Study Protocol

Protocol Name:	The BEACON Study: Protocol for a pilot randomized controlled trial of smartphone-assisted problem solving therapy in men who present with intentional self-harm to Emergency Departments in Ontario
Clinical Trial Type:	Non-Regulated Investigational Clinical Trial
REB Reference Number	CTO-0790
Funder	Ontario SPOR Support Unit (OSSU)
Sponsor	Ottawa Hospital Research Institute (OHRI)
Principal Investigator	Dr. Simon Hatcher
Co-Principal Investigator	Dr. Marnin Heisel

PROTOCOL SIGNATURE PAGE

The clinical study as detailed within this research protocol (Version 1, dated 24-Feb-2017 or any subsequent amendments will be conducted in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) and Good Clinical Practice (GCP), an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

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World Health Organization Trial Registration Data Set Items

DATA CATEGORY	INFORMATION
Primary registry and trial identifying number	ClinicalTrials.gov NCT03473535
Date of registration in primary registry	22-Mar-2018
Source(s) of monetary or material support	Ontario SPOR Support Unit (OSSU)
Primary sponsor	Ottawa Hospital Research Institute
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Public title	The BEACON Study
Scientific title	The BEACON Study: Protocol for a pilot randomized controlled trial of smartphone-assisted problem solving therapy in men who present with intentional self-harm to Emergency Departments in Ontario
Countries of recruitment	Canada
Health condition(s) or problem(s) studied	Intentional Self-harm
Intervention(s)	Intervention: smartphone-assisted PST
Key inclusion and exclusion criteria	Ages eligible for study: ≥18 years Genders eligible for study: Men and Trans-Men Accepts healthy volunteers: No Inclusion criteria: adult patient (≥ 18 years); patient identifies as male, patient presents to Emergency Department for an index episode of intentional self-harm at one of the Emergency Departments randomized to receive the study intervention.

DATA CATEGORY	INFORMATION
	Exclusion criteria: patient presented to an Emergency Department randomized to receive the study intervention for a reason other than intentional self-harm; patient does not have a valid OHIP card; patient is unable to read and understand English, French or is unable to read or understand Oji Cree; patient is unable and/or unwilling to provide informed consent; is unwilling to return to hospital for follow-up appointments.; patient is unlikely to commit to a one year study.
Study type	Randomized controlled trial Allocation: 2:1 Intervention model: parallel group Masking: none Primary purpose: prevention
Target sample size	100
Primary outcome(s)	Beck Scale for Suicide Ideation (BSS)
Key secondary outcomes	Masculinity (CMNI); Depression (PHQ-9); Anxiety (GAD-7); PTSD (PC-PTSD); Health-related quality of life (EQ-5D-5L); Meaning in Life (EMIL); Social Supports (MSPSS); Alcohol Misuse (AUDIT-C & AUDIT), Substance Misuse (DAST-10); Health Costs (TiC-P); Problem-Solving Skills (SPSI-R:S).

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

1. FUNDING

The Ontario SPOR Support Unit (OSSU) is funding the costs for the BEACON trial and recruitment of 100 men in 5 Emergency Departments across Ontario. OSSU is a partnership between the Government of Ontario and the Canadian Institutes of Health Research (CIHR). Funding for this trial covers the cost of research staff salaries; capacity building; study-related expenses; including the cost of the smartphone application, statistical analyses and knowledge translation; as well as meetings and organizational costs.

2. ROLES AND RESPONSIBILITIES

2.1. Contributorship

The following individuals assisted with the development of this study protocol: Drs. Simon Hatcher[1], Marnin Heisel[2], Monica Taljaard[1], Kednapa Thavorn[3], Daniel Corsi[4], Ayal Schaffer[5], Sakina Rizvi[6], Ian Colman[7], Mark Sinyor[8], Sidney Kennedy[6], Christian Vaillancourt[1], Venkatesh Thiruganasambandamoorthy[1], John Lavis[9], Paul Links[10], Christopher Mushquash[11], Peter Voros[12]; and Valerie Testa[1], Sarah MacLean[4], Megan Schellenberg[13], Julie Kathleen Campbell[14], Alicia Raimundo[15] and Alaaddin Sidahmed[15].

2.1.1. Author's Contributions

Drs. Simon Hatcher and Marnin Heisel conceived of the study and are the grant holders. Dr. Monica Taljaard provided expertise in the design of randomized controlled trials (RCTs). Dr. Daniel Corsi provided statistical expertise in designing the clinical trial and will be conducting the primary statistical analysis. Dr. Kednapa Thavorn designed a health economic evaluation and will supervise the health economic analysis. Valerie Testa and Sarah MacLean assisted with the drafting of the study protocol. All authors contributed to

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refinement of the study protocol and approved the final manuscript.

2.2. Sponsor contact information

This is an investigator-initiated clinical trial and is sponsored by the Ottawa Hospital Research Institute (OHRI):

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The sponsor (OHRI) had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

2.3. Committees

2.3.1. Principal Investigator and co-Principal Investigator:

- 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).

2.3.2. Steering Committee (refer to title page for members):

- 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.

2.3.3. Trial Management Committee (TMC):

- Includes Principal Investigator, co-Principal Investigator, Clinical Research Program Manager and Research Coordinator;
- Study planning;
- Organization of Steering Committee meetings;
- Organization of Data and Safety Monitoring Committee (DSMC) meetings;
- Provide annual reporting to Research Ethics Board;
- Serious Adverse Event (SAE) reporting to DSMC and Research Ethics Board (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.

2.3.4. Data and Safety Monitoring Committee (DSMC):

- Comprised of four members from the following fields of expertise: statistics/biostatistics, epidemiology, methodology, psychiatry and the ethics of clinical trials.
- 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.

2.3.5. Lead Investigators

At each participating site, a site co-Investigator will be identified, to be responsible for identifying and recruiting participants, collecting data, and completing all study documentation, along with coordinating follow up of study participants and adherence to study protocol. All site co-Investigators will be Steering Committee members.

3. INTRODUCTION

3.1. Background and Rationale

3.1.1. Why is Intentional Self-Harm an Important Problem?

Definition of Self-Harm

We define self-harm as intentional self-poisoning or self-injury, whether or not there is clear evidence that the act was intended to result in death. Previous terms used include "attempted suicide" and "deliberate self-harm"; however, patients' motives for self-harm are highly variable, as a person may have more than one motive and motivation is difficult to assess and stated intent can fluctuate with time. In line with usual public policy in health and social care, we use the term 'self-harm' – avoiding the word 'deliberate' because many service users dislike its connotations and as it ignores/simplifies the issue of ambivalent and co-existing wishes to live and to die. We opted to use the term "self-harm" rather than Non-Suicidal Self-Injury (NSSI), a term being increasingly used in the clinical literature [1], given that it is associated with risk for lethal and non-lethal self-harm and as some individuals engage in self-harm with suicidal intent at times, and without stated suicidal intent at other times. The term "self-harm" also focuses on behaviour rather than on its motivation, which is

often complex, multi-determined, and open to interpretation and recall bias and historical revision.

Presenting to Hospitals with Self-Harm is Common

In Ontario, the number of people who present to hospital Emergency Departments with self-harm is difficult to ascertain accurately due to chronic under-detection and variable inconsistency in the definition and recording of self-harm episodes. The Canadian Institute for Health Information (CIHI) estimates the 2014 Ontario provincial rate of self-harm to be 61 per 100,000 population members, resulting in an estimate of approximately 8,250 Emergency Department presentations a year, province-wide [2]. However, local data collected from Ottawa Emergency Departments indicate approximately 1,600 presentations per year, reflecting a rate of 123 per 100,000 a year, or approximately double that estimated by CIHI for this region. Therefore, the provincial rate for Ontario may exceed 16,000 unique self-harm episodes per year. The under-detection of self-harm is further compounded by the recognition that official statistics do not capture those cases that did not involve a presentation to hospital or other healthcare services, and under-detection or misclassifications of presentations for self-harm. This issue has been identified as a significant problem by Statistics Canada [3].

The most common form of self-harm seen in Emergency Departments, accounting for approximately 80% of all episodes, is the intentional consumption of an excess of a medicinal or toxic substance. Injuries, most commonly including self-cutting, account for the remaining 15-20% of episodes. Two-thirds of patients presenting to Emergency Departments for the treatment of self-harm are under 35 years of age, with a mean age of approximately 30 [4, 5]. Self-harm occurs more commonly in lower socioeconomic groups. In Ontario, hospitalization rates for those from the most affluent sectors of the community are 26% lower than the provincial average [6]. There is also evidence to suggest that the rate of self-harm is increasing in Ontario, especially in younger adults [6].The number of deaths by suicide among older men is increasing secondary to the aging of the vast baby-boom cohort, adding further impetus to the need to enhance mental healthcare for at-risk men [7].

Self-Harm is Related to Suicide, Premature Mortality and High Use of Services

Self-harm has a strong association with suicide: 1.6% of people presenting to Emergency Departments 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%) [8]. After five years approximately four percent of individuals who have presented to the Emergency Department for the treatment of self-harm die by suicide [8]. 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 [8]. 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 [9]. As presentation to the Emergency Department with self-harm is a major identifiable risk factor for suicide, with at least one quarter of deaths by suicide being preceded by a hospital visit due to non-fatal self-harm in the previous year [10, 11], 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 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 [12].

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 [13]. Some studies report an all-cause mortality of 15% five years after a hospital presentation with self-harm with two thirds of deaths due to non-suicide causes [14]. Being male, single and repeated attempts are risk factors for premature mortality. A recent population-based cohort study investigating administrative datasets in the province of Ontario discovered that: "all-cause mortality following a first episode of self-poisoning was 1,107 per 100,000 person-years…[with] nearly half of all deaths being suicides, accidents or [of] undetermined intent" [15]. These premature deaths are greatly over-represented among young people and the potential years of life lost in the community are many.

Individuals who self-harm are frequent users of health and social services [16]. Approximately 10% of those who present in an Emergency Department following self-harm will engage in repeat self-harm in the following month and up to 27% after six months [17]. Recurrent self-harm is associated with significant distress and many unresolved interpersonal problems [18].

Why Focus on Men?

Whereas only four out of ten people who present to the Emergency Department with self-harm are men, they represent nearly two-thirds of those who die by suicide after an index episode of self-harm and they are also far more likely than women to die of premature death from other causes [13]. In Ontario, from 2006-2008, 75% of those who died by suicide were men [19]. The rates are even more pronounced in indigenous communities, with suicide rates of 126 per 100,000 young men (15-24) compared to a rate of 24 per 100,000 in non-Indigenous men of the same age [20]. Men who self-harm are more likely to misuse alcohol compared to women; for instance, in one large study in the U.K., 45% of 7,893 men who presented with self-harm misused alcohol compared to 29% of women [21]. Further, men repeat self-harm at similar or higher rates than women; for example, a study conducted in Western Northern Ireland revealed an annual repetition rate of 19.3% in men compared to 16.8% in women [22]. Previous trials have found that providing generic treatments to everyone is not particularly effective [23]; effective interventions target health behaviours and values consistent with the target group. The intervention we will offer builds on previous work by trying to extend the range and intensity of a focused psychotherapy by supplementing it with a sophisticated smartphone application that has already demonstrated its effectiveness in men with substance abuse disorders [24]. We will be offering an intervention specifically designed for men who self-harm who, historically, are difficult to engage in psychotherapeutic treatment and who are more likely than women to have substance abuse problems [25].

Summary of Relevant Studies of Psychological Therapies After Self-Harm

A 2012 U.S. review of literature on the screening and treatment of suicide risk indicated that trials among individuals who presented with self-harm to be limited by lack of power, although "trends suggested incremental benefits from some interventions (in particular, Problem-Solving Therapy (PST) for patients aged 15 or older)" [26]. The 2011 National Institute for Health and Care Excellence (NICE) guideline on management of self-harm (followed by a further NICE search and published update in 2014) found little that is likely to help with routine practice but concluded that there was sufficient evidence to recommend “a well conducted RCT” of psychosocial interventions [27]. The recently updated 2016 Cochrane review on interventions following self-harm found 55 trials involving 17,699 participants, of which 18 trials investigated cognitive behaviour therapy (CBT) [23]. Here, CBT included problem solving therapy which is a cognitive therapy focused on current difficulties which aims to teach participants a cognitive skill, namely problem-solving, 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 participants repeating self-harm (odds ratio (OR) 0.70, 95% confidence interval (CI) 0.55 to 0.88; number of studies k = 17; N = 2,665; GRADE: low quality evidence), but with no reduction in the frequency of self-harm (mean difference (MD) -0.21, 95% CI -0.68 to 0.26; k = 6; N = 594; GRADE: low quality) [28]. The authors concluded that CBT, including PST, requires further investigation in order to clarify which patients benefit from these types of interventions. They further noted the need for more information about potential sex differences in the manner in which psychosocial interventions might work.

The potential impact of this study is that it could improve patient and health system outcomes by decreasing repeat episodes of self-harm and deaths by suicide, presentations to Emergency Departments (as well as linked hospital admissions), and ultimately reduce healthcare costs.

Summary of Relevant Studies of Blended Therapy in the Treatment of Self-Harm

The electronic support of psychotherapy in the treatment of mental disorders has been called “blended care,” referring to the combination of online and face-to-face therapy in one treatment protocol [28]. Blended therapy potentially offers numerous benefits to both patients and health care providers, including increasing the intensity of mental health treatment without a reduction in the number of sessions [29], increasing patient agency by fostering increased self-management skills [30] as well as case management benefits for mental health professionals [31]. Studies have also shown that blended therapies have the potential to reduce the number of face-to-face therapy sessions required by patients, thereby reducing the total cost to the health care system [32]. These interventions may be especially beneficial for the financially and geographically disadvantaged, including those individuals whose financial situation prohibits their seeking care during the work day, and those residing in rural and remote regions.

The use of smartphone applications for the self-management and monitoring of mental health have been found to be acceptable by both research participants [33] and the wider community as long as appropriate privacy and security measures are taken [34]. There have been only a small number of studies that have investigated blended therapy but no studies that have examined blended therapy in secondary health care settings or in patients

who are at high risk for suicide. Large trials in routine clinical settings are needed in order to assess the effectiveness of blended therapy interventions in those suffering from mental disorders. In recognition of this, the European Commission has funded a large study, the European Comparative Effectiveness Research on Internet-Based Depression Treatment project (E-COMPARED) in which the effectiveness of blended therapy for treating depression will be assessed in a RCT in eight European countries [32]. However, the E-COMPARED study specifically excludes suicidal participants and those with co-morbid mental disorders, such as bipolar disorder or substance abuse.

Assessment, Care and Discharge from the Emergency Department

People attending Emergency Departments following self-harm receive variable levels of care in Ontario, and there is no standard protocol for therapy. Many are not assessed for psychological needs, and the little psychological therapy available is usually not covered by provincial healthcare plans, and is thus only accessible to individuals with greater financial resources, including employer-paid supplemental health benefits. Published work from other countries confirm the fact that variation in the provision of care is the norm [35]. Local audit data from hospitals in Ottawa show that only four out of ten men who present with intentional self-harm are seen by a mental health professional, and few are offered an evidence-based treatment aimed at reducing their risk of suicide or repeated self-harm.

Assessment of suicide risk is currently a Required Operating Practice for Canadian Hospital accreditation; however, individuals identified as being at-risk for suicide rarely receive recommended care. A cohort study of 7,355 Emergency Department presentations for self-harm in the U.S. found that less than half of those who presented with self-harm (47.5%) received any mental health assessment while in the Emergency Department [36]. The same study found that the lethality of self-harm was not associated with mental health assessment in the Emergency Department. In a study of patients who presented to the Emergency Department with deliberate self-harm, Hickey, Hawton, Faag & Weitzel (2001) also found that those who were discharged from the Emergency Department without a psychiatric assessment were more likely to: be male, 20-34 years of age, have a previous history of self-harm, to demonstrate difficult behaviour while in hospital and to be intoxicated than patients who were assessed prior to discharge [37]. Follow-up after discharge from Emergency Departments for many disorders is often poor, with one study in Ontario finding that between 15% and 31% of patients discharged from an Emergency Department with chronic heart failure, diabetes or chronic obstructive lung disease did not see any physician within 30 days of their Emergency Department contact [38]. Fewer than one in three primary care physicians in Canada report being told when their patients attend an Emergency Department [39].

Following intentional self-harm, even fewer patients receive outpatient mental health follow-up, with only half attending an appointment with a mental health professional within 30 days of presentation to the Emergency Department for an episode of self-harm [36]. Here, too, policies vary by institution regarding the acceptable duration between discharge and an outpatient mental health visit. Even in RCTs, which typically involve rigorous specification in methods of approaching, recruiting, and determining eligibility of patients, the proportion of people who consent and then actually receive treatment is low, with one study reporting 38% of people randomized to cognitive behaviour therapy attending no clinical sessions [40]

and another trial finding 20% of people consenting to PST having received no sessions [41]. Methods to address the low rate of engagement include providing patients with a written discharge plan in the Emergency Department [28]; enabling Emergency Department physicians to make electronic bookings for follow-up; staff training; and feedback on the proportion of people receiving care after leaving the Emergency Department [42]. The U.S. Suicide Prevention Resource Center (SPRC) has produced a "consensus guide" for caring for adult patients at high-risk of suicide in the Emergency Departments which recommends a package of brief patient education; safety planning; lethal means counselling; rapid referral; and caring contacts, which include crisis line information [43]. They also recommend focused interventions targeting men in their middle years at elevated risk for suicide [43]. A Cochrane Systematic Review of interventions to improve outpatient referrals from primary care to secondary care concluded that local educational interventions and dissemination of guidelines with structured referral sheets were effective strategies [42]. These features are included as part of the BEACON Suicide Prevention Smartphone Application in this study.

Rationale

Whilst clinical interventions involving technology appear attractive there are significant obstacles to implementation including clinicians perceptions that they may lower barriers to access (sic); organisational difficulty in incorporating technology into practice particularly around issues of confidentiality and privacy (especially when considering "high risk" patients in mental health settings); and a lack of evidence that adding technological interventions to existing services provide any significant benefits. This pilot aims to provide preliminary evidence to address these concerns and pave the way for a definitive multi-site individualised RCT and implementation study.

3.2. Objectives and Hypotheses

3.2.1. Primary Objective & Hypotheses

The primary objective of this study is to assess whether a multi-site individualised RCT of the management of men who presented with self-harm is an appropriate trial design and is feasible with regard to i) eligibility, recruitment and retention ii) patient use and acceptability of the blended intervention iii) to inform the primary outcome measure and sample size for a definitive RCT and iii) adherence to the protocol.

3.2.2. Secondary Objectives & Hypotheses

The key secondary objectives are to determine whether, in men who present to the Emergency Department with self-harm, smartphone-assisted PST designed specifically for men results in better health-related outcomes including: a decrease in the severity of suicidality, a decrease in the severity of depression symptoms, a decrease in the severity of anxiety symptoms, improved overall health, better health-related quality of life and lower rates of alcohol/drug misuse. We will also examine the mechanism of change by assessing problem solving skills assessed by the Social Problem Solving Inventory.

We hypothesize that participants who complete three sessions of smartphone-assisted PST or more, will experience statistically significant improvements in participant scores on the following measures:

- 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):

- 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.

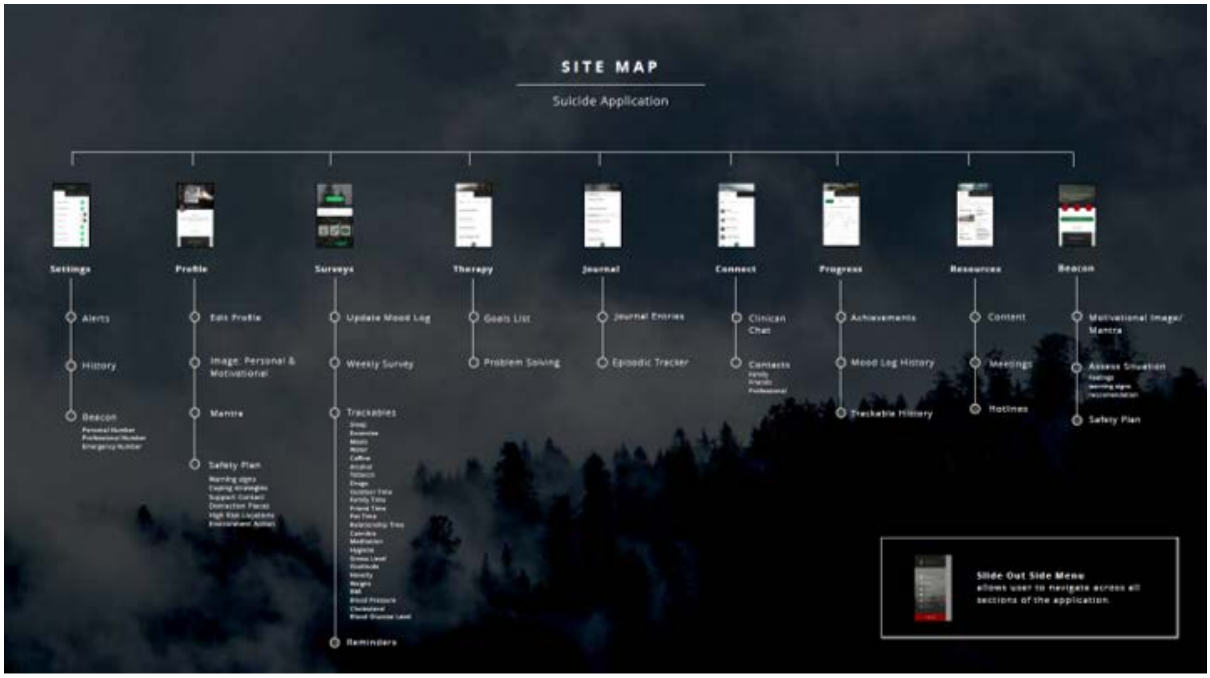


Figure 2. BEACON Suicide Prevention Smartphone Application Map

PST has been used previously by this research team. Staff training will take place over two days followed by weekly supervision. Supervision will be provided by the Principal Investigator using the Ontario Telemedicine Network (OTN) for therapists in different locations. Existing PST training materials can be found at the following link: www.problemsolvingtherapy.ac.nz. Adherence to the therapy will be assessed by number of sessions attended and an adherence tool (unpublished) used in previous studies.

4.1.4. Outcome Measures

Primary Outcome Variable

Feasibility

To evaluate the primary outcome of the study, feasibility, we will consider the following: i) eligibility, recruitment and retention ii) patient use and acceptability of the blended intervention iii) the primary outcome measure and sample size for a definitive RCT and iv) adherence to the protocol.

i) Eligibility, Recruitment, and Retention

For eligibility, we will retain screen failure data of those participants who have consented to be in the study to assess the frequency at which each inclusion/exclusion criteria are not met. We will assess recruitment by comparing group level demographics at each hospital of men who presented to the ED with self-harm compared with those who enrolled in the study. Lastly, for retention we will assess the characteristics of those who complete 0-2 sessions, 3-6 sessions but not the 6 month assessments and those who complete 3-6 sessions and all outcome assessments.

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

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

questionnaire (EQ-5D-5L). This is a 5-item questionnaire that assesses health-related quality of life, including mobility, self-care, ability to participate in one's usual activities, pain or discomfort, and anxiety or depression. The EQ-5D-3L was released in 1990 and asked participants to assess their health-related quality of life on a three-point scale from no dysfunction to extreme dysfunction. In 2005, the EQ-5D-5L was released to improve the sensitivity and reliability of the measure [54]. Respondents are now asked to rate their health-related quality of life on a five-point Likert scale, with the following response categories:

- Level 1: indicating no problem;
- Level 2: indicating slight problems;
- Level 3: indicating moderate problems;
- Level 4: indicating severe problems;
- Level 5: indicating extreme problems.

The EQ-5D-5L is then able to define a unique health state based on the responses to each of the five dimensions of health described above. Respondents fall into one of 3,125 different health states depending on their responses to the questionnaire. For instance, an overall score of 11111 indicates no problems on any of the five health dimensions, whereas a score of 12345 indicates that a respondent has no problems with mobility, slight problems with washing or dressing, moderate problems with doing usual activities, severe pain or discomfort and extreme anxiety or depression. The measure also includes a Visual Analogue Scale (VAS) which asks participants to evaluate their overall health on a scale from 0-100.

Meaning in Life

Previous research has demonstrated perceived meaning in life to be negatively associated with depression and suicidal ideation [55]. In the current study, meaning in life will be evaluated using the Experienced Meaning in Life Scale (EMIL) [56], which consists of four 10-item sub-scales: Creative, Experiential, Attitudinal and Ultimate meaning in life. The EMIL includes 40 items rated on a Likert scale from "strongly disagree" (1) to "strongly agree" (5), with higher scores reflecting greater perceived meaning in life.

This measure was developed and validated with a community-based sample of older adults [56] and has high internal consistency (α=0.95). For the purposes of this study, we have will be using the Creative and Attitudinal subscales only in order to reduce the burden on participants and investigators.

Perceived Social Supports

Perceived social supports will be assessed using the Multidimensional Scale of Perceived Social Support (MSPSS) [57].

The MSPSS is a 12-item questionnaire that addressing the following sources of perceived social support: Family, Friends or Significant Other. Each sub-scale consists of four-items that are rated on a seven-point Likert scale from "very strong disagree" (1) to "very strongly agree" (7). The MSPSS performs well psychometrically with high internal consistency and test-retest reliability (refer to Table 2).

Table 2. MSPSS Reliability Statistics

Subscale	Internal Consistency (α)	Test-Restest Reliability (ICC)
Family	0.87	0.85
Friends	0.85	0.75
Significant Other	0.91	0.72
Total	**0.88**	**0.85**

Source: Zimet et al., 1988

Alcohol Misuse

Alcohol misuse will be evaluated using the Alcohol Use Disorder Identification Test (AUDIT). Two versions of the AUDIT will be used in this study: the AUDIT-C is a 3-item questionnaire that assesses alcohol misuse. This will be used as a screening questionnaire, participants who score above 4 on the AUDIT-C will also be asked to complete the Full AUDIT (an additional seven questions). The AUDIT questionnaire is designed to assess the following four dimension of alcohol misuse:

- Alcohol consumption (3 items);
- Drinking behaviour (3 items);
- Adverse reactions (2 items);
- Alcohol-related problems (2 items).

The validity of the AUDIT questionnaire has been established through an examination of sensitivity and specificity. Among those who were known to misuse alcohol, the AUDIT successfully detected an alcohol use disorder 99% of the time [58]. Similarly, among those who did not misuse alcohol, only 0.5% were categorized as potentially having an alcohol use disorder [59].

Drug Misuse

Drug misuse will be measured using the Drug Abuse Screening Test (DAST-10), a 10-item questionnaire that assesses drug abuse within the last 12 months. Participants are asked to answer 10 questions about their substance use using a binary response of yes or no, with each response indicating a possible drug use problem being awarded one point. The total possible scores on this instrument range from 0 to 10, with higher scores indicating a greater likelihood of a substance use problem. The DAST-10 has been evaluated among psychiatric patients and has been found to have high internal consistency (α=0.94) [60] and a test-retest reliability score of 0.71 [61]. Scores on the DAST have been found to be significantly correlated with the frequency of drug use (r ranging from 0.19 to 0.55). However, this can be difficult to estimate as frequency of use is often drug-specific (i.e. marijuana compared to heroin) [61].

Adherence to Masculine Gender Roles

The increased risk for self-harm and suicide has been established in this protocol. As discussed earlier in this document, men are less likely to seek help for mental disorders, including self-harm, and are difficult to engage in psychological treatment. One potential explanation for this is gender role strain. That is, dominant forms of masculinity place

societal pressures on men to meet certain gendered expectations (i.e. emotional control, self-reliance, and dominance). When individual men are unable to meet these expectations, they experience strain which may impact their behaviour in a number of problematic ways, including a resistance to seeking psychological help.

The Conformity to Masculine Norms Scale [62] is a 94-item questionnaire that assesses the conformity to the following masculine gender norms: Winning, Emotional Control, Risk-taking, Violence, Power over Women, Dominance, Playboy, Self-Reliance, Primacy of Work, Disdain for Homosexuals, and Pursuit of Status. The CMNI performs well methodologically, with strong measures of internal consistency across all 11 subscales ((α ranging from 0.72 to 0.91; refer to Table 5 for more information)[62]. It is also strongly correlated with other measures of masculinity including: Brannon Masculinity Scale [63], the Gender Role Conflict Scale [64] and the Masculine Gender Role Stress Scale [65].

Table 3. Internal Consistency Statistics for CMNI Subscales

Subscale	Internal Consistency (α)
Winning	0.88
Emotional Control	0.91
Risk-Taking	0.82
Violence	0.84
Power Over Women	0.87
Dominance	0.73
Playboy	0.88
Self-Reliance	0.85
Primacy of Work	0.76
Disdain for Homosexuals	0.90
Pursuit of Status	0.72
Total Conformity	0.94

Source: Mahalik et al., 2003

The CMNI differs from other measures of masculinity in one key respect: while other measures assess the extent to which an individual has internalized the cultural beliefs associated with masculinity and the male role, the CMNI assesses an individual's personal conformity to these established ideals. This is an important distinction when seeking to address gender role strain as it differentiates between the understanding of the importance and prevalence of gendered norms (i.e. emotional control) and an individual's man's ability to meet those gender role expectations in his own life. This, in turn, may lead to gender differences in help-seeking, making men more vulnerable to self-harm and suicide. For the purposes of this study, only the following subscales will be used: Emotional Control (CMNI-EC) and Self-Reliance (CMNI-SR) as they are the most applicable to the study population. This will also reduce participant and investigator burden.

Health Service Use

Health service use will be captured using routinely collected administrative health data for participants obtained from the Institute for Clinical Evaluative Sciences (ICES). This includes:

- Previous hospitalizations for self-harm;
- Presentation to hospital for self-harm;
- Presentations to hospital for any reason other than self-harm;
- Admission to hospital for any reason;
- Outpatient appointment for any reason; and
- Primary care visits.

A questionnaire has also been adapted by the research team to capture data not available in ICES. Specifically, relevant questions from the Questionnaire on Healthcare Consumption and Productivity losses for patients with a Psychiatric Disorder (TiC-P) will be used to collect health service use and work productivity not otherwise captured. Items removed from the questionnaire are either optional as noted by the developers, are captured elsewhere in a more reliable manner (such as current medications or demographics), or were adapted to services in Ontario healthcare system. The TiC-P is a brief self-report questionnaire, taking most respondents less than 10 minutes to complete with good test-retest reliability (ICC=0.83) [66].

Problem-Solving Skills

In order to assess the impact of the smartphone-assisted PST intervention, we will be assessing participant's social problem solving skills throughout the study intervention period using the Social Problem Solving Inventory- Revised Short Form (SPSI-R:S) [67]. This is a 25-item questionnaire that assesses individual's strengths and weaknesses in their problem-solving abilities so that deficits can be addressed and progress monitored. This is a short form of the Social Problem Solving Inventory (SPSI), which had strong psychometric properties, including high internal consistency (α=0.94), test-retest reliability (ICC=0.87) and was correlated with other measures of stress and psychological symptomatology among both college students and community residents (refer to Table 6 below for more information):

Table 4. Correlations Between SPSI Measures and Measures of Stress and Psychological Symptomatology in a College Student Sample and a Community Resident Sample

	College Students	Community Residents
	SPSI	SPSI
DSP/TSS	-0.45**	-0.56**
DSP/EES	-0.35**	-0.43*
DSP/PMS	-0.14	0.40*
DSP/ERS	-0.53**	0.49**
PPC	-0.26**	-0.19
SCL-90-R	-0.37**	-0.45**

Source: D'Zurilla & Nezu, 1990
Note: SPSI=Social Problem-Solving Inventory; DSP = Derogatis Stress Profile; TSS = Total Stress Score; EES =- Environmental Events Score; PMS = Personality Mediators Score; ERS = Emotional Response Score; PPC = Personal Problems Checklist; SCL-90-R = Symptom Distress Checklist-90-Revised Global Severity Index.
**** p <0.05***
***** p <0.01***

Influence of the Media on Suicide

Numerous studies have shown that mainstream media reports on suicide influence

some people to attempt and die by suicide through a copycat phenomenon known as the Werther Effect [68–71]. This has not been well described in males who present to the emergency room after an episode of self-harm. Adding this measure will help determine the extent to which a Werther Effect occurs in this population and could inform future prevention efforts both at a population level and also within the application (e.g. blocking media stories with suicide-related content).

In order to assess the potential impact of the media on self-harm presentations during the study intervention period, each participant will be asked if, in the month prior to their self-harm episode, they were aware of any high profile suicides in the news, whether they used the internet to research self-harm methods and whether they used the internet to get access to help for their emotional distress.

All outcome measures will be administered via an electronic data capture system (EDCS) for all visits. The system used is outlined in Section 4.3.2 Data Management of this protocol. The following questionnaires are not included in the EDCS and will be completed as an interview by the delegated study staff member and a summary entered into the EDCS: BSS, SPSI-R:S and demographics. Administration will occur as per Time and Events Schedule in Table 5.

4.1.5. Sample Size

Calculating sample size for pilot studies is a controversial area. Calculations may be based on estimation of important parameters with sufficient precision[72], the likelihood of unforeseen problems[73] or rules of thumb such as 12 participants per group[74], at least 9% of the main trial's sample size[75] , or at least 50 participants[76] . Further there is a lack of guidance on calculating sample size for pilots of multicenter trials where clustering at the different sites may be a factor. Based on previous randomised controlled trials of interventions in this population we expect that in the main trial the effect size will be small and the sample size large. We have designed the pilot to estimate the proportion of patients who would meet our feasibility criteria using confidence intervals. Based on our experience with previous studies conducted in this population we estimate that enrolling 100 patients, with 20 participants consenting in each site, would allow us to assess our feasibility outcomes and maximize the chance of identifying unexpected barriers to carrying out a larger trial across multiple centers.

4.1.6. Recruitment

After presentation to an Emergency Department with self-harm, male patients may be approached by Emergency Department staff with information about the study. A delegated study staff member at each site may check-in regularly with Emergency Department staff to confirm there are no potentially eligible participants. At sites where medical records have a “Consent to be Contacted for Research” option, a delegated study staff member at the site will routinely review the Electronic Medical Records at their respective site to ensure that no potentially eligible patients have been missed. These patients will be provided with information about the study by telephone. Patients interested in participating in the study will be scheduled for a Consent and Baseline Appointment with a delegated study staff member. The consent visit and other study visits may occur using videoconference platforms such as MS Teams, Zoom for Healthcare, Zoom in Epic or OTN. Electronic signatures will be

obtained on consent forms in any circumstance where in-person visits are not possible.. At their consent visit, patients will be provided with information about the study and will have an opportunity to ask any questions they may have pertaining to the study. The delegated study staff member will then conduct the informed consent discussion in accordance with ICH Good Clinical Practice (GCP) guidelines with interested patients. Once they provided written informed consent, participants will be screened for eligibility to participate in the study. All eligible participants will be scheduled for a Baseline Visit. At the Baseline Visit, participants randomized to the BEACON arm will be guided in how to download the BEACON smartphone application and a delegated study team member will walk them through the onboarding process and set-up of their profile. Once this is complete, participants will be asked to complete all necessary Baseline Intake assessments and will be referred for their first PST session, to be conducted by a delegated study staff member. In order to limit participant burden, they will have the choice to either complete their baseline visit and first PST session in one study appointment or to split them into two study appointments. Prior to their first visit, participants will receive an email containing a secure link to complete their baseline assessments. For in person visits, the participant can complete the questionnaires directly on a study computer.

4.2. Assignment of Interventions

4.2.1. Allocation to Intervention

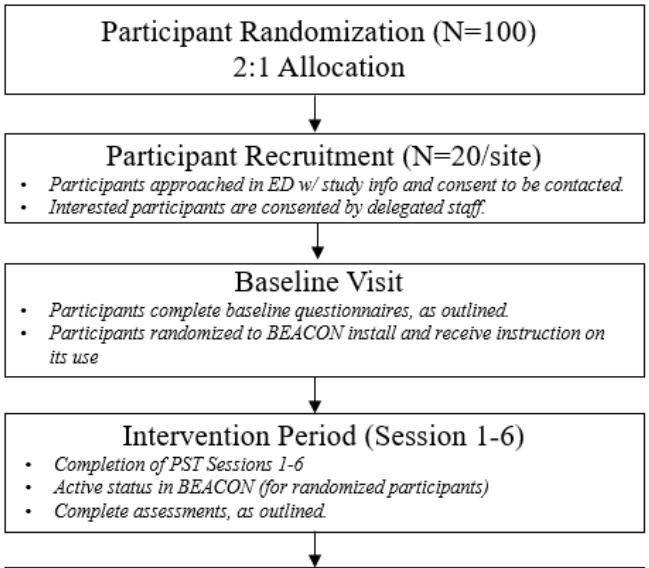
Five (5)sites in Ontario have agreed to participate in this pilot RCT. Randomization for this study will occur with 2:1 (67:33) allocation in favour of the blended therapy model. Given the small sample size, there will be no stratification across sites to ensure an equitable allocation to the conditions. A web randomization system hosted by the Ottawa Methods Centre (OMC) will be used. Participants will be randomized by each site coordinator using the web system as they are enrolled.

4.2.2. Blinding

There is no blinding in this study as all patients who consent to participate in this study will receive at least PST therapy. It would not be practical or possible to blind the receipt of the mobile application as both the participant and therapist will be using the platform.

4.2.3. Participant Timeline

Figure 2. Participant Timeline



4.3. Data Collection, Management and Analysis

4.3.1. Data Collection

Data Collection Methods

All outcome measures will be administered via an Electronic Data Capture System (EDCS), with the exception of the SPSI-R:S and the BSS which will be completed on paper and entered into the EDCS by delegated site staff, at the all visits as per the table below (refer to Appendix A for estimated completion times for each measure). When visits occur via video conference, the SPSI-R:S and the BSS will be administered using screen sharing or interview.

Table 5. Outcome Variables

Outcome	Data Source	Explanation	Administered
Demographic and descriptive information			
Demographic Information	Baseline Questionnaire	To describe similarities and differences between the groups	Session 1 (Baseline Visit)
Influence of media on self-harm	Baseline Questionnaire	To describe similarities and differences between the groups	Session 1 (Baseline Visit)
Masculinity	CMNI-EC; CMNI-SR	To describe similarities and differences between the groups	Session 1 (Baseline Visit)
Primary Outcome			
Suicidality	BSS	To assess the impact of the smartphone-assisted PST intervention	Baseline Visit; Session 6; 12 weeks, 6 months
Secondary Outcomes			
Severity of depression symptoms	PHQ-9	To assess the impact of the smartphone-assisted PST intervention	Baseline Visit; Session 6; 12 weeks, 6 months

Severity of Anxiety Symptoms	GAD-7	To assess the impact of the smartphone-assisted PST intervention	Baseline Visit; Session 6; 12 weeks, 6 months
PTSD	PC-PTSD-5	To assess the impact of the smartphone-assisted PST intervention	Baseline Visit; Session 6; 12 weeks, 6 months
Health-related quality of life	EQ-5D-5L	To assess the impact of the smartphone-assisted PST intervention	Baseline Visit; Session 6; 12 weeks, 6 months
Meaning in Life	EMIL-Attitudinal; EMIL - Creative	To assess the impact of the smartphone-assisted PST intervention	Baseline Visit; Session 6; 12 weeks, 6 months
Social Support	MSPSS	To assess the impact of the smartphone-assisted PST intervention	Baseline Visit; Session 6; 12 weeks, 6 months
Alcohol use/misuse	AUDIT	To assess the impact of the smartphone-assisted PST intervention	Baseline Visit; Session 6; 12 weeks, 6 months
Drug use/misuse	DAST-10	To assess the impact of the smartphone-assisted PST intervention	Baseline Visit; Session 6; 12 weeks, 6 months
Health Care Use and Cost	NARCS (ICES); OHIP (ICES); TiC-P	To assess the impact of the smartphone-assisted PST intervention	Baseline Visit; Session 6; 12 weeks, 6 months
Problem-Solving Skills	SPSI-R:S	To assess the impact of the smartphone-assisted PST intervention	Baseline Visit; Session 6; 12 weeks, 6 months

Data Sources: ***NACRS, National Ambulatory Care Reporting System; OHIP, Ontario Health Insurance Plan Claims Database***

The following data will be collected as part of the assessment of feasibility and acceptability:

Table 6. Assessment of Feasibility and Acceptability

Data Collection Method	Data Collected
Program documentation and observation (to assess fidelity, dose and reach)	Number of PST sessions attended.
	Smartphone Application Usage, including: total number of mood log entries; surveys completed; journal entries; goals completed; views/downloads of resource material and BEACON button presses.
	Whether or not each site implemented other hospital-based suicide reduction measures during the study intervention period.
Structured qualitative interviews (to assess barriers, facilitators and suggestions for improvement)	Interview participants regarding what helped and what did not help, the effect of the intervention on help seeking behaviours, assessments, the application.

Retention

A major difficulty in all clinical trials is ensuring that patients attend their baseline appointment. As such, a key component to our patient recruitment strategy is to ensure minimal loss to follow-ups between the point of referral and study enrollment. Delegated study staff will develop an ongoing relationship with clinical staff to encourage referrals to be provided as soon as possible. Delegated study staff will aim to contact potential participants within two business days of the referral.

Once enrolled in the study, PST sessions will be scheduled as per patient preference with the Research Therapist and standard lost to follow-up procedures will be followed for patients who do not complete their next scheduled follow-up appointment. This is an escalated response which may include any combination of the following: continued attempts to contact the participant by postal mail, telephone and/or email, contacting a participant's emergency contact and contacting a participant's family physician. An additional 12-week follow-up visit has been included to minimize attrition between 6 weeks and 24 weeks.

The BEACON Suicide Prevention smartphone application will also be designed to increase participant engagement with the study. For instance, participants will have "instant" and time-delayed communication with their Research Therapist through the messaging feature of the mobile application. Research Therapists will also have access to a Clinician Dashboard which will allow them to identify patterns of use which might indicate that a participant may at risk of being lost to follow-up (i.e. through decreased use of the smartphone application). This will provide Research Therapists with an opportunity to reach out to participants and attempt to re-engage them in the intervention. Research Therapists will monitor the dashboard, including connect features during regular business hours, as outlined with each participant at their first visit.

4.3.2. Data Management

Electronic Data Capture System

All data will be entered electronically using a username and password-protected electronic data capture system (EDCS) at each site. The BEACON web-app is designed and coded using Microsoft Visual Studio .NET 2015 and JQuery/Java scripts. The back-end database is designed and configured using the validated MS SQL Server 2008 R2. The Ottawa Method Centre-Data Management Services (OMC DMS) uses the Agile Methodology for software development. All network, server security and privacy settings are regularly tested and comply with Health Canada recommendations and Good Clinical Practice (GCP) for secured data management services. The BEACON EDCS is hosted on a physical server, not in the cloud, that is located at The Ottawa Hospital (TOH) data centre in a secure server room with limited access to authorized personnel behind lock doors. The web/database server is behind the TOH firewalls. The OHRI web site is secured with the highest rating from Entrust SSL virtual test. The data transfer between the client and server is protected with Entrust SSL 256-bit encryption. All data transfers between the client computers/browsers and the server/database are encrypted via https. The BEACON EDCS does not collect/retain any personal health identifier (PHI) or personal identifying information (PII). If PHI or PII is inappropriately entered into the EDCS in error, it cannot be removed at the site level. The site must notify OMC DMS to remove the information.

Paper Data Collection

The following information will be entered into the EDCS: all study outcome

questionnaires, concomitant medications, and the adverse event log. The BSS, SPSI-R:S, adverse event log and concomitant medication will be completed on paper and entered into the EDCS by site delegated study staff. If visits occur via videoconference methods, the questionnaire may be completed using screen sharing or an interview format. All paper-based data collection will be saved by delegated study staff members at each site on the secure hospital server. On a monthly basis, each site will send their de-identified study data (password protected and encrypted) to the Research Coordinator via email as per N2 Standard Operating Procedure 016 File Transfer and its associated OHRI Addendum. This data will then be imported into the study master database in SPSS. This database will be stored on the OHRI hospital server at the Coordinating Site and only the TMC will have access to it.

All hardcopies of original study documentation will be stored in the participant research charts which will be categorized in numerical order, according to sequential numbering (i.e. 001 to 350). 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.

4.3.3. Statistical Methods

Categorical participant characteristics, such as gender identity, marital status and education level will be reported using descriptive statistics, using frequencies and percentages. Continuous characteristics, such as age, will be reported using mean ±SD for continuous variables that are normally distributed and as median and 25th and 75th percentiles for non-normally distributed variables. Non-normally distributed variables will also be dichotomized and analyzed as categorical data, as described above. Changes in participants' scores from their baseline visit to follow up at one year will be by repeated measures ANOVA with generalized linear mixed modelling (GLMM) to account for missing variables. Multivariate linear regression analyses will be performed to determine which participant characteristics moderate primary and secondary treatment outcomes.

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

We will also conduct a process evaluation to explore the implementation, receipt and context of the intervention with a view to helping understand the results in accordance with the Medical Research Council's guidelines on assessing complex interventions [77]. This will describe the processes of the intervention group, provide information about the contexts in which the treatments are delivered and supply information about the experience of being part of the trial. This will also include an exploration of the uptake of the intervention at various sites, including subgroup analyses of the number of face-to-face sessions completed as well as the extent to which participants used the smartphone application

Missing Data

The analysis of the primary outcome will be based on self-report data collected through the BEACON Suicide Prevention Smartphone Application. As such, the

completeness of the data will be impacted by participant withdrawals. In order to minimize the impact of participant drop out, withdrawal and those who are lost to follow-up, the research team will follow-up with participants regarding the completion of the study questionnaires at their PST appointments. The smartphone application will also be used to prompt and remind participants to complete the study questionnaires. Should participants be lost to follow-up, a delegated study staff member will follow-up with them directly to complete the questionnaires either by telephone or by mail. Where possible, a delegated study staff member will attempt to ascertain the reasons for drop out or withdrawal from participants in order to address any issues within the research team's control in order to prevent future study withdrawals.

As such, it is possible that there may be missing data. Characteristics of participants with missing data will be compared to those of participants with complete data to examine the assumption of Missing at Random. In the case of substantial missingness (e.g., >5%), missing outcomes will be imputed using multiple imputation prior to analysis.

4.4. Monitoring

4.4.1. Data Monitoring

An independent Data and Safety Monitoring Committee (DSMC) has been convened to assess the progress of the clinical trial, the integrity of the data, the safety of all participants and to provide recommendations to the Principal Investigators. The members of the DSMC serve in an individual capacity and provide their expertise and recommendations. The DSMC will review cumulative study data to evaluate safety, study conduct, and scientific validity and data integrity of the study. The general responsibilities of the DSMC are:

- To evaluate, on an ongoing basis, the accumulating safety assessments to ensure the ongoing safety of study participants;
- To consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study;
- To review the conduct of the study, including protocol violations and deviations;
- To review 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;
- DSMC members will review Adverse Events (AEs) and Serious Adverse Events (SAEs); and
- To make recommendations to continue, modify, or terminate the study.

4.4.2. Harms

In this clinical trial, an Adverse Event (AE) will be defined as any untoward medical occurrence which may or may not be related to the study intervention. This includes unfavourable changes in symptoms, signs, or health conditions. AEs will be collected by

study staff at each study time point from the point of consent until the end of a participant's involvement in the study (due to withdrawal, discontinuation, or study completion). If a participant reports an AE after the point of consent but prior to receiving the study intervention, this AE will be categorized as unrelated to the study treatment.

All AEs will be reviewed and classified by the site co-Principal Investigator, at his/her discretion. Investigators will determine relatedness of an event to the study intervention based on a temporal relationship to the study intervention, as well as whether the event is unexpected or unexplained given the participant's clinical course, previous medical conditions/history, and concomitant medications or interventions.

In this clinical trial, a Serious Adverse Event (SAE) will be defined as any untoward medical occurrence that meets one of the following criteria: results in death; is life threatening; requires inpatient hospitalization or prolongs existing hospitalization; results in persistent or significant disability/incapacity; or, causes a congenital anomaly/birth defect. All AEs that meet the criteria for an SAE will be reported to the Coordinating Study Site, DSMC and REB within seven (7) days of their occurrence. All subsequent suicidal behaviour will be treated as an SAE and will be monitored, investigated and tracked by the research team. A file will be kept by delegated study staff members in which all SAEs will recorded. A participant's physician and/or other specialists will also be contacted to advise them of their patient's participation in the study (with consent) and in the case of a Serious Adverse Event (SAE).

The following occurrences will be routinely collected and assessed by delegated study staff members:

- Death by suicide;
- Subsequent self-harm;
- Visits to the Emergency Department or other unscheduled hospitalizations; and,
- Re-presentations to the Emergency Department for self-harm.

After Session 6 of the face-to-fact PST, study participants will be classified as "passive participants" within the BEACON smartphone application. That is, while they are no longer receiving routine follow-up from study staff, they will still be considered study participants and will have access to all the resources housed within the smartphone application. This will occur between Session 6 (final PST session) and Session 7 (6 month/End of Study). During this time, participants will receive automated safety monitoring through the BEACON smartphone application. If participants find themselves in a mental health crisis and select the "BEACON" feature, they will be prompted to connect with one of the following: emergency services via 911, a local mental health crisis line or one of their listed emergency contacts. Through the Clinician Dashboard, their Research Therapist will also be notified that they have enacted the "BEACON" feature. The Research Therapist will then follow-up with the participant in order to ensure their ongoing safety and document any required AE or SAE information.

4.4.3. Study Monitoring

A site initiation meeting/videoconference will be conducted once the site has received all regulatory and REB approvals, but before recruitment has begun. All study team members for this site will attend in addition to the Research Coordinator, Principal Investigator and co-Principal Investigator for the trial. The Principal Investigator and Research Coordinator will conduct site initiation and will cover the items listed below in order to ensure that all study staff are aware of their delegated duties:

- Study Protocol;
- Study-specific SOPs;
- Complete review of Baseline Appointment and follow-up appointment documentation;
- ICH-GCP compliance;
- Adverse Event and Serious Adverse Event recording and reporting;
- Protocol deviation and violation management;
- Internal study monitoring procedures and requirements; and
- Delegated study staff responsibilities (including site co-Principal Investigator).

The Principal Investigator, or appropriate delegate, will generate a brief report on the material covered and any additional training required. The Principal Investigator, or appropriate delegate will forward the report to the site for review and sign-off no later than 10 business days from site initiation. Once the site initiation visit is complete, an internal monitor will be selected. This monitor will not be involved in data collection activities and will be one-step removed from the clinical trial.

The internal monitor will perform the first monitoring visit at each site shortly after the site has recruited their first participant to ensure that research personnel have implemented the appropriate recruitment processes and procedures, such as eligibility sign-off and consent. This visit will be completed prior to the site recruiting more participants. Any corrective actions implemented in regards to inconsistencies identified during the previous monitoring visits will be assessed for completeness. Based on the research category and participant/institute risk exposure, remote monitoring visits will occur every month after the first monitoring visit. The internal monitor may schedule more visits or on-site visits as needed.

During the remote monitoring visit(s), the monitor will perform the following source document verification and study master file review:

- 25% of patients' Informed Consent Forms (ICFs) and Eligibility Criteria;
- 25% of the Adverse Events and all Serious Adverse Events that have been reported since the previous monitoring visit will be reviewed and verified;
- 25% of protocol-related endpoints will be assessed for all applicable participants;
- 15% of patients' charts will be audited for accuracy and completeness;
- All training documentation/records and delegation log;
- All regulatory documentation including REB approvals/amendments (stored at coordinating site).

If the monitor notices a large number of discrepancies during the visit, they may perform additional verification of source documents and/or internal monitoring visits as needed.

The monitor will also conduct close-out procedures once the last enrolled participant has completed his/her final study visit. During close-out, the monitor will perform the following tasks:

- Ensure the completion of outstanding charting documents;
- Ensure all previous monitoring corrections have been addressed;
- Collect outstanding patient data forms and study forms such as the screening and enrolment logs;
- Perform a final review of the study file documents;
- Review the plans for record retention;
- Ensure all Adverse Events and Serious Adverse Events have been reported appropriately; and
- Ensure that the local REB has been notified of the site closure.

The monitor will prepare the final monitoring report and send it to the site for their records. The site will address all monitoring observations (including observations from previous monitoring reports) prior to final study closeout.

5. ETHICS AND DISSEMINATION

5.1. Research Ethics Approval

A pilot study was conducted for this study over a period of nine months from September 2016 to June 2017 that evaluated the acceptability and feasibility of using a beta version of smartphone-assisted problem-solving therapy with seven men who presented to the Emergency Department with intentional self-harm. A key goal of this study was to evaluate the process of using a smartphone application in conjunction with face-to-face psychotherapy. This study was reviewed and approved by the Ottawa Hospital Health Science Network Research Ethics Board (OHSN-REB Protocol # 20150765-01H). Through this REB review, the research team was able to solve a number of issues relating to data confidentiality and participant privacy which have been incorporated into the design of the BEACON Suicide Prevention Smartphone Application. Trial design and conduct has been informed by Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) and Good Clinical Practice (GCP), an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with these standards provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that clinical trial data are credible. This study protocol and the attached Informed Consent Forms (refer to Appendix B) will be reviewed and approved by the REB of Record, as assigned by Clinical Trials Ontario (CTO), and any other local Research Ethics Board (REB) required by participating sites. Subsequent to initial review, the Principal Investigator will complete annual progress reports, to be submitted to the REB annually, which will describe the progress of the trial, including recruitment and follow-up rates, participant safety and any changes to the study protocol and/or Informed Consent Forms.

This study protocol will be registered with clinicaltrials.gov.

5.2. Protocol Amendments

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. Any modifications or new information that may impact a participant's willingness to participate in the study will be relayed to participant's as soon as possible and they will be asked to sign a Consent Update Form, as approved by the REB.

5.3. Consent

5.3.1. Informed Consent

Staff at the intervention sites, including psychiatrists, residents, , nurses and/or other clinical staff will approach patients with information about the study. To avoid coercion and overburdening of staff, they will be not be responsible for any consent-related tasks. If the patient is interested in participating in the study, staff will obtain consent for a research staff member to contact them. The delegated research staff will then contact the patient to provide further information about the study, answer any questions and schedule a consent visit.

At the consent visit, a delegated study staff member will provide the patient with additional information about the study and confirm their interest in participating. Once this is complete, the delegated study staff member will conduct an informed consent discussion with the patient, in accordance with ICH GCP regulations, and the patient will have an opportunity to ask any study-related questions prior to signing the consent form. Consent visits may occur using videoconference platforms, including MS Teams, Zoom for Healthcare, Zoom in Epic and OTN. Written consent will also be accepted as an electronic signature, including scan and email or digital signature. Once written informed consent has been obtained, the delegated study staff member will schedule the Baseline Visit as detailed in this study protocol. While all versions of the consent form will be standardized, they will be edited to include appropriate language and letterhead, as dictated by each study site's local regulations. The consent forms will be translated into French and Oji Cree (as appropriate).

5.3.2. Ancillary Studies

If this protocol is amended to include any ancillary studies, upon approval of the REB, all participants involved in these ancillary studies will be asked to sign a Consent Update Form. If a separate Informed Consent Form is required, a copy of the consent form will be stored with the BEACON Study consent documentation. Copies of all REB approvals for the ancillary studies will be stored at the Coordinating Study Site. A data file tracking all signed ancillary consent forms must be maintained by the ancillary study and provided to the Clinical Research Coordinator of the BEACON Study.

5.4. Confidentiality

All study-related documentation will be double-locked in areas with limited access at the appropriate study site. For virtual visits, electronic documents may be completed and stored on the study-specific SharePoint. Study documents should be password protected and a log kept separately from the documents so that access to the files is not lost. Electronic documents should not be stored on mobile devices (such as a USB or directly on a laptop). All participants will be assigned a unique participant identification number, which will appear on all documentation included in a participant's research chart, including study forms, questionnaires, participant progress notes and correspondence in order to maintain participant confidentiality. All correspondence with participants' will be de-identified in order to remove names and other potentially identifying information prior to being included in the study chart. All documentation, including signed Informed Consent Forms, the participant information form and messaging logs will be stored in double-locked filing cabinets in areas with limited access and stored separately for participant research charts to avoid linking a participant's name and unique identification number.

Each study site will have a separate Master Tracking Log which will link participants' names and identification numbers. These will be password-protected and only delegated research staff at that site will have access to it. Participant information will be stored on the secured hospital servers at each study site. The password-protected documents containing participant study data will be transferred to the coordinating study site by email, as per N2 and OHRI guidelines. Data entered into the EDCS is stored on the OHRI secure server. Study staff are all provided unique username and password combinations. The EDCS will not capture or store any identifiable information. All data is encrypted at rest as well as in transit. Participants' study information will not be released unless a delegated study staff member obtains written permission from the participant or where required by law. Participants will not be identified in study presentations or publications. All participant records will be kept for a period of ten years, as indicated in the ICH GCP guidelines.

5.5. Declaration of Interests

The study Investigators have the following interests to declare:

1. Dr. Sakina Rizvi:
    - 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.

5.6. Access to Data

The Coordinating Study Site will be responsible for the sharing of data between study Investigators. Upon request, all Investigators will be provided with cleaned copies of the study datasets (please refer to Section 5.8.3 "Reproducible Research" regarding the sharing of data). All trial data will be stored on the OHRI secured server at the Coordinating Study Site and will be password-protected. Site co-Principal Investigators will have direct access to data collected from their site and may obtain access to the data from other sites upon request (refer to Section 5.8.3 "Reproducible Research" regarding the sharing of data). In order to protect participant confidentiality, all potentially identifying information will be removed from the datasets prior to intra-study sharing.

5.7. Ancillary and Post-Trial Care

In the event of a study-related injury or illness, participants will be provided with appropriate medical treatment and care. Financial compensation for lost wages, disability or discomfort due to an injury or illness is not generally available.

5.8. Dissemination Policy

5.8.1. Trial Results

Data Analysis and Release of Results

To protect the scientific integrity of this study, data from all sites will be analyzed and reported together. While 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 ICES. 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 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, and 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 outcomes publications. Primary outcomes publications refer to any presentation or publication that presents data on the primary outcome measure 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 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

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.

6. APPENDICES

6.1. Appendix A – Completion Time Required for All Outcome Measures included in Study

Domain	Measure	Purpose of Measure	Time Needed to Complete Measure	Baseline & Session 1	During Study Intervention	6 Week Follow-Up	Post-Study 3 month and 12 month
Demographics	Demographic Questionnaire	Descriptive Statistics/ Covariates	3-5 min.	X			
Media	Influence of the Media Questionnaire	Covariate	3-5 min.	X			
Masculinity	CMNI	Covariate	5-10 min.	X			
Suicidality	BSS	Primary Outcome	5-10 min.	X		X	X
Depression	PHQ-9	Secondary Outcome	5-10 min.	X		X	X
Anxiety	GAD-7	Secondary Outcome	5-10 min.	X		X	X
PTSD	PC-PTSD-5	Secondary Outcome	3-5 min.	X		X	X
Health-Related Quality of Life	EQ-5D	Secondary Outcome	3-5 min.	X		X	X
Meaning in Life	Experienced Meaning in Life Scale	Secondary Outcome	5-10 min.	X		X	X
Social Support	Multidimensional Scale of Perceived Social Support	Secondary Outcome	5-10 min.	X		X	X
Alcohol Misuse	AUDIT-C	Covariate	2-3 min.	X		X	X
Alcohol Misuse	AUDIT* *Only to be administered in the event of a positive screen on the AUDIT_C	Covariate	3-5 min.	X		X	X
Drug Misuse	DAST-10	Covariate	3-5 min.	X		X	X
Costs	TiC-P	Secondary Outcome	5-10 min	X		X	X
Problem-Solving Skills	SPSI-R:S	Secondary Outcome	5-10 min.	X		X	X
Health service use data* *Collected from ICES databases	• Previous hospitalizations for self-harm (NACRS);	Secondary Outcome	N/A	X			X

	• 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.

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