prevention Strategy has also identified people who have attended hospital because of non-fatal self-harm as a high-risk group to target in order to prevent suicide (5).

Mortality from non-suicidal causes is also high for those who self-harm, with significantly more than the expected numbers of deaths from natural causes and from accidents (6). A population-based cohort study investigating administrative datasets in the province of Ontario found all-cause mortality following a first episode of self-poisoning was 1,107 per 100,000 person-years, a rate 5.5 times that of the control population. Nearly half of all deaths in this study were attributed to suicides (23.4%), accidents (16.4%) or undetermined intent (5.4%) (7). Approximately 10% of those who present in an ED following self-harm will engage in repeat self-harm in the following month and up to 27% after six months (8). Recurrent self-harm is associated with significant distress and many unresolved interpersonal problems (9).

Individuals who self-harm are also frequent users of health and social services (10,11). For instance, Morrison & Laing (2011) reviewed death records of Alberta patients aged 25 to 64 who died by suicide to develop health care use profiles of those who died by suicide compared to those who died from other causes. They found that those who died by suicide averaged more than twice the number of health service visits per person when compared to those who died by other causes (12). Similarly, those who died by suicide were more likely to have had an ED visit, inpatient hospitalization separation or community mental health service than those who did not die by suicide (12).

Psychological Treatments for Self-Harm

The updated 2016 Cochrane review on interventions following self-harm identified 55 trials involving almost 18,000 participants with 18 trials investigating cognitive behaviour therapy (CBT) (13). In that review, CBT included problem-solving therapy (PST), a variant of cognitive therapy focused on current difficulties which aims to teach participants problem-solving skills that can be applied across contexts and situations. The authors found there was a significant treatment effect for CBT compared to usual treatment at final follow-up, with fewer CBT participants repeating self-harm (odds ratio (OR): 0.70, 95%

CI: 0.55 to 0.88; number of studies (k) = 17; N = 2,665; GRADE: low quality evidence). The authors concluded that CBT, including PST, requires further investigation to clarify which patients benefit from these types of interventions. They further noted the need for more information about the role of sex differences in the efficacy of psychosocial interventions. In addition, there is now an opportunity to support the delivery of face to face therapy with sophisticated technologies – so called “blended therapies”.

Objectives {7}

This study’s research objectives, primary and secondary research questions, and associated hypotheses are outlined in Tables 1 and 2.

Table 1
Primary Objective, Research Question and Hypothesis

Objective	Research Question	Testable Hypothesis
To evaluate the impact of a smartphone-assisted PST service for men on suicide/self-harm re-presentation rates compared to usual care.	In men who present to ED with intentional self-harm does the provision of a service that delivers smartphone-assisted PST specifically designed for men compared to usual care result in fewer suicides and/or re-presentations for self-harm, in the following year?	12 months following site initiation, intervention sites will have a lower proportion of suicide and self-harm representations when compared to control sites.
^a The primary outcome measure is a composite measure of suicides and/or self-harm re-presentations.		

Table 2
Secondary objectives, research questions and hypotheses

Objective	Research Question	Testable Hypothesis
To evaluate the impact of a smartphone-assisted PST service for men on healthcare use.	In men who present to ED with intentional self-harm does the provision of a service that delivers smartphone-assisted PST specifically designed for men compared to usual care result, after one year, in fewer:	Reduction in healthcare contacts: 12 months following site initiation, intervention sites will have a lower proportion of healthcare contacts when compared to control sites.
	...suicides?	
	...self-harm ED representations?	
	...re-presentations to the ED for reasons other than self-harm?	
	...admissions to hospital for any reason?	
	...hospital outpatient appointments for any reason?	
	...deaths for reasons other than suicide?	
To evaluate the impact of a smartphone-assisted PST service for men on costs to the healthcare system.	...primary care visits ^a ?	
	In men who present to ED with intentional self-harm does the provision of a service that delivers smartphone-assisted PST specifically designed for men compared to usual care result, after one year, in fewer:	Reduction in healthcare costs: 12 months following site initiation, intervention sites will incur fewer costs to the healthcare system when compared to control sites.
	...physician-related costs?	
	...hospitalization-related costs?	
	...ED-related costs?	
	...other healthcare system costs?	
^a Defined by contact with a family physician.		

Trial Design {8}

This is a pragmatic, multicentre pre- and post-design cRCT comparing the offer of a service that delivers smartphone-assisted PST to usual care, in men who present to the ED with self-harm. We have chosen a cluster randomized design because we are testing the introduction of a service for suicidal men that addresses both the need to manage the transition from the ED to outpatient care and the provision of care specifically designed for men who have intentionally self-harmed. We have also included a nested

cohort study of outcomes in men who receive the blended therapy (to be published as a separate protocol). By randomizing entire sites with a waiver of informed consent for data collection with inclusion of all eligible men using routinely collected data, external validity of the study is maximized, in comparison to an individually randomized trial with a requirement to seek informed consent.

Methods: Participants, Interventions And Outcomes

Study setting {9}

This study protocol describes a multicenter cRCT will be conducted in 25 sites in Ontario, Canada. Once site allocation is completed, the Principal Investigator (PI) [SH] will contact members of the Department of Psychiatry and Department of Emergency Medicine at each intervention site to be site co-Investigators, to assume responsibility for all study-related activities at their respective site. The PI will then travel to each study site in order to present information about the study in a rounds-style presentation and meet with key stakeholders who will be responsible for the implementation of the study.

Eligibility criteria {10}

Site eligibility was determined using Ontario administrative health data collected from IC/ES. Sites were deemed eligible if they averaged at least 50 self-harm presentations by men per year and had a mean absolute re-presentation of at least six men per year over three years. This resulted in a list of 25 eligible EDs in Ontario. Individual men at each site will be identified using IC/ES data. Eligibility criteria are outlined in Table 3.

Table 3
Participant Eligibility Criteria

Inclusion Criteria
1. Patient has presented with an index episode of intentional self-harm at an eligible ED in Ontario, Canada.
2. Patient is identified as male in health records
3. Patient is 18 years of age or older.
4. Patient has a valid OHIP number.
Exclusion Criteria
1. Patient has presented to the ED for a reason other than intentional self-harm at an eligible ED in Ontario, Canada.
2. Patient is biologically female
3. Patient is under 18 years of age.
4. Patient does not have a valid OHIP number.
^a Intentional self-harm is defined as intentional self-poisoning or self-injury, whether or not there is evidence that the act was intended to result in death. This will be identified using ICD-10-CM codes T14.91, X71-X83 ICD-10 codes from health administrative databases held at IC/ES.
^b Index episode is defined as the episode of intentional self-harm that occurred immediately prior to and triggering enrolment in the trial.

Who will take informed consent? {26a}

We will not ask patients presented to Emergency Departments for their consent to take part in the study as the outcome data that we are collecting are already routinely collected by ICES.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not Applicable.

Interventions

Explanation for the choice of comparators {6b}

An alternative to developing new interventions is to optimize standard clinical care. This usually consists of referral for psychiatric or psychological treatment as well as other health or non-health services.

However, neither a systematic review nor a large multicentre study found a clear relationship between the

nature and intensity of standard hospital care and subsequent fatal or non-fatal repetition of self-harm (13). Specialist services offer intensive and lengthy treatment, such as dialectical behaviour therapy or mindfulness-based therapy for the minority of people who self-harm who are diagnosed with personality disorders. The evidence for the effectiveness of these therapies comes almost entirely from studies in women (14).

Intervention description {11a}

Intervention: Problem-Solving Therapy Service

EDs randomized to receive the study intervention will receive: 1) staff education, 2) resource materials, and, 3) the option of referral to the blended PST therapy.

Staff Training

Staff education will be incorporated into regular teaching rounds at intervention sites at least twice a year about the management of self-harm in the ED. This will include the dissemination of guidelines such as those produced by the American Psychiatric Association (APA), NICE (<https://www.nice.org.uk/guidance/cg133>; <https://www.nice.org.uk/guidance/cg16>), Suicide Prevention Resource Centre (SPRC) and the Canadian Coalition for Seniors' Mental Health (CCSMH) on how to ask questions about suicide, assessment of suicide risk, the creation of a management plan and how to refer patients to local mental health resources, including the study.

Resource Materials

Written materials will be developed by service users to be given to men who self-harm that outline local resources, distress centre helplines and follow-up arrangements. The materials will be available in French and English and we will be discussing with Aboriginal partners translation of some materials into Ojibwe or Oji Cree.

Referral to the blended PST service

Men who present with intentional self-harm to an ED in the intervention arm will be offered, in addition to usual care, six sessions of PST with a “booster” session at six months supplemented by the BEACON Rx platform. The therapy may be delivered “in house” by hospital services or by external providers depending on the site.

Comparator: Usual Care (UC)

EDs randomized to the control group will continue to provide treatment using usual clinical pathways. This typically constitutes assessment of clinical risk, the need for medical intervention to treat the effects of self-harm, and for inpatient or outpatient mental healthcare. All men who present to the ED with intentional self-harm will have access to the full range of mental health and other services that are usually available to individuals in the different regions. This includes inpatient admission and other crisis services.

Criteria for discontinuing or modifying allocated interventions {11b}

Not Applicable.

Strategies to improve adherence to interventions {11c}

Not Applicable.

Relevant concomitant care permitted or prohibited during the trial {11d}

Not Applicable.

Provisions for post-trial care {30}

As participants will not be enrolled in this study, in the event of injury or illness, all patients will receive usual care through the hospital or service provider of their choice.

Outcomes {12}

Primary Outcome

The primary outcome measure will be a composite of the incidence of suicides and/or re-presentations to any ED in Ontario for self-harm in the year after the index episode of self-harm. The incidence of suicide and re-representation to ED will be measured using ICD-10-CM codes T360-T50992, T510-T6592, T71112-T71232, X71-X83 (refer to Additional File 2 for full list of codes and descriptors) (18). Individuals who died by suicide will be identified in IC/ES using the Vital Statistics - Death Database. A potential problem with the outcome measures in this trial is that the intervention may also change help-seeking behaviour. That is, men may seek out healthcare that they would not have in the past, which may lead to an increase

in re-presentations to the ED for patients in the intervention group. In order to explore changes to health-related help-seeking, we will also collect data on primary care and hospital outpatient care not driven by emergencies through IC/ES. This will be measured in IC/ES, using the Ontario Health Insurance Plan (OHIP) Claims Database and National Ambulatory Care Reporting System Metadata (NACRS). We will also address this through the cohort study of men who receive the smartphone-assisted PST in the intervention sites (described in a separate publication).

Secondary Outcomes

The secondary outcome measures will include total number of suicides; re-presentations to any ED in Ontario for the repetition of self-harm; re-presentations to any ED in Ontario for any reason; other health system use including use of primary care and hospital outpatient appointments; mortality not related to suicide; and, health system costs within one year which will inform an economic analysis (Table 5). All outcomes will be identified and measured using routinely collected data housed at IC/ES. Men who present with intentional self-harm in the study ED will be identified from IC/ES administrative health data.

Participant timeline {13}

Table 4
Schedule of Enrolment, Interventions, and Assessments

	STUDY PERIOD		
	Allocation	Post-allocation	
TIMEPOINT	0	Baseline (t ₁)	12 Months (t ₂)
Site Allocation	X		
INTERVENTIONS:			
PST Service (Intervention)		X	X
Usual Care (Control)		X	X
ASSESSMENTS:			
Death by Suicide and/or Re-Presentation for Self-Harm		X	X
Total Deaths by Suicide		X	X
Total Re-Presentations to ED for Self-Harm		X	X
Total Re-Presentations to ED for any reason		X	X
Total Primary Care Visits		X	X
Total Hospital Outpatient Visits		X	X
Total Deaths not Related to Suicide		X	X
Health System Costs		X	X

Sample size {14}

Power calculations for this trial were carried out within the logistical and practical constraints of the trial; in particular, a maximum of 25 sites are available for randomization, whereas the intervention can be implemented at only 10 sites due to funding restrictions. Consistent with previous clinical trials, we would consider a minimum relative reduction of 50% in the repetition rate to be both clinically important and achievable (15–17). To conduct an accurate power calculation, we obtained data from IC/ES regarding the number of presentations with self-harm by men and the re-presentation rate to every hospital in Ontario from 2012 to 2014. Using these data, we calculated an anticipated baseline repetition rate (primary outcome) after 12 months of 13%. We also calculated an intracluster correlation coefficient (ICC) of 0.01 and an inter-period correlation of 0.008 (to account for over time correlations between pre- and post-intervention measures of the primary outcome). Given an average cluster size of 80 men and a coefficient of variation of cluster sizes (to account for imbalances in sizes) of 30%, 10 intervention clusters and 15 control clusters (2000 men) achieve 90% power to detect the minimum clinically

important difference. With 80% power, the detectable difference is a relative reduction of 41%, i.e., from a control arm rate of 13% to an intervention arm rate of 7.7% (an absolute reduction of 5.3%).

Recruitment {15}

Given that this cRCT relies on administrative health data collected from the Institute for Clinical Evaluative Sciences (IC/ES), individual consent requirements have been waived by the Ottawa Health Science Network Research Ethics Board (OHSN-REB). As such, no individual participant recruitment will take place for this study.

Assignment Of Interventions: Allocation

Sequence generation {16a}

To minimize the risk of imbalances between the study arms, allocation to the intervention or control arm was implemented using covariate constrained allocation (14). Allocation was constrained based on: i) geographic areas, defined by whether the catchment area was predominantly urban or rural; ii) whether there was an onsite psychiatric service which assesses people in the ED; iii) size, defined by the average number of presentations for self-harm for both men and women over a 3 year period; and iv) re-presentation rate among men with intentional self-harm 12 months after the index episode. There was a total of over 3 million possible allocations of 10 intervention and 15 control sites, of which 7,131 of 100,000 randomly selected allocations met the pre-specified balancing constraints, namely a maximum difference of 3 between number of urban/rural sites, a maximum difference of 3 in number of sites with onsite psychiatric service, a maximum difference in mean cluster size of 60, and a maximum difference in baseline re-presentation rate of 3%. Among the 7,131 possible acceptable allocations, one allocation was selected at random using a computer-generated random number.

Concealment mechanism {16b}

Sites allocated to the control condition were not informed of their inclusion in the study as there were concerns regarding changes in institutional behaviour at the control sites as a result of knowing about the study

Implementation {16c}

Site randomization was completed by one of the study contributors (MJ) with expertise in the design, analysis, and reporting of cRCTs.

Assignment Of Interventions: Blinding

Who will be blinded {17a}

Once randomization was complete, study sites allocated to the intervention arm were approached regarding their interest to participate in the study. Gatekeepers were not approached prior to randomization as the investigative team determined that informing 25 sites and getting their agreement

prior to randomization would result in significant delays to the study and that it was unlikely that hospitals would decline to participate in this study. Additionally, there were concerns regarding changes in institutional behaviour at the control sites as a result of knowing about the study. Should any intervention sites refuse to participate in the trial, they will be included in the final analyses as part of the intervention arm in order to respect the intent-to-treat (ITT) principle. Control sites will be unaware of their participation in the study as men who present with self-harm will be receiving their usual care and all outcome measures are routinely collected by IC/ES.

Procedure for unblinding if needed {17b}

Not applicable.

Data Collection And Management

Plans for assessment and collection of outcomes {18a}

Trial outcomes comprise routinely collected data which are housed at IC/ES. Access to all outcome data has been agreed upon with IC/ES. The study team has developed a case report form (CRF) (Additional File 3) for IC/ES data collection which will be completed at the University of Ottawa IC/ES satellite site.

Plans to promote participant retention and complete follow-up {18b}

Emergency Departments

Once randomization of the study sites is completed, the Principal Investigator will contact members of the Department of Psychiatry and Department of Emergency Medicine at each intervention site to be site co-Investigators, to assume responsibility for all study-related activities at their respective site. They will act as study “champions” and, in conjunction with Research Assistants, will provide study support to Emergency Department staff members.

Each study site will also receive training, as described in Section 4.1.3 Interventions, in the identification and management of self-harm as well as access to an electronic booking system for study referrals and Research Assistant(s) to coordinate all study-related activities.

Participants

This study will focus on the evaluation of a complex intervention based on routinely collected population-level health data. Given this, there will be no individual participant recruitment for this study. All data collected through ICES will thus be included in the primary analysis irrespective of uptake of the smartphone-assisted PST.

Data management {19}

The study team will only receive aggregated data from IC/ES as it is their institutional policy that no individual data is to leave their facilities. All other electronic and hardcopies of the study data will be stored at the coordinating study site in areas with limited access. All electronic data will be stored on a secured server at The Ottawa Hospital (TOH) (Ottawa, Canada). Once all data monitoring, validation and cleaning activities are complete, these records will be archived at a secure storage facility for a period of ten years, as required by ICH GCP guidelines.

Confidentiality {27}

All study-related cohorts will be created by Data Analytic Services at ICES Central. These cohorts will be transmitted to The Ottawa Hospital Civic Campus, a satellite ICES location, for analyses by statisticians affiliated with the Ottawa Methods Centre at The Ottawa Hospital. All data provided by ICES are de-identified, anonymized routinely collected data. All study-related documentation will be double-locked in areas with limited access at the appropriate study site. All documentation, including Case Report Forms will be stored in double-locked filing cabinets in areas with limited access. All study records will be kept for a period of ten years, as indicated in the ICH GCP guidelines, or more depending on local regulations.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not Applicable.

Statistical Methods

Statistical methods for primary and secondary outcomes {20a}

The unit of analysis will be the individual patient. To evaluate the effectiveness of the complex intervention at population-level (primary trial analysis), all outcomes will be obtained from IC/ES, regardless of whether men received or participated in the study therapy. Dichotomous primary and secondary outcomes will be described, by arm, using frequencies and percentages. The primary composite outcome as well as its individual components (death by suicide and re-presentations within 1 year) will be compared between the intervention and control sites using generalized linear mixed effects regression, accounting for the pre-and post-intervention measures using repeated cross-sectional analysis (21). Differences between the arms will be expressed as absolute and relative differences in proportions, together with 95% confidence intervals. Models will account for clustering at the ED-level and over time

using random effects. Cluster level covariates for factors used in the allocation procedure, namely urban/rural geography, onsite psychiatric service, and size will be included in regression models. Additional analyses will adjust for individual prognostic variables including age, ethnicity, pre-specified comorbidities (such as previous hospitalizations for substance use), and repeat as compared with first-time presentations for self-harm.

All binary secondary outcomes (representation to the ED for any reason, admission to hospital for any reason, and mortality for any reason) will be analyzed as described for the primary outcome. Length of hospital stay for any reason, number of hospital outpatient appointments, number of primary care appointments and cost data will be analyzed as described for the primary outcome, that is, using generalized linear mixed effects regression, but with either the Poisson or negative binomial distribution and using the log link function. Differences between the arms will be expressed as rate ratios together with 95% confidence intervals.

Interim analyses {21b}

Not applicable.

Methods for additional analyses (e.g. subgroup analyses) {20b}

Additional subgroup analyses will be carried out for the following subgroups: first time presentations of self-harm compared to repeat presentations; Francophone versus Anglophone; men with substance abuse disorders versus no substance abuse disorder; and rural versus urban residence.

Health Economic Evaluation

We will conduct a cost-utility analysis from health system's perspective to assess the value for money of the smartphone-assisted PST compared to usual care. A decision analytic model will be used to synthesize data on resource use, clinical outcomes, and health utility values obtained from the trial and the published literature. Costs associated with the intervention will be summarized over the one-year period. Total costs of the intervention will include the cost of smartphone-assisted PST development, training, data plan, supplies/materials and costs associated with the health care use over the one-year period. We will use a micro-costing technique by identifying, measuring, and valuing resources used (22). Health care resource use will be obtained from the health administrative databases housed at IC/ES which contain information on physician visits including primary care and specialists, inpatient hospital admissions, including mental health institutions, emergency and ambulatory care visits, home care and rehabilitation claims, use of laboratory services, and prescription drug claims for those with high drug costs compared to their income. The health utility values associated with self-harm and smartphone-

assisted PST will be derived from the current study. A one-year time horizon will be adopted in a base case analysis, and a lifetime horizon will be used in a scenario analysis. As a secondary analysis, we will take the societal perspective and include productivity loss in a cost calculation. The loss of productivity data will be gathered from the published literature.

An incremental cost per one additional quality-adjusted life year (QALY) gained will be estimated. Uncertainty in the analysis will be assessed using one-way and probabilistic sensitivity analyses. The cost-utility analysis will adhere to the best practices for conducting and reporting of health economic evaluations (23,24). Both costs and health outcomes will be discounted using an annual rate of 1.5% as recommended by the Canadian Agency for Drugs and Technologies in Health (23). The analysis will be performed by a health economist at the Ottawa Methods Centre and will be overseen by a health economist (KT).

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Not Applicable as all data will be obtained through administrative health data collected from the Institute for Clinical Evaluative Sciences (IC/ES).

Plans to give access to the full protocol, participant level-data and statistical code {31c}

Anonymized research data will be deposited in an online repository, hosted by the Open Science Framework (OSF) (refer to: <https://osf.io/>). The Open Science Framework (OSF) is a tool that promotes open, centralized workflows by enabling capture of different aspects and products of the research lifecycle, including developing a research idea, designing a study, storing and analyzing collected data, and writing and publishing reports or papers. It is developed and maintained by the Center for Open Science (COS), a nonprofit organization founded in 2013 that conducts research into scientific practice, builds and supports scientific research communities, and develops research tools and infrastructure to enable managing and archiving research

Oversight And Monitoring

Composition of the coordinating centre and trial steering committee {5d}

Principal Investigator (SH) and co-Principal Investigator (SH):

- Design and conduct of the BEACON Study;

- Preparation of protocol and revisions;
- Preparation of study documentation;
- Organization of Steering Committee meetings;
- Publication of study reports; and
- Participation as members of Trial Management Committee (TMC).

Steering Committee

- Includes: Principal Investigator (SH), Co-Principal Investigator (MH), and Site Principal Investigators.
- Approval of the final protocol;
- All co-Investigators at each intervention site will be steering committee members;
- Recruitment of patients and liaising with Principal Investigator and co-Principal Investigator; and
- Reviewing progress of study and, if necessary, approval of changes to the protocol and/ to facilitate the smooth running of the study.

Trial Management Committee (TMC)

- Includes: Principal Investigator (SH), co-Principal Investigator (MH), and Clinical Research Associates (NE, SM).
- Study planning;
- Organization of Steering Committee meetings;
- Organization of Data and Safety Monitoring Committee (DSMC) meetings;
- Provide annual reporting to Research Ethics Board (REB);
- Serious Adverse Event (SAE) reporting to DSMC and REB;
- Responsible for Master Tracking Log;
- Budget administration and contractual issues with individual centres;
- Advice for lead investigators;
- Coordination of study monitoring;
- Assistance with REB applications;
- Data verification; and
- Randomization.

Composition of the data monitoring committee, its role and reporting structure {21a}

The Data and Safety Monitoring Committee (DSMC) is comprised of four members from the following fields of expertise: statistics/biostatistics, epidemiology, methodology, psychiatry and the ethics of clinical trials.

Responsibilities:

- Ensures the ongoing safety of study participants;
- Reviews the conduct of the study, including protocol violations and deviations;
- Reviews data on participant recruitment, accrual, and retention, as well as assessments of data quality, completeness, timeliness, data retention, data storage, data transmission and data access;
- Reviews Adverse Events (AEs) and Serious Adverse Events (SAEs) reported between meeting dates;
- Protects the confidentiality of the study data and the DSMC discussions; and
- Makes recommendations to continue, modify, or terminate the study.

Adverse event reporting and harms {22}

The anticipated harms in this study are minimal and do not exceed the risks associated with usual care. In this clinical trial, given that all outcome data are routinely collected population-level data through ICES and no participants will be enrolled in the study, Adverse Events (AEs) will not be collected and assessed. However, all AEs and Serious Adverse Events (SAEs) will be collected, monitored and reported as appropriate for all related sub-studies as this will involve the enrollment and follow-up of participants.

Frequency and plans for auditing trial conduct {23}

Not Applicable as this is a data linkage study, it does not include any trial conduct.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any subsequent modifications to the study protocol, including changes to study objectives, study design, patient population, sample sizes, study procedures, or significant administrative changes will be agreed upon by the Steering Committee and submitted to the REB for review and approval prior to implementation.

Dissemination plans {31 a}

Data Analysis and Release of Results

To protect the scientific integrity of this study, data from all clusters will be analyzed and reported together. Although sub-analyses with specific groups will be conducted, no centre is expected to report data collected from their centre alone. The primary data analysis will be conducted by the Ottawa Methods Centre (OMC) at OHRI in conjunction with IC/ES. All statisticians will be blind to the allocation of the study sites. All study publications and presentations are expected to adhere to the BEACON Study objectives as detailed in this protocol.

Review Process

A Publications Committee, a subcommittee of the Steering Committee, will be established to coordinate all study publications and presentations. All presentation and publication abstracts must be submitted for review by the Publications Committee. This committee will create a running list of all potential publications, review all abstracts submitted for publication by the Investigative Team, identify a lead author for each publication, review all publication manuscripts, and submit publications to peer-reviewed journals for publication. They will also ensure that all publication guidelines and regulations are respected, including adherence to the study's objectives and the CONSORT statement for cluster RCTs.

Each presentation or publication abstract/manuscript must be submitted to the Research Coordinator prior to each Publications Committee Meeting. The abstracts will be reviewed at the subsequent Publications Committee meeting. All members will vote on each abstract and will provide feedback. The Research Coordinator will include all feedback in the meeting minutes and, after each meeting, will circulate all feedback appropriately. Authors will be expected to review the committee's feedback and re-submit their final abstract or manuscript for final approval by the Publications Committee.

Primary Outcome Publications

The Publications Committee will ensure that no presentation or publication undermines the dissemination of any primary outcome publications. Primary outcome publications refer to any presentation or publication that presents data on the primary outcomes as detailed in this protocol. During the review process, the Publications Committee will determine if an abstract/manuscript will undermine any primary outcome publications. If it is determined that this is the case, the author will be asked to delay publication until such a time as the primary outcome publication is released.

Other Study Papers, Abstracts and Presentations

This refers to all presentations and publications that do not report on the primary outcome of this trial, as detailed in this protocol. All presentation and publications abstracts/manuscripts must be reviewed and approved by the Publications Committee prior to submission.

Close-Out Procedures

The primary outcome publication is expected to be submitted for publication within two years of the completion of follow-up data collected (i.e. after the last study participant has completed the study). However, this may occur at an earlier or later date if the circumstances warrant. Study close-out will occur in two stages:

- Period of analysis and documentation of primary outcome results; and
- Debriefing of participants and dissemination of all other study results.

Reporting of Study Results

All study results will be released to study participants, referring clinicians, patients and the general medical community. Results will be communicated to study participants through the use of a newsletter or presentation, as per the overall preference of the participants. Other forms of dissemination include: academic publications, conference presentations and presentations to the general public.

SPIRIT guidance: 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.

Discussion

The majority of suicides in Canada are in men yet they are hard to engage in treatment. This trial uses a novel intervention that provides a service for suicidal men who present to hospital with intentional self-harm. The service delivers a treatment that combines face to face therapy with technology. The trial should help with understanding of the pathways to care, acceptability and effectiveness of using this intervention in the treatment of a group at high risk of suicide. It will also inform the practice of using technology in face to face treatment. An important operational issue has been maintaining engagement of the different sites given the lengthy regulatory approval process. There has been considerable staff turnover at most sites with frequent changes of leadership. This is the reality of doing cluster randomized trials in the health service outside academic institutions and has meant extra travel and attention to relationships.

Trial Status

This study received initial approval by the OHSN-REB in January, 2018 and site initiation is currently ongoing. It is anticipated that all sites will be initiated within the next three to six months. At the time of

manuscript submission, no participants had been enrolled in the study. The estimated completion date for primary data collection is March, 2021.

Abbreviations

APA: American Psychiatric Association

CASP: Canadian Association for Suicide Prevention

CBT: Cognitive Behavioural Therapy

CCSMH: Canadian Coalition for Seniors' Mental Health

CRF: Case Report Form

CI: Confidence Interval

CONSORT: Consolidated Standards of Reporting Trials

cRCT: Cluster Randomized Controlled Trial

ED: Emergency Department

GCP: Good Clinical Practice

GRADE: Grading of Recommendations, Assessment, Development and Evaluations

ICC: Intraclass correlation coefficient

ICD-10-CM: International Classification of Diseases, Tenth Revision, Clinical Modification IC/ES: Institute for Clinical and Evaluative Sciences

ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

ITT: Intent-to-Treat

NACRS: National Ambulatory Care Reporting System

NICE: National Institute for Health and Care Excellence

OHIP: Ontario Health Insurance Plan

OHSN-REB: Ottawa Health Science Network Research Ethics Board

OR: Odds Ratio

PI: Principal Investigator

PST: Problem-Solving Therapy

QALY: Quality-Adjusted Life Year

REB: Research Ethics Board

SPRC: Suicide Prevention Resource Centre

SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

TCPS-2: Tri-Council Policy Statement

TOH: The Ottawa Hospital

UC: Usual Care

Declarations

Acknowledgements

Not Applicable.

Authors' contributions {31b}

SH and MH conceived of the study and are the grant holders. MT provided expertise in the design of cluster RCT and conducted the randomization procedure. DC provided statistical expertise in designing the clinical trial and will be conducting the primary statistical analysis. KT designed a health economic evaluation and will supervise the health economic analysis. SM assisted with the preparation of this manuscript and was a major contributor in the writing of the study protocol. VT assisted with the drafting of the study protocol. All authors contributed to refinement of the study protocol and approved the final manuscript.

Funding {4}

The trial is sponsored by the Ottawa Hospital Research Institute (OHRI) and funded by the Ontario Strategy for Patient Orientated Research (SPOR) Support Unit (OSSU), funded through the Canadian Institutes of Health Research (CIHR) and the Government of Ontario. The funders had no role in the review or approval of the manuscript for publication.

Availability of data and materials {29}

Not Applicable.

Ethics approval and consent to participate {24}

This protocol has received Research Ethics Board (REB) approval from the OHSN-REB via Clinical Trials Ontario (CTO, Reference: CTO-790). The OHSN-REB granted a waiver of individual consent for this protocol under Chapter 2, Article 2.4 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. This applies to all study sites.

Consent for publication {32}

Not Applicable.

Competing interests {28}

The study Investigators have the following interests to declare:

1. SR is a co-Investigator with the Canadian Biomarker Integration Network in Depression (CAN-BIND), funded by the Ontario Brain Institute (OBI). She also received research grant funding from Pfizer Canada.

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