Developing an adaptive intervention for suicidal adolescents following inpatient hospitalization: A pilot SMART

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STUDY AIMS

Youth suicide, one of the leading causes of death among adolescents,[1] has tragically increased in recent years[2] and is a national priority.[3] However, there is a paucity of effective interventions for adolescent suicidal behavior.[4-6] In particular, there is a critical need for developing interventions for psychiatrically hospitalized suicidal teens, many of whom are at a high risk for repeated suicide attempts, persisting suicidal ideation, emergency department (ED) visits, and rehospitalizations.[7-9] These events are associated with long-term psychosocial impairment[10,11] and increased healthcare system costs.[12] Intervening with suicidal teens during and shortly after hospitalization offers a promising window of opportunity to prevent relapse of suicide-related events. Because suicidal youth are at varying levels of risk after discharge[7,13] and vary in their response to interventions,[14-16] interventions should ideally be adapted to their heterogeneous treatment needs. Concerned with optimizing outcomes while reducing burden and cost, an adaptive intervention (AI) is a treatment design that individualizes the type, intensity, and timing of treatment.[17-20] However, there currently are no AIs for youth suicide prevention. Moreover, despite the ubiquity and youths' preference for mobile communication,[21,22] using mobile technology to augment interventions for suicidal youth is understudied. The significant need to address heterogeneity in suicidal youth transitioning from inpatient care, and the potential of mobile technology to facilitate engagement and increase intervention impact, calls for adaptive technology-enhanced interventions to reduce suicide-related outcomes. We propose to conduct a Sequential Multiple Assignment Randomized Trial (SMART) pilot to inform the development of a technology-augmented AI for suicidal youth. The AI will focus on strengthening adolescents' motivation and self-efficacy to use their safety plans and adaptive coping post-discharge. The proposed intervention (MI-SafeCope) will include three components: (1) a Motivational Interview (MI)-enhanced safety plan delivered during hospitalization, which incorporates an individual and a family meeting; (2) post-discharge MI-enhanced booster calls; and (3) personalized daily text messages delivered to adolescents for one month after discharge. Specific aims are:

Aim 1. To finalize intervention components, study implementation protocol, and fidelity assessment tools in preparation for the pilot SMAR. Specifically, we will develop and refine the text message boosters. The message content will be iteratively refined based on consultation with experts and feedback from adolescent.

Aim 2. To conduct the pilot SMART with adolescent inpatients to demonstrate acceptability and feasibility of study procedures, including the sequencing of intervention components. Participants will be randomized to MI-enhanced safety plan with and without text boosters (Phase 1 intervention) and then re-randomized to an added telephone booster call or no call (Phase 2 intervention). We will:

2a) Evaluate feasibility of study procedures and implementation of intervention components and sequencing;

2b) Assess intervention acceptability (i..e. participant satisfaction; rates of attrition and adherence);

2c) Define indicators of response to Phase 1 intervention by exploring candidate tailoring variables.

2d) Conduct exploratory analyses of intervention effects on proximal /mechanisms (e.g., coping, safety plan use, self-efficacy) and distal (suicidal ideation/behavior) outcomes.

INTERVENTION COMPONENTS

MI-Enhanced Safety Plan Developed at Hospitalization (all teens receive this component).
Individual Meeting: An individualized safety plan, incorporating common elements of safety planning,[23 27] will be developed with the teen to use during a suicidal crisis. This "best practices" approach for treating suicidal individuals[23-41] is augmented with MI[28] as a core strategy to explicitly elicit adolescents' motivation and commitment to behavior change (i.e. use safety plan; adaptive coping), address barriers or ambivalence, and strengthen self-efficacy. A 4-phase MI framework[28] will be used, which includes engaging, focusing, evoking, and planning to guide the session.

Family Meeting: Similarly guided by MI, the family meeting includes a focus on preparing parents, with input from the adolescent, for how they may support the adolescent in implementing the individualized safety plan after discharge and on strengthening parents' commitment and self-efficacy to follow through with these recommendations. Parents' roles are also crucial in maintaining adequate monitoring, securing lethal means, and providing general support to their adolescents. Involving parents in safety planning is thus essential.

Post-Discharge Components (teens receive none, one, or both components; see Figure). Because heterogeneity in post-discharge functioning (e.g. suicidal ideation severity) and response to the MI-enhanced safety plan (e.g. coping behavior) is expected, the safety plan may or may not need to be supplemented with additional follow-up components to further strengthen adolescents' motivation and self-efficacy for healthy coping. Because the highest risk for the relapse of suicide-related events is during the first month after discharge,[5] we propose to deliver these follow-up components within this most critical risk period.

Text Message Boosters: The safety plan component may be followed with daily text message boosters for a month after discharge to further enhance adolescents' self-efficacy and motivation to use adaptive coping in their natural environment, which has the potential to increase the impact of the intervention. For example, the messages will be tailored to encourage use of individualized coping strategies identified as part of safety planning at hospitalization. Messages will also encourage accessing different types of support and introduce additional coping tools (e.g. coping tips and skills) and resources (e.g. crisis lines, websites). The text message content and tone will be consistent with principles of MI (e.g. affirming statements; open-ended questions encouraging reflection and generating solutions; MI-consistent language to provide coping tips).

Booster Calls: The safety plan component may be followed with a booster call with the adolescent and the parent in week 3 after discharge to further adjust the safety plan to better meet post-discharge needs, to further enhance adolescents' motivation and commitment to use coping strategies, and to further support adolescents' and parents' self-efficacy to manage suicidal crises.

METHODS

Eligibility and Enrollment of Participant Recruitment. Participants will include 80 adolescents (ages 13 to 17) recruited from the Child and Adolescent Psychiatry Inpatient Program at the University of Michigan. Charts will be screened for eligibility based on either (1) past-month suicide attempt or (2) past-week suicidal ideation with method, intent, or plan (based on Columbia-Suicide Severity Rating Scale[29]). Exclusion criteria will include (1) severe cognitive impairment or altered mental status (psychosis, manic state), (2) transfer to medical unit or residential placement, (3) no availability of a legal guardian, or (4) no cell phone with text messaging capability. Adolescents and parents will be approached during admission or visiting hours. Those who provide consent/assent will participate in Aim 1(text component development) or Aim 2 (pilot SMART).

Aim 2 activities are described below.

Pilot Design. Eighty adolescents (ages 13-17) meeting inclusion/exclusion criteria and their parents will participate in the SMART pilot. All participants who complete the baseline assessment will receive the in-person intervention components (individua and family meeting) on the inpatient unit and will subsequently be randomized as outlined below.

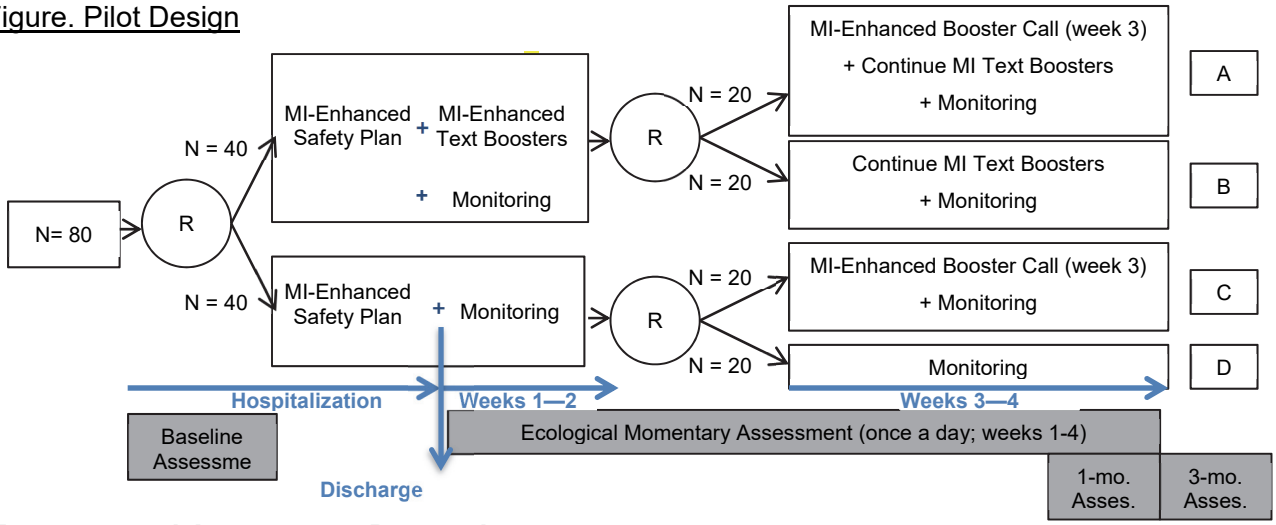
The in-person MI-SafeCope intervention will be delivered during the inpatient stay and the adolescent's condition (stabilization; e.g. likely not on the first day of being admitted) will be considered for the timing of intervention delivery. The meeting with the adolescent will take approximately 60 minutes, the family meeting approximately 30 minutes. The in-person intervention component will be guided by the goal to develop personalized coping strategies that the adolescent has self-efficacy and motivation to use after discharge (a safety plan template will be used in the session) and by empowering the adolescent's parent/guardian to supporting the adolescent's coping (Parent Crisis Card will be used in the session). Sessions will be tape recorded for clinician supervision purposes, and participants will be asked to provide a brief feedback survey.

As shown in the Figure, adolescents will be randomized twice. The first randomization will be to either MI-enhanced safety plan at hospitalization alone (the in-person intervention component described above) or MI-enhanced safety plan at hospitalization in combination with text boosters for two weeks after discharge **(Phase**

1). At the end of week 2, all participants will be re-randomized to two additional weeks of either: (a) continuation of Phase 1 intervention or (b) continuation of Phase 1 intervention with the addition of the MI-enhanced booster call in week 3 **(Phase 2)**. Thus, participants will receive one of four treatment sequences (A-D; see Figure).

For those randomized to receive the MI-enhanced booster call, the study therapist will call the adolescent and parent approximately three weeks of discharge. The booster phone call with adolescent and with parent, each conducted separately, will take approximately 15 minutes. In the even that a teen is rehospitalized prior to the booster call being completed, we will try to complete the follow-up call during the teen's hospitalization stay (if appropriate, e.g. the teen has been stabilized) or approximately within one or two weeks following the new discharge. For participants randomized to receive text boosters, messages will be sent once a day ("pushes") for a total of 4 weeks, and teens will receive a second text message enabling them to request additional support messages by texting a pre-specified keyword ("pulls"). Thus, teens will receive two supportive text messages per day. The "bank" of these messages is based on feedback from teens obtained in Aim 1. Participants will receive the messages at a time that is identified by participants. Messages will be sent to participants' phone using an automated and secure text message delivery system.

Figure. Pilot Design



Measures and Assessment Protocol.

Primary Outcome Measures:

1. Percentage of eligible participants recruited will be used to assess feasibility and acceptability.
2. Percentage of randomized participants and who complete intervention components will be used to assess feasibility and acceptability.
3. Percentage of participants who complete study assessments will be used to assess feasibility and acceptability.
4. Satisfaction ratings will be used to assess acceptability.

All other measures are considered exploratory.

Assessments:

a. Baseline Assessments (adolescents and guardians/parents)

Participants will be asked to complete baseline measures using Qualtrics on Tablet computers. Participants will be provided the option of filling out the baseline 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. In addition, parents who are not able to fill out baseline surveys in person, will have the option to complete these by phone or via internet (Qualtrics) survey link sent to their email or by text message. Participating adolescents and parents will be compensated $20 and $10, respectively, for completing the baseline assessment.

b. 1- and 3-month Follow-ups (adolescents and guardians/parents)

These assessments will be completed over the phone, however, participants will have the option of completing all or some of these follow-up measures online; they may also have the option to receive these measures online but provide their answers to a research staff member over the phone to facilitate the phone assessment. For each of the 1- and 3-month follow-up assessment, adolescents will receive $30 and parents will receive $20 as a thank you for their time. The compensation will be provided as a gift card in person and follow-up compensation will be loaded after completing the follow-up assessments.

c. Daily Surveys) (adolescents)

Participating adolescents will be asked to complete daily surveys for 4 weeks after discharge. Participants will be compensated up to $142 for completing daily surveys ($4 x 28 days and an additional $30 if they complete 75% daily surveys). Online survey links will be sent via text message to participants' phones once a day in the evening for a month. The Qualtrics survey links (using the University of Michigan Qualtrics system) will be sent to participants by a text message. Participants will be able to complete these 2-5 minute surveys on their phone or by copying the link into a computer browser (if they do not have a smartphone). Participants may be contacted by phone if they miss three consecutive surveys to inquire if they are experiencing technical difficulties. We will assess suicidal ideation/behavior, coping behavior, self-efficacy, and other factors (affect, connectedness, hopelessness, etc.). Of note, the automated text message delivery system will not store identifiable information, including names, demographic information, any other sensitive information, or data. The survey links themselves received by participants will link to the University of Michigan Qualtrics data collection tool. No identifying information will be collected via daily diaries using Qualtrics.

Risk Management.

a. Daily Diaries:

Participant daily responses (particularly suicidal ideation questions) will be monitored very closely to determine if there is an increase in level of suicide risk. This will be achieved in several ways.

(1) An endorsement of an acute/high level of risk (defined as an endorsement of current suicidal ideation together with current suicidal intent or plan OR an endorsement of a suicide attempt in the last 24 hours) on the daily questionnaire will result in an automated message displayed as part of the survey urging that the participant seeks support and providing phone numbers to the crisis line and emergency contacts. The PI, or the backup clinician on call, will also receive an automated message from Qualtrics that a participant with a specific ID number endorsed acute risk. To protect confidentiality, this notification will only indicate a specific ID number associated with a participant endorsing this response. As the primary on-call psychologist, the PI, or backup on-call clinician, will initiate the Action Plan, which will involve calling the adolescent and parent/guardian as soon as possible on the same day. Once a participant is contacted, an Action Plan will be filled out and recommendations will be made. If the adolescent and/or parent are not reachable after several tries to reach them, the PI, or backup clinician on-call, may contact appropriate emergency services or authorities to seek assistance. This will be described in the consent form and discussed with participants during the consent process. It is important to also note that participant responses will be reviewed daily to safeguard against the unlikely possibility that acute/high risk participants were missed via the automated alert process.

(2) An endorsement of a moderate level of risk (defined as an endorsement of suicidal ideation within the last 24 hours but no current suicidal intent or plan) on the daily questionnaire will result in an automated message displayed as part of the survey urging that the participant seems support and providing phone numbers to the crisis line and emergency contacts.

b. Follow-up Assessments and Follow-up Phone Call:

Participants who disclose either a) current active suicidal thoughts (within the last week) or b) who disclose suicidal action (actual attempt, aborted, or interrupted suicide attempt) since last assessment will be asked follow-up questions, as per Action Plan, and appropriate recommendations – in consultation with an on-call clinician— will be provided. Risk management procedures will be reviewed regularly to ensure compliance with the protocol.

Therapist Training and Fidelity. Training and fidelity protocols/tools will be developed in Aim 1. Therapists will participate in a MI training workshop and will complete intervention-specific training that will be developed and provided by the PI. Therapists will demonstrate proficiency by completing a series of role-plays prior to delivering the intervention. To monitor fidelity, therapists will audiotape all sessions. Audiotapes will be reviewed by the PI, and a randomly selected subset (25%) will be coded using the fidelity assessment tool. Regular supervision and booster trainings to reduce therapist drift will be provided by the PI. Therapists will also be trained in crisis management and the study's risk management protocol.

Data Analysis. We will obtain data related to intervention feasibility and acceptability, including retention and adherence rates, participant satisfaction with intervention, and intervention fidelity/adherence. We will also explore candidate primary tailoring variables for Phase 2 re-randomization and estimate rates of respondents/non-respondents to Phase 1 intervention. Receiver Operating Characteristic (ROC) analyses will be used to explore predictive validity and utility (sensitivity/specificity) of candidate primary tailoring variables collected via daily surveys within 2 weeks post discharge in predicting 1- and 3-month outcomes (e.g., suicidal ideation/behavior). Using multi-level analyses for continuous (SAS PROC MIXED) and non-normally distributed (SAS PROC GLIMMIX) variables, exploratory analyses of the effect of the Phase 1 and 2 interventions on daily-level mechanisms (e.g., coping behavior, self-efficacy to refrain from suicidal action, safety plan use) as well as the 1- and 3-month proximal (e.g., self-efficacy to cope with suicidal urges, parent self-efficacy) and distal (e.g., suicidal ideation/behavior) outcomes will be conducted. Using multi-level analyses, exploratory analyses of potential baseline moderators (e.g., attempt history) will be conducted to determine who might benefit more from Phase 1 and 2 interventions. Because pilot studies are not powered for efficacy,[30] we will examine if the pattern of change is in the desired direction (e.g. increase in self-efficacy; decrease in suicidal ideation).

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