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

NCT: Not yet assigned

Date: October 31, 2017

RESEARCH CONSENT FORM – PARTICIPANT CONSENT

Title of the Research Project:

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

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Study Funder:

The Peter Cundill Centre for Child and Youth Depression and the SickKids Foundation

Conflicts of Interest

Dr. Korczak, and the other research team members have no conflict of interest to declare.

Introduction

We would like to invite both you and your parent(s), or a caregiver (who is your legal guardian) to take part in our research study. This consent form describes the research study and what it means for you to participate.

Before deciding to take part, please take as much time as you need to ask any questions that you have. You are encouraged to discuss this study with anyone at SickKids, with family, friends, your family doctor, or any members of your community that you trust if that is helpful to you. Participation in any research study is voluntary, and you do not have to take part if you don't want to.

Why am I being asked to participate?

This research study compares how helpful two different programs are for preventing suicidal behaviour in youth. You are invited to participate in this trial because you are between the ages of 12 and 18 years old, and you have attended the hospital Emergency Department (ED) because of risk of hurting yourself, and our study team has screened you and found you to be eligible for the study.

As part of your usual care, the team in the ED will help you and your family to create a safety plan. They will also recommend a course of treatment. This might include admitting you to the hospital inpatient unit, prescribing you a medication, referral to treatment either at SickKids or mental health resources for children and families in the community, follow up with your usual care provider, or a combination of these things.

If you take part in this study, you and your parent(s) or caregiver will receive the usual care described above. In addition to your usual care, as part of the study, you will be assigned to one of two types of suicide prevention strategies: an in-person program or a telephone-based program. The in-person program is now available for youth admitted to the inpatient unit at SickKids. We want to know if it will be effective for youth in an outpatient setting as well.

This study requires the participation of you and your parent(s) or caregiver.

Why is this study being done?

The purpose of this study is to compare two different programs of care for adolescents at risk of hurting themselves, and to see if one program is more helpful than the other. The findings of this study could be used to inform how care is provided in the future.

What other choices are there?

You do not have to take part in this study in order to receive usual treatment or care. The team in the ED will talk to you and your family about your choices for treatment.

How many participants will be in this study?

This study is being done at SickKids, and will involve both youth and their parent(s) or caregivers. We hope to enroll 128 youth with at least 128 parent(s) or caregivers.

How long will the study take?

You will be in this study for about 24 weeks (6 months). Regardless of which group you are assigned to, you and your parent(s) or caregiver will be asked to complete three in-person study visits: one at the beginning of the study, and follow-up visits at 6-weeks and 24-weeks. If you are assigned to the in-person program you will also be expected to attend six treatment appointments in addition to the three study visits mentioned above.

This study should take two years to complete and the results should be known in about three years' time.

What will happen if you join this study?

You and your parent(s) or caregiver will either be assigned to the in-person program or the telephone program, in addition to the care recommended for you by the ED circle of care. If you decide to participate you will be "randomized" into one of the study programs described below. Randomization means that you are put into either the in-person program or the telephone contact group by chance. It is like flipping a coin. Neither you nor your doctor can choose what group you will be in. You will have a 50/50 chance of being placed in either program.

You and the study therapist will know whether you are receiving the in-person or telephone program; however some study staff members will not know which program you are in. The staff will tell you whether or not they are allowed to know what program you are in. We hope that you help us maintain the study properly, and do not speak about the program with staff unless they have told you that you may. You are able to speak about the program with your friends, family or care providers outside the health team as you wish.

What is the study intervention?

Group 1 (In-person program and usual care): If you and your parent(s) or caregiver are assigned to this program, you will need to come to SickKids once a week for six weeks to meet with a therapist. Each session takes about two hours. As part of this program, the therapist will use a workbook to help guide your treatment, and to ensure your safety.

The workbook explores the common thoughts, feelings and conflicts that suicidal youth experience. It teaches coping and safety skills to adolescents and their families, and teaches families how to talk about feelings. The therapist can also talk about other problems you may have like problems at school, or problems with your family or friends.

Both you and your parent(s) or caregiver will take part in each session. Your therapist will spend the first hour with you one-on-one, and the last hour with you and your parent(s) or caregiver together.

The in-person sessions will be audio recorded with you and your parent(s) or caregiver's permission. This is done to make sure that the therapist is properly following the program. The recordings will not be used as part of the research study.

Group 2 (Telephone program and usual care): If you are randomized to this program, then your parent(s) or caregiver will receive a telephone call from our research team once per week for 6 weeks to follow-up with your progress. The team will speak with your parent(s) or caregiver to make sure they get detailed information about your usual care. The phone call will be in addition to the usual care recommended in the ED.

During the phone call the research team member will ask your parent(s) or caregiver whether there have been any changes to your treatment, or to your use of health care services. The team member will provide information on treatments in your community if you and your parent(s) or caregiver need them.

What are the study procedures?

Screening Visit: You are being asked to consent to this study because you have been found to be eligible during the screening visit in the ED.

With you and your parent(s) or caregiver's verbal permission, the research staff gave you questionnaires that ask about thoughts, feelings and behaviours related to mental health. The staff also has recorded the date and time of your visit to the ED, the reason for your visit, and your acuity score – which is a rating of how quickly the staff needed to see you in the ED. They used this information to determine if you are eligible for the study.

Baseline Study Visit: A research team member will contact you and your parent(s) or caregiver approximately one business day after your ED visit, and they will provide you with more details about the study. They will book your baseline study visit for approximately one week before your program starts.

During the baseline visit you will be asked to complete five questionnaires, and your parent(s) or caregiver will be asked to complete five questionnaires as well. The questionnaires will ask about your mood, your relationship with your parent(s) or caregiver, and problems or difficulties you may have recently experienced. The baseline visit will last approximately 60 to 90 minutes, and may be completed at SickKids hospital or at your home, depending on what is most convenient.

Randomization: Immediately after your baseline visit is complete you will be randomly assigned to either the in-person or telephone program. There is a 50/50 chance (like flipping a coin) of being assigned to either program. After you are randomized a research staff member will contact you to explain what program you are in, and schedule your first appointment. The first session will usually be scheduled within two weeks of today.

Weeks 1 – 6 In-Person Program: If you and your parent(s) or caregiver are randomized to receive the in-person program, you will then attend six weekly sessions, each lasting about two hours.

Weeks 1 – 6 Telephone Program: If you and your parent(s) or caregiver are randomized to receive telephone program you will receive a weekly follow-up call from study staff, each lasting about 10 minutes.

Week 6 and Week 24 Study Visits: Six weeks, and 24 weeks after your first in-person/telephone visit you will be asked to complete seven questionnaires, and your parent(s) or caregiver will be asked to complete six questionnaires. These will be similar to the questionnaires you completed at your baseline visit. You will also be asked to provide feedback about your experience in the program. These visits will last approximately 60 to 90 minutes, and may be completed at SickKids hospital or at your home, depending on what is most convenient.

Withdrawal or End of Study Visit: If you and your parent(s) or caregiver are taken out of the study for any reason, or if you decide not to participate any longer, you will be asked to complete a final study visit to make sure you are safe. This will be scheduled as soon as possible.

Visit	Activity
Screening (Today)	• Answer questions with the nurse • Fill out questionnaires • Read consent form
Baseline **(Within the next week)**	• Receive phone call • Complete questionnaires • Parent(s) fill out questionnaires • Assigned to in-person treatment or phone appointment • First appointment scheduled
Week 1 – Week 5 (Week 1 within the next 2 weeks)	• Attend in-person **or** receive phone call each week
Week 6	• Attend in-person **or** receive phone call • Complete questionnaires in-person • Parent(s) complete questionnaires in-person
Week 24	• Complete questionnaires in-person • Parent(s) complete questionnaires in-person

Optional Component, Long Term Follow-Up:
As part of this study we wish to study our participants' use of health care services. We will look at your scheduled and unscheduled medical appointments over a longer period of time, including after you are finished this study. We will do so by using the Institute of Clinical Evaluative Sciences (ICES) database. ICES is a secure database based in Ontario that stores patient records.

We are asking your permission to collect your health card number (OHIP number) for this optional component. At the end of the study, your health card number will be provided to ICES where it will be linked with other health care databases to obtain information about your use of health care. The ICES follows processes and procedures approved by the Privacy Commissioner of Ontario to ensure personal health information is protected at all times.

Your OHIP number has already been recorded as part of your emergency department visit at SickKids, and by signing "yes" below you are agreeing to allow the research staff to use your OHIP number to access the records within ICES's pre-existing database. All of the data ICES gives us is anonymous, and we will not be able to trace it back to you.

This is an extra, optional component of the study. You do not have to agree to this optional component to take part in the study. You will not have any extra study visits if you agree to take part in this component.

What are the risks, harms or discomforts of the study?

Some of the questionnaires ask about your thoughts and feelings. In rare instances, these questions may cause anxiety or emotional distress. If you do feel distress while answering questions, please let the study team know, and they will either provide you with a break, or stop the questionnaires depending on your preferences. The information you provide during all study visits is for research purposes only. You can choose not to answer questions if you do not feel comfortable doing so.

If your symptoms have worsened during the study, and there is concern for immediate risk to your safety, or someone else's safety, the staff may call 911 or advise your parent(s) or caregiver to bring you to a hospital.

If you and your parent(s) or caregiver are randomized into the in-person program group, you will all be asked to attend weekly, two-hour sessions for six weeks which may be a significant time commitment. There is a possibility that in person visits may be scheduled during regular office hour and may result in missed school or work.

Are there benefits from being in the study?

You may not benefit from being part of this study. If you and your family receive the in-person program, you will have the additional benefit of 6 sessions with the study therapist in addition to standard care. If you receive the telephone contact program, you will have the additional benefit of regular follow-up regarding your engagement with ongoing mental health care.

The information we gain from this study may provide information which can be used to improve the care provided to adolescents at risk of suicide.

What are your responsibilities in this study?

If you choose to participate in this study, you will be expected to:

- Tell the study team about your current medical conditions;

- Tell the study team if you are thinking about participating in another research study;
- Ask the study team about anything that worries you;
- Tell the study team about anything that has changed about your health;
- Tell the study team if you change your mind about being in this study.

Can I choose to leave the study?
Being in the study is voluntary. You can change your mind and withdraw from the study at any time. You do not need to give a reason. If you withdraw from the study then your parent(s) or caregiver will also be withdrawn. We will ask that you and your parent(s) or caregiver complete a final visit before withdrawing from the study.

Withdrawal from the study will not have any effect on the care you or your family will receive at SickKids. If you decide to leave the study, you can contact the Principal Investigator or a member of the study team to let them know.

How will your privacy be protected?

We will respect your privacy. The funder is also committed to respecting your privacy. No information about you will be given to anyone or be published without your permission, unless the law requires us to do this.

The SickKids study staff will collect personal health information about you. This includes things learned from the study procedures described in this consent form and/or information from your medical records. They will only collect the information they need for the study.

All personal health information or personal information collected about you will be "de-identified" by replacing your identifiable information with a "study number". The SickKids study staff are in control of the study code key, which is needed to connect your personal health information/personal information to you. The link between the study number and your identity will be safeguarded by the SickKids study staff and will not be available to the sponsor. SickKids guidelines include the following:

- All information that identifies you, both paper copy and electronic information, will be kept confidential and stored and locked in a secure place that only the study staff will be able to access.
- Electronic files will be stored securely on hospital or institutional networks or securely on any portable electronic devices.
- No information identifying you will be allowed off site in any form without your consent. Examples include your hospital or clinic charts, copies of any part of your charts, or notes made from your charts.

The study will also collect personal information that could identify you, such as:

- Name;
- Address;
- Full date of birth;
- Sensitive information about mental health problems.

The study staff and the others listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

Access to your personal health information will take place under the supervision of the Study Doctor. You have the right to access, review and request changes to your personal health information.

The following people may come to the hospital to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of the SickKids Research Ethics Board and/or Research Quality and Risk Management team.

The study staff will keep any personal health information about you in a secure and confidential location for 7 years and then destroy it according to SickKids policy. When the results of this study are published, your identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete.

For example, the law could make us give information about you or your child

- If a child has been abused
- If you have an illness that could spread to others
- If you or someone else talks about harming themselves or others, or
- If the court orders us to give them study papers

Representatives of the SickKids Research Ethics Board and the Office of Research Quality may see your child's summarized data and consent form to make sure that the study is being done properly.
The study staff will not disclose any of your personal health information to the study funders.

Will it cost you anything to be in this study?

Participation in this study will not involve any additional costs to you or your private health care insurance. Costs for travel or parking will not be reimbursed by the study.

Will I be reimbursed if I join this study?

While you will not be paid for participating in this study, you will receive a gift card of $20 at your final visit in recognition of your time and effort. All participants will also receive community service hours in recognition of their time commitment.

What if I am injured during/in this study?

If you suffer an injury from participation in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this consent form waive you or your legal rights nor release the study doctor(s), sponsors or involved institutions from their legal and professional responsibilities.

How will I be informed about new information?

We may learn new information during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information in a timely manner. You may also be asked to sign a new consent form discussing these new findings if you decide to continue in the research study.

What are your rights when participating in a research study?

You have the right to receive all information that could help you make a decision about participating in this study. You also have the right, throughout the study, to ask questions about this study and to have them answered to your satisfaction, before you make any decisions.

Who can I call if I have questions about the study?

If you have any questions during your participation in this research study you can contact the Study Coordinator at 416-813-7654 x201575 or the Principal Investigator, Dr. Daphne Korczak, at 416-813-7531. Both can be reached during regular office hours, Monday – Friday from 9 AM to 5 PM.

For any concerns outside of regular office hours, Kids Help Phone is available at 1-800-668-6868 (KidsHelpPhone.ca). If there is an emergency please call 911 or go to your nearest hospital Emergency Department.

Research Ethics Board Contact information

If you have any questions regarding your rights as a research participant, you may contact the Office of the Research Ethics Board at 416-813-8279 during business hours.

Consent to Participate in a Research Study

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

By signing this research consent form, I understand and confirm that:

1. The study has been explained to me and all of my questions have been answered.
2. I have the right not to take part in the study.
3. I can stop participating or withdraw from the study at any time without affecting the quality of care myself or my family receives at SickKids.
4. The possible harms and benefits (if any) of this study have been explained to me.
5. I have been told that my medical records will be kept private except as described to me.
6. I know that no information about me will be given to anyone or be published without first asking permission, unless required by law.
7. I have been told that I have not waived my legal rights nor released the investigators, sponsors, or involved institutions from their legal and professional responsibilities.
8. I have been given sufficient time to read and think about the information in this consent form.
9. I know that I may ask now, or in the future, any questions I have about the study.

I consent to participate in this study. I have been told I will be given a signed and dated copy of this consent form.

Printed Name of Participant	Participant signature & date

Printed Name of person who obtained consent	Role of person obtaining consent	Signature & date

Permission to link OHIP number to ICES File

As part of this study we wish to study our participants' use of health care services. We will look at your scheduled and unscheduled medical appointments over a longer period of time, including after you are finished this study. We will do so by using the Institute of Clinical Evaluative Sciences (ICES) database. ICES is a secure database based in Ontario that stores patient records.

We are asking your permission to collect your health card number (OHIP number) for this optional component. At the end of the study, your health card number will be provided to ICES where it will be linked with other health care databases to obtain information about your use of health care. The ICES follows processes and procedures approved by the Privacy Commissioner of Ontario to ensure personal health information is protected at all times.

Your OHIP number has already been recorded as part of your emergency department visit at SickKids, and by signing "yes" below you are agreeing to allow the research staff to use your OHIP number to access the records within ICES's pre-existing database. All of the data ICES gives us is anonymous, and we will not be able to trace it back to you.

This is an extra, optional component of the study. You do not have to agree to this optional component to take part in the study. You will not have any extra study visits if you agree to take part in this component.

Do you agree to let us use your heath card number to link with your ICES patient record?

☐ **Yes** **Initials: _____**

☐ **No** **Initials: _____**

Consent for Audio Recording

The tapes produced from this study will be stored in a secure, locked location and used for training. Only members of the research team (and maybe the SickKids monitor, will have access to them. Following completion of the study the tapes/pictures will be kept as long as required in the SickKids "Records Retention and Destruction" policy. They will then be destroyed according to this same policy.

By signing this form,

1) I also agree to be taped during this study. These tapes will be used by the research team to ensure that the study therapist provides care according to their standards.

2) I understand that I have the right to refuse to take part in this study. I also have the right to withdraw from this part of the study at any time. E.g., before or even after the tapes are made. My decision will not affect my health care at SickKids.

3) I am free now, and in the future, to ask questions about the taping.

4) I have been told that my medical records will be kept private. You will give no one information about me, unless the law requires you to.

5) I understand that no information about me (including these tapes) will be given to anyone or be published without first asking my permission."

6) I have read and understood this consent form. I agree, or consent, to having my picture taken/being taped as part of the study.

_____	_____
Printed Name of Subject	*Subject's signature & date*
_____	_____
Printed Name of person who explained consent	*Signature & date*
_____	_____
Printed Witness' name (subject does not read English)	

Witness' signature & date

In addition, I agree or consent for this tape(s) to be used for:

1. *Other studies on the same topic.*
2. *Teaching and demonstration at SickKids.*
3. *Teaching and demonstration at meetings outside SickKids.*
4. *Not to be used for anything else.*

In agreeing to the use of the tapes for other purposes, I have been offered a chance to hear the tapes. I also have the right to withdraw my permission for other uses of the tapes at any time.

_____	_____
Printed Name of Subject	*Subject's signature & date*
_____	_____
Printed Name of person who explained consent	*Signature & date*

RESEARCH CONSENT FORM – PARENT OR CAREGIVER AS PARTICIPANT CONSENT

Title of the Research Project:

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

Principal Investigator:

Daphne Korczak, MD, MSc FRCPC 416-813-7531
Department of Psychiatry

Co-Principal Investigator:

Yaron Finkelstein, MD, FACMT, Divisions of Emergency Medicine and Clinical Pharmacology and Toxicology, Sick Kids, University of Toronto

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Gloria Chaim, Child, Youth and Family Program, Centre for Addiction and Mental Health
Joanna Henderson, Centre for Child, Youth and Family Mental Health, Centre for Addiction and Mental Health
Suneeta Monga, Department of Psychiatry, Hospital for Sick Children
David Juurlink, Scientist, Institute for Clinical Evaluative Sciences
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Research Team Member Contact:

Matthew Tracey 416 813 7654 X201575
Reva Schachter 416 813 7654 X201469
Julia Zucker 416 813 7654 X202056

Study Funder

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Conflicts of Interest

Dr. Korczak, and the other research team members have no conflict of interest to declare.

Introduction

We would like to invite you to take part in our research study. This consent form describes the research study and what it means to participate.

Before deciding to take part, please take as much time as you need to ask any questions that you have. You may discuss this study with anyone at SickKids; or with your child, friends, your family doctor; or any members of your community that you trust if that is helpful to you. Participation in any research study is voluntary, and you do not have to participate if you don't want to.

Why am I being asked to participate?

This research study compares the effectiveness of two different programs for preventing suicidal thoughts and behaviours in youth. You are being invited to participate in this trial because you are the parent or caretaker of a child that is between the ages of 12 and 18 years old who has attended the hospital Emergency Department (ED) because he or she is at risk of self-harm, and our study team has screened your child and found him or her to be eligible for the study.

As part of your child's usual care, the team in the ED will help you to create a safety plan. They will also recommend a course of treatment. This might include admitting your child to the hospital inpatient unit, prescription a medication, referral to treatment either at SickKids or mental health resources for children and families in the community, follow up with your usual care provider, or a combination of these things.

If you participate in this study, you and your child will receive the usual care described above. In addition to your usual care, as part of the study, you and your child will be assigned to one of two types of suicide prevention strategies: an in-person or a telephone-based program. The in-person program is now available for youth admitted to the inpatient unit at SickKids. We want to know if it will be effective for youth in an outpatient setting as well.

Both programs require the participation of both the child and the parent(s) or caregiver. This form provides information on what it means for you to participate in this study as a parent or caregiver.

Why is this study being done?

The purpose of this study is to compare two different programs of care for adolescents at risk of self-harm, and to see if one program is more helpful than the other. The findings of this study could be used to inform how care is provided in the future.

What other choices are there?

You and your child do not have to take part in this study in order to receive usual treatment or care. The team in the ED will talk to you about your choices for treatment.

How many participants will be in this study?

This study is being done at SickKids, and will involve both youth and their parent(s) or caregivers. We hope to enroll 128 youth with at least 128 parent(s) or caregivers.

How long will the study take?

You will be in this study for about 24 weeks (6 months). Regardless of which group you and your child are assigned to, you and your child will be asked to complete three in-person study visits: one at the beginning of the study, and follow-up visits at 6-weeks and 24-weeks. If you are assigned to the in-person program you will also be expected to attend six treatment appointments in addition to the three study visits mentioned above.

This study should take two years to complete and the results should be known in about three years.

What will happen if you join this study?

You and your child will either be assigned to the in-person or the telephone program, in addition to the care recommended for your child by the ED circle of care. If you and your child decide to participate then you will be "randomized" into one of the study groups described below. Randomization means that you and your child will have a 50/50 chance of being assigned to either the in-person program or the telephone program by chance. It's like flipping a coin. You cannot choose what program to be in, nor can your doctor.

You, your child and the study therapist will know whether you are assigned to the in-person or telephone program, however some study staff members will not know which program you are in. The staff will tell you whether or not they are allowed to know what program you are in. We hope that you help us maintain the study properly, and do not speak about your program with staff unless they have told you that you may. You are able to speak about your treatment with your friends, family, or care providers outside the health team as you wish.

What is the study intervention?

Group 1 (In-person program and usual care): If you and your child are assigned to this program you will need to come to SickKids once a week for six weeks to meet with a therapist. Each session takes two hours. As part of the program the therapist will use a workbook to help guide the treatment, and to ensure your child's safety. The workbook explores the common thoughts, feelings and conflicts that suicidal youth experience, and teaches coping and safety skills to adolescents and their families.

The program is family centered, which means both you and your child are required for each session. The therapist will spend the first hour with your child one-on-one, and the last hour with you and your child together. They will address sources of conflict between you and your child, improve communication between you. The program will be tailored to address key concerns that you and your child might have,

including: mental health, academic problems, social or family conflict, acculturation issues, gender concerns or other stressors.

In-person sessions will be audio recorded with you and child's permission. This is done to make sure that the therapist is properly following the structure of the program. The recordings will not be used as part of the analysis of the program or any reports.

Group 2 (Telephone contact program and usual care): If you and your child are assigned to this program, you will receive a telephone call from our research team once per week for six weeks to follow-up with your child's progress. We will speak with you to ensure we receive accurate information about your child's usual care. The phone calls will be in addition to the usual care recommended in the ED.

During the phone conversation the research staff member will ask you about whether there have been any changes to your child's treatment, or to your child's connection to mental health care services. The team member will provide information on treatments in your community, if you and your child need them.

What are the study procedures?

Screening Visit: You are being asked to consent to this study because your child has been found to be eligible during the screening visit in the ED.

With you and your child's verbal permission, a research nurse provided your child with two questionnaires about thoughts, feelings and behaviours related to mental health, and asked your child several additional questions about mental health. The nurse also recorded several pieces of information from your child's clinical chart, including the date and time of admission to the ED, the reason for admission, and the acuity score – which determines how fast a patient is seen in the ED. The research nurse used the results of these questionnaires to see if you are eligible for the study..

Baseline Study Visit: A research team member will contact you approximately one business day after your child's ED visit, and they will provide you with more details about the study. They will book your baseline study visit for approximately one week before the program starts.

During the baseline visit you will be asked to complete five questionnaires about your child's mood, your relationship with your child, and problems or difficulties your child may have recently experienced. The baseline visit will last approximately 60 to 90 minutes, and may be completed in-person at SickKids hospital or at your home, depending on what is most convenient.

Randomization: Immediately after the baseline visit you and your child will be randomly assigned to receive either the in-person or telephone contact program. There is a 50/50 chance (like flipping a coin) of being assigned to either group. After you are randomized a research staff member will contact you to schedule your first appointment. The first session will usually be scheduled within two weeks of today.

Weeks 1 – 6 In-Person Program: If you and your child are randomly selected to receive the in-person then you will attend six weekly sessions each lasting about two hours. The first session will usually be scheduled within two weeks from today.

Weeks 1 – 6 Telephone Program: If you and your child are randomized to receive telephone program then you will receive a weekly follow-up call from a research team member, each lasting about 10 minutes

Week 6 and Week 24 Study Visits: Six weeks, 24 weeks after your first in-person/telephone visit, you will be asked to complete six questionnaires. They will be similar to the questionnaires you completed at your baseline visit. You will also be asked to provide feedback about your experience in the program. These visits will each last approximately 60 to 90 minutes, and may be completed at SickKids hospital or at your home, depending on what is most convenient.

Withdrawal or End of Study Visit: If you are taken out of the study for any reason, or if you decide not to participate any longer, you will be asked to complete a final study visit to make sure your child is safe. This will be scheduled as soon as possible.

Visit	Activity
Screening (Today)	• Child answer questions with the nurse • Fill out questionnaires • Read consent form
Baseline Phone Call **(Within the next week)**	• Receive phone call. • Parent(s) or caregiver fill out questionnaires • Assigned to in-person treatment or phone appointment • First appointment scheduled
Week 1 – Week 5 **(Week 1 within the next 2 weeks)**	• Attend in-person **or** receive phone call each week
Week 6	• Attend in-person **or** receive phone call • Complete questionnaires in-person • Parent(s) or caregiver complete questionnaires in-person
Week 24	• Complete questionnaires in-person • Parent(s) or caregiver complete questionnaires in-person

What are the risks, harms or discomforts of the study?

Some of the questionnaires ask about thoughts and feelings. In rare instances, these questions may cause anxiety or emotional distress. If you do experience distress while answering questions, please let the study team know; they will provide you with a break, or stop the questionnaires depending on your preferences. The information you provide during all study visits is for research purposes only. You can choose not to answer questions if you do not feel comfortable doing so.

If your child's symptoms have worsened and there is concern for immediate risk to their safety, or someone else's safety, the staff may call 911 or advise you to bring your child to a hospital

If you and your child are randomized into the in-person program group, you will all be asked to attend weekly, two-hour sessions for six weeks, which may be a significant time commitment for you. There is a possibility that in-person visits may be scheduled during regular office hour and may result in missed work.

Are there benefits from being in the study?

You may not benefit from being part of this study. If you receive the in-person program you will have the additional benefit of six sessions with the study therapist in addition to standard care. If you receive the telephone program, you will have the additional benefit of regular follow-up regarding your engagement with ongoing mental health care.

The information we gain from this study may provide information which can be used to improve the care provided to adolescents at risk of suicide.

What are my responsibilities in this study?

If you choose to participate in this study, you will be expected to:

- Tell the study team if you are thinking about participating in another research study;
- Ask the study team about anything that worries you;
- Tell the study team if you change your mind about being in this study.

Can I choose to leave the study?

Being in the study is voluntary. You can change your mind about participating at any time. You do not need to give a reason to withdraw from the study. If you withdraw from the study then your child will also be withdrawn. We will ask that you and your child complete a final visit before withdrawing from the study.

Withdrawal from the study will not have any effect on the care you and your child will receive at SickKids. If you decide to leave the study, you can contact the Principal Investigator or a research team member of the study team to let them know.

How will your privacy be protected?

We will respect you your child's privacy. The funder is also committed to respecting your privacy. No information about you or your child will be given to anyone or be published without you and your child's permission, unless the law requires us to do this.

The SickKids study staff will collect personal health information about you and your child. This includes things learned from the study procedures described in this consent form and/or information from your medical records. They will only collect the information they need for the study.

All personal health information or personal information collected about you and your child will be "de-identified" by replacing your identifiable information with a "study number". The SickKids study staff are in control of the study code key, which is needed to connect you and your child's personal health information/personal information to you. The link between the study number and your identity will be safeguarded by the SickKids study staff and will not be available to the sponsor. SickKids guidelines include the following:

- All information that identifies you and your child, paper copy and electronic information will be kept confidential and stored and locked in a secure place that only the study staff will be able to access.
- Electronic files will be stored securely on hospital or institutional networks or securely on any portable electronic devices.
- No information identifying you or your child will be allowed off site in any form without you and your child's consent. Examples include hospital or clinic charts, copies of any part of your child's charts, or notes made from the charts.

The study will also collect personal information that could identify you or your child, such as:

- Name;
- Address;
- Education and occupation information

The study staff and the others listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

Access to you and your child's personal health information will take place under the supervision of the Study Doctor. You have the right to access, review and request changes to your personal health information.

The following people may come to the hospital to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of the SickKids Research Ethics Board and/or Research Quality and Risk Management team.

The study staff will keep any personal information about you in a secure and confidential location for seven years and then destroy it according to SickKids policy. When the results of this study are published, your identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete.

No information about who are will be given to anyone outside of the research team or be published without your permission, unless required by law.

For example, the law could make us give information about you

- If a child has been abused
- If you have an illness that could spread to others
- If you or someone else talks about harming themselves or others, or
- If the court orders us to give them study papers

Representatives of the SickKids Research Ethics Board and the Office of Research Quality may see your child's summarized data and consent form to make sure that the study is being done properly.

The study staff will not disclose any of your personal information to the study funders.

Will it cost me anything to be in this study?

Participation in this study will not involve any additional costs to you or your child's private health care insurance. You may incur travel costs for being part of this study. Costs for travel or parking will not be reimbursed by the study.

Will I be reimbursed for being part of this study?

You will not be reimbursed for participating in this study.

What if I am injured during/in this study?

If you suffer an injury from participation in this study, medical care will be provided in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this consent form waive your legal rights nor release the study doctor(s), funders or the hospital from their legal and professional responsibilities.

How will my child and I be informed about new information?

We may learn new information during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information in a timely manner. You may also be asked to sign a new consent form discussing these new findings if you decide to continue in the research study.

What are your rights when participating in a research study?

You have the right to receive all information that could help you make a decision about participating in this study. You also have the right, throughout the study, to ask questions about this study and you and to have them answered to your satisfaction, before you make any decisions.

Who can I call if I have questions about the study?

If you have any questions during your participation in this research study you can contact the Study Coordinator at 416-813-7654 x201575 or the Principal Investigator, Dr. Daphne Korczak, at 416-813-7531. Both can be reached during regular office hours, Monday – Friday from 9 AM to 5 PM.

For any concerns outside of regular office hours, Kids Help Phone is available at 1-800-668-6868 (KidsHelpPhone.ca). If there is an emergency please call 911 or go to your nearest hospital Emergency Department.

Research Ethics Board Contact information

If you have any questions regarding your rights as a research participant, you may contact the Office of the Research Ethics Board at 416-813-8279 during business hours.

Consent to Participate in a Research Study

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

By signing this research consent form, I understand and confirm that:

10. The study has been explained to me and all of my questions have been answered.
11. I have the right not to take part in the study.
12. I can stop participating or withdraw from the study at any time without affecting the quality of care my child or my family receives at SickKids.
13. The possible harms and benefits (if any) of this study have been explained to me.
14. I have been told that my medical records will be kept private except as described to me.
15. I know that no information about me will be given to anyone or be published without first asking permission, unless required by law.
16. I have been told that I have not waived my legal rights nor released the investigators, sponsors, or involved institutions from their legal and professional responsibilities.
17. I have been given sufficient time to read and think about the information in this consent form.
18. I know that I may ask now, or in the future, any questions I have about the study.

I consent to participate in this study. I have been told I will be given a signed and dated copy of this consent form.

Printed Name of Participant	Participant signature & date

Printed Name of person who obtained consent	Role of person obtaining consent	Signature & date

Consent for Audio Recording

The tapes produced from this study will be stored in a secure, locked location and used for training. Only members of the research team (and maybe the SickKids monitor, will have access to them. Following completion of the study the tapes/pictures will be kept as long as required in the SickKids "Records Retention and Destruction" policy. They will then be destroyed according to this same policy.

By signing this form,

1) I also agree to be taped during this study. These tapes will be used by the research team to ensure that the study therapist provides care according to their standards.

2) I understand that I have the right to refuse to take part in this study. I also have the right to withdraw from this part of the study at any time. E.g., before or even after the tapes are made. My decision will not affect my health care at SickKids.

3) I am free now, and in the future, to ask questions about the taping.

4) I have been told that my medical records will be kept private. You will give no one information about me, unless the law requires you to.

5) I understand that no information about me (including these tapes) will be given to anyone or be published without first asking my permission."

6) I have read and understood this consent form. I agree, or consent, to having my picture taken/being taped as part of the study.

_____ _____

Printed Name of Subject *Subject's signature & date*

_____ _____

Printed Name of person who explained consent *Signature & date*

_____ _____

Printed Witness' name (subject does not read English) *Witness' signature & date*

In addition, I agree or consent for this tape(s)/photograph(s) to be used for:

1. *Other studies on the same topic.*
2. *Teaching and demonstration at SickKids.*
3. *Teaching and demonstration at meetings outside SickKids.*
4. *Not to be used for anything else.*

. I also have the right to withdraw my permission for other uses of the tapes at any time.

_____ _____

Printed Name of Subject *Subject's signature & date*

_____ _____

Printed Name of person who explained consent *Signature & date*