- Meaning in life; and
- Perceived social supports.

We also hypothesized that the study intervention (three sessions or more) will lead to amelioration of the following:

- Suicidality;
- Depression symptoms;
- Anxiety symptoms;
- PSTD symptoms; and
- Health care costs.

We expect that the treatment outcomes will be moderated by the following variables:

- Conformity to "masculine" gender norms;
- Exposure to suicide in the media;
- Use of the internet to research means of self-harm; and
- Use of the internet to access self-harm resources.

3.3. Study Design

This randomized controlled pilot trial will study the feasibility and potential effectiveness of a blended problem-solving therapy (BEACON) compared to face to face problem solving alone in men who present to Emergency Departments with intentional self-harm. Exposure to the study intervention will be dichotomized at three sessions (i.e. participants who complete 0-2 sessions versus those who complete 3 sessions or more).

All adult men (≥ 18 years of age) who present to one of the five intervention sites with intentional self-harm will be approached with information about the study. Patients who are interested in participating in the study will be scheduled for a Baseline Visit with a delegated study staff member who will obtain written informed consent and screen the patients for eligibility to participate in the study. We propose to manage the transition from the Emergency Department to outpatient care by providing staff training, written information for patients and an electronic referral service at each site.

Patients who are eligible and consent to participate in the study will be randomized to receive six sessions of face-to-face PST or six sessions of face-to-face PST supplemented by the BEACON Suicide Prevention smartphone application. PST sessions will be delivered by a trained Research Therapist. PST Sessions and other study visits may take place over videoconference, using a platform such as MS Teams, Zoom Health, or OTN..

4. METHODS

4.1. Participants, Interventions and Outcomes

4.1.1. Study Setting

This study will be conducted in five hospitals across Ontario: Kingston General Hospital; Unity Health - St. Michael's Hospital Toronto; Sunnybrook Hospital Toronto; Victoria and University Hospitals, London; and The Ottawa Hospital, Ottawa. Recruitment will occur through staff that see these patients clinically in the Emergency Department of

these hospitals.

4.1.2. Eligibility Criteria

Eligible participants will be men aged 18 years or older who present to Emergency Departments with intentional self-harm regardless of whether they are admitted to hospital or not. For the purpose of this study, "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.

Table 1. Participant Eligibility Criteria

Inclusion Criteria	
1.	Identifies as Male.
2.	18 years of age or older.
3.	Has presented via the Emergency Department with self-harm in the preceding 4 weeks;
4.	Able to read and understand English, French or read or understand Oji Cree.
5.	Willing to attend six problem-solving therapy sessions for a period of up to eight weeks.
6.	Willing to use a smartphone application to facilitate the treatment of self-harm.
7.	Willing to return to hospital for follow-up appointments.
8.	Willing and able to provide informed consent.
9.	Willing to use e-mail for study activities.
Exclusion Criteria	
1.	Identifies as female.
2.	Has presented to the Emergency Department for a reason other than self-harm.
3.	In the opinion of the investigator is unlikely to commit to a six-month study.

Participants are not required to have a smartphone with a data plan in order to participate. Participants who do not have a smartphone with a data plan will be provided with one pre-paid smartphone with voice and data services for a period of six months from the date of their study enrollment. Provision of a second phone in the event of loss or theft will be evaluated on a case by case basis.

4.1.3. Interventions

All individuals will receive usual care and six sessions of PST. Individuals randomized to the blended-therapy arm will be have six sessions of PST supplemented by the BEACON platform, developed in partnership with CHESS Health Inc. (http://www.chessmobilehealth.com). As of October 2019, CHESS Health Inc. is no longer involved with the BEACON app or the BEACON study in any way. The OHRI is responsible for all maintenance and operation of the app. The original version of this smartphone application was tested in an RCT in male Veterans in the USA [24] and found to be effective in reducing harmful substance use. It has been re-designed for the purpose of this study to facilitate the treatment of self-harm in men who present to the Emergency Department. This smartphone application contains eight integrated sections (refer to Figure 2):

We will consider these feasibility objectives to be successfully met if:

1) At least 20% of eligible men consent to take part in the study.
2) That at least 1 patient per week, on average, is randomised in each participating site
3) That 50 of the 100 participants complete at least 3 sessions of face to face PST
4) That 70 of the 100 participants complete questionnaire outcomes at 6 months

ii) Patient Use and Acceptability

We will assess patient use of the application using de-identified usage statistics including number of BEACON presses, number of red pins activated, and any periods of app inactivity (more than 7 days). We will also conduct qualitative interviews with participants to assess the use of the application and the acceptability of the blended therapy, as well as other treatments used by the participants.

iii). Inform future primary outcome measures and determine sample size for a definitive RCT

We will measure the severity of suicidal ideas at six months as measured by the Beck Scale for Suicide Ideation (BSS). This is a 24-item self-report questionnaire for detecting and measuring the current intensity of participant's attitudes, behaviors, and plans to die by suicide during the past week. It consists of five screening items, if the participant reports any active or passive desire to die by suicide, then an additional 19 items are administered. Participants are asked to rate each item (i.e. "Wish to live") on a scale from 0 (moderate to strong) to 2 (none). Responses are then scored according to the following three factors, with total scores ranging from 0 to 48 with higher scores indicating greater suicidality.

- Active Suicidal Desire (10 items);
- Passive suicide Desire (3 items);
- Preparation (3 items).

The BSS has strong psychometric properties, with strong internal consistency (α=0.89) and high inter-rater reliability [44, 45]. It has also been found to be significantly correlated with self-harm measures on the Beck Depression Inventory (BDI) [44] and has been found to be a strong predictor of admission to hospital for suicidality [46]. The BSS has been frequently used in sucidology research as a criterion measure of suicidality, which makes comparisons to other clinical trials and subgroups possible [47, 48].

We will use the change in responses as well as the qualitative interviews to determine whether the BSS to measure suicidality is an appropriate outcome measure for the definitive RCT. We will also use the change in responses on the BSS to inform sample size calculations for the large RCT.

Lastly, we will evaluate the responses of the secondary outcome measures, in combination with the qualitative interview responses, to determine which variables are critical to measure in the definitive RCT while minimizing participant burden.

iv) Adherence to the protocol

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 date 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.

5.8.2. Authorship

Authorship guidelines to be followed for this trial have been adapted from the OHRI Authorship Guidelines for Researchers and criteria recommended by the International Committee of Medical Journal Editors (ICMJE).

Qualification for Authorship

Whether or not investigators and/or research staff members are eligible for authorship credit will be determined using the following ICMJE criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Anyone who qualifies for authorship, based on the above, should be listed, including research staff, consultants, trainees and students. Those who do not meet all four of the above criteria should be acknowledged (refer to Acknowledgements"). These criteria are not intended to be used as a means of disqualifying study Investigators from authorship. Anyone

	• Presentation to hospital for self-harm (NACRS); • Presentations to hospital for any reason other than self-harm (NACRS); • Admission to hospital for any reason (OHIP); • Outpatient appointment for any reason (OHIP); • Primary care visits (OHIP).						
Estimated Total Completion Time (in Minutes)				**60-113**	**18-35**	**33-60**	**49-93**

6.2. Appendix B- List of Study Sites

- Kingston General Hospital, Kingston, ON;
- London Health Sciences Centre (Victoria Hospital Site), London, ON;
- Unity Health, St. Michael's Hospital, Toronto, ON;
- Sunnybrook Health Sciences Centre, Toronto, ON;
- The Ottawa Hospital, Ottawa, ON.

- Profile: Participants are asked to setup a user profile, which includes an image and their personal motivation/mantra as well as set up a safety plan to prevent future self-harm. This will be done in conjunction with their therapist at their initial PST session.

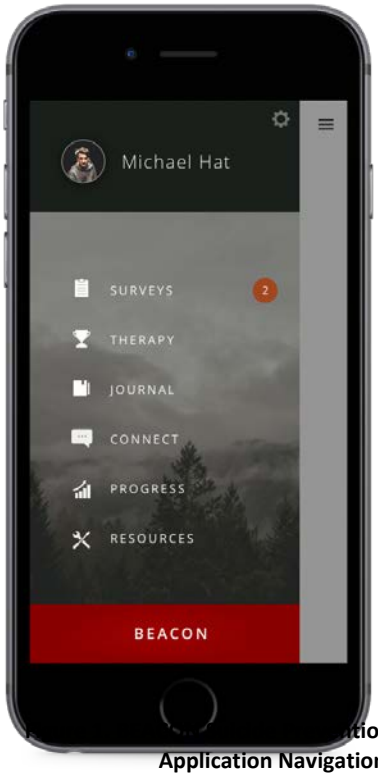
- Surveys: Participants will be prompted to provide an update on their mood.

- Therapy: This section will walk the user through the steps of problem solving and end with the creation of a smart goal. This section will allow not only the creation of new goals based on current problems, but also allow users to look at the goals they've created and update their progress on them. The creation of a goal will be a step by step process that follows the principles of PST.

- Journal: The journal allows participants to create a written entry complete with images and audio. The smartphone application will then check back in with the user after a chosen amount of time to ask if they are still feeling upset. Should they still be feeling negatively after the chosen amount of time has passed they will be recommended an activity or action to help negative feelings pass.

- Connect: Allows participants to maintain instant and time-delayed contact with their important contacts (family, friends, coworkers) as well as their therapist.

- Progress: This feature allows participants to monitor their progress throughout the study, including their achievements, mood log history and trackable history.



tion Smartphone Application Navigation

- Resources: In this section of the smartphone application, participants will have access to content uploaded by their clinicians, which can be targeted to participants on an as-needed basis. Participants will also have access to a map which geo-locates the nearest local mental health services as well as a list of local crisis line telephone numbers which they may access as needed.

- BEACON: When participants are in crisis, they may access the BEACON screen. This section of the smartphone application allows participants to assess their current situation and safety plan for warning signs that they may be at risk for subsequent self-harm. It also provides activity recommendations to help participants reduce stress, including relaxation and breathing exercises. Participants also have quick access to their important contacts directly from this screen, including their therapist and emergency contacts. At any time, participants can also press the BEACON button and be connected to a crisis line.

We will evaluate any protocol deviations, planned or unplanned, as well as modifications site request to make to the conduct of the study at site submission to the REB. We will evaluate site level frequency of completion of the Therapy Adherence Form that is completed by the therapist at each study visit documenting which activities were completed.

Secondary Outcome Variables

Depression Symptoms

Changes in depression scores over the study intervention period will be assessed using the Patient Health Questionnaire (PHQ-9), a 9-item questionnaire that assesses the severity of depression symptoms experienced within the last two weeks. Participants are asked to rate each symptom of depression on a Likert scale from 0 (not at all) to 3 (nearly every day), with total scores ranging from 0 (minimal depression) to 27 (severe depression). The PHQ-9 has strong methodological properties with an internal consistency of 0.89 and strong test re-test reliability [49]. Increasing scores on the PHQ-9 have also been found to be correlated with deteriorating scores on all six subscales of the Medical Outcomes Survey Short Form-20 (SF-20) [50].

This measure was selected not only for its strong psychometric properties but also because of its commonality. The PHQ-9 is often used as a screen tool for Major Depression Disorder (MDD) in primary care practice [51]. As such, in the case of an Adverse Event (AE), such as worsening depression scores, the familiarity of the PHQ-9 will facilitate interactions between study investigators and participant's family physicians.

Anxiety Symptoms

Changes in anxiety scores over the course of this study will be assessed using the Generalized Anxiety Disorder questionnaire (GAD-7), a 7-item questionnaire that assesses the severity of anxiety symptoms experienced within the last two weeks. The initial validation study, conducted by Spitzer et al. (2006), demonstrated high internal consistency (α=0.92) and test-retest reliability (intraclass correlation = 0.83) [52]. Similar to the PHQ-9, the GAD-7 is familiar to primary care physicians, which will facilitate the coordination of care for study participants.

Post-Traumatic Stress Disorder (PTSD) Symptoms

Changes in PTSD symptoms during the study period will be evaluated using the Primary Care Post-Traumatic Stress Disorder Screen for DSM-5 (PC-PTSD-5) screening tool, which consists of five items which evaluate the presence of PTSD-related symptoms. The screening tool was initially developed and validated with male and female Veteran Affairs primary care patients [53]. Prins et al. (2016) recommend using a cutoff score of three (out of a possible five points) to detect possible PTSD, with a sensitivity of 0.93, specificity of $\geq$0.80 and efficiency of 0.63[53].

Health-Related Quality of Life

Health-related quality of life will be assessed using the EuroQol 5 Dimensions

who meets the first criterion will be given the opportunity to participate in the review, drafting, and final approval of the manuscript.

Author's Contribution

Prior to the launch of the study, co-authors that are responsible for the various aspects of the trial will be identified. Author contributions will be determined using the Contributor Roles Taxonomy (CRediT), a high-level classification system which includes 14 possible contributor roles. Some journals require that information is published about the relative contributions of each author on the manuscript. Where this is not a requirement of the journal, if possible, this information will be provided in the acknowledgements section of the manuscript. Since authorship itself does not specify the relative contributions of each author, a brief author contribution statement will be included in order to resolve any potential ambiguity surrounding contributions.

Order of Authorship

For this trial, order of authorship will be determined by contribution: the person who took the lead in writing the manuscript or doing the research will be listed first and the most experienced contributor will be listed last. All other co-authors will be listed alphabetically.

In order to avoid any disputes as to the order of authorship, the following precautions will be taken:

1. The authors will decide on authorship and authorship order together, prior to drafting their manuscript; and
2. Authors should specify in their manuscript a description of the contributions of each author so that readers can interpret their roles correctly.

Acknowledgments

All those who have made a contribution to the work, but who do not fulfil the criteria for authorship (noted above in the "Qualification for Authorship" section), should be acknowledged by name in the manuscripts acknowledgement section. Authors should request permission before acknowledging anyone. Examples of individuals who may be appropriate to acknowledge include: those responsible for general supervision of a research group, or those who provided administrative, clinical or technical support.

5.8.3. Reproducible Research

The Coordinating Study Site will be responsible for the sharing of data between study Investigators. The Principal Investigator and co-Principal Investigator will maintain exclusive access to the data for two years post-study closeout. After which the data will be available to the wider study team for sub-analyses for a period of 3 years. At 5 years post-study closeout, de-identified study data will be published in an online repository and become publically available.

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