Developing Text-based Support for Parents of Adolescents After an Emergency Department Visit

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RESEARCH PROTOCOL

FULL STUDY TITLE: Developing text-based support for parents of suicidal adolescents after emergency department visits: A multi-component intervention pilot

SHORT STUDY TITLE: Developing text-based support for parents of adolescents after an emergency department visit

BACKGROUND

Suicide, the second leading cause of death among 13 to 17-year-olds in the United States,[1] is a major public health crisis. Emergency departments (EDs) increasingly serve as the first and only line of clinical contact for suicidal adolescents,[2-4] many of whom experience post-discharge suicide attempts and related crises requiring return ED visits.[5-7] Unfortunately, a considerable number of youth at risk for suicide seen in EDs do not link to outpatient treatment or, if they do, these services may be delayed or prematurely discontinued.[8-11] During this high-risk period, parents or other caregivers are often at the forefront of suicide prevention, yet they report feeling overwhelmed and unsure about how to best care for their child's post-discharge needs.[12-14] Thus, intervening with suicidal youth and their families during or shortly after an ED visit offers a promising window of opportunity to prevent post-discharge crises.

Thus, to improve post-ED bridging care and reduce youth suicidal crises, we propose to develop and pilot an adaptive, text-based intervention targeting two interrelated domains: (1) supporting parents in promoting the safety and well-being of suicidal adolescents and (2) providing support directed at enhancing parents' own well-being.

Text messages offer an accessible continuity of care strategy after ED care, as they are nearly ubiquitous in the United States,[22] and have been used to support a range of behavioral and health outcomes.[23-27] Because suicidal adolescents are heterogeneous with respect to varying levels of suicide risk[33,34]—and parents may experience varying caregiving challenges and stress—a texting intervention should ideally be tailored to address parents' unique and changing needs. Aiming to maximize outcomes while minimizing burden, a Just-In-Time Adaptive Intervention (JITAI) is an intervention design that adapts the provision of mobile-based interventions to meet the dynamically changing needs of individuals in the "real" world.[35,36] This study will build the foundation for an effective JITAI for parents of suicidal youth by investigating the feasibility and acceptability of employing a micro-randomized trial (MRT)—an experimental design used for optimizing JITAIs.[38]

STUDY PURPOSE

This study seeks to develop and pilot an adaptive, text-based intervention for parents of suicidal youth transitioning from ED care. The study will address an urgent need for efficacious continuity of care strategies for suicidal youth post ED care using a scalable approach. The study's aims are as follows:

Aim 1 (Non-Clinical Trial):

Finalize text-based intervention components in preparation for the pilot study. Drawing on theoretical and clinical considerations, as well as our preliminary parent focus group data, we will develop text messages focused on two domains: (1) messages encouraging parental provision of adolescent-focused (A-F) support (e.g., suicide prevention activities, communication, tips for supporting at-risk youth); and (2) messages providing parent-focused (P-F) support (e.g., affirmation, tips for parents' own well-being). Text messages will be iteratively refined based on input from experts and parents.

Aim 2:

2a: As part of Aim 2, Pilot the text-based intervention to demonstrate its feasibility and acceptability. Parents of suicidal adolescents seeking ED services will be randomized to one of three groups: a control group or one of two 6-week intervention groups receiving either the A-F or A-F plus P-F texting components. Beyond feasibility and acceptability, we will explore the effect of intervention groups on the proposed mechanism (parental self-efficacy) and distal outcomes (engagement in suicide prevention activities) assessed over 2-, 6-, and 12-weeks post ED visit. Follow-up youth outcomes (e.g., suicide attempt and ED visit) will also be explored.

2b: As part of Aim 2, pilot an embedded MRT to inform the development of a JITAI for parents of suicidal youth. Because all elements of A-F are seen as essential, while P-F support may require adaptation, the A-F plus P-F arm will include an embedded MRT involving two daily randomizations to P-F message vs. no message conditions for the duration of the 6-week intervention. We will explore if, and when, the P-F message vs. no message condition influences within-person proximal outcomes (parental stress, mood) assessed daily for the 6 weeks.

Aim 1 is preparatory non-trial work to Aim 2 - the clinical trial.

METHODS

Participants and Study Enrollment Criteria: Participants will include adolescent-parent pairs recruited from Psychiatric Emergency Services (PES) at the University of Michigan. Research assistants will screen admission logs for participant eligibility based on adolescents' age (13-17) and presenting problem due to (1) last-week suicidal ideation and/or (2) recent (within a month) suicide attempt/behavior (actual, interrupted, aborted suicide attempt). Exclusion criteria will include (1) youth with severe cognitive impairment or altered mental status (e.g., psychosis, manic state), (2) youth with severe aggression/agitation, (3) no availability of a legal guardian, or (4) parents not owning a cell phone with text messaging capability. Eligible PES patients and their parents will be approached by research assistants for parent/guardian consent and adolescent assent during recruitment shifts.

Eligible participants who provide consent/assent will participate in Aim 1 or Aim 2. Separate consent/assent forms for Aim 1 and Aim 2 will be provided at enrollment. Methods specific to Aims 1 and 2 are described below.

Unless listed in the Primary Analysis under "*Data Analysis for Aim 2*" section, all outcomes and assessments are exploratory or ancillary.

Aim 1 (Non-Clinical Trial) Methods:

Initial Development of Text Messages: An initial "bank" of text messages for the A-F and P-F intervention components will be developed using an iterative process. This process will draw on (a) relevant theory, (b) best-practice recommendations, (c) content area knowledge, and (d) our research team's preliminary data drawn from previous focus groups conducted with parents of suicidal adolescents after ED discharge. The tone of the messages will incorporate Motivational Interviewing (MI) principles as an additional strategy to increase parents' self-efficacy and motivation to implement the suggested recommendations and tips for adolescent- and parent-directed support. Some messages will incorporate links to additional online resources or information.

Description of Components and Sample Messages:

Adolescent-focused support (A-F component): The A-F texting component will include content consistent with best-practice recommendations for parents to buffer youth against suicide risk. This will incorporate messages focusing on: (1) restricting access to lethal means; (2) recognizing and attending to suicide warning signs; (3) encouraging adolescent's use of coping strategies; (4) ways parents can support and assist the youth in using the safety plan; (5) monitoring and supervising the youth with sensitive queries about mood and suicidality; (6) responding in a sensitive manner to disclosures of distress and suicidality; (7) tips for communication; (8) providing emotional support and engaging in activities promoting connectedness; and (9) reminders about crisis resources.

Parent-focused support (P-F component): The P-F texting component will include content focused on providing parent-directed support (e.g., encouragement, affirmations), as well as tips for parents' self-care and own well-being.

Procedures for Obtaining Parent Feedback in Aim 1: Parents meeting inclusion/exclusion criteria, as described above, will be recruited during or shortly after their adolescent's ED visit. Parents will provide feedback during or following the ED visit using an online survey to maximize retention. We will compile parents' ratings of messages with regard to the extent to which each message was perceived positively (5-point scale ranging from "disliked a lot" to "liked a lot"). For each message, parents' specific feedback will also be solicited and used to modify or discard specific messages. Moreover, parents will be asked to provide their opinions regarding message content they would prefer to receive as well as the proposed structure of the text-based intervention (e.g., frequency and duration of text messages). Feedback will be obtained with a survey build using a Qualtrics survey system, and the survey will take approximately 20-30 minutes to complete. Participating parents will be compensated $30, and their feedback will be used to finalize the bank of messages.

Aim 2 Methods:

Overview of Aim 2 Procedures:
After providing informed consent / assent, participants will be enrolled in the study. After completing a baseline survey, parent-adolescent pairs will be randomized to one of three groups: control (standard ED care), A-F texting component alone, or A-F in combination with P-F texting component. Parents randomized to either A-F or A-F plus P-F intervention groups will receive the text-based intervention over a course of six weeks following their adolescent's ED discharge. The P-F component includes an embedded MRT, which will allow us to examine the feasibility and acceptability of conducting an MRT, as well as explore if and under what conditions receiving the P-F message may be most beneficial. Participants who are randomized to receive the P-F texting component (as part of the A-F + P-F intervention arm) will be randomized twice each day (morning and evening) to either receive or not receive the P-F message at each randomization; at each randomization, the probability of either receiving or not receiving the P-F message will be 50%. As such, parents receiving the P-F component will receive between none and two P-F messages on any given day, on average receiving one P-F message on any given day. Over the course of the 6-week intervention, parents in the A-F condition will receive 1 message each day, and parents in the A-F + P-F condition will receive between 1-3 messages, based on randomization (on average, 2 messages each day).

Assessment Procedures for Aim 2:
Participating parents and adolescents will complete baseline assessment during the index ED visit. Parents and adolescents will be asked to complete baseline measures using Qualtrics on a study-provided tablet computer. Participants will also be provided the option of filling out the measures using a paper and pencil format if they prefer or if any technological difficulties are encountered that would

prevent the completion of the surveys on a tablet computer. Parents and adolescents will each receive $10 for completing the baseline assessment. Follow-up assessments will be conducted approximately 2, 6, and 12 weeks after enrollment. Parents and adolescents will complete assessments at 2 and 6 weeks using online surveys (using Qualtrics software). Parents will be compensated $20, and adolescents will be compensated $15 for completing each of the two online surveys. The 12-week follow-up, which will be used to assess youth suicide attempts and return ED visits, will be conducted over the telephone by a trained research interviewer. Adolescents and parents will each receive $30 for completing the 12-week assessment. Chart data will also be abstracted to obtain relevant clinical information (e.g. psychiatric diagnoses, reason for hospitalization, previous hospitalizations). Finally, parent satisfaction with intervention components will also be assessed.

Aim 2 assessments were not collected for assessing primary or exploratory outcomes unless noted within the Aim 2 data analysis section.

Baseline Assessments

Parents at Baseline:
- Demographics
- DERS-SF
- Parental Self-Efficacy Scale
- PSC-17
- Mental Health Service Utilization Scale
- Multidimensional Scale of Perceived Social Support
- PHQ-4
- PHQ-10
- CGSQ-SF7
- Family History Screen
- GF-FAD
- Social/Emotional Support
- PANAS
- Munich Chronotype Questionnaire
- Safety measures (home environment lethal means restriction)

Adolescents at Baseline:
- Demographics
- DERS-SF
- AUDIT-C
- C-SSRS
- NIDA-modified ASSIST
- NSSI
- PHQ-9
- GAD-7
- Brief Hopelessness Scale
- Self-Efficacy to Cope with Suicidal Thoughts and Urges Scale
- Self-Rated Expectations of Risk
- Parent-Family Connectedness Scale
- GF-FAD
- Parent-Family Connected Scale
- Pediatric Family Relationships

Follow-Up Assessments at 2, 6 and 12 weeks

Parents:
- Parents' engagement in suicide prevention activities
- Parental Self-Efficacy Scale (parental coping self-efficacy)
- Social/Emotional Support
- PHQ-4 (depression and anxiety symptoms)
- PHQ-10 (areas of functioning in daily life)
- CGSQ-SF7 (caregiver stress)
- PANAS (positive and negative affect)
- Mental Health Service Utilization Scale (only at 6 and 12 weeks)
- Intervention Feedback (only at 6 weeks)
- Multidimensional Scale of Perceived Social Support (only at 12 weeks)
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Adolescents:
- Parents' engagement in suicide prevention activities
- PHQ-4 (depression and anxiety symptoms)
- PHQ-10 (areas of functioning in daily life)
- Brief Hopelessness Scale (hopelessness)
- Self-Efficacy to Cope with Suicidal Thoughts and Urges Scale (suicide coping self-efficacy)
- Self-Rated Expectations of Risk (perceived suicidal behavior risk)
- Parent-Family Connectedness Scale (perceived connectedness to parents/family)
- Pediatric Family Relationships (family support)
- Mental Health Service Utilization (only at 12 weeks)
- C-SSRS (only at 12 weeks)

Daily Surveys:
All parents will respond to brief daily surveys over the 6-week intervention. Two brief (1-2 min) online surveys will be sent to parents' phone each day (morning and afternoon/evening) via text message using a secure automated delivery system. Parents will be provided with approximately 2 hours to complete the daily survey. To increase adherence, parents will be provided with an incentive of $2 for each daily survey. Items will be brief and drawn from known and validated scales.

Data Analysis for Aim 2:

Primary Analysis: We will obtain descriptive data related to intervention feasibility and acceptability as measured by: (1) percentage of eligible participants who agree to participate in the study, (2) percentage of participants who complete follow-up assessments, (3) of those randomized to the texting intervention, percentages of parents who remain active (i.e. do not request to stop receiving messages), and (4) parents' satisfaction with the intervention.

Exploratory Analyses: In exploratory analyses, we will explore the effect of intervention on the proposed mechanism of change (parental self-efficacy) assessed at 2-, 6-, and 12-weeks post enrollment, we will use multi-level analyses for continuous variables (linear mixed-effects models). We will also conduct exploratory analyses of the effect of intervention on the proposed distal outcome of parental engagement in supportive and suicide prevention activities, assessed at 2-, 6-, and 12-weeks post enrollment. Analyses will be conducted using an intent-to-treat approach. Finally, we will describe differences between intervention vs. control regarding youth suicidal behavior outcomes at the 12-week follow-up.

We will conduct exploratory analyses on the primary proximal outcome (parental stress) using a generalization of regression developed for analyzing MRT data, specifically developed to ensure unbiased estimated of effects of time-varying treatments (i.e. sending a P-F message vs. not) on a time-varying outcomes (i.e. parental stress). Finally, for the exploratory analyses on the secondary proximal outcome, i.e. parental positive and negative affect, we will also use the generalization of regression analyses to explore if, on average across participants, receiving the P-F message is associated with a decrease in parental negative affect and an increase in positive affect.

RISK MANAGEMENT

The use of trained research staff for completing assessments will ensure that any potential safety issues are identified and appropriately addressed in accordance with study protocol. The PI will closely supervise research staff. Ensuring that any potential safety issues are appropriately addressed will be enhanced by the availability of an on-call psychologist. To this end, the study will have a comprehensive Risk Management Protocol detailing guidelines for managing safety concerns, including responding to high suicide risk and appropriate documentation. In particular, adolescents' suicidal ideation and behavior will be assessed at the time of the 12-week assessment. Trained research interviewers conducting the assessments will complete an Action Plan, detailing criteria and steps for initiating consultation with an on-call psychologist and includes documenting whether or not a participant met the study's high-risk criteria. The on-call supervisor will be available by telephone during scheduled assessments in case an adolescent meets high suicide risk criteria (e.g., recent suicidal ideation with thoughts of method, suicidal intent and/or plan; and/or disclosure of suicidal behavior since index ED visit). An endorsement of responses items indicating a high level of risk will result in the research staff member initiating the Action, which specifies next steps (e.g., contact the adolescent's parent/guardian; contact the on-call psychologist; provide recommendations in consultation with the on-call psychologists; contact emergency services, if needed).

CONFIDENTIALITY

The study team will be trained in maintaining the confidentiality of participant data, and every effort will be made to ensure that study data storage practices will ensure that data cannot be linked to a particular person. Unique identification numbers will be assigned to all participants. Participants' names and study IDs will be kept in a separate file from study data. All linking files will be maintained in a secure password-protected file on a secure server. All data will be coded with this ID rather than with a name. Electronic data files (e.g. surveys) will not contain any identifying information. Consent forms will be stored separately from data. Steps will also be taken to minimize breaches of confidentiality associated with the data collection tools used in the study. Online surveys will be developed in Qualtrics, with no identifying information collected via Qualtrics.

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