

Title: A Focused Suicide Prevention Strategy for Youth Presenting to the Emergency Department with Suicide Related Behaviour: A Randomized Controlled Trial

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**A Focused Suicide Prevention Strategy for Youth
Presenting to the Emergency Department with Suicide Related Behaviour:
A Randomized Controlled Trial**

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NARRATIVE SUMMARY

Suicide is the leading cause of death due to illness among Canadian youth, claiming more lives than any medical illness, including cancer. Suicide prevention is possible, and early intervention is urgently needed. Consistent with previous research highlighting the need for emergency department (ED) based suicide prevention strategies we previously showed that youth who present to the ED seeking help for suicide-related behaviours are at particularly high risk of eventual suicide after discharge¹⁻³. The standard of care for youth presenting with suicidal ideation and risk behaviour (SRB) to the ED is that the ED personnel places a referral to a community mental health agency (CMHA), or refers the patient back to their usual health care provider for ongoing care. This represents usual care (UC). It is common for the standard of care that (i) immediate service does not occur, as patients are often placed on wait lists; (ii) families are expected to make the CMHA contact there is often no follow through; (iii) the treatment provided does not include crisis management; and (iv) many youth are connected to therapists inexperienced with crises, all of which result in further ED re-visits for suicidal behaviour.

This study will examine the effectiveness of a previously-piloted, ED-based suicide prevention intervention using a randomized clinical trial design. We will determine whether our patient- and Family-centered Suicide Prevention Strategy added to usual care (F-SPS + UC) is more effective than enhanced usual care (EUC) in reducing suicide-related behaviors in 128 youth at high-risk of suicide. F-SPS is a 6-week, outpatient program that teaches participants to identify and challenge the thoughts, feelings and conflicts that suicidal youth experience, and teaches them skills to manage impulses effectively. Piloting by the SickKids team has established the feasibility and acceptability of the intervention. Enhanced usual care consists of 6 weekly telephone calls to ensure that the participant has connected with community resources suggested by the ED team and provide additional resources as needed. Rigorous evaluation will investigate the intervention for an effect on suicide-related behavior and mental health crises (primary outcomes), mental health symptoms, patient/family functioning, economic costs, scale up/implementation feasibility and intervention fidelity (secondary outcomes). The proposed study is novel, in that it is the **first clinical trial of a youth suicide intervention in Canada**; it is efficient, in that it leverages the research-base and therapeutic infrastructure of a highly experienced child health team; and it is important, in that it targets the prevention of recurrent suicide attempts and of suicide, a leading cause of death. This study will be the first step toward developing an effective suicide prevention program that can be scaled-up and implemented across Ontario and Canada, to provide youth at high risk of suicide access to effective, evidence-based treatment, regardless of the community in which they live.

BACKGROUND

Suicide is the second leading cause of death among youth in Canada⁴, responsible for 1 in 4 deaths among adolescents aged 15 to 19 years in 2011⁵. Indeed in Canada, more youth take their own lives than die by cancer and the top 10 fatal diseases in this population combined⁴. Suicide also has profound implications for families and communities and incurs massive societal costs, estimated at 2.4 billion dollars per year in Canada⁶. For these reasons, suicide is of considerable national and global significance⁷, and is a priority area of the Mental Health Commission of Canada (MHCC) and the World Health Organization. Many advocates argue that truly addressing this massive problem requires that suicide is recognized as fulfilling the criteria for a specific mental disorder⁸⁻¹⁰. Despite the enormity and the gravity of youth suicide nationally, Canada, unlike other developed countries, lacks a national youth suicide prevention strategy¹¹.

To our knowledge, this study is the first controlled clinical trial of an intervention to prevent suicide among high-risk adolescents in Canada.

Despite the widespread appeal of primary suicide prevention programs, successes have been limited. In fact, studies examining trends have identified increasing suicide rates among Canadian females between 1980 and 2008⁵, with both males and females experiencing an increase in the medical severity of their emergency department (ED) presentations for suicide-related behaviours since 2004¹². For every completed suicide in Canada there are 20 to 40 attempts⁵. The majority (90%) of youth who attempt suicide either have an underlying mental illness¹³ that is commonly undetected and untreated¹³ or they are at risk of emergence of a psychiatric disorder in young adulthood (e.g. schizophrenia, depression or bipolar disorder, anxiety disorder or personality disorder). Unlike more violent methods of suicide (e.g., firearms), which are frequently fatal, drug overdose has high survival rates. Two recent Ontario studies led by Finkelstein (Co-PI) reported on the associations between self-harm attempts and completed suicide in the general population¹⁴ and in adolescents (n= 20,471)². More than 99.9% of adolescents who presented to the ED with intentional overdose survived to discharge. However, roughly 1 in 100 of them died by suicide, compared to 1 in 3,500 matched peers from the general population, within a median interval of 7.2 years². Also, a recent review of systematic reviews carried out by Bennett et al¹ (with co-IP) concluded that the ED is likely the most promising site for the introduction of an effective suicide prevention strategy. Taken together, these data confirm that adolescents presenting to the ED following a suicide attempt are at high risk of having a previously undetected emerging mental illness, are at increased risk of suicide, and provide a very promising opportunity for secondary suicide prevention and early detection of mental illness through the use of an effective suicide prevention strategy (SPS).

There is presently an urgent unmet need for effective SPSs for high-risk youth, to prevent suicide and also to reduce suicidal SRBs which are common and frequently precede subsequent manifestations of mental health morbidity, impairment, and their resultant economic impacts. Because of the strong association between mental illness, particularly depression, and suicide, some researchers have targeted depression (or other underlying mental disorder) among youth in order to improve suicidality. However, several of these interventions have been ineffective in decreasing SRBs¹⁵. As such, interventions aimed at improving mental health have not been shown to reduce SRBs for high-risk youth.

The current study is informed by available data examining the effectiveness of direct SPSs among youth¹⁵. One systematic review (2011) of youth suicide-prevention intervention studies for high-risk youth noted that of 15 RCT's, only 1 reported effects on SRB, and that overall, methodological weaknesses (e.g. risk of bias, report of outcome data) limit interpretation of the data and progress in the field¹⁶. When effective, SPSs involved lengthy (6 -12 months) therapies^{11, 17}, which are impractical in the current Ontario fiscal environment, and report participation rates as low as 50%¹⁷. Conversely, ultra-brief interventions (e.g. single session or telephone follow-up) have not been effective in decreasing SRBs¹⁸⁻²⁰ as they are likely of insufficient duration and depth to yield therapeutic benefit. It was further demonstrated that an effective SPS for adolescents must include a family component in order to impact suicidal behaviour¹⁵. This is consistent with the large literature that has highlighted family conflict as a particularly salient risk factor for SRB among adolescents^{21, 22}. In a study comparing three months of weekly family-based therapy (FBT) for 66 suicidal adolescents, FBT led to greater reductions in suicidal thinking and depressive symptoms compared with treatment as usual²³. However, the study had several important weaknesses: assessors were not blinded to intervention status, suicide attempts were not captured, and the sample consisted of predominantly (~75%) very low income African-American families; all considerations that may limit validity of the study and its generalizability to an Ontario context.

The present study addresses both the practical and the methodological limitations of previous research in several ways. First, it targets the most vulnerable, high-risk adolescents (those with SRB), as identified by

data we have generated^{2, 14}. Second, it incorporates the key therapeutic components previously shown to be possibly effective^{8, 23, 24}. Third, it optimizes treatment duration and intensity, as an immediate-access, 6-week intervention. Fourth, the intervention is evaluated using an innovative, rigorous Randomized Control Trial (RCT) design, thereby maximizing potential therapeutic benefit, acceptability, scalability and confidence in the study results. Fifth, by defining suicide as a disorder, and intervening early on the outcome of SRBs directly, the present study is consistent with leading edge conceptualization and prevention strategy for this highly impairing, and frequently fatal, mental health condition among youth⁸.

STUDY GOALS, SPECIFIC AIMS, HYPOTHESES

Youth who present to the ED with a suicide attempt often suffer from an underlying mental illness that is neither detected nor treated. These youth are at high risk of poor mental health outcomes in young adulthood, including repeat suicide attempts and death. There is an urgent need for an effective suicide prevention strategy, based in the ED, to facilitate early intervention for, and prevention of, youth suicide. Consistent with the Four-Point Plan for Suicide Prevention recently outlined in the journal *Nature*⁸, RCT (1) defines suicide as a distinct disorder, (2) has a focused prevention strategy aimed at a high-risk population (youth with SRB), (3) utilizes rigorous methodology, and (4) targets early suicide-related outcomes directly.

Objectives:

The primary objective of this study is to determine the effectiveness of a novel, ED-based, Focused Suicide Prevention Strategy combined with usual care (F-SPS + UC) in reducing suicidal ideation and risk behaviours (SRB).

The secondary objectives are to compare these treatment arms to assess the effect of F-SPS on (2a) symptoms of mental illness; (2b) level of functional impairment; (2c) family communication; (2d) cost effectiveness; (2e) and to examine fidelity of intervention delivery; and potential barriers and facilitators to subsequent implementation and scale-up, should the F-SPS prove to be cost-effective.

In future, we would like to follow these participants into adulthood, and examine the effectiveness of the F-SPS over a longer period of time using ICES data. This study will provide the preliminary results needed to inform a large, externally-funded, youth suicide prevention study that will enable a longer period of follow-up into adulthood.

Research Question:

Among youth 12-18 years of age, presenting with SRB to the ED, does a focused suicide prevention strategy added to usual care (F-SPS + UC) lead to decreased SRB in the 6 month follow-up, as compared with enhanced usual care (EUC)?

Hypothesis

1. To determine the effect of a Focused Suicide Prevention Strategy added to usual care (F-SPS + UC) on SRB. Hypothesis 1 (H1): Compared with EUC, we hypothesize that the F-SPS + UC will be effective in decreasing SRBs over the 6-month follow up period.
2. To examine the effect of F-SPS + UC on future acute mental health crises (ED and unscheduled health care visits). Hypothesis 2 (H2): Compared with EUC, we hypothesize that participants who

receive the F-SPS + UC intervention will have significantly fewer acute mental health crises.

METHODS

Design:

This is a single centre, single-blinded RCT of an F-SPS intervention with EUC in high-risk youth who present to the ED with suicidality.

Participant Selection

Youth ages 12 to 18 years who present to the ED at Sick Kids with acute suicidal ideation or behaviour (including suicide attempt), and who provide informed consent, will be randomized to F-SPS + UC or EUC.

Inclusion criteria:

1. Youth presenting in the Emergency Department with SIQ-Jr score ≥ 31 ,
2. Has a participating parent or caregiver who is able to communicate easily in English, or is willing to communicate using a hospital-organized translator,
3. Between the ages 12-18 years old,
4. Living in the greater Toronto area and access to a telephone.

Exclusion criteria:

1. Score of 3 on KSADS screen for current psychosis or elevated mood
2. Moderate to severe intellectual disability, and/or autism based on clinical chart.

Procedure:

The clinical research nurse in the ED will conduct a pre-screen of patients admitted to the the ED using the Emergency Department Information System (EDIS), identifying patients within the eligible age range (12 – 18 years old) who present with SRB. A clinical nurse who is a part of the patient’s circle of care will ask the youth and parent(s) or caregiver for permission to be approached about research. If the youth and parent(s) or caregiver give permission then the clinical staff will introduce the research nurse who will conduct a screening assessment to determine whether the youth is eligible. The assessment will consist of a clinical interview for psychosis and two self-report measures for suicidal ideation and behaviour. If the youth is eligible for the study then the nurse will alert the study research coordinator. . If the patient is eligible the clinical research nurse will review the consent or assent with the youth and parent(s), who will consent separately for their involvement with the Family-based component of the intervention. If both the youth and parent(s) or caregiver sign consent forms, then they will be enrolled into the study. It will be considered as refusal if one of the two parties does not consent, and they will not be enrolled in the study.

The study coordinator will contact the participant by telephone within a business day of their discharge from the ED to review the study procedures and to book their study assessment visits at baseline, to occur within two weeks of the index ED visit. They will also book their study visits six weeks post-randomization, and 24 weeks post-randomization. The study assessment visits will be completed either at SickKids or at the participant’s home, depending on availability. The study coordinator will then randomize the participant to receive either to the F-SPS intervention + UC arm or EUC arm.

The study therapist will contact the participants randomized to receive the F-SPS intervention + UC arm and scheduled for their first treatment. The study coordinator will contact participants randomized to the EUC arm and schedule their EUC first phone call, and will provide resources to the child and family.

The research assistant will be responsible for administering outcome measures at study assessment visits, and will therefore be blinded to treatment allocation. We cannot blind the study coordinator, study therapist or families to treatment allocation.

In total there are four study visits. Participants will be assessed once by the study nurse at screening (the time of presentation in the ED), once by the study coordinator at baseline, and twice by the research assistant at 6 weeks post-randomization (at post-intervention), and 24 weeks post-randomization. Please see Table 1 for a complete measure administration schedule.

Treatment allocation (F-SPS+UC or EUC): Participants will be randomized to either receive the intervention, in addition to usual care (F-SPS+UC), or EUC only. They will be assigned in a 1:1 ratio of F-SPS+UC to EUC.

We will audio record F-SPS sessions if both the youth and the parent(s) or caregiver consent. These sessions will be reviewed by the principal investigators and the study staff in order to ensure fidelity to the treatment model.

In order to determine whether F-SPS+UC or EUC is related to a patient's health care service use, an analysis of participants' emergency room visits and unexpected medical appointments will also be conducted. OHIP numbers will be obtained at consent to link to ICES databases. .

We will recruit 128 adolescents to be randomized (64 adolescents per treatment arm) for this study (see 4.3 "Power Analysis").

Intervention: F-SPS + UC (i) is a manualized program that addresses the most common thoughts, feelings and conflicts that suicidal youth experience and teaches coping and safety skills to adolescents and their families. The program is the result of 3-years of development and quality improvement led by the PI (Korczak), developed collaboratively with youth, families, and therapists. The program will be administered once weekly over 6 weeks by a trained therapist on an outpatient basis. Sessions consist of 1-hour spent one-to-one with the youth, followed by 1-hour with the youth and parent(s) or caregiver.

The therapist provides the youth and parent(s) or caregiver with a manual to use both during and between sessions. The program and manual address sources of conflict, ways to improve communication and ensure safety. The program resembles the only ED-based adolescent and family programs that have demonstrated effectiveness in decreasing suicidality²³. It is tailored to address the key concerns of the adolescent or family including mental health, academic problems, social or family conflict, acculturation issues, gender concerns or other stressors.

Participants will also have access to the UC recommended by the ED circle of care. The F-SPS program will not interfere with the youth's ongoing plan of care. The F-SPS therapist will communicate with the youth's UC provider following the completion of the intervention, and provide detailed information about the intervention to the UC provider. This communication ensures that the UC provider is also informed about the challenges and strategies for the participant, so that the UC therapist is better able to assist the participant should similar situations reoccur in the future.

Comparator: Enhanced Usual Care. The comparator arm consists of weekly telephone checks for six weeks following the ED visit in addition to the UC recommended by the ED circle of care. The study coordinator will also contact parents in the comparator arm by telephone once weekly for six weeks. They will review changes to the youth's usual care and their contact with community resources in the 7 days prior to the phone call. As such, the aim of the EUC comparator is to improve access to mental health resources. It is not a therapeutic intervention in and of itself. The study coordinator will provide further information regarding community mental health resources as needed. If the parent indicates that the youth is in immediate risk for suicidal behaviour, 911 will be called. The ED team's referral suggestions plus weekly telephone follow-up represents EUC.

Study Staff:

The **Clinical Research Nurse** is a staff member of the Emergency Department trained in the study measures. They will be responsible for approaching and consenting participants. They will complete the screening measures in the ED.

The **Research Coordinator** is responsible for randomizing the participants, scheduling the participants' initial study visits, emailing electronic REDCap surveys, completing the enhanced usual care telephone visits, and overseeing the operation of the study. The research coordinator is trained to conduct the screening sessions if the clinical research nurse is unavailable.

The **Research Assistant** is responsible for completing the 6-week and 24-week study visits and is trained in the administration and scoring of the measures. The RA is also responsible for reimbursing participants. They are blinded to the intervention and group assignment.

The **Therapist** is responsible for scheduling and administering the F-SPS intervention with participants, and communicating with UC providers.

All staff will be certified in TCPS-II and GCP training, and fully trained on study measures that they are responsible for implementing. Certificates and training logs will be stored in an essential documents binder in the coordinators office.

Measures:

Primary Outcome Measures: Completed by Patient

The **Suicide Ideation Questionnaire Junior High School Version (SIQ-Jr)** is a 15-item measure self-report of suicide ideation (e.g., thoughts about death and dying) completed by the patient. Items are scored from 0 to 6. The measure takes 5 minutes, and is completed in-person at baseline, week 6 and week 24.

The **Suicide Behavior Questionnaire – Revised (SBQ-R)** is a 4-item self-report questionnaire that measures suicide behaviour (i.e., previous suicide attempts or the likelihood of future attempts) over the

lifetime (at baseline) or over 1 month period (follow-up). The measure takes less than 5 minutes, and is completed in-person at baseline, week 6 and week 24.

Secondary Outcome Measures: Completed by Child

The **Clinical Information** form is a 3-item record completed by the clinical research nurse. It captures the date and time of admission, the Canadian Triage and Acuity Scale score of the patient. It is completed at screening by the nurse using the clinical chart.

The **Columbia Impairment Scale – Child (CIS-C)** is a 13-item self-report scale designed to measure functioning on a 5 point Likert scale. This measure is completed by both the child and the parent(s) or caregiver. The measure takes 5 minutes, and is completed through REDcap at baseline, week 6 and week 24.

The **Conflict Behavior Questionnaire– Child (CBQ-C)** is a 20-item self-report scale that has a child report and parent report version that examines the parent-child relationship and measures conflict over a 6 month period at baseline, and over a 2 week period at follow-up. The child report version is to be completed about each parent. The measure takes 5 minutes, and is completed through REDcap at baseline, week 6 and week 24.

The **Life Problems Inventory (LPI)** is a 60-item self-report scale that measures life stressors on a 5 point Likert scale. The measure takes 15 minutes, and is completed through REDCap at baseline, week 6 and week 24.

The **Schedule for Affective Disorders and Schizophrenia for School Age Children, Present and Life Version (K-SADS-PL)** is a semi-structured psychiatric interview designed for use with children and adolescents. Parents and children are asked about current and lifetime history of psychiatric symptoms, including screens for depression, mania and psychosis. The mania and psychosis items take 15 minutes, and are administered by the study nurse at screening visit. The depression interview (DEP-C) takes 20 minutes, and is conducted by the research coordinator at baseline.

The **Feedback Form: Child Version** is an 8-item self-report measure created for this study that includes both quantitative and qualitative items and solicits feedback from youth enrolled in both the F-SPS + UC arm and the ECU arm. The measure takes less than five minutes, and is completed through REDCap at week 6.

The **Youth Self Report (YSR)** is a 112-item self-report measure of behavioral, emotional and social problems over a 6 month period at baseline, and over a 2 week period at follow-up. There are eight subscales: anxious/depressed, withdrawn/depressed, somatic complaints, social problems, thought problems, attention problems, rule-breaking behavior, and aggressive behavior. The measure takes 30 minutes, and is completed through REDCap at baseline, week 6 and week 24.

Secondary Outcome Measures: Completed by Parent(s) or Caregiver

The **Child Behavior Checklist (CBCL)** is a 112-item measure, completed by a parent or caregiver, of a child's behavioral, emotional and social problems over a 6 month period at baseline, and a 2 week period at follow-up. There are eight subscales: anxious/depressed, withdrawn/depressed, somatic complaints, social problems, thought problems, attention problems, rule-breaking behavior, and aggressive behavior. The measure takes 30 minutes, and is completed through REDCap at baseline, week 6 and week 24.

The **Children's Affective Liability Scale (CAL)** is a 20 item parent-report instrument that measures difficulties with emotion regulation on 5 point Likert scale. The measure takes five minutes, and is completed through REDcap at baseline, week 6 and week 24.

The **Columbia Impairment Scale – Parent Report (CIS-PR)** is a 13 item scale designed to measure functioning on a 5 point Likert scale. This measure is completed by both the child/adolescent and the parent(s). The measure takes 5 minutes and is completed through REDcap at baseline, week 6 and week 24.

The **Conflict Behavior Questionnaire– Parent Report (CBQ-PR)** is a 20 item scale that has a youth report and parent report version that examines the parent-child relationship and measures conflict over a 6 month period at baseline, and over a 2 week period at follow-up. The measure takes 5 minutes, and is completed through REDcap at baseline, week 6 and week 24.

The basic **demographic information** is collected at the initial assessment. This will include age, sex, date of birth, education, household income, parent occupation, and ethnicity. The measure takes five minutes, and is completed through REDcap at baseline.

The **Evaluation Form: Parent Version** is an 8-item, mixed quantitative and qualitative measure designed for this study that solicits feedback from parents of children enrolled either the F-SPS + UC arm or the ECU arm. This measure takes 5 minutes, and is completed through REDCap at week 6.

The **Health Care Utilization Survey (HCUS)** is a self-report questionnaire of participants' use of available health care services, medication, and the costs associated with those services. There are 11 questions that a participant answers, with an additional follow-up questions depending on answers. It takes 15 minutes, and is completed by the parent(s) or caregiver through REDCap at baseline and 24-weeks.

The **Usual Care Tracking Survey** is an abbreviated version of the Health Care Utilization Survey used to record changes in the patient's usual care over the course of the study. It is administered by the study therapist in-person to the parent(s) at week 1 through 6 for youth who are randomized to the F-SPS + UC, and is administered by the study coordinator over the phone at week 1 through week 6 for those randomized to the EUC arm. The measure takes 5 minutes.

Reimbursement

Participants will receive a \$20 gift card on their final visit of the study. They may also receive community service hours.

Table 1: Assessment Schedule

	Session								
	Screening	Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 24
<i>Patient Measures</i>									
K-SADS Mania and Psychosis Screen	x								
Clinical Information	x								
SIQ-JR	x							x	x
SBQ-R	x							x	x
Youth Demographic Form		x							
K-SADS DEP_C		x							
CIS-CR*		x						x	x
CBQ-C*		x						x	x
LPI*		x						x	x
YSR*		x						x	x
Feedback Form: Youth Version								x	
<i>Parent Measures</i>									
Caregiver Demographic Form*		x							
CALS*		x						x	x
CBCL*		x						x	x
CIS-P*		x						x	x
CBQ-P*		x						x	x
Health Care Utilization Survey*		x							x
Usual Care Tracking Survey			x	x	x	x	x	x	
Feedback Form: Parent Version*								x	

* Completed on REDcap Survey

Potential harms, discomforts and inconveniences to subjects

Participants and parents may experience negative emotions when completing the study measures, which inquire about difficult thoughts or feelings that the participant may be experiencing. However, as all children referred to the study have presented to the ED with suicidal ideation or suicide-risk behaviours, children and families will encounter similar questions during their clinical assessment. There are no harms associated with the suicide prevention intervention. There were no adverse effects of the pilot of the intervention. The intervention is two hours per week and may present a significant commitment of time for the family.

Questionnaires that measure potential immediate risk, such as suicidal ideation, will be administered in person to the patient. They will be reviewed at the time of completion. If there is any indication of immediate safety risk the research staff member will alert the appropriate staff – either the study clinician administering the suicide intervention, or the treating physician, and will follow the suicide risk standard operating procedure that we have developed.

Adverse Event Reporting

There are no expected adverse events related to the focused prevention suicide strategy or enhanced usual care. All expected and unexpected adverse events that occur during the participants' enrollment will be documented and reported as per Sickkids policy.

Potential benefit to subjects and society

Patients may benefit from participating in the intervention by accessing a suicide prevention program in addition to their treatment as usual. They are also assessed during at least two study time points for any immediate risk of self-harm, and an appropriate intervention can be applied if required.

There is currently no provincial or national strategy for preventing suicide attempts in Canadian adolescents. This study examines the effectiveness of one potential strategy that could be used as a foundation for creating such a strategy.

Participant Withdrawal Criteria

Participants and/or parents or guardians have the right to withdraw from the study at any time for any reason. The investigator also has the right to withdraw participants from the study if it is in the best interest of the participant. Should a participant and/or parent or guardian decide to withdraw, efforts will be made to document the reason for the withdrawal, if provided.

Participant withdrawal criteria are as follows:

- Withdrawal of informed consent (participant's decision to withdraw for any reason)
- Serious adverse event which, in the opinion of the investigator, indicates that continued participation in the study is not in the best interest of the participant
- Participant or parent or guardian non-compliance

In the event a subject is withdrawn due to an AE, this will be documented and participants will continue to be followed until these events are resolved or stabilized, if possible.

DATA MANAGEMENT AND ANALYSIS

Outcomes: This project will evaluate individual clinical outcomes, health care service utilization, client satisfaction, and implementation considerations; outcomes important to youth, family members, clinicians and policy-makers.

The *primary outcome measure* is change in Suicide Ideation Junior (SIQ-Jr) score. The SIQ-Jr is a youth-report measure of suicide risk behaviours that is valid, reliable, and sensitive to change²⁸ and in accordance with youth preferences for self-administered mental health and SRB measures. The SIQ-Jr has 15 items, is reliable and valid in 12-18 year olds, and has been used in clinical trials, providing known effect sizes for sample size calculations.

Secondary outcomes include measures that are also feasible, reliable, valid and sensitive to change. These include:

(2a) Mental illness symptom severity, including those of depression, anxiety, substance use, psychosis, affective lability, and disruptive behaviour, as reported by youth and parents and measured by the Youth Self-Report, Life Problems Inventory, and Children’s Behaviour Checklist¹⁷); (2b) functional impairment, as assessed by the Columbia Impairment Screen¹⁹(youth and parent report); (2c) family communication, assessed by the Conflict Behaviour Questionnaire²⁰(youth and parent report); (2d) cost-effectiveness analysis (CEA) of the incremental costs of the F-SPS as compared with UC in reducing SIQ-Jr score; and The frequency of ED and unscheduled (crisis) health appointments, using a health and social services diary and ICES databases, will be used to assess the effect of the F-SPS intervention on acute mental health crises. (2e) fidelity to the F-SPS intervention (implementation outcome) will employ a self-report measure to be developed by the project team. Measurement of treatment fidelity is key to understanding clinical and system level outcomes because an intervention cannot be effective unless it is appropriately implemented in the care pathway and developed with fidelity²⁹.

Power Analysis and Data Analytic Plan

The sample size calculation is based on the assessment of between-group difference in change in SIQ-Jr score. This is a superiority study in which the implementation of the F-SPS intervention should only be recommended for study in a larger, multi-centre sample if the change in the primary outcome is significantly greater than in the control group. Two controlled clinical trials of an ED based intervention for suicidal youth have reported effect sizes of 0.4 for suicide attempt and 0.95 for suicidal ideation as measured by the SIQ-JR²³. A sample size of 128 participants provides 80% power ($p=0.05$; 2-tailed t-test) to detect an effect size ≥ 0.5 , (based on a standard deviation [SD] of 14 and smallest clinically important difference of 7).

The principle of intent-to-treat will be applied to the analysis of outcomes. *H1*: The primary outcome SIQ-Jr will be compared between arms using repeated measures ANOCOVA with the corresponding baseline measure as the covariate. Mean differences and corresponding confidence intervals will be calculated. A two-sided, p-level of 0.05 will be applied for the primary outcome. *H2*: The number of unscheduled hospital visits will be compared between arms using a Poisson model. The two-sided level for the secondary outcomes will be adjusted (Bonferoni) to account for multiple testing. Implementation outcomes (i.e., fidelity to the intervention protocols) will inform client outcomes. Analysis of implementation data will be descriptive (fidelity to implementation of F-SPS model in both sites), and associative (statistical association of clinician fidelity to F-SPS and patient outcomes).

Feasibility. The ED at SickKids manages more adolescents with acute mental health presentations than any other hospital in the Toronto Central LHIN (TC-LHIN), on average 842 per year, (we estimate more than half for SRB). Sick Kids also has a strong history of successfully conducting ED-based RCTs and has

an established research infrastructure for identification and recruitment of potential research participants (Pediatric Research Academic Initiative at SickKids Emergency [PRAISE]). In addition, through our previous development work including an open pilot in the Urgent Care (Crisis) Clinic, several therapists at our centre are familiar with the intervention and have experience using it with acutely suicidal youth and families.

Privacy and Confidentiality

The confidentiality of clinical trial participants will be maintained. Participants will be assigned a unique study ID number. Information collected from participants will be de-identified, entered and stored in the REDCap external research database that is supported by SickKids research IT. Consent forms will be stored separately from registry data in a research folder that will be stored in a locked cabinet in a locked research office. Information linking identifying information to the registry ID will be stored separately in a password protected electronic file on a SickKids computer, only accessible to the PI and research team.

Data destruction and retention: Following completion of the study, the data will be kept as long as required then securely destroyed as required by SickKids policy. Hard copy documents will be shredded and disposed of in a secure manner. Electronic documents will be deleted securely.

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Figure 1: Study Flow Diagram

