Study Protocol

Protocol Name:	The BEACON Study: Protocol for a cluster randomized controlled trial of a service to deliver smartphone-assisted problem solving therapy compared to usual care in men who present with intentional self-harm to Emergency Departments in Ontario
Clinical Trial Type:	Non-Regulated Investigational Clinical Trial
REB Reference Number	Pending
Funder	Ontario SPOR Support Unit (OSSU)
Sponsor	Ottawa Hospital Research Institute (OHRI)
Study Status	Active, not yet recruiting
Principal Investigator	Dr. Simon Hatcher
Co-Principal Investigator	Dr. Marnin Heisel
Members of Steering Committee	1. Dr. Simon Hatcher 2. Dr. Marnin Heisel 3. Dr. Paul Links 4. Dr. Chris Mushquash 5. Dr. Sidney Kennedy 6. Dr. Susan Finch 7. Dr. Ayal Schaffer 8. Dr. Mark Sinyor 9. Dr. Monica Taljaard 10. Dr. David Koczerginski
Date of Trial Initiation (dd-mmm-yyyy)	

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.

Principal Investigator Name: Dr. Simon Hatcher
Co-Principal Investigator Name: Dr. Marnin Heisel

Coordinating Site: Ottawa Hospital Research Institute
Contact details: Tel No: (613) 798-5555, ext. 73011
Email: shatcher@uottawa.ca

Signature	Date (dd-mmm-yyyy)

Signature	Date (dd-mmm-yyyy)

Site Co-Principal Investigator Name:

Site Name: **[XXXXXXXXXXXXXXXXXX]**
Contact details: Tel No: **[XXXXXXXXXXXXXXXXXX]**
Email: **[XXXXXXXXXXXXXXXXXX]**
Fax: **[XXXXXXXXXXXXXXXXXX]**

Signature	Date (dd-mmm-yyyy)

Site Co-Principal Investigator Name:

Site Name: **[XXXXXXXXXXXXXXXXXX]**
Contact details: Tel No: **[XXXXXXXXXXXXXXXXXX]**
Email: **[XXXXXXXXXXXXXXXXXX]**
Fax: **[XXXXXXXXXXXXXXXXXX]**

Signature	Date (dd-mmm-yyyy)

World Health Organization Trial Registration Data Set Items

DATA CATEGORY	INFORMATION
Primary registry and trial identifying number	ClinicalTrials.gov Pending
Date of registration in primary registry	Pending
Source(s) of monetary or material support	Ontario SPOR Support Unit (OSSU)
Primary sponsor	Ottawa Hospital Research Institute
Contact for public queries	*Dr. Simon Hatcher*, MD Ottawa Hospital Research Institute, Ottawa, ON Tel: (613) 798-5555, ext. 73011 Email: shatcher@uottawa.ca
Contact for scientific queries	*Dr. Simon Hatcher*, MD Ottawa Hospital Research Institute, Ottawa, ON Tel: (613) 798-5555, ext. 73011 Email: shatcher@uottawa.ca
Public title	The BEACON Study
Scientific title	Protocol for a cluster RCT of a service to deliver smartphone assisted PST compared to usual care in men who present with intentional self-harm to Emergency Departments in Ontario: The BEACON Study
Countries of recruitment	Canada
Health condition(s) or problem(s) studied	Self-harm
Intervention(s)	Intervention: smartphone-assisted Problem-Solving Therapy (PST)

DATA CATEGORY	INFORMATION
	Control: standard clinical care
Key inclusion and exclusion criteria	Ages eligible for study: ≥18 years Sexes eligible for study: Male 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 an eligible Emergency Departments in Ontario, Canada. Exclusion criteria: patient presents to an eligible Emergency Department for a reason other than intentional self-harm.
Study type	Interventional Allocation: randomized, unbalanced Intervention model: parallel assignment Masking: none Primary purpose: prevention
Date of first enrolment	Pending
Target sample size	25 hospitals; anticipated total sample size of approximately 2,000 men
Recruitment status	Active, not yet recruiting
Primary outcome(s)	Composite measure of suicides and/or proportion of re-presentations to any Emergency Department in Ontario for intentional self-harm
Key secondary outcomes	Within one year of enrollment: • Number of suicides; • Proportion of self-harm re-presentations to any

DATA CATEGORY	INFORMATION
	Emergency Department in Ontario; • Proportion of re-presentations for any reason to any Emergency Department in Ontario; • Proportion of hospital admissions for any reason to any hospital in Ontario; • Length of stay at any hospital in Ontario for any reason; • Proportion of hospital outpatient appointments for any reason at any hospital in Ontario; • Number of deaths (mortality rate), for reasons other than suicide and undetermined deaths; • Proportion of primary care visits, defined as any visit to a general practitioner; • Total health care costs for the treatment of self-harm; • Physician costs for the treatment of self-harm; • Emergency Department costs for the treatment of self-harm; • Hospitalization costs for the treatment of self-harm; • Other costs related to the treatment of self-harm.

Table of Contents

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

Explanatory note: This protocol describes an evaluation of the effectiveness of the provision of a smartphone-assisted face-to-face clinical intervention in men who present to the Emergency Departments in Ontario. Randomization has been conducted at the cluster level (i.e. at the level of the Emergency Department). However, the unit of analysis in this study is the individual patient. This is a health systems analysis of a complex intervention, individual patients will be identified and followed-up using routinely collected administrative health information obtained through the Institute for Clinical Evaluative Sciences (ICES). As such, while the unit of analysis is the individual patient, no patients will be actively recruited and enrolled in this study. A separate protocol describes the evaluation of the impact of the smartphone-assisted face-to-face clinical information on the well-being of individual male participants. We have chosen to present the protocols in this way to provide clarity around methodological and ethical issues for this trial.

1. FUNDING

The Ontario SPOR Support Unit (OSSU) is funding the costs for the BEACON trial and recruitment of 25 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].

[1] University of Ottawa; Ottawa Hospital Research Institute
[2] Western University; Lawson Health Research Institute
[3] University of Ottawa; Ottawa Hospital Research Institute; Institute for Clinical Evaluative Sciences
[4] Ottawa Hospital Research Institute
[5] University of Toronto; Sunnybrook Health Sciences Centre
[6] University of Toronto; St. Michael's Hospital
[7] University of Ottawa
[8] University of Toronto; Sunnybrook Health Sciences Centre
[9] McMaster University
[10] Western University; St. Joseph's Health Care London; London Health Sciences Centre
[11] Lakehead University; Dilico Anishinabek Family Care
[12] Thunder Bay Regional Health Sciences Centre
[13] Mental Health Commission of Canada
[14] Suicide Prevention Consultant; Centre prévention suicide Le Faubourg - Laurentides Quebec
[15] Service User Representative

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 cluster randomized controlled trials (RCTs) and conducted the randomization procedure. 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 refinement of the study protocol and approved the final manuscript.

2.1.2. Sponsor contact information

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

Trial Sponsor: Ottawa Hospital Research Institute (OHRI)
Sponsor's Reference: 20150765
Contact name: Dr. Duncan Stewart
Address: 501 Smyth Road, Ottawa, ON K1H 8L6
Telephone: (613) 798-5555, ext.79017
Email: djstewart@ohri.ca

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.

2.2. Committees

2.2.1. 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).

2.2.2. Steering Committee (refer to title page for membership)

- 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.

2.2.3. 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 (REB);
- Serious Adverse Event (SAE) reporting to DSMC and REB;
- Responsible for Master Tracking Log;
- Budget administration and contractual issues with individual centres;
- Advice for lead investigators;
- Coordination of study monitoring;
- Assistance with REB applications;
- Data verification; and
- Randomization.

2.2.4. 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.

2.2.5. 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 Emergency Departments within the Champlain Local Health Integration Network indicate approximately 1,767 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]. Approximately four percent of individuals who have presented to the Emergency Department for the treatment of self-harm die by suicide within five years of their index presentation [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 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"[9].

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]. As such, 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]. 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 [14]. 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 [15]. Recurrent self-harm is associated with significant distress and many unresolved interpersonal problems [16].

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 [17]. 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 [18]. 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 [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]. Previous trials have found that providing generic treatments to everyone is

not particularly effective [21]; 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 [22]. 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 [23].

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)"[24]. 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 [25-26]. 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) [21]. 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) [27]. 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.

3.1.2. 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 [27]. 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 [28], increasing patient agency by fostering increased self-management skills [29], as well as case management benefits for mental health professionals [30]. 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 [31]. 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 [32] and the wider community as long as appropriate privacy and security measures are taken [33]. 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 [31]. However, the E-COMPARED study specifically excludes suicidal participants and those with co-morbid mental disorders, such as bipolar disorder or substance abuse.

3.1.3. 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 that variation in the provision of care is the norm [34]. 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 [35]. 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 [36]. 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 [37]. Fewer than one in three primary care physicians in Canada report being told when their patients attend an Emergency Department [38].

Following intentional self-harm, even fewer patients receive outpatient 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 [35]. 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 [37] and another trial finding 20% of people consenting to PST having received no sessions [40]. Methods to address the low rate of engagement include providing patients with a written discharge plan in the Emergency Department [27]; 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 [41]. 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 [42]. 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 [41]. These features are included as part of the BEACON Suicide Prevention Smartphone Application in this study.

3.2. Explanation for Choice of Comparators

An alternative to developing new interventions is to optimize standard clinical care. This usually consists of referral for psychiatric or psychological treatment as well as other health or non-health services. However, neither a systematic review nor a large multicentre study found a clear relationship between the nature and intensity of standard hospital care and subsequent fatal or non-fatal repetition of self-harm [44]. Specialist services offer intensive and lengthy treatment, such as dialectical behaviour therapy or mindfulness-based therapy for the minority of people who self-harm who are diagnosed with personality disorders. The evidence for the effectiveness of these therapies comes almost entirely from studies in women [21].

3.3. Objectives and Hypotheses

3.3.1. Primary Hypotheses and Objective

To determine whether the provision of a service that delivers smartphone-assisted PST specifically designed for men who present to the Emergency Department with self-harm, results in fewer suicides and/or contacts with Emergency Departments for self-harm, compared with usual care, in the year after the index episode.

We anticipate that in sites implementing a service that delivers smartphone-assisted PST specifically designed for men, 12 months after the index episode, there will be:

1. Fewer deaths by suicide; and/or
2. Fewer contacts with the Emergency Departments in Ontario for the repetition of self-harm.

3.3.2. Secondary Hypotheses and Objectives

The key secondary objectives are to determine, compared to usual care, whether the provision of a service that delivers smartphone-assisted PST specifically designed for men who present to the Emergency Department with self-harm, results in:

1. Lower suicide rates;
2. Fewer contacts with any Emergency Departments in Ontario for the repetition of self-harm;
3. Fewer contacts with any Emergency Department in Ontario for any reason;
4. Fewer admissions to hospital for any reason;
5. Fewer outpatient appointments for any reason at any hospital in Ontario;
6. Lower mortality rates, not related to suicide;
7. Lower use of primary care services (defined by contact with a family physician); and/or
8. Decreased costs to the health care system, including physician, hospitalization, Emergency Department, and other costs.

3.4. Trial Design

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

By randomizing entire sites with a waiver of informed consent for data collection with inclusion of all eligible men using routinely collected data, external validity of the study is maximized, in comparison to an individually randomized trial with a requirement to seek informed consent (refer to Section 5.3 Consent).

4. METHODS

4.1. Participants, Interventions and Outcomes

4.1.1. Study Setting

This multicenter cluster RCT will be conducted in 25 Emergency Departments in Ontario. The unit of randomization is selected Emergency Departments in each region (refer to Appendix A for a complete list of intervention and control sites).

4.1.2. Eligibility Criteria

Sites were deemed eligible if they averaged at least 50 self-harm presentations by men per year. and an absolute re-presentation rate of at least 6 over three years. This resulted in a list of 25 eligible Emergency Departments in Ontario. Eligible patients will be identified in

Table 1. Patient Eligibility Criteria

ICES, using the following criteria:

Inclusion Criteria	
1.	Patient has presented with an index episode of intentional self-harm at an eligible Emergency Department in Ontario, Canada.
2.	Patient is biologically male.
3.	Patient is 18 years of age or older.
4.	Patient has a valid OHIP number.
Exclusion Criteria	
1.	Patient has presented to the Emergency Department for a reason other than intentional self-harm at an eligible Emergency Department in Ontario, Canada.
2.	Patient is biologically female.
3.	Patient is under 18 years of age.
4.	Patient does not have a valid OHIP number.

Intentional self-harm is defined as intentional self-poisoning or self-injury, whether or not there is evidence that the act was intended to result in death. This will be identified using ICD-10-CM codes T14.91, X71-X83 ICD-10 codes from health administrative databases held at ICES.

4.1.3. Interventions

Emergency Departments randomized to the study intervention will receive:

1. Staff education incorporated into regular teaching rounds at least twice a year about the management of self-harm in the Emergency Department. This will include the dissemination of guidelines (APA, NICE, SPRC and CCSMH) [45] on how to ask questions about suicide, assessment of suicide risk, the creation of a management plan and how to refer patients to local mental health resources, including the study.

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

3. The option to refer men who self-harm to a service that will deliver smartphone-assisted PST specifically designed for men.

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

4.1.4. Outcomes

The primary outcome measure will be a composite of the incidence of suicides and/or re-presentations to any Emergency Department in Ontario for self-harm in the year after the index episode of self-harm. The incidence of suicide and re-representation to Emergency Department will be measured using ICD-10-CM codes T360-T50992, T510-T6592, T71112-T71232, X71-X83 (refer to Appendix A for full list of codes and descriptors) [46]. Individuals who died by suicide will be identified in ICES using the Vital Statistics - Death Database. A potential problem with the outcome measures in this trial is that the intervention may also change help-seeking behaviour. That is, men may seek out healthcare that they would not have in the past, which may lead to an increase in re-presentations to the Emergency Department for patients in the intervention group. In order to explore changes to health-related help-seeking, we will also collect data on primary care and hospital outpatient care not driven by emergencies through ICES. This will be measured in ICES, using the Ontario Health Insurance Plan (OHIP) Claims Database and National Ambulatory Care Reporting System Metadata (NACRS). We will also address this through a sub-study of smartphone-assisted PST.

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

Table 2. Outcome Measures

	Justification	Data Source	Data Collection Period
Primary Outcome Variable (composite outcome variable)			
Death by Suicide and/or re-presentation to any Emergency Department in Ontario for Self-harm	To assess the clinical impact of the provision of a smartphone-assisted PST service.	ORGD, NACRS (ICES)	Baseline; 12 months
Secondary Outcomes			
Death by Suicide	To assess the clinical impact of the provision of a smartphone-assisted PST service.	ORGD (ICES)	Baseline; 12 months
Re-presentation to any Emergency Department in Ontario for Self-harm	To assess the clinical impact of the provision of a smartphone-assisted	NACRS (ICES)	Baseline; 12 months

	PST service.		
Re-presentation to any Emergency Department for any reason	To assess the clinical impact of the provision of a smartphone-assisted PST service.	NACRS (ICES)	Baseline; 12 months
Admission to any hospital in Ontario for any reason	To assess the clinical impact of the provision of a smartphone-assisted PST service.	NACRS (ICES)	Baseline; 12 months
Hospital outpatient appointments in Ontario for any reason	To assess the clinical impact of the provision of a smartphone-assisted PST service.	OHIP (ICES)	Baseline; 12 months
Primary care appointments	To assess the clinical impact of the provision of a smartphone-assisted PST service.	OHIP (ICES)	Baseline; 12 months
Mortality for reasons other than suicide	To assess the clinical impact of the provision of a smartphone-assisted PST service.	ORGD (ICES)	Baseline; 12 months
Total Health Care Costs	To assess the economic impact of the provision of a smartphone-assisted PST service.	OHIP, DAD, NACRS, NRS, CCRS, OMHRS, ODB, ADP (ICES)	Baseline; 12 months
Physician Health Care Costs	To assess the economic impact of the provision of a smartphone-assisted PST service.	OHIP (ICES)	Baseline; 12 months
Emergency Department Health Care Costs	To assess the economic impact of the provision of a smartphone-assisted PST service.	NACRS (ICES)	Baseline; 12 months
Hospitalization Health Care Costs	To assess the economic impact of the provision of a smartphone-assisted PST service.	DAD (ICES)	Baseline; 12 months
Other Health Care Costs	To assess the economic impact of the provision of a	NRS, CCRS, OMHRS, ODB, ADP (ICES)	Baseline; 12 months

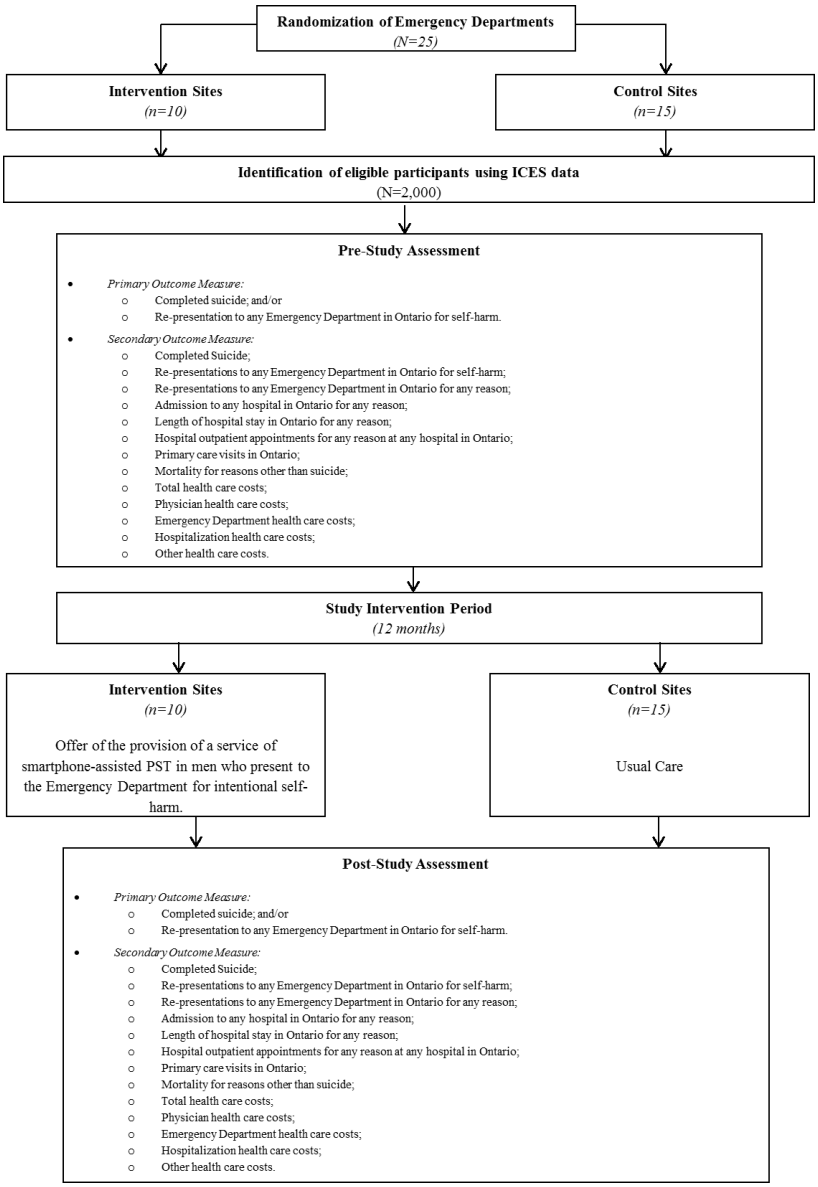
	smartphone-assisted PST service.		
Prognostic outcome measures			
Age	To assess differences between subgroups.	RPDB (ICES)	Baseline
Previous hospitalization for self-harm	To assess differences between subgroups.	NACRS (ICES)	Baseline
Previous hospitalization for substance use	To assess differences between subgroups.	NACRS (ICES)*	Baseline

**** Appendix B for list of ICD-10-CM codes.***
Data Sources: *ADP, Assistive Devices Program; CCRS, Continuing Care Reporting System; DAD, Discharge Abstract Database; NACRS, National Ambulatory Care Reporting System; NRS, National Rehabilitation Reporting System; ODB, Ontario Drug Benefit Claims; OHIP, Ontario Health Insurance Plan Claims Database; OMHRS, Ontario Mental Health Reporting System; RPBD, Registered Persons Database; ORGD, Vital Statistics – Death.*

4.1.5. Sample Size

Power calculations for this trial were carried out within the logistical and practical constraints of the trial; in particular, a maximum of 25 sites are available for randomization, whereas the intervention can be implemented at only 10 sites. Consistent with previous clinical trials, we would consider a **minimum relative reduction of 50%** in the repetition rate to be both clinically important and achievable [47-49]. To conduct an accurate power calculation, we obtained data from ICES regarding the number of presentations with self-harm by men and the re-presentation rate to every hospital in Ontario from 2012 to 2014. Using these data, we calculated an anticipated baseline repetition rate (primary outcome) after 12 months of 13%. We also calculated an intracluster correlation coefficient (ICC) of 0.01 and an inter-period correlation of 0.008 (to account for over time correlations between pre- and post-intervention measures of the primary outcome). Given an average cluster size of 80 men and a coefficient of variation of cluster sizes (to account for imbalances in sizes) of 30%, 10 intervention clusters and 15 control clusters (2000 men) achieve **90% power** to detect the minimum important difference. With 80% power, the detectable difference is a relative reduction of 41%, i.e., from a control arm rate of 13% to an intervention arm rate of 7.7% (an absolute reduction of 5.3%).

4.1.6. Study Timeline



4.2. Assignment of Interventions

4.2.1. Allocation to Intervention

To minimize the risk of imbalances between the study arms, allocation to the intervention or control arm was implemented using covariate constrained allocation [50]. Allocation was constrained based on: i) geographic areas, defined by whether the catchment area was predominantly urban or rural; ii) whether there was an onsite psychiatric service which assesses people in the Emergency Department; iii) size defined by the average number of presentations for self-harm for both men and women over a 3 year period; and iv) re-presentation rate among men with intentional self-harm 12 months after the index episode. There was a total of over 3 million possible allocations of 10 intervention and 15 control sites, of which 7,131 of 100,000 randomly selected allocations met the pre-specified balancing constraints, namely a maximum difference of 3 between number of urban/rural

sites, a maximum difference of 3 in number of sites with onsite psychiatric service, a maximum difference in mean cluster size of 60, and a maximum difference in baseline re-presentation rate of 3%. Among the 7,131 possible acceptable allocations, one allocation was selected at random using a computer-generated random number.

4.2.2. Blinding

Once randomization was complete, study sites allocated to the intervention arm were approached regarding their interest to participate in the study. Gatekeepers were not approached prior to randomization as the investigative team determined that informing 25 sites and getting their agreement prior to randomization would result in significant delays to the study and that it was unlikely that hospitals would decline to participate in this study. Additionally, there were concerns regarding changes in institutional behaviour at the control sites as a result of knowing about the study. Should any intervention sites refuse to participate in the trial, they will be included in the final analyses as part of the intervention arm in order to respect the intent-to-treat (ITT) principle.

Control sites will be unaware of their participation in the study as men who present with self-harm will be receiving their usual care and all outcome measures are routinely collected by ICES.

4.3. Data Collection, Management and Analysis

4.3.1. Data Collection

Data Collection Methods

Trial outcomes comprise routinely collected data which are housed at ICES. Access to all outcome data has been agreed upon with ICES.

Retention

Emergency Departments

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

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

Participants

This study will focus on the evaluation of a complex intervention based on routinely collected population-level health data. **Given this, there will be no individual participant**

recruitment for this study. All data collected through ICES will thus be included in the primary analysis irrespective of uptake of the smartphone-assisted PST.

4.3.2. Data Management

All electronic and hardcopies the study Case Report Forms will be stored at the Coordinating Study Site in areas with limited access. All electronic data will be stored on a secured server at The Ottawa Hospital. Once all data monitoring, validation and cleaning activities are complete, these records will be archived at a secure storage facility for a period of ten years, as required by ICH GCP guidelines.

4.3.3. Statistical Methods

Outcomes

The unit of analysis will be the individual patient. To evaluate the effectiveness of the complex intervention at population-level (primary trial analysis), all outcomes will be obtained from ICES, regardless of whether men received or participated in the study therapy. Dichotomous primary and secondary outcomes will be described, by arm, using frequencies and percentages. The primary composite outcome as well as its individual components (completed suicides and re-presentations within 1 year) will be compared between the intervention and control sites using generalized linear mixed effects regression, accounting for the pre-and post-intervention measures using repeated cross-sectional analysis [51]. Differences between the arms will be expressed as absolute and relative differences in proportions, together with 95% confidence intervals. Models will account for clustering at the Emergency Department level and over time using random effects. Cluster level covariates for factors used in the allocation procedure, namely urban/rural, onsite psychiatric service, and size will be included in regression models. Additional analyses will adjust for individual prognostic variables including age, ethnicity, pre-specified comorbidities (such as previous hospitalizations for substance use), and repeat as compared with first-time presentations for self-harm.

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

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

Health Economic Evaluation

We will conduct a cost-utility analysis from health system's perspective to assess the value for money of the smartphone-assisted PST compared to standard clinical care. A decision analytic model will be used to synthesize data on resource use, clinical outcomes, and health utility values obtained from the trial and the published literature. Costs associated with the intervention will be summarized over the one-year period. Total costs of the intervention will include the cost of smartphone-assisted PST development, training, data plan, supplies/materials and costs associated with the health care use over the one-year period. We will use a micro-costing technique by identifying, measuring, and valuing resources used [52]. Health care resource use will be obtained from the health administrative databases housed at ICES which contain information on physician visits including primary care and specialists, inpatient hospital admissions, including mental health institutions, emergency and ambulatory care visits, home care and rehabilitation claims, use of laboratory services, and prescription drug claims for those with high drug costs compared to their income. The efficacy of the smartphone-assisted PST will be obtained from the concurrent trial while the health utility values associated with self-harm and smartphone-assisted PST will derived from the concurrent cohort study. A one-year time horizon will be adopted in a base case analysis, and a lifetime horizon will be used in a scenario analysis. As a secondary analysis, we will take the societal perspective and include productivity loss in a cost calculation. The loss of productivity data will be gathered from the published literature.

An incremental cost per one additional quality-adjusted life year (QALY) gained will be estimated. Uncertainty in the analysis will be assessed using one-way and probabilistic sensitivity analyses. The cost-utility analysis will adhere to the best practices for conducting and reporting of health economic evaluations[53-54]. Both costs and health outcomes will be discounted using an annual rate of 1.5% as recommended by the Canadian Agency for Drugs and Technologies in Health. The analysis will be performed by a health economist at the Ottawa Methods Centre and will be overseen by Dr. Kednapa Thavorn.

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);
- To make recommendations to continue, modify, or terminate the study.

4.4.2. Harms

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

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 the site initiation visit 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 intake and follow-up 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, on-site monitoring visits will occur every eight months after the first monitoring visit. The internal monitor may schedule more visits as needed.

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

- 15% of all Case Report Forms will be audited for accuracy and completeness;
- All training documentation/records and delegation log; and
- All regulatory documentation including REB approvals/amendments.

If the monitor notices a large number of discrepancies during the visit, they may perform additional verification of source documents and/or recommend additional 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 all previous monitoring corrections have been addressed;
- Collect outstanding patient data forms and study forms such as Case Report Forms;
- Perform a final review of the study file documents;
- Review the plans for record retention;
- 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

Trial design and conduct has been informed by TCPS 2 and ICH 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 will be reviewed and approved by the Research Ethics Board (REB) of Record, as assigned by Clinical Trials Ontario (CTO), and any other local REB required by participating sites. Subsequent to initial review, the Principal Investigator will complete 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 published in *Trials Journal*, will be reported in accordance with CONSORT guidelines for cluster randomized trials [55], and 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.

5.3. Consent

5.3.1. Waiver of Consent

In order to appropriately address the research questions and objectives of this study, we will be requesting a waiver of informed consent from the 25 Emergency Departments to be included in this study. We will not ask patients presented to Emergency Departments for their consent to take part in the study as the outcome data that we are collecting are already routinely collected by ICES. As per the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), an exception to the requirement to seek prior consent may be requested if the clinical trial meets the following criteria:

1. The research involves no more than minimal risk to the participants;
2. The alteration to consent requirements is unlikely to adversely affect the welfare of participants;
3. It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
4. In the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and
5. The plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B [56].

We will be conducting a sub-study of the effectiveness of smartphone-assisted PST at the intervention sites. Eligible patients in this sub-study will be consented and enrolled according to TCPS 2 and GCP recommended guidelines. There are numerous precedents of studies analyzing ICES data which do not ask for individual patient consent to use their data [57].

5.4. Ancillary Studies

There is a cohort study planned for this protocol which will evaluate the effectiveness of smartphone-assisted PST. The protocol for this ancillary study will be submitted to the REB and, upon approval of the REB, all participants involved in this ancillary study will be asked to sign an Informed Consent Form. Copies of all REB approvals for the ancillary study will be stored at the study site as well as the Coordinating Study Site. All study files will be stored at the study site according to TCPS 2 and GCP guidelines.

5.5. Confidentiality

All study-related cohorts will be created by Data Analytic Services at ICES Central. These cohorts will be transmitted to The Ottawa Hospital Civic Campus, a satellite ICES

location, for analyses by statisticians affiliated with the Ottawa Methods Centre at The Ottawa Hospital. All data provided by ICES are de-identified, anonymized routinely collected data.

All study-related documentation will be double-locked in areas with limited access at the appropriate study site. All documentation, including Case Report Forms will be stored in double-locked filing cabinets in areas with limited access. All study records will be kept for a period of ten years, as indicated in the ICH GCP guidelines, or more depending on local regulations.

5.6. 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-BINDED), funded by the Ontario Brain Institute (OBI). She also received research grant funding from Pfizer Canada.

5.7. 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 (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.

5.8. Ancillary and Post-Trial Care

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

5.9. Dissemination Policy

5.9.1. Trial Results

Data Analysis and Release of Results

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

Review Process

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

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

Primary Outcome Publications

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

Other Study Papers, Abstracts and Presentations

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

Close-Out Procedures

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

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

Reporting of Study Results

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

5.9.2. 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 who are responsible for the various aspects of the trial will be identified. 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 in order of contribution.

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;

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, including those who have completed their involvement with the study.

5.9.3. 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 retain exclusive access to the data for two years post-study closeout. After this time, 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 data will become publically available upon request.

6. APPENDCIES

6.1. Appendix A – Complete List of Study Sites

- Brant Community Health System (Brantford General Hospital Site), Brantford, ON ;
- Cambridge Memorial Hospital, Cambridge, ON;
- Grand River Memorial Hospital Corporation (Waterloo Site), Waterloo, ON;
- Guelph General Hospital, Guelph, ON;
- Halton Healthcare Services Corporation (Oakville Site), Oakville, ON;
- Health Sciences North (Laurentian Site), Sudbury, ON;
- Hotel-Dieu Grace Healthcare (St. Joseph's Site), Windsor, ON;
- Kingston General Hospital, Kingston, ON;
- Lakeridge Health (Oshawa Site), Oshawa, ON;
- London Health Sciences Centre (Victoria Hospital Site), London, ON;
- Mount Sinai Hospital, Toronto, ON;
- Niagara Health System (Greater Niagara and St. Catharines General Sites), Greater Niagara and St. Catharines, ON;
- The Ottawa Hospital (General and Civic Sites), Ottawa, ON;

- Peterborough Regional Health Centre, Peterborough, ON;
- Queensway-Carleton Hospital; Ottawa, ON;
- Royal Victoria Regional Health Centre, Barrie, ON;
- Sault Area Hospital, Sault Ste. Marie, ON;
- Sioux Lookout Meno-Ya-Win Health Centre, Sioux Lookout, ON;
- St. Joseph's Healthcare System (Hamilton Site), Hamilton, ON;
- St. Joseph's Healthcare Centre, Toronto, ON;
- St. Michael's Hospital, Toronto, ON;
- Sunnybrook Health Sciences Centre, Toronto, ON;
- Thunder Bay Regional Health Sciences Centre, Thunder Bay, ON;
- Trillium Health Partners (Mississauga Site), Mississauga, ON;
- William Osler Health System (Civic Site), Brampton, ON.

6.2. Appendix B – ICD-10-CM Self-Harm Codes Included in Collection

Code*	Description
Self-Injury	
X710XXA, X710XXD, X710XXS	Intentional self-harm by drowning or submersion while in bathtub.
X711XXA, X711XXD, X711XXS	Intentional self-harm by drowning or submersion while in swimming pool.
X712XXA, X712XXD, X712XXS	Intentional self-harm by drowning or submersion after jump into swimming pool.
Self-Injury	
X713XXA, X713XXD, X713XXS	Intentional self-harm by drowning and submersion in natural water.
X718XXA, X718XXD, X718XXS	Other intentional self-harm by drowning or submersion.
X719XXA, X719XXD, X719XXS	Intentional self-harm by drowning or submersion, unspecified.
X72XXXA, X72XXXD, X72XXXS	Intentional self-harm by handgun discharge.
X730XXA, X730XXD, X730XXS	Intentional self-harm by shotgun discharge.
X731XXA, X731XXD, X731XXS	Intentional self-harm by hunting rifle discharge.
X732XXA, X732XXD, X732XXS	Intentional self-harm by machine-gun discharge.
X738XXA, X738XXD, X738XXS	Intentional self-harm by other larger firearm discharge.
X739XXA, X739XXD, X739XXS	Intentional self-harm by unspecified larger firearm discharge.
X7401XA, X7401XD, X7401XS	Intentional self-harm by airgun.
X7402XA, X7402XD, X7402XS	Intentional self-harm by paintball gun.

Self-Injury	
X7409XA, X7409XD, X7409XS	Intentional self-harm by other gas, air or spring operated gun.
X748XXA, X748XXD, X748XXS	Intentional self-harm by other firearm discharge.
X749XXA, X749XXD, X749XXS	Intentional self-harm by unspecified firearm discharge.
X75XXXA, X75XXXD, X75XXXS	Intentional self-harm by explosive material.
X76XXXA, X76XXXD, X76XXXS	Intentional self-harm by smoke, fire and flames.
X770XXA, X770XXD, X770XXS	Intentional self-harm by steam or hot vapours.
X771XXA, X771XXD, X771XXS	Intentional self-harm by hot tap water.
X772XXA, X772XXD, X772XXS	Intentional self-harm by other hot fluids.
X773XXA, X773XXD, X773XXS	Intentional self-harm by hot household appliances.
X778XXA, X778XXD, X778XXS	Intentional self-harm by other hot objects.
X779XXA, X779XXD, X779XXS	Intentional self-harm by unspecified hot objects.
X780XXA, X780XXD, X780XXS	Intentional self-harm by sharp glass.
X781XXA, X781XXD, X781XXS	Intentional self-harm by knife.
X782XXA, X782XXD, X782XXS	Intentional self-harm by sword or dagger.
X788XXA, X788XXD, X788XXS	Intentional self-harm by other sharp object.
X789XXA, X789XXD, X789XXS	Intentional self-harm by unspecified sharp object.
X79XXXA, X79XXXD, X79XXXS	Intentional self-harm by blunt object.
X80XXXA, X80XXXD, X80XXXS	Intentional self-harm by jumping from a high place.
X810XXA, X810XXD, X810XXS	Intentional self-harm by jumping or lying in front of a motor vehicle.
X811XXA, X811XXD, X811XXS	Intentional self-harm by jumping or lying in front of (subway) train.
X818XXA, X818XXD, X818XXS	Intentional self-harm by jumping or lying in front of other moving object.
X820XXA, X820XXD, X820XXS	Intentional collision of motor vehicle with other motor vehicle.
X821XXA, X821XXD, X821XXS	Intentional collision of motor vehicle with train.

Self-Injury	
X822XXA, X822XXD, X822XXS	Intentional collision of motor vehicle with tree.
X828XXA, X828XXD, X828XXS	Other intentional self-harm by crashing of motor vehicle.
X830XXA, X830XXD, X830XXS	Intentional self-harm by crashing of aircraft.
X831XXA, X831XXD, X831XXS	Intentional self-harm by electrocution
X832XXA, X832XXD, X832XXS	Intentional self-harm by exposure to extremes of cold
X838XXA, X838XXD, X838XXS	Intentional self-harm by other specified means.

Poisoning:	
T360X2A, T360X2D, T360X2S	Poisoning by penicillins, intentional self-harm.
T361X2A, T361X2D, T361X2S	Poisoning by cephalosporins and other beta-lactam antibiotics, intentional self-harm.
T362X2A, T362X2D, T362X2S	Poisoning by chloramphenicol group, intentional self-harm.
T363X2A, T363X2D, T363X2S	Poisoning by macrolides, intentional self-harm.
T364X2A, T364X2D, T364X2S	Poisoning by tetracyclines, intentional self-harm.
T365X2A, T365X2D, T365X2S	Poisoning by aminoglycosides, intentional self-harm.
T366X2A, T366X2D, T366X2S	Poisoning by rifampicins, intentional self-harm.
T367X2A, T367X2D, T367X2S	Poisoning by antifungal antibiotics, intentional self-harm.
T368X2A, T368X2D, T368X2S	Poisoning by other systemic antibiotics, intentional self-harm.
T3692XA, T3692XD, T3692XS	Poisoning by unspecified systemic antibiotic, intentional self-harm.
T370X2A, T370X2D, T370X2S	Poisoning by sulfonamides, intentional self-harm.
T371X2A, T371X2D, T371X2S	Poisoning by antimycobacterial drugs, intentional self-harm.
T372X2A, T372X2D, T372X2S	Poisoning by antimalarials and drugs acting on other blood protozoa, intentional self-harm.
T373X2A, T373X2D, T373X2S	Poisoning by other antiprotozoal drugs, intentional self-harm.
T374X2A, T374X2D, T374X2S	Poisoning by anthelminthics, intentional self-harm.
T375X2A, T375X2D, T375X2S	Poisoning by antiviral drugs, intentional self-harm.
T378X2A, T378X2D, T378X2S	Poisoning by other specified systemic anti-infectives and antiparasitics, intentional self-harm.
T3792XA, T3792XD, T3792XS	Poisoning by unspecified systemic anti-infective and antiparasitics, intentional self-harm.
T380X2A, T380X2D, T380X2S	Poisoning by glucocorticoids and synthetic analogues, intentional self-harm.
T381X2A, T381X2D, T381X2S	Poisoning by thyroid hormones and substitutes, intentional self-harm.
T382X2A, T382X2D, T382X2S	Poisoning by antithyroid drugs, intentional self-harm.
T383X2A, T383X2D, T383X2S	Poisoning by insulin and oral hypoglycemic [antidiabetic] drugs, intentional self-harm.
T384X2A, T384X2D, T384X2S	Poisoning by oral contraceptives, intentional self-harm.
T385X2A, T385X2D, T385X2S	Poisoning by other estrogens and progestogens, intentional self-harm.
T386X2A, T386X2D, T386X2S	Poisoning by antigonadotrophins, antiestrogens, antiandrogens, not elsewhere classified, intentional self-harm.

Poisoning:	
T387X2A, T387X2D, T387X2S	Poisoning by androgens and anabolicongeners, intentional self-harm.
T38802A, T38802D, T38802S	Poisoning by unspecified hormones and synthetic substitutes, intentional self-harm.
T38812A, T38812D, T38812S	Poisoning by anterior pituitary [adenohypophyseal] hormones, intentional self-harm.
T38892A, T38892D, T38892S	Poisoning by other hormones and synthetic substitutes, intentional self-harm.
T38902A, T38902D, T38902S	Poisoning by unspecified hormone antagonists, intentional self-harm.
T39012A, T39012D, T39012S	Poisoning by aspirin, intentional self-harm.
T39092A, T39092D, T39092S	Poisoning by salicylates, intentional self-harm.
T391X2A, T391X2D, T391X2S	Poisoning by 4-Aminophenol derivatives, intentional self-harm.
T392X2A, T392X2D, T392X2S	Poisoning by pyrazolone derivatives, intentional self-harm.
T39312A, T39312D, T39312S	Poisoning by propionic acid derivatives, intentional self-harm.
T39392A, T39392D, T39392S	Poisoning by other nonsteroidal anti-inflammatory drugs [NASID], intentional self-harm.
T394X2A, T394X2D, T394X2S	Poisoning by antirheumatics, not elsewhere classified, intentional self-harm.
T398X2A, T398X2D, T398X2S	Poisoning by other nonopioid analgesics and antipyretics, not elsewhere classified, intentional self-harm.
T3992XA, T3992XD, T3992XS	Poisoning by unspecified nonopioid analgesic, antipyretic and antirheumatic, intentional self-harm.
T400X2A, T400X2D, T400X2S	Poisoning by opium, intentional self-harm.
T401X2A, T401X2D, T401X2S	Poisoning by heroin, intentional self-harm.
T402X2A, T402X2D, T402X2S	Poisoning by other opioids, intentional self-harm.
T403X2A, T403X2D, T403X2S	Poisoning by methadone, intentional self-harm.
T404X2A, T404X2D, T404X2S	Poisoning by other synthetic narcotics, intentional self-harm.
T405X2A, T405X2D, T405X2S	Poisoning by cocaine, intentional self-harm.
T40602A, T40602D, T40602S	Poisoning by unspecified narcotics, intentional self-harm.
T407X2A, T407X2D, T407X2S	Poisoning by cannabis (derivatives), intentional self-harm.
T408X2A, T408X2D, T408X2S	Poisoning by lysergide [LSD], intentional self-harm.
T40902A, T40902D, T40902S	Poisoning by unspecified psychodysleptics [hallucinogens], intentional self-harm.
T40992A, T40992D, T40992S	Poisoning by other psychodysleptics [hallucinogens], intentional self-harm.
T410X2A, T410X2D, T410X2S	Poisoning by inhaled anesthetics, intentional self-harm.
T411X2A, T411X2D, T411X2S	Poisoning by intravenous anesthetics, intentional self-harm.
T41202A, T41202D, T41202S	Poisoning by unspecified general anesthetics, intentional self-harm.
T41292A, T41292D, T41292S	Poisoning by other general anesthetics, intentional self-harm.
T413X2A, T413X2D, T413X2S	Poisoning by local anesthetics, intentional self-harm.
T4142XA, T4142XD, T4142XS	Poisoning by unspecified anesthetic, intentional self-harm.
T415X2A, T415X2D, T415X2S	Poisoning by therapeutic gases, intentional self-harm.
T420X2A, T420X2D, T420X2S	Poisoning by hydantoin derivatives, intentional self-harm.
T421X2A, T421X2D, T421X2S	Poisoning by iminostilbenes, intentional self-harm.
T422X2A, T422X2D, T422X2S	Poisoning by succinimides and oxazolidinediones, intentional self-harm.
T423X2A, T423X2D, T423X2S	Poisoning by barbiturates, intentional self-harm.
T424X2A, T424X2D, T424X2S	Poisoning by benzodiazepines, intentional self-harm.

Poisoning:	
T425X2A, T425X2D, T425X2S	Poisoning by mixed antiepileptics, intentional self-harm.
T426X2A, T426X2D, T426X2S	Poisoning by other antiepileptic and sedative-hypnotic drugs, intentional self-harm.
T428X2A, T428X2D, T428X2S	Poisoning by antiparkinsonism drugs and other central muscle-tone depressants, intentional self-harm.
T43012A, T43012D, T43012S	Poisoning by tricyclic antidepressants, intentional self-harm.
T431X2A, T431X2D, T431X2S	Poisoning by monoamine-oxidase-inhibitor antidepressants, intentional self-harm.
T43202A, T43202D, T43202S	Poisoning by unspecified antidepressants, intentional self-harm.
T43212A, T43212D, T43212S	Poisoning by selective serotonin and norepinephrine reuptake inhibitors, intentional self-harm.
T43222A, T43222D, T43222S	Poisoning by selective serotonin reuptake inhibitors, intentional self-harm.
T43292A, T43292D, T43292S	Poisoning by other antidepressants, intentional self-harm.
T433X2A, T433X2D, T433X2S	Poisoning by phenothiazine antipsychotics and neuroleptics, intentional self-harm.
T434X2A, T434X2D, T434X2S	Poisoning by butyrophenone and thiothixene neuroleptics, intentional self-harm.
T43502A, T43502D, T43502S	Poisoning by unspecified antipsychotics and neuroleptics, intentional self-harm.
T43592A, T43592D, T43592S	Poisoning by other antipsychotics and neuroleptics, intentional self-harm.
T43602A, T43602D, T43602S	Poisoning by unspecified psychostimulants, intentional self-harm.
T43612A, T43612D, T43612S	Poisoning by caffeine, intentional self-harm.
T43622A, T43622D, T43622S	Poisoning by amphetamines, intentional self-harm.
T43632A, T43632D, T43632S	Poisoning by methylphenidate, intentional self-harm.
T43692A, T43692D, T43692S	Poisoning by other psychostimulants, intentional self-harm.
T438X2A, T438X2D, T438X2S	Poisoning by other psychotropic drugs, intentional self-harm.
T4392XA, T4392XD, T4392XS	Poisoning by unspecified psychotropic drug, intentional self-harm.
T440X2A, T440X2D, T440X2S	Poisoning by anticholinesterase agents, intentional self-harm.
T441X2A, T441X2D, T441X2S	Poisoning by other parasympathomimetics [cholinergics], intentional self-harm.
T442X2A, T442X2D, T442X2S	Poisoning by ganglionic blocking drugs, intentional self-harm.
T443X2A, T443X2D, T443X2S	Poisoning by other parasympatholytics [anticholinergics and antimuscarinics] and spasmolytics, intentional self-harm.
T444X2A, T444X2D, T444X2S	Poisoning by predominantly alpha-adrenoreceptor agonists, intentional self-harm.
T446X2A, T446X2D, T446X2S	Poisoning by alpha-adrenoreceptor antagonists, intentional self-harm.
T447X2A, T447X2D, T447X2S	Poisoning by beta-adrenoreceptor antagonists, intentional self-harm.
T448X2A, T448X2D, T448X2S	Poisoning by centrally-acting and adrenergic-neuron-blocking agents, intentional self-harm.
T44902A, T44902D, T44902S	Poisoning by unspecified drugs primarily affecting the autonomic nervous system, intentional self-harm.
T450X2A, T450X2D, T450X2S	Poisoning by antiallergic and antiemetic drugs, intentional self-harm.

Poisoning:	
T451X2A, T451X2D, T451X2S	Poisoning by antineoplastic and immunosuppressive drugs, intentional self-harm.
T452X2A, T452X2D, T452X2S	Poisoning by vitamins, intentional self-harm.
T453X2A, T453X2D, T453X2S	Poisoning by enzymes, intentional self-harm.
T454X2A, T454X2D, T454X2S	Poisoning by iron and its compounds, intentional self-harm.
T45512A, T45512D, T45512S	Poisoning by anticoagulants, intentional self-harm.
T45522A, T45522D, T45522S	Poisoning by antithrombotic drugs, intentional self-harm.
T45602A, T45602D, T45602S	Poisoning by unspecified fibrinolysis-affecting drugs, intentional self-harm.
T45612A, T45612D, T45612S	Poisoning by thrombolytic drug, intentional self-harm.
T45622A, T45622D, T45622S	Poisoning by hemostatic drug, intentional self-harm.
T45692A, T45692D, T45692S	Poisoning by other fibrinolysis-affecting drugs, intentional self-harm.
T457X2A, T457X2D, T457X2S	Poisoning by anticoagulant antagonists, vitamin K and other coagulants, intentional self-harm.
T458X2A, T458X2D, T458X2S	Poisoning by other primarily systemic and hematological agents, intentional self-harm.
T460X2A, T460X2D, T460X2S	Poisoning by cardiac-stimulant glycosides and drugs of similar action, intentional self-harm.
T461X2A, T461X2D, T461X2S	Poisoning by calcium-channel blockers, intentional self-harm.
T462X2A, T462X2D, T462X2S	Poisoning by other antidysrhythmic drugs, intentional self-harm.
T463X2A, T463X2D, T463X2S	Poisoning by coronary vasodilators, intentional self-harm.
T464X2A, T464X2D, T464X2S	Poisoning by angiotensin-converting-enzyme inhibitors, intentional self-harm.
T465X2A, T465X2D, T465X2S	Poisoning by other antihypertensive drugs, intentional self-harm.
T466X2A, T466X2D, T466X2S	Poisoning by antihyperlipidemic and antiarteriosclerotic drugs, intentional self-harm.
T467X2A, T467X2D, T467X2S	Poisoning by peripheral vasodilators, intentional self-harm.
T468X2A, T468X2D, T468X2S	Poisoning by antivaricose drugs, including sclerosing agents, intentional self-harm.
T46902A, T46902D, T46902S	Poisoning by unspecified agents primarily affecting the cardiovascular system, intentional self-harm.
T46992A, T46992D, T46992S	Poisoning by other agents primarily affecting the cardiovascular system, intentional self-harm.
T470X2A, T470X2D, T470X2S	Poisoning by histamine H2-receptor blockers, intentional self-harm.
T471X2A, T471X2D, T471X2S	Poisoning by other antacids and anti-gastric-secretion drugs, intentional self-harm.
T472X2A, T472X2D, T472X2S	Poisoning by stimulant laxatives, intentional self-harm.
T473X2A, T473X2D, T473X2S	Poisoning by saline and osmotic laxatives, intentional self-harm.
T474X2A, T474X2D, T474X2S	Poisoning by other laxatives, intentional self-harm.
T475X2A, T475X2D, T475X2S	Poisoning by digestants, intentional self-harm.
T476X2A, T476X2D, T476X2S	Poisoning by antidiarrheal drugs, intentional self-harm.
T477X2A, T477X2D, T477X2S	Poisoning by emetics, intentional self-harm.
T478X2A, T478X2D, T478X2S	Poisoning by other agents primarily affecting gastrointestinal system, intentional self-harm.

Poisoning:	
T4792XA, T4792XD, T4792XS	Poisoning by unspecified agents primarily affecting gastrointestinal system, intentional self-harm.
T480X2A, T480X2D, T480X2S	Poisoning by oxytocic drugs, intentional self-harm.
T481X2A, T481X2D, T481X2S	Poisoning by skeletal muscle relaxants [neuromuscular blocking agents], intentional self-harm.
T48202A, T48202D, T48202S	Poisoning by unspecified drugs acting on muscles, intentional self-harm.
T483X2A, T483X2D, T483X2S	Poisoning by antitussives, intentional self-harm.
T484X2A, T484X2D, T484X2S	Poisoning by expectorants, intentional self-harm.
T485X2A, T485X2D, T485X2S	Poisoning by other anti-common-cold drugs, intentional self-harm.
T486X2A, T486X2D, T486X2S	Poisoning by antiasthmatics, intentional self-harm.
T48902A, T48902D, T48902S	Poisoning by unspecified agents primarily acting on the respiratory system, intentional self-harm.
T48992A, T48992D, T48992S	Poisoning by other agents primarily acting on the respiratory system, intentional self-harm.
T490X2A, T490X2D, T490X2S	Poisoning by local antifungal, anti-infective and anti-inflammatory drugs, intentional self-harm.
T491X2A, T491X2D, T491X2S	Poisoning by antipruritics, intentional self-harm.
T492X2A, T492X2D, T492X2S	Poisoning by local astringents and local detergents, intentional self-harm.
T493X2A, T493X2D, T493X2S	Poisoning by emollients, demulcents and protectants, intentional self-harm.
T494X2A, T494X2D, T494X2S	Poisoning by keratolytics, keratoplastics, and other hair treatment drugs, intentional self-harm.
T495X2A, T495X2D, T495X2S	Poisoning by ophthalmological drugs and preparations, intentional self-harm.
T496X2A, T496X2D, T496X2S	Poisoning by otorhinolaryngological drugs and preparations, intentional self-harm.
T497X2A, T497X2D, T497X2S	Poisoning by dental drugs, topically applied, intentional self-harm.
T498X2A, T498X2D, T498X2S	Poisoning by other topical agents, intentional self-harm.
T4992XA, T4992XD, T4992XS	Poisoning by unspecified topical agent, intentional self-harm.
T500X2A, T500X2D, T500X2S	Poisoning by mineralocorticoids and their antagonists, intentional self-harm.
T501X2A, T501X2D, T501X2S	Poisoning by loop [high-ceiling] diuretics, intentional self-harm.
T501X2A, T501X2D, T501X2S	Poisoning by carbonic-anhydrase inhibitors, benzothiadiazides and other diuretics, intentional self-harm.
T503X2A, T503X2D, T503X2S	Poisoning by electrolytic, caloric and water-balance agents, intentional self-harm.
T504X2A, T504X2D, T504X2S	Poisoning by drugs affecting uric acid metabolism, intentional self-harm.
T505X2A, T505X2D, T505X2S	Poisoning by appetite depressants, intentional self-harm.
T506X2A, T506X2D, T506X2S	Poisoning by antidotes and chelating agents, intentional self-harm.
T507X2A, T507X2D, T507X2S	Poisoning by analeptics and opioid receptor antagonists, intentional self-harm.

Poisoning:	
T508X2A, T508X2D, T508X2S	Poisoning by diagnostic agents, intentional self-harm.
T50A12A, T50A12D, T50A12S	Poisoning by pertussis vaccine, including combinations with a pertussis component, intentional self-harm.
T50A22A, T50A22D, T50A22S	Poisoning by mixed bacterial vaccines, intentional self-harm.
T50A92A, T50A92D, T50A92S	Poisoning by other bacterial vaccines, intentional self-harm.
T50B12A, T50B12D, T50B12S	Poisoning by smallpox vaccines, intentional self-harm.
T50B92A, T50B92D, T50B92S	Poisoning by other viral vaccines, intentional self-harm.
T50Z12A, T50Z12D, T50Z12S	Poisoning by immunoglobulin, intentional self-harm.
T50Z92A, T50Z92D, T50Z92S	Poisoning by other vaccines and biological substances, intentional self-harm.
T50902A, T50902D, T50902S	Poisoning by unspecified drugs medicaments, and biological substances, intentional self-harm.
T50992A, T50992D, T50992S	Poisoning by other drugs, medicaments and biological substances, intentional self-harm.

Toxic Effects	
T510X2A, T510X2D, T510X2S	Toxic effect of ethanol, intentional self-harm.
T511X2A, T511X2D, T511X2S	Toxic effect of methanol, intentional self-harm.
T512X2A, T512X2D, T512X2S	Toxic effect of 2-Propanol, intentional self-harm.
T513X2A, T513X2D, T513X2S	Toxic effect of fusel oil, intentional self-harm.
T518X2A, T518X2D, T518X2S	Toxic effect of other alcohols, intentional self-harm.
T519X2A, T519X2D, T519X2S	Toxic effect of unspecified alcohol, intentional self-harm.
T520X2A, T520X2D, T520X2S	Toxic effect of petroleum products, intentional self-harm.
T521X2A, T521X2D, T521X2S	Toxic effect of benzene, intentional self-harm.
T522X2A, T522X2D, T522X2S	Toxic effect of homologues of benzene, intentional self-harm.
T523X2A, T523X2D, T523X2S	Toxic effect of glycols, intentional self-harm.
T524X2A, T524X2D, T524X2S	Toxic effect of ketones, intentional self-harm.
T528X2A, T528X2D, T528X2S	Toxic effect of other organic solvents, intentional self-harm.
T5292XA, T5292XD, T5292XS	Toxic effect of unspecified organic solvents, intentional self-harm.
T530X2A, T530X2D, T530X2S	Toxic effect of carbon tetrachloride, intentional self-harm.
T531X2A, T531X2D, T531X2S	Toxic effect of chloroform, intentional self-harm.
T532X2A, T532X2D, T532X2S	Toxic effect of trichloroethylene, intentional self-harm.
T534X2A, T534X2D, T534X2S	Toxic effect of dichloromethane, intentional self-harm.
T535X2A, T535X2D, T535X2S	Toxic chlorofluorocarbons, intentional self-harm.
T536X2A, T536X2D, T536X2S	Toxic effect of other halogen derivative of aliphatic hydrocarbons, intentional self-harm.
T537X2A, T537X2D, T537X2S	Toxic effect of other halogen derivative of aromatic hydrocarbons, intentional self-harm.
T5392XA, T5392XD, T5392XS	Toxic effect of unspecified halogen derivative of aliphatic and aromatic hydrocarbons, intentional self-harm.
T540X2A, T540X2D, T540X2S	Toxic effect of phenol and phenol homologues, intentional self-harm.
T541X2A, T541X2D, T541X2S	Toxic effect of other corrosive organic compounds, intentional self-harm.
T542X2A, T542X2D, T542X2S	Toxic effect of corrosive acids and acid-like substances, intentional self-harm.
T543X2A, T543X2D, T543X2S	Toxic effect of corrosive alkalis and alkali-like substances, intentional self-harm.

Toxic Effects	
T5492XA, T5492XD, T5492XS	Toxic effect of unspecified corrosive substance, intentional self-harm.
T550X2A, T550X2D, T550X2S	Toxic effect of soaps, intentional self-harm.
T551X2A, T551X2D, T551X2S	Toxic effect of detergents, intentional self-harm.
T560X2A, T560X2D, T560X2S	Toxic effect of lead and its compounds, intentional self-harm.
T561X2A, T561X2D, T561X2S	Toxic effect of mercury and its compounds, intentional self-harm.
T562X2A, T562X2D, T562X2S	Toxic effect of chromium and its compounds, intentional self-harm.
T563X2A, T563X2D, T563X2S	Toxic effect of cadmium and its compounds, intentional self-harm.
T564X2A, T564X2D, T564X2S	Toxic effect of copper and its compounds, intentional self-harm.
T565X2A, T565X2D, T565X2S	Toxic effect of zinc and its compounds, intentional self-harm.
T566X2A, T566X2D, T566X2S	Toxic effect of tin and its compounds, intentional self-harm.
T567X2A, T567X2D, T567X2S	Toxic effect of beryllium and its compounds, intentional self-harm.
T56812A, T56812D, T56812S	Toxic effect of thallium and its compounds, intentional self-harm.
T56892A, T56892D, T56892S	Toxic effect of other metals, intentional self-harm.
T5692XA, T5692XD, T5692XS	Toxic effect of unspecified metal, intentional self-harm.
T570X2A, T570X2D, T570X2S	Toxic effect of arsenic and its compounds, intentional self-harm.
T571X2A, T571X2D, T571X2S	Toxic effect of phosphorus and its compounds, intentional self-harm.
T572X2A, T572X2D, T572X2S	Toxic effect of manganese and its compounds, intentional self-harm.
T573X2A, T573X2D, T573X2S	Toxic effect of hydrogen cyanide, intentional self-harm.
T578X2A, T578X2D, T578X2S	Toxic effect of other specified inorganic substances, intentional self-harm.
T579X2A, T579X2D, T579X2S	Toxic effect of unspecified inorganic substances, intentional self-harm.
T5802XA, T5802XD, T5802XS	Toxic effect of carbon monoxide from motor vehicle exhaust, intentional self-harm.
T5812XA, T5812XD, T5812XS	Toxic effect of carbon monoxide from utility gas, intentional self-harm.
T582X2A, T582X2D, T582X2S	Toxic effect of carbon monoxide from incomplete combustion of domestic fuels, intentional self-harm.
T588X2A, T588X2D, T588X2S	Toxic effect of carbon monoxide from other source, intentional self-harm.
T5892XA, T5892XD, T5892XS	Toxic effect of carbon monoxide from unspecified source, intentional self-harm.
T590X2A, T590X2D, T590X2S	Toxic effect of nitrogen oxides, intentional self-harm.
T591X2A, T591X2D, T591X2S	Toxic effect of sulfur dioxide, intentional self-harm.
T592X2A, T592X2D, T592X2S	Toxic effect of formaldehyde, intentional self-harm.
T593X2A, T593X2D, T593X2S	Toxic effect of lacrimogenic gas, intentional self-harm.
T594X2A, T594X2D, T594X2S	Toxic effect of chlorine gas, intentional self-harm.
T595X2A, T595X2D, T595X2S	Toxic effect of fluorine gas and hydrogen fluoride, intentional self-harm.
T596X2A, T596X2D, T596X2S	Toxic effect of hydrogen sulfide, intentional self-harm.

Toxic Effects	
T597X2A, T597X2D, T597X2S	Toxic effect of carbon dioxide, intentional self-harm.
T59812A, T59812D, T59812S	Toxic effect of smoke, intentional self-harm.
T59892A, T59892D, T59892S	Toxic effect of other gases, fumes and vapors, intentional self-harm.
T5992XA, T5992XD, T5992XS	Toxic effect of unspecified gases, fumes and vapors, intentional self-harm.
T600X2A, T600X2D, T600X2S	Toxic effect of organophosphate and carbamate insecticides, intentional self-harm.
T601X2A, T601X2D, T601X2S	Toxic effect of halogenated insecticides, intentional self-harm.
T602X2A, T602X2D, T602X2S	Toxic effect of other insecticides, intentional self-harm.
T603X2A, T603X2D, T603X2S	Toxic effect of herbicides and fungicides, intentional self-harm.
T604X2A, T604X2D, T604X2S	Toxic effect of rodenticides, intentional self-harm.
T608X2A, T608X2D, T608X2S	Toxic effect of other pesticides, intentional self-harm.
T6092XA, T6092XD, T6092XS	Toxic effect of unspecified pesticide, intentional self-harm.
T6102XA, T6102XD, T6102XS	Ciguatera fish poisoning, intentional self-harm.
T6112XA, T6112XD, T6112XS	Scombroid fish poisoning, intentional self-harm.
T61772A, T61772D, T61772S	Other fish poisoning, intentional self-harm.
T61782A, T61782D, T61782S	Other shellfish poisoning, intentional self-harm.
T618X2A, T618X2D, T618X2S	Toxic effect of other seafood, intentional self-harm.
T619X2A, T619X2D, T619X2S	Toxic effect of unspecified seafood, intentional self-harm.
T620X2A, T620X2D, T620X2S	Toxic effect of ingested mushrooms, intentional self-harm.
T621X2A, T621X2D, T621X2S	Toxic effect of ingested berries, intentional self-harm.
T622X2A, T622X2D, T622X2S	Toxic effect of other ingested (parts of) plant(s), intentional self-harm.
T628X2A, T628X2D, T628X2S	Toxic effect of other specified noxious substances eaten as food, intentional self-harm.
T6292XA, T6292XD, T6292XS	Toxic effect of unspecified noxious substance eaten as food, intentional self-harm.
T63002A, T63002D, T63002S	Toxic effect of unspecified snake venom, intentional self-harm.
T63012A, T63012D, T63012S	Toxic effect of rattlesnake venom, intentional self-harm.
T63022A, T63022D, T63022S	Toxic effect of coral snake venom, intentional self-harm.
T63032A, T63032D, T63032S	Toxic effect of taipan venom, intentional self-harm.
T63042A, T63042D, T63042S	Toxic effect of cobra venom, intentional self-harm.
T63062A, T63062D, T63062S	Toxic effect of venom of other North and South American snake, intentional self-harm.
T63072A, T63072D, T63072S	Toxic effect of venom of other Australian snake, intentional self-harm.
T63082A, T63082D, T63082S	Toxic effect of venom of African and Asian snake, intentional self-harm.
T63092A, T63092D, T63092S	Toxic effect of venom of other snake, intentional self-harm.
T63112A, T63112D, T63112S	Toxic effect of venom of gila monster, intentional self-harm.
T63122A, T63122D, T63122S	Toxic effect of venom of other venomous lizard, intentional self-harm.
T63192A, T63192D, T63192S	Toxic effect of venom of other reptiles, intentional self-harm.
T632X2A, T632X2D, T632X2S	Toxic effect of venom of scorpion, intentional self-harm.
T63302A, T63302D, T63302S	Toxic effect of venom of unspecified spider venom, intentional self-harm.
T63312A, T63312D, T63312S	Toxic effect of venom of black widow spider, intentional self-harm.
T63322A, T63322D, T63322S	Toxic effect of venom of tarantula, intentional self-harm.

Toxic Effects	
T63332A, T63332D, T63332S	Toxic effect of venom of brown recluse spider, intentional self-harm.
T63392A, T63392D, T63392S	Toxic effect of venom of other spider, intentional self-harm.
T63412A, T63412D, T63412S	Toxic effect of venom of centipedes and venomous millipedes, intentional self-harm.
T63422A, T63422D, T63422S	Toxic effect of venom of ants, intentional self-harm.
T63432A, T63432D, T63432S	Toxic effect of venom of caterpillars, intentional self-harm.
T63442A, T63442D, T63442S	Toxic effect of venom of bees, intentional self-harm.
T63452A, T63452D, T63452S	Toxic effect of venom of hornets, intentional self-harm.
T63462A, T63462D, T63462S	Toxic effect of venom of wasps, intentional self-harm.
T63482A, T63482D, T63482S	Toxic effect of other arthropod, intentional self-harm.
T63512A, T63512D, T63512S	Toxic effect of contact with stingray, intentional self-harm.
T63592A, T63592D, T63592S	Toxic effect of contact with other venomous fish, intentional self-harm.
T63612A, T63612D, T63612S	Toxic effect of contact with Portuguese Man-o-war, intentional self-harm.
T63622A, T63622D, T63622S	Toxic effect of contact with sea anemone, intentional self-harm.
T63692A, T63692D, T63692S	Toxic effect of contact with other venomous marine animals, intentional self-harm.
T63712A, T63712D, T63712S	Toxic effect of contact with venomous marine plant, intentional self-harm.
T63812A, T63812D, T63812S	Toxic effect of contact with venomous frog, intentional self-harm.
T63822A, T63822D, T63822S	Toxic effect of contact with venomous toad, intentional self-harm.
T63832A, T63832D, T63832S	Toxic effect of contact with other venomous amphibian, intentional self-harm.
T63892A, T63892D, T63892S	Toxic effect of contact with other venomous animals, intentional self-harm.
T6392XA, T6392XD, T6392XS	Toxic effect of contact with unspecified venomous animal, intentional self-harm.
T6402XA, T6402XD, T6402XS	Toxic effect of aflatoxin, intentional self-harm.
T6482XA, T6482XD, T6482XS	Toxic effect of other mycotoxin food contaminants, intentional self-harm.
T650X2A, T650X2D, T650X2S	Toxic effect of cyanides, intentional self-harm.
T651X2A, T651X2D, T651X2S	Toxic effect of strychnine and its salts, intentional self-harm.
T65212A, T65212D, T65212S	Toxic effect of chewing tobacco, intentional self-harm.
T65222A, T65222D, T65222S	Toxic effect of tobacco cigarettes, intentional self-harm.
T65292A, T65292D, T65292S	Toxic effect of other tobacco and nicotine, intentional self-harm.
T653X2A, T653X2D, T653X2S	Toxic effect of nitroderivatives and aminoderivatives of benzene and its homologues, intentional self-harm.
T654X2A, T654X2D, T654X2S	Toxic effect of carbon disulfide, intentional self-harm.
T655X2A, T655X2D, T655X2S	Toxic effect of nitroglycerin and other nitric acids and esters, intentional self-harm.
T656X2A, T656X2D, T656X2S	Toxic effect of paints and dyes, not elsewhere classified, intentional self-harm.
T65812A, T65812D, T65812S	Toxic effect of latex, intentional self-harm.
T65822A, T65822D, T65822S	Toxic effect of harmful algae and algae toxins, intentional self-harm.
T65832A, T65832D, T65832S	Toxic effect of fiberglass, intentional self-harm.

Toxic Effects	
T65892A, T65892D, T65892S	Toxic effect of other specified substances, intentional self-harm.
T6592XA, T6592XD, T6592XS	Toxic effect of unspecified substance, intentional self-harm.

Asphyxiation:	
T71112A, T71112D, T71112S	Asphyxiation due to smothering under pillow, intentional self-harm.
T71122A, T71122D, T71122S	Asphyxiation due to plastic bag, intentional self-harm.
T71132A, T71132D, T71132S	Asphyxiation due to being trapped in bed linens, intentional self-harm.
T71152A, T71152D, T71152S	Asphyxiation due to smothering in furniture, intentional self-harm.
T71162A, T71162D, T71162S	Asphyxiation due to hanging, intentional self-harm.
T71192A, T71192D, T71192S	Asphyxiation due to mechanical threat to breathing due to other causes, intentional self-harm.
T71222A, T71222D, T71222S	Asphyxiation due to being trapped in a car trunk, intentional self-harm.
T71232A, T71232D, T71232S	Asphyxiation due to being trapped in a (discarded) refrigerator, intentional self-harm.

**** Note:** Please note that all codes end in either **A**, **D** or **S**. These codes refer to (**A**) Initial Encounter, (**D**) Subsequent Encounter, or (**S**) Sequela.*

6.3. List of Substance Abuse ICD-10-CM Codes Included in Data Collection

Code	Description
Alcohol:	
F1010	Alcohol abuse, uncomplicated.
F10120	Alcohol abuse with intoxication, uncomplicated.
F10121	Alcohol abuse with intoxication delirium.
F10129	Alcohol abuse with intoxication, unspecified.
F1014	Alcohol abuse with alcohol-induced mood disorder.
F10150	Alcohol abuse with alcohol-induced psychotic disorder with delusions.
F10151	Alcohol abuse with alcohol-induced psychotic disorder with hallucinations.
F10159	Alcohol abuse with alcohol-induced psychotic disorder, unspecified.
Alcohol:	
F10180	Alcohol abuse with alcohol-induced anxiety disorder.
F10181	Alcohol abuse with alcohol-induced sexual dysfunction.
F10182	Alcohol abuse with alcohol-induced sleep disorder.
F10188	Alcohol abuse with other alcohol-induced disorder
F1019	Alcohol abuse with unspecified alcohol-induced disorder.

Opioids:	
F1110	Opioid abuse, uncomplicated.
F11120	Opioid abuse with intoxication, uncomplicated.
F11121	Opioid abuse with intoxication delirium.
F11122	Opioid abuse with intoxication with perceptual disturbance.

Opioids:	
F11129	Opioid abuse with intoxication, unspecified.
F1114	Opioid abuse with opioid-induced mood disorder.
F11150	Opioid abuse with opioid-induced psychotic disorder with delusions.
F11151	Opioid abuse with opioid-induced psychotic disorder with hallucinations.
F11159	Opioid abuse with opioid-induced psychotic disorder, unspecified.
F11181	Opioid abuse with opioid-induced sexual dysfunction.
F11182	Opioid abuse with opioid-induced sleep disorder.
F11188	Opioid abuse with other opioid-induced disorder.
F1119	Opioid abuse with unspecified opioid-induced disorder.

Cannabis:	
F12120	Cannabis abuse with intoxication, uncomplicated.
F12121	Cannabis abuse with intoxication delirium.
F12122	Cannabis abuse with intoxication with perceptual disturbance.
F12129	Cannabis abuse with intoxication, unspecified.
F12150	Cannabis abuse with psychotic disorder with delusions.
F12151	Cannabis abuse with psychotic disorder with hallucinations.
F12159	Cannabis abuse with psychotic disorder, unspecified.
F12180	Cannabis abuse with cannabis-induced anxiety disorder.
F12188	Cannabis abuse with other cannabis-induced disorder.
F1219	Cannabis abuse with unspecified cannabis-induced disorder.

Sedatives:	
F1310	Sedative, hypnotic or anxiolytic abuse, uncomplicated.
F13120	Sedative, hypnotic or anxiolytic abuse with intoxication, uncomplicated.
F13121	Sedative, hypnotic or anxiolytic abuse with intoxication delirium.
F13129	Sedative, hypnotic or anxiolytic abuse with intoxication, unspecified.
F1314	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced mood disorder.
F13150	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced psychotic disorder with delusions.
F13151	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced psychotic disorder with hallucinations.
F13159	Sedative hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced psychotic disorder, unspecified.
F13180	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced anxiety disorder.
F13181	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced sexual dysfunction.
F13182	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced sleep disorder.
F13188	Sedative, hypnotic or anxiolytic abuse with other sedative, hypnotic or anxiolytic-induced disorder.
F1319	Sedative, hypnotic or anxiolytic abuse with unspecified sedative, hypnotic or anxiolytic-induced disorder.

Stimulants:	
F1410	Cocaine abuse, uncomplicated.
F14120	Cocaine abuse with intoxication, uncomplicated.
F14121	Cocaine abuse with intoxication with delirium.
F14122	Cocaine abuse with intoxication with perceptual disturbance.
F14129	Cocaine abuse with intoxication, unspecified.
F1414	Cocaine abuse with cocaine-induced mood disorder.
F14150	Cocaine abuse with cocaine-induced psychotic disorder with delusions.
F14151	Cocaine abuse with cocaine-induced psychotic disorder with hallucinations.
F14159	Cocaine abuse with cocaine-induced psychotic disorder, unspecified.
F14180	Cocaine abuse with cocaine-induced anxiety disorder.
F14181	Cocaine abuse with cocaine-induced sexual dysfunction.
F14182	Cocaine abuse with cocaine-induced sleep disorder.
F14188	Cocaine abuse with other cocaine-induced disorder.
F1419	Cocaine abuse with unspecified cocaine-induced disorder.
F1510	Other stimulant abuse, uncomplicated.
F15120	Other stimulant abuse with intoxication, uncomplicated.
F15121	Other stimulant abuse with intoxication delirium.
F15122	Other stimulant abuse with intoxication with perceptual disturbance.
F15129	Other stimulant abuse with intoxication, unspecified.
F1514	Other stimulant abuse with stimulant-induced mood disorder.
F15150	Other stimulant abuse with stimulant-induced psychotic disorder with delusions.
F15151	Other stimulant abuse with stimulant-induced psychotic disorder with hallucinations.
F15159	Other stimulant abuse with stimulant-induced psychotic disorder, unspecified.
F15180	Other stimulant abuse with stimulant-induced anxiety disorder.
F15181	Other stimulant abuse with stimulant-induced sexual dysfunction.
F15182	Other stimulant abuse with stimulant-induced sleep disorder.
F15188	Other stimulant abuse with other stimulant-induced disorder.
F1519	Other stimulant abuse with unspecified stimulant-induced disorder.

Hallucinogens:	
F1610	Hallucinogen abuse, uncomplicated.
F16120	Hallucinogen abuse with intoxication, uncomplicated.
F16121	Hallucinogen abuse with intoxication with delirium.
F16122	Hallucinogen abuse with intoxication with perceptual disturbance.
F16129	Hallucinogen abuse with intoxication, unspecified.
F1614	Hallucinogen abuse with hallucinogen-induced mood disorder.
F16150	Hallucinogen abuse with hallucinogen-induced psychotic disorder with delusions.

Hallucinogens:	
F16151	Hallucinogen abuse with hallucinogen-induced psychotic disorder with hallucinations.
F16159	Hallucinogen abuse with hallucinogen-induced psychotic disorder, unspecified.
F16180	Hallucinogen abuse with hallucinogen-induced anxiety disorder.
F16183	Hallucinogen abuse with hallucinogen persisting perception disorder (flashbacks).
F16188	Hallucinogen abuse with other hallucinogen-induced disorder.
F1619	Hallucinogen abuse with unspecified hallucinogen-induced disorder.

Inhalants:	
F1810	Inhalant abuse, uncomplicated.
F18120	Inhalant abuse with intoxication, uncomplicated.
F18121	Inhalant abuse with intoxication delirium.
F18129	Inhalant abuse with intoxication, unspecified
F1814	Inhalant abuse with inhalant-induced mood disorder.
F18150	Inhalant abuse with inhalant-induced psychotic disorder with delusions.
F18151	Inhalant abuse with inhalant-induced psychotic disorder with hallucinations.
F18159	Inhalant abuse with inhalant-induced psychotic disorder, unspecified.
F1817	Inhalant abuse with inhalant-induced dementia.
F18180	Inhalant abuse with inhalant-induced anxiety disorder.
F18188	Inhalant abuse with other inhalant-induced disorder.
F1819	Inhalant abuse with unspecified inhalant-induced disorder

Other Psychoactive Substances:	
F1910	Other psychoactive substance abuse, uncomplicated.
F19120	Other psychoactive substance abuse with intoxication, uncomplicated.
F19121	Other psychoactive substance abuse with intoxication delirium.
F19122	Other psychoactive substance abuse with intoxication with perceptual disturbances.
F19129	Other psychoactive substance abuse with intoxication, unspecified.
F1914	Other psychoactive substance abuse with psychoactive substance-induced mood disorder.
F19150	Other psychoactive substance abuse with psychoactive substance-induced psychotic disorder with delusions.
F19151	Other psychoactive substance abuse with psychoactive substance-induced psychotic disorder with hallucinations.
F19159	Other psychoactive substance abuse with psychoactive substance-induced psychotic disorder, unspecified.
F1916	Other psychoactive substance abuse with psychoactive substance-induced persisting amnestic disorder.

Other Psychoactive Substances:	
F1917	Other psychoactive substance abuse with psychoactive substance-induced persisting dementia.
F19180	Other psychoactive substance abuse with psychoactive substance-induced anxiety disorder.
F19181	Other psychoactive substance abuse with psychoactive substance-induced sexual dysfunction.
F19182	Other psychoactive substance abuse with psychoactive substance-induced sleep disorder.
F19188	Other psychoactive substance abuse with other psychoactive substance-induced disorder.

7. REFERENCES

1. Klonsky ED (2011) Non-suicidal self-injury in United States Adults: Prevalence, sociodemographics, topography and functions. Psychological Medicine 41(9):1981-1986. doi: 10.1017/S0033291710002497
2. Canadian Institute for Health Information (2014) Health System Performance 2014. https://yourhealthsystem.cihi.ca/epub/SearchServlet. Accessed February 20 2017
3. Bethell J, Rhodes AF (2009) Identifying deliberate self-harm in emergency department data. Health Reports. Statistics Canada, Ottawa
4. Gunnell D, Bennewith O, Peters TJ, House A, Hawton K (2005) The epidemiology and management of self-harm amongst adults in England. Journal of Public Health 27 (1):67-73
5. Hawton K, Bergen H, Casey D, Simkin S, Palmer B, Cooper J, Kapur N, Horrocks J, House A, Lilley R, Noble R, Owens D (2007) Self-harm in England: a tale of three cities. Multicentre study of self-harm. Social Psychiatry & Psychiatric Epidemiology 42 (7):513-521
6. Canadian Institute for Health Information (2013) Health Indicators 2013. Canadian Institute for Health Information,
7. Heisel, M.J., & Duberstein, P.R. (2016). Working sensitively and effectively to reduce suicide risk among older adults. In P.M. Kleespies (Ed.), The Oxford Handbook of Behavioral Emergencies and Crises (Chapter 22), pp. 335-359. Oxford University Press.
8. Carroll R, Metcalfe C, Gunnell D (2014) Hospital Presenting Self-Harm and Risk of Fatal and Non-Fatal Repetition: Systematic Review and Meta-Analysis. PlosOne. doi: http://dx.doi.org/10.1371/journal.pone.0089944
9. Finkelstein Y, MacDonald EM, Hollands S, Sivilotti MLA, Hutsn JR, Mamdani MM, Koren G, Juurlink DN (2015) Risk of suicide following deliberate self-poisoning. JAMA Psychiatry 72 (6):570-575
10. Owens D, House A (1994) General hospital services for deliberate self-harm. Haphazard clinical provision, little research, no central strategy. Journal of the Royal College of Physicians of London 28 (4):370-371
11. Da Cruz D, Pearson A, Saini P, Miles C, While D, Swinson N, Williams A, Shaw J, Appleby L, Kapur N (2011) Emergency department contact prior to suicide in mental health patients. Emergency Medicine Journal 28 (6):467-471. doi:http://dx.doi.org/10.1136/emj.2009.081869
12. Canadian Association for Suicide Prevention (2009) The CASP blueprint for a Canadian national suicide prevention strategy. Winnipeg, MB, Canada

13. Hawton K, Harriss L, Zahl D (2006) Deaths from all causes in a long-term follow-up study of 11,583 deliberate self-harm patients. Psychological Medicine 36 (3):397-405
14. Comtois K, Russo J, Snowden M, Srebnik D, Ries R, Roy-Byrne P (2003) Factors associated with high use of public mental health services by persons with borderline personality disorder. Psychiatric Services 54:1149-1154
15. Owens D, Horrocks J, House A (2002) Fatal and non-fatal repetition of self-harm: Systematic review. British Journal of Psychiatry 181 (3):193-199. doi:10.1192/bjp.181.3.193
16. Milnes D, Owens D, Blenkiron P (2002) Problems reported by self-harm patients: perception, hopelessness, and suicidal intent. Journal of Psychosomatic Research 53 (3):819-822
17. Statistics Canada (2012) Canadian coroner and medical examiner database: Annual report (82-214-X). Ottawa: Public Health Agency of Canada. www.statcan.gc.ca/pub/82-214-x/82-214-x2012001-eng.pdf Accessed May 12 2017
18. Ness J, Hawton K, Bergen H, Cooper J, Steeg S, Kapur N, Clarke M, Waters K (2015) Alcohol use and misuse, self-harm and subsequent mortality: an epidemiological and longitudinal study from the multicentre study of self-harm in England. Emergency Medicine Journal 32:793-799
19. Public Health Agency for Northern Ireland (2015) Northern Ireland Registry of Self-Harm Western Area: Six Year Summary Report 2007-2012.
20. Health Canada. (2010). Acting on what we know: Preventing youth suicide in First Nations. Retrieved from http://www.hc-sc.gc.ca/fniah-spnia/pubs/promotion/_suicide/prev_youth-jeunes/index-eng.php#tphp. Accessed on December 1, 2017.
21. Hawton K, Witt KG, Taylor Salisbury TL, Arensman E, Gunnell D, Hazell P, Townsend E, van Heeringen K (2016) Psychosocial interventions for self-harm in adults. Cochrane Database of Systematic Reviews (5). doi:10.1002/14651858.CD012189
22. Gustafson D, McTavish FM, Chih M-Y, Atwood AK, Johnson RA, Boyle MG, Levy MS, Driscoll H, Chisholm SM, Dillenburg L, Isham A, Shah D (2014) A smartphone application to support recovery from alcoholism: A randomized controlled trial. JAMA Psychiatry 71 (5):566-572
23. Haw C, Hawton K, Casey D, Bale E, Shepherd A (2005) Alcohol dependence, excessive drinking and deliberate self-harm: trends and patterns in Oxford, 1989-2002. Social Psychiatry & Psychiatric Epidemiology 40 (12):964-971
24. O'Connor E, Gaynes BN, Burda BU, Soh C, Whitlock EP (2013) Screening for and treatment of suicide risk relevant to primary care: A systematic review for the US Preventive Services Task Force. Annals of Internal Medicine 158 (10):741-754
25. National Center for Health Statistics (2016) ICD-10-CM: International classification of diseases, 10th revision, clinical modification. https:www.cdc.gov/nchs/icd/icd10cm.htm. Accessed May 11 2017
26. National Center for Health Statistics (2016) ICD-10-CM: International classification of diseases, 10th revision, clinical modification. https:www.cdc.gov/nchs/icd/icd10cm.htm. Accessed May 11 2017
27. Krieger T, Meyer B, Sude K, Urech A, Maercker A, Berger T (2014) Evaluating an e-mental health program ("deprexis") as adjunctive treatment tool in psychotherapy for depression: Design of a pragmatic RCT. BMC Psychiatry 14:285-292
28. Kooistra LC, Wiersma J, Ruwaard J, van Oppen P, Smit F, Lokkerbol J (2014) Blended vs. face-to-face cognitive behavioural treatment for major depression in specialized mental health care: Study protocol of a randomized controlled cost-effectiveness trial. BMC Psychiatry 14:290-301

29. Thompson SC, Schlehofer MM (2008) The many sides of control motivation for high, low and illusory control. In: Shah JY, Gardner WL (eds) Handbook of Motivation Science. Guilford Press, New York, pp 41-56
30. Wright JH, Wright AS, Albano AM, Basco MR, Goldsmith LJ, Raffield T (2005) Computer-assisted cognitive therapy for depression: Maintain efficacy while reducing therapist time. American Journal of Psychiatry 162 (6):158-1164
31. Kleiboer A, Smit J, Bosmans J, Ruwaard J, Andersson G, Topooco N (2016) European COMPARative effectiveness research on blended depression treatment versus treatment-as-usual (E-COMPARED): Study protocol for a randomized controlled, non-inferiority trial in eight European countries. Trials 17:387-396
32. Reid SC, Kauer SD, Hearps SJ, Crooke AH, Khor AS, Sanci LA (2011) A mobile phone application for the assessment and management of youth mental health problems in primary care: A RCT. BMC Family Practice 12:131
33. Proudfoot J, Parker G, Pavlovic JD, Manicavasgar V, Adler E, Whitton A (2010) Community attitudes to the appropriation of mobile phones for monitoring and managing depression, anxiety and stress. Journal of Medical Internet Research 12 (4)
34. Cooper J, Steeg S, Bennewith O, Lowe M, Gunnell D, House A, Hawton K, Kapur N (2013) Are hospital services for self-harm getting better? An observational study examining management, service provision and temporal trends in England. BMJ Open 19 (3):e003444. doi:10.1136/bmjopen-2013-003444
35. Olfson M, Marcus SC, Bridge JA (2012) Emergency treatment of deliberate self-harm. Archives of General Psychiatry 69 (1):80-88. doi:10.1001/archgenpsychiatry.2011.108
36. Hickey, L., Hawton, K., Fagg, J., & Weitzel, H. (2001). Deliberate self-harm patients who leave the accident and emergency department without a psychiatric assessment. Journal of Psychosomatic Research, 50, 87-93.
37. Schull M, Vermeulen T, Stukel T, Fisher E (2013) Follow-Up and Shared Care following Discharge from the Emergency Department for exacerbations of Chronic Disease. Canadian Journal of Emergency Medicine 15 (Suppl 1):LOP05
38. Schoen CR, Osborn D, Squires MM, Doty P, Rasmussen R, Pierson R, Applebaum S (2012). Survey of Primary Care Doctors in Ten Countries Shows Progress in Use of Health Information Technology, Less in Other Areas. Health Affairs (Millwood) 31 (12):2805-2816
39. Tyrer P, Thompson S, Schmidt U, Jones V, Knapp M, Davidson K, Catalan J, Airlie J, Baxter S, Byford S, Byrne G, Cameron S, Caplan R, Cooper S, Ferguson B, Freeman C, Frost S, Godley J, Greenshields J, Henderson J, Holden N, Keech P, Kim L, Logan K, Manley C, MacLeod A, Murphy R, Patience L, Ramsay L, De Munroz S, Scott J, Seivewright H, Sivakumar K, Tata P, Thornton S, Ukoumunne OC, Wessely S (2003) Randomized controlled trial of brief cognitive behaviour therapy versus treatment as usual in recurrent deliberate self-harm: the POPMACT study. Psychological Medicine 33 (6):969-976
40. Hatcher S, Sharon C, Parag V, Collins N (2011) Problem solving therapy for people who present to hospital with self-harm: Zelen randomised controlled trial. British Journal of Psychiatry 199:310-316
41. Akbari A, Mayhew A, Al-Alawi MA, Grimshaw J, Winkens R, Glidewell E, Pritchard C, Thomas R, Fraser C (2008) Interventions to improve outpatient referrals from primary care to secondary care. Cochrane Database of Systematic Reviews (4). doi:10.1002/14651858.CD005471.pub2
42. Waltham MA (2015) Caring for adult patients with suicide risk: A consensus guide for emergency departments.

43. Suicide Prevention Resource Center. (2016). Preventing suicide among men in the middle years: Recommendations for suicide prevention programs. Waltham, MA: Education Development Center, Inc.
44. Carroll R, Metcalfe C, Gunnell D (2014) Hospital management of self-harm patients and risk of repetition: Systematic review and meta-analysis. Journal of Affective Disorders 168:476-483
45. Canadian Coalition for Seniors' Mental Health (2006). National Guidelines for Seniors' Mental Health: The Assessment of Suicide Risk and Prevention of Suicide. Toronto, Canada: Canadian Coalition for Seniors' Mental Health.
46. National Center for Health Statistics (2016) ICD-10-CM: International classification of diseases, 10th revision, clinical modification. https:www.cdc.gov/nchs/icd/icd10cm.htm. Accessed May 11 2017.
47. Andreasson, K., Krogh, J., Rosenbaum, B., Gluud, C., Jobes, D. A., & Nordentoft, M. (2014). The DiaS trial: dialectical behavior therapy versus collaborative assessment and management of suicidality on self-harm in patients with a recent suicide attempt and borderline personality disorder traits-study protocol for a randomized controlled trial. Trials, 15(1), 194.
48. Andreasson, K., Krogh, J., Wenneberg, C., Jessen, H. K., Krakauer, K., Gluud, C., ... & Nordentoft, M. (2016). Effectiveness of dialectical behavior therapy versus collaborative assessment and management of suicidality treatment for reduction of self-harm in adults with borderline personality trains and disorder – a randomized observer-blinded clinical trial. Depression and anxiety.
49. Morthorst, B., Krogh, J., Erlangsen, A., Alberdi, F., & Nordentoft, M. (2012). Effect of assertive outreach after suicide attempt in the AID (assertive intervention for deliberate self harm) trial: randomised controlled trial. BMJ, 345, e4972.
50. Moulton LH (2004) Covariate-based constrained randomization of group-randomized trials. Clinical Trials 1:297-305
51. Ukoumunne OC, Thompson SG. (2001) Analysis of cluster randomized trials with repeated cross-sectional binary measurements. Statistics in Medicine 20(3):417-433
52. Gold MR, Siegel JE, Russell LB, Weinstein MC, editors. (1996) Cost-effectiveness in health and medicine. New York: Oxford University Press.
53. Canadian Agency for Drugs and Technologies in Health. (2017) Guidelines for the economic evaluation of health technologies: Canada. 4th ed. Ottawa: Canadian Agency for Drugs and Technologies in Health. https://www.cadth.ca/guidelines-economic-evaluation-health-technologies-canada-4th-edition Accessed May 11 2017
54. Husereau D, Drummond M, Petrou S, Carswell C, Moher D, Greenberg D, Augustovski F, Briggs AH, Mauskopf J, Loder E; ISPOR Health Economic Evaluation Publication Guidelines – CHEERS Good Reporting Practices Task Force. (2013) Consolidated Health Economic Evaluation Reporting Standards (CHEERS)—explanation and elaboration: A report of the ISPOR Health Economic Evaluation Publication Guidelines Good Reporting Practices Task Force. Value in Health 16(2):231-250.
https://www.ncbi.nlm.nih.gov/pubmed/23538175 Accessed May 11 2017
55. Campbell ML, Elbourne DR, Altman DG (2004) CONSORT statement: Extension to cluster randomized trials. BMJ 328 (7441):702-708
56. Canadian Institutes of Health Research, Natural Science and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council (2014) Tri-council policy statement: Ethical conduct for research involving humans. Ottawa: Government of Canada
www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf Accessed May 11 2017

57. Schaffer A, Sinyor M, Kurdyak P, Vigod S, Sareen J, Reis C, Green D, Bolton J, Rhodes A, Grigoriadis S, Cairney J, Cheung A (2016) Population-based analysis of health care contacts among suicide decedents: Identifying opportunities for more targeted suicide prevention strategies. World Psychiatry 15(2): 135-145. doi: 10.1002/wps.20321