WHO Data Set

Data Category	Information
Primary registry and trial identifying number	ClinicalTrials.gov: NCT03488602
Date of registration in primary registry	April 4, 2018
Secondary identifying numbers	Not applicable
Source(s) of monetary or material support	The Cundill Centre for Child and Youth Depression at the Centre for Addiction and Mental Health (CAMH); The SickKids Foundation; the Centre for Brain and Mental Health at SickKids.
Primary sponsor(s)	
Secondary sponsor(s)	
Contact for public queries	Matthew Tracey, MA – matthew.tracey@sickkids.ca
Contact for Scientific queries	Daphne Korczak, MD, MSc The Hospital for Sick Children The University of Toronto
Public title	Focused Suicide Prevention Strategy for Youth (FSPS)
Scientific title	A Focused Suicide Prevention Strategy for Youth Presenting to the Emergency Department with Suicide Related Behaviour: A Randomized Controlled Trial
Countries of recruitment	Canada
Health condition(s) or problem(s) studies	Suicidal ideation and behaviour
Interventions	Intervention: Manualized individual and family program. Weekly individual and family sessions with a therapist for 6 weeks.
	Active comparator: Weekly telephone contact with parents regarding participant health care utilization. Referrals to community mental health resources provided as needed.
Key inclusion and exclusion criteria	Ages eligible for study: ≥12 < 18 years Sexes eligible for study: both Accepts healthy volunteers: no
	Inclusion criteria: Presenting to the ED with Suicidal Ideation Questionnaire-Jr[24] (SIQ-Jr) score ≥ 31,
	Exclusion Criteria: Active psychosis or mania (ie a mood elevation score ≥3 on Kiddie Schedule of Affective Disorders and Schizophrenia[25] (KSADS) screen)
Study type	Interventional
	Allocation: Randomized controlled trial. Masking: single-blinded (outcome assessor)
	Phase: Not applicable
Date of first enrolment	March 01, 2018
Target sample size	128
Recruitment status	Recruiting
Primary outcome(s)	Change in suicidal ideation Method of measurement: Suicidal Ideation Questionnaire - Jr Timepoint: Screening, 6 weeks, 24 weeks
Key secondary outcomes	Symptoms of mental health, health care use, family communication, impairment.

ALCOHOL AND SUBSTANCE USE

Alcohol

1. How old were you when you first drank any alcoholic beverage, such as beer, mixed drinks or liquor?

- ☐ Has never drank alcohol. (SKIP to question 2)
- ☐ Has drank alcohol. Age of first use: _____

1a. How many days in the last month did you drink any amount of alcohol?

_____ days/months

1c. Did you drink on the day of your visit to the ED?

- ☐ Yes
- ☐ No

Cannabis

2. How old were you when you used cannabis, including drugs like marijuana, THC, or hash?

- ☐ Has never used cannabis
- ☐ Has used cannabis. Age of first use: _____

2a. How many days in the last month did you use any amount of cannabis?

_____ days/month

2c. Did you use any cannabis on the day of your visit to the ED?

- ☐ Yes
- ☐ No

Tobacco

3. Have you ever smoked cigarettes?

- ☐ Yes
- ☐ No

3a. During the last 30 days (one month), on the days that you smoked, how many cigarettes did you usually smoke?

- ☐ I did not smoke during the last 30 days (one month)
- ☐ Less than 1 cigarette per day
- ☐ 1 cigarette per day
- ☐ 2-5 cigarettes per day
- ☐ 6-10 cigarettes per day

- ☐ 11-20 cigarettes per day
- ☐ More than 20 cigarettes per day

Other Substances

4. Have you ever used any other substances (check all that apply)

- ☐ None
- ☐ Stimulants (*Speed, uppers, amphetamines, dexedrine, diet pills, crystal meth*)
- ☐ Sedatives/Hypnotics/Anxiolytics (*Barbiturates (sedatives, downers), Benzodiazepine, quaalude (ludes), valium, librium, Xanax*)
- ☐ Cocaine (*Coke, crack*)
- ☐ Opioids (*Heroin, morphine, codeine, methadone, demerol, percodan, oxycontin*)
- ☐ PCP (*Angel dust*)
- ☐ Hallucinogens (*Psychedelics, LSD, mescaline, peyote*)
- ☐ Solvents/Inhalants (*Glue, gasoline, chloroform, ether, paint*)
- ☐ Energy Drinks *(Monster Energy, Redbull, Rockstar, etc.)*
- ☐ Caffeine *(Coffee, Iced Coffee, Soft Drinks, etc.)*
- ☐ Other (*Prescription drugs, nitrous oxide, ecstasy, MDA, etc.*)

Health Care Utilization Survey

Record ID: _____

Extracurricular Activities

Does your child participate in extracurricular activities (outings/sports/hobbies)?
- ◯ No
- ◯ Yes
- ◯ Don't know

If yes, how many hours of extracurricular activities has [Youth] participated in over the last 6 months? (Estimate to best of ability) _____

Academic Activities

Is [YOUTH] currently enrolled in school?
- ◯ Yes
- ◯ No

Reason _____

Does [YOUTH] attend full-time (every day) or part time?
- ◯ Full-time
- ◯ Part-time

How many days of school has [YOUTH] missed over the last 6 months ? _____

DOCTOR VISITS

Has [YOUTH] seen a medical doctor in the last month?
- ◯ Yes
- ◯ No

When [YOUTH] attended medical doctor appointments, did someone typically go with [him/her]?
- ◯ Yes
- ◯ No

If yes, who?
- ☐ Mother
- ☐ Father
- ☐ Stepmother
- ☐ Stepfather
- ☐ Brother
- ☐ Sister
- ☐ Other relative
- ☐ Partner (boyfriend/girlfriend)
- ☐ Friend
- ☐ Other

Please specify: _____

How does [YOUTH] travel to and from the doctor's office?
- ☐ Personal Vehicle
- ☐ Public Transit
- ☐ Taxi/Uber

If [YOUTH] uses public transit how much do they normally spend traveling to and from the doctor's office? _____

If [YOUTH] uses taxi or uber how much do they normally spend traveling to and from the doctor's office? _____

If [YOUTH] or another family member drives, what is the distance to [YOUTHs] doctor's office? _____

Insurance Coverage

Do you have a drug plan that pays for any of [YOUTH] medications?
- ◯ No
- ◯ Yes
- ◯ Don't know

What is your Drug Plan?
- ◯ employee benefit package
- ◯ Ontario Drug Benefit Program (social assistance)
- ◯ Other
- ◯ Don't know, don't remember
- ◯ Not applicable

Please specify: _____

Do you pay a specific amount before the drug plan begins (in other words, a deductible)?
- ◯ No
- ◯ Yes
- ◯ Don't Know

What is the amount of the deductible? _____

Per:
- ◯ Month
- ◯ Year
- ◯ Don't know what the deductible is

Do you have to pay a certain amount of the total drug price or dispensing fee every time you buy prescription medications (in other words, a co-payment)?
- ◯ No
- ◯ Yes
- ◯ Don't Know

What is the amount of this co-payment? _____

What is the fraction or percentage of prescription medication costs that you pay? _____

Do you have a private health plan that covers other medical expenses such as physical therapy, ambulance services, medical devices etc?
- ◯ No
- ◯ Yes
- ◯ Don't Know

How much do you pay into this plan (the premium)? _____

Time Frame
- ◯ Per Month
- ◯ Per Year

Do you have a private disability insurance?
- ◯ No
- ◯ Yes
- ◯ Don't Know

How much do you pay into this plan (the premium)? _____

Time Frame
- ◯ Per Month
- ◯ Per Year

Emergency Room Visits

Has [YOUTH] gone to the hospital in an ambulance in the last 6 months?
- ◯ Yes
- ◯ No

How many times did [YOUTH] do so? _____

When [YOUTH] went to the hospital in an ambulance, did someone typically go with [him/her]?
- ◯ Yes
- ◯ No

If yes, who?
- ☐ Mother
- ☐ Father
- ☐ Stepmother
- ☐ Stepfather
- ☐ Brother
- ☐ Sister
- ☐ Other relative
- ☐ Partner (boyfriend/girlfriend)
- ☐ Friend
- ☐ Other

Please specify: _____

Did you have to pay for the ambulance services?
- ◯ Yes
- ◯ No
- ◯ Don't know/can't remember
- ◯ Not applicable

How much did you spend on these ambulance services? _____

Has [YOUTH] gone to the emergency room by some other method of transportation in the last 6 months?
- ◯ Yes
- ◯ No

How many times did [YOUTH] do so? _____

Please describe the reasons [YOUTH] went to the emergency room

_____

Hospital Admissions

Has [YOUTH] been admitted to the hospital in the last 6 months?
- ◯ Yes
- ◯ No

How many times was [YOUTH] admitted to the hospital? _____

When [YOUTH] was admitted to the hospital, did someone typically visit you [him/her]?
- ◯ Yes
- ◯ No

If yes, who?
- ☐ Mother
- ☐ Father
- ☐ Stepmother
- ☐ Stepfather
- ☐ Brother
- ☐ Sister
- ☐ Other relative
- ☐ Partner (boyfriend/girlfriend)
- ☐ Friend
- ☐ Other (please specify)

Please describe the dates and reasons for these admissions to the hospital:

Date of admission _____

Reason for being admitted _____

Length of time in hospital (days) _____

Date of admission _____

Reason for being admitted _____

Length of time in hospital (days) _____

Allied Health Professionals and Social Service Providers

Have [YOUTH] made visits to health care or social service providers (physiotherapist, social worker, adolescent/school counsellor, children's aid, family counsellor, occupational therapist, psychologists, nurse, chiropractor, police officer, parole officer, support group) in the last 6 months?

◯ Yes
◯ No

When [YOUTH] made these visits, did someone typically go with [him/her]?

◯ Yes
◯ No

If yes, who?

☐ Mother
☐ Father
☐ Stepmother
☐ Stepfather
☐ Brother
☐ Sister
☐ Other relative
☐ Partner (boyfriend/girlfriend)
☐ Friend
☐ Other (please specify)

Please specify: _____

Can you describe who [YOUTH] went to see, how many visits there were, how much was spent on each of these visits and whether you had to pay for this visit yourself or if it was covered by insurance?

Health Professional

◯ Family Counsellor
◯ Adolescent/School Counsellor
◯ Social Worker
◯ Psychologist
◯ Nurse
◯ Other

Please specify: _____

Number of Visits _____

Amount Spent _____

Self-Paid or Insurance

◯ Self-paid
◯ Insurance

Mileage/Parking _____

Health Professional

◯ Family Counsellor
◯ Adolescent/School Counsellor
◯ Social Worker
◯ Psychologist
◯ Nurse
◯ Other

Please specify: _____

Number of Visits _____

Amount Spent _____

Self-Paid or Insurance

◯ Self-paid
◯ Insurance

Mileage/Parking _____

Health Professional

◯ Family Counsellor
◯ Adolescent/School Counsellor
◯ Social Worker
◯ Psychologist
◯ Nurse
◯ Other

Please specify: _____

Number of Visits _____

Amount Spent _____

Self-Paid or Insurance

◯ Self-paid
◯ Insurance

Mileage/Parking _____

Loss of time from work (paid or unpaid)

Do you work in paid employment?

◯ Yes
◯ No

Do you participate in any volunteer activities or unpaid employment?

◯ Yes
◯ No

Have you had to miss any time from work/volunteer activities to go to the doctor, emergency room or while your child was admitted to the hospital?

◯ Yes
◯ No
◯ Not applicable

Can you estimate how many days, in total, you had to take off? _____

When [YOUTH] went to the doctor, emergency room or were admitted to the hospital, has anyone else (ie. another caregiver) had to miss time from paid employment to help you care for [YOUTH] or accompany [YOUTH]?

◯ Yes
◯ No
◯ Not applicable

Can you estimate how many days, in total, they had to take off? _____

During the XXX weeks, were you or other family members prevented from engaging in any activities such as shopping volunteer work, visiting friends, going to the movies etc., to care for [youth]

◯ Yes
◯ No
◯ Not applicable

Can you estimate how many days (or hours), in total, this was?

_____

During the XXX weeks, were you or other family members prevented from engaging in your regular homemaking tasks to care for [youth]

◯ Yes
◯ No
◯ Not applicable

Can you estimate how many days (or hours), in total, this was?

_____

Do you pay for any individual to assist you with homemaking activities?

◯ Yes
◯ No
◯ Not applicable

Can you estimate how much you spent in the last XXX weeks?

_____

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

Therapy Fidelity Checklist

Participant ID: **Provider:**

Session: **Date:**

Item	Rating
Referred to the SAFETY manual	☐ Yes ☐ No
Conducted the correct module for the session (e.g., Module 1 in session 1)	☐ Yes ☐ No
Reviewed the safety plan with the youth	☐ Yes ☐ No
Reviewed what strategies from the preceding session that the youth used over the week	☐ Yes ☐ No
Incorporated previous content (e.g., motivations, goals, coping strategies) in session ("remember when we talked about…")	☐ Yes ☐ No
Brought the parents/caregiver into the session	☐ Yes ☐ No
Reviewed the last week with parent/caregiver	☐ Yes ☐ No
Set an agenda with family at the beginning of session	☐ Yes ☐ No
Addressed communication between youth and parent/caregiver	☐ Yes ☐ No
Assigned tasks for youth and parent/caregiver between sessions	☐ Yes ☐ No