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Adaptive intervention for prevention of adolescent suicidal behavior after hospitalization: a pilot sequential multiple assignment randomized trial

Running head: Pilot SMART for an adaptive intervention for suicidal youth

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Background: The need for effective interventions for psychiatrically hospitalized adolescents who have varying levels of post-discharge suicide risk calls for personalized approaches, such as adaptive interventions (AIs). We conducted a non-restricted pilot Sequential, Multiple Assignment, Randomized Trial (SMART) to guide the development of an AI targeting suicide risk after hospitalization. **Methods:** Adolescent inpatients (N=80; ages 13-17; 67.5% female) were randomized in Phase 1 to a Motivational Interview-Enhanced Safety Plan (MI-SP), delivered during hospitalization, alone or in combination with post-discharge text-based support (Texts). Two weeks after discharge, participants were re-randomized in Phase 2 to added telephone booster calls or to no calls. Mechanisms of change were assessed with daily diaries for four weeks and over a 1- and 3-month follow-up. This trial is registered with clinicaltrials.gov (identifier: NCT03838198). **Results:** Procedures were feasible and acceptable. Mixed-effects models indicate that adolescents randomized to MI-SP+Texts (Phase 1) and those randomized to booster calls (Phase 2) experienced significant improvement in daily-level mechanisms, including safety plan use, self-efficacy to refrain from suicidal action, and coping by support-seeking. Those randomized to MI-SP+Texts also reported significantly higher coping self-efficacy at 1 and 3 months. Although exploratory, results were in the expected direction for MI-SP+Texts, versus MI-SP alone, in terms of lower risk of suicide attempts (Hazard ratio=0.30; 95% CI=0.06, 1.48) and suicidal behavior (Hazard ratio=0.36; 95% CI=0.10, 1.37) three months after discharge. Moreover, augmentation with booster calls did not have an overall meaningful impact on suicide attempts (Hazard ratio= 0.65; 95% CI=0.17, 3.05) or suicidal behavior (Hazard ratio=0.78; 95% CI=0.23, 2.67), however boosters benefited most those initially assigned to MI-SP+Texts. **Conclusions:** The current SMART was feasible and acceptable for the purpose of informing an AI for suicidal adolescents, warranting additional study. Findings also indicate that post-discharge text-based support offers a promising augmentation to safety planning delivered during hospitalization. **Keywords:** Adolescents; suicide attempt; safety planning; adaptive intervention; sequential multiple assignment randomized trial.

Introduction

Suicide deaths have increased significantly among adolescents in the last decade over the United States, rising by nearly 60% between 2007 and 2017 (Curtin & Heron, 2019). Similarly, the rates of emergency department (ED) visits and psychiatric hospitalizations due to suicide-related concerns have been steadily increasing (Mercado, Holland, Leemis, Stone, & Wang, 2017; Plemmons et al., 2018). While psychiatric hospitalization provides critical stabilization services for managing acute psychiatric symptoms and elevated suicide risk, it may itself serve as a marker of future suicide risk (Czyz, Berona, & King, 2016). Discharged adolescents remain at high risk for psychiatric rehospitalizations and suicide attempts (Goldston et al., 1999; Yen et al., 2013). Although significant efforts have been made toward identifying promising interventions for adolescents suicide risk, there are few established interventions with replicated efficacy (Glenn, Esposito, Porter, & Robinson, 2019; Ougrin, Tranah, Stahl, Moran, & Asarnow, 2015). Moreover, relatively few randomized controlled trials involving adolescent inpatients, and focusing on the high-risk post-discharge period, have been conducted (Kennard et al., 2018; King et al., 2009; Rengasamy & Sparks, 2019).

The need for effective interventions targeting reduction in suicidal behavior during the transition from psychiatric hospitalization is clear, particularly as vulnerability to suicide risk is heightened in the first weeks following discharge (Chung et al., 2019). Importantly, as not all suicidal adolescents respond to interventions in a uniform fashion (Abbott, Zisk, Bounoua, Diamond, & Kobak, 2019; Harrington et al., 1998), and show markedly varying levels of post-discharge risk (Berona, Horwitz, Czyz, & King, 2017; Goldston et al., 2016), a single intervention approach may not be efficacious for all suicidal youths. Instead, more flexible interventions that dynamically match intervention components to individuals may hold promise for maximizing intervention effectiveness.

Adaptive Interventions (AIs) provide empirically-based guidelines for addressing the unique and changing needs of individuals by sequencing and adapting intervention components. Practically, AIs specify how, when, and for whom interventions should be delivered; by providing the type of intervention needed and minimizing the delivery of unnecessary treatment, AIs optimize outcomes while conserving resources and reducing burden (Collins & Kugler, 2018; Nahum-Shani et al., 2020). AIs can be empirically developed using a sequential multiple assignment randomized trial (SMART), an experimental design wherein some or all participants

are randomized multiple times to different intervention options at selected decision points (Murphy, 2005). While AIs have shown promise across different problems and populations, including youth (Gunlicks-Stoessel et al., 2019; Kasari et al., 2014; Pelham et al., 2016), there have been no studies attempting to empirically construct an AI for suicidal adolescents.

As a first step toward developing an AI for reducing post-discharge suicidal behavior, we conducted a non-restricted pilot SMART of a multi-component intervention, which is the focus of the current paper. Conceptualized as adjunctive, MI-SafeCope builds on the best-practice intervention of safety planning, which centers on identifying personalized coping strategies to mitigate suicidal crises. Empirical evidence among adults suggests that a stand-alone safety planning intervention, combined with phone contacts, was associated with lower suicidal behavior risk among veterans (Stanley et al., 2018) while a related crisis response planning intervention showed reduced suicide attempts in a military sample (Bryan et al., 2017). Safety plans have also been incorporated in multi-component interventions for adolescent at risk for suicide (Asarnow, Hughes, Babeva, & Sugar, 2017; Asarnow et al., 2011; Kennard et al., 2018). MI-SafeCope builds on safety planning by applying principles and strategies of Motivational Interviewing (MI) (Miller & Rollnick, 2013) to simultaneously strengthen adolescents' self-efficacy and motivation to follow the safety plan after discharge, as well as by incorporating targeted post-discharge support. MI has notably been applied in other interventions for suicidal adolescents as well as adults (e.g., Doupnik et al., 2020; Esposito-Smythers, Spirito, Kahler, Hunt, & Monti, 2011; Kennard et al., 2018; O'Brien et al., 2018). Here, MI is used as a core strategy guiding the manner in which safety planning and other intervention components are delivered. MI-SafeCope includes three components, with the first two provided to both adolescents and parents: (1) MI-enhanced safety plan (MI-SP) delivered during hospitalization, (2) post-discharge booster calls, and (3) post-discharge text-based support (Texts) provided to adolescents over a 4-week period. The focus on self-efficacy and motivation to sustain safety plan adherence and healthy coping are emphasized across all components because adolescents at elevated suicide risk tend to use less adaptive coping, engage in suicidal behavior to manage distress, and endorse low confidence in their ability to cope with suicidal urges (Boergers, Spirito, & Donaldson, 1998; Czyz et al., 2016; Guerreiro et al., 2013). However, because of expected heterogeneity in post-discharge functioning, MI-SP delivered during hospitalization

may or may not need to be supplemented with follow-up components for all youth or to the same extent.

Previous studies showed that MI-SP, booster calls, and Texts can be feasibly delivered and are acceptable among suicidal adolescents inpatients and their parents (Czyz, King, & Biermann, 2019; Czyz, Arango, Healy, King, & Walton, 2020). Here, extending this prior work, the current non-restricted pilot SMART included all three components and was conducted to begin obtaining the needed empirical basis for constructing an AI for suicidal youth transitioning from inpatient hospitalization. Laying the foundation for a full-scale SMART, this pilot was carried out as an important step in the process of empirically optimizing (i.e. developing an effective and practical; Collins & Kugler, 2018) an AI. The long-term goal is to optimize the sequencing and adaptation of MI-SP, booster calls, and Texts. Using a non-restricted SMART design (i.e. sequential randomizations are not restricted; Nahum-Shani et al., 2012), participants were initially randomized to receive MI-SP alone or together with Texts (Phase 1 intervention) and were subsequently re-randomized two weeks after discharge to receive added booster calls or no calls (Phase 2 intervention). The primary objectives of this study were to investigate the feasibility and acceptability of SMART study procedures, including the sequencing of intervention components. In addition, consistent with the experimental therapeutics framework for research (Raghavan, Munson, & Le, 2019), we report on the preliminary impact of Phase 1 and Phase 2 interventions on mechanisms of change (safety plan use, coping, self-efficacy) and distal (suicidal ideation and behavior) outcomes.

Methods

Procedures

This study was approved by the participating university's Institutional Review Board. Participants, recruited between March 2019 and January 2020, included 80 psychiatrically hospitalized adolescents (ages 13-17) presenting with suicide risk concerns. These included last-week suicidal ideation with thoughts of method, intent, or plan (based on the Columbia-Suicide-Severity Rating Scale [Posner et al., 2011], which is routinely administered before admission) and/or last-month suicide attempt. Exclusion criteria included: cognitive impairment or altered

mental status (psychosis, mania), residential placement, no availability of legal guardian, or no cell phone access. Eligibility was determined based on a screening of admission records and consultation with the unit's treatment team. Those meeting eligibility criteria were approached for parent consent and adolescent assent. Self-report baseline surveys were completed during hospitalization. Follow-up assessments were completed by phone, at 1 and 3 months post discharge, by interviewers masked to randomization conditions. Adolescents additionally completed daily surveys between 5-8pm, sent automatically to their phones via text message, starting on the first day after discharge for 28 days. Adolescents' responses were monitored by on-call research staff who contacted participants if suicidal ideation with intent/plan or a suicide attempt were endorsed. Adolescents were compensated up to $222 and parents up to $50. This trial (NCT03838198) was registered on clinicaltrials.gov.

Study design

SMART design and randomization. Participants were randomized twice using a computerized assignment system available through Consulting for Statistics, Computing, and Analytics Research at the University of Michigan; each randomization was on 1:1 basis and stratified based on sex and multiple suicide attempt history. After baseline, participants were initially randomized (Phase 1) to MI-SP or MI-SP with text-based support (MI-SP+Texts). Phase 1 randomization was concealed until after MI-SP was delivered, which on average took place 2.16 (SD=1.85) days prior to discharge. Two weeks after discharge, participants were re-randomized (Phase 2) to added booster calls or no calls conditions. Thus, participants followed one of four treatment sequences (A-D; Figure 1).

SMART studies may restrict Phase 2 randomization based on response status such that only non-responders (e.g., those showing insufficient improvement following Phase 1 intervention) are re-randomized in Phase 2. Here, Phase 2 randomization was not restricted, that is all participants were re-randomized; this design is known as non-restricted SMART (see Nahum-Shani et al., 2012). While a non-restricted SMART may seem like a standard factorial design, the key difference is that randomizations in a non-restricted SMART happen sequentially since the goal is to inform the construction of an AI (Nahum-Shani et al., 2012). The non-restricted SMART was selected as the appropriate design for this pilot in the absence of well-established criteria for classifying early non-responders (versus responders) to MI-SP.

Intervention components

In addition to the MI-SafeCope components described below, all participants in the study received usual care during hospitalization (e.g., assessment and case formulation, stabilization, safety planning, disposition planning with referrals for post-discharge treatment, etc.).

MI-Enhanced Safety Plan (MI-SP). Previously piloted with psychiatrically hospitalized adolescents (Czyz et al., 2019), MI-SP builds on the Safety Planning Intervention developed by Stanley and Brown (2012) and a safety planning protocol for adolescents (King, Ewell Foster, & Rogalski, 2013) by emphasizing common safety planning elements (e.g., warning signs; coping strategies; non-professional and professional support; reducing lethal means access). The MI-SP simultaneously incorporates MI strategies (e.g., open-ended questions, affirmation, reflective listening, providing information using Elicit-Provide-Elicit strategy, autonomy-supportive statements, confidence and importance rulers, eliciting "change talk," rolling with "sustain talk," etc.) to increase adolescents' motivation toward change (adhere to safety plan and coping), resolve ambivalence, and support self-efficacy after discharge. Moreover, the 4-phase MI framework (Miller & Rollnick, 2013)—i.e. engaging, focusing, evoking, and planning—is used to guide a 60-minute individual and 30-minute family sessions during hospitalization. The individual session with the adolescent culminates in the adolescent and study counselor collaboratively developing a personalized safety plan. The family session, involving the adolescent and parent, focuses on sharing the safety plan and facilitating a discussion of parent's role in supporting the adolescent in implementing the individualized safety plan. A more detailed description of MI-SP can be found elsewhere (Czyz et al., 2018). The counselors (N=3) delivering the intervention had a master's-level training in psychology or social work. After receiving training in motivational interviewing, the counselors were trained in the MI-SP protocol; training incorporated didactic instruction, role plays, and audio-recorded mock sessions. Counselors attended twice-monthly supervision meetings to review cases and monitor fidelity. Fidelity was assessed using a previously developed adherence measure (Czyz et al., 2019). Intervention sessions were audio-recorded, and over 30% of sessions were rated for adherence (first 2 sessions and 25% of randomly-selected sessions). Adherence was 94.4% for individual and 93.1% for family sessions.

Texts. Adolescents randomized to support texts in Phase 1 received two automated text messages daily for four weeks. Drawn from a previously-developed library of messages piloted with adolescents' input (Czyz et al., 2020a), texts included content focused on: (1) self-efficacy to cope with suicidal urges, (2) motivation to maintain safety, (3) tailored messages referencing personal reasons for living and coping strategies, (4) coping tips, (5) reminders about crisis resources, (6) encouragement to use personal safety plan, (7) affirmations, and (8) strengthening social connectedness. MI-consistent strategies and language were also incorporated. Message examples can be found in Czyz and colleagues (2020a). The first message of the day was sent each morning ("push"), while the second message was sent in the afternoon in the form of an automated prompt, providing adolescents an option of requesting the second message using a pre-specified keyword ("pull" message).

Booster calls. Piloted as part of the same study as MI-SP above (Czyz et al., 2019), the booster call condition in Phase 2 involved one call with the adolescent and, separately, one call with the parent. Conducted by the same counselor who delivered MI-SP, the purpose of these boosters was to adjust the safety plan to better meet post-discharge needs, to further enhance adolescents' motivation and commitment to use adaptive coping and their safety plan, address barriers, and to further enhance parents' self-efficacy to support their adolescents in the post-discharge period, including in utilizing their safety plan. As with the MI-SP, the booster calls are delivered in a manner consistent with MI.

Measures

Mechanisms of change

Adolescent self-efficacy to cope with suicidal thoughts (baseline and follow-up). The Efficacy to Cope with Suicidal Thoughts and Urges Scale (Czyz et al., 2016) was used to assess respondents' level of confidence to perform 12 coping responses when experiencing suicidal thoughts. Answer choices ranged from 0 ("not at all confident") to 10 ("extremely confident"). The scale demonstrated strong psychometrics, including predictive validity of suicide attempts. The internal consistency in this sample was 0.91.

Parental self-efficacy (baseline and follow-up). Parents' confidence regarding engaging in 10 supportive and suicide prevention activities was assessed with the Parental Self-Efficacy Scale (Czyz, Horwitz, Yeguez, Ewell Foster, & King, 2017). Answer choices range from 0 (not at all confident) to 10 (completely confident). In the original sample, low parental self-efficacy was prospectively associated with adolescents' suicidal crises. The internal consistency in this sample was 0.79.

Safety plan use (daily). Each day, adolescents were asked: "In the last 24 hours, how much did you think about, look at, or use your safety plan?" Responses were rated on a 3-point scale (from "not at all" to "a lot") and were dichotomized for analyses.

Self-efficacy to refrain from suicidal action (daily). In reference to the last 24-hours, adolescents rated, using a scale from 0 ("not at all confident") to 10 ("completely confident"), "How confident are you that you will be able to keep yourself from attempting suicide?" This item was adapted from the Self-Assessed Expectations of Suicide Risk Scale (Czyz, Horwitz, & King, 2016).

Coping behavior (daily). Each day, adolescents rated on a 3-point scale the extent to which they used eight coping strategies, either in reference to suicidal ideation (on days ideation was endorsed) or coping with feelings or stressful events (on days ideation was not endorsed). These included: (1) talked with a parent or family member, (2) talked with a friend or peer, (3) talked with a therapist, counselor, or doctor, (4) contacted a crisis line (call, text, or chat line), (5) distracted self with something else (reading, music, painting, drawing, writing, TV, walk, homework, other), (6) did something relaxing or comforting (deep breaths, nap, soothing/pleasant activity, other), (7) tried to tell self something calming or positive, and (8) tried a cognitive strategy that involved either (a) thinking about reasons for living (on days ideation was endorsed) or (b) thinking about something that makes self feel better (on days ideation was not endorsed). These strategies were grouped into four dichotomous categories: coping using personal support, coping using professional support, coping using non-cognitive strategies, and coping using cognitive strategies.

Distal outcomes

Suicidal ideation and attempts (baseline and follow-up). The Columbia-Suicide Severity Rating Scale (C-SSRS) (Posner et al., 2011) was used to assess suicidal ideation severity, on a 0-5 scale (from "wish to be dead" to "suicidal ideation with specific plan and intent"), and suicidal behavior (actual, interrupted, and aborted suicide attempts). We report on last-week suicidal ideation severity and lifetime suicide attempts at admission, obtained via medical record review. We also report on suicidal ideation severity and suicidal behavior assessed at the 1- and 3-month assessment.

Suicidal ideation (daily surveys). Each day, adolescents rated, on a 5-point scale (from "not at all" to "all the time"), the frequency with which they experienced thoughts of suicide. An endorsement of suicidal ideation was followed by a question assessing suicidal ideation duration on a 5-point scale (from "a few seconds or minutes" to "more than 8 hours/continuous"). These items were based on the C-SSRS (Posner et al., 2011). Adolescents were also asked to rate, using a 7-point scale (from "low" to "high"), the intensity of suicidal urges, which was modeled after another intensive longitudinal study (Nock, Prinstein, & Sterba, 2009).

Additional measures

Non-suicidal self-injury (NSSI). At baseline, adolescents were asked about NSSI history using a self-report measure adapted from the Non-Suicidal Self Injury portion of the Self-Injurious Thoughts and Behaviors Interview (Nock et al., 2007).

Data analyses

Group differences in baseline characteristics were compared using t-tests and Chi-square tests. To explore the effect of Phase 1 and Phase 2 randomizations, we conducted linear mixed effects models for continuous measures and generalized linear mixed effects models for dichotomous measures. Models of mechanisms and distal outcomes assessed at baseline and 1- and 3- month follow-ups included the indicators for Phase 1 and Phase 2 interventions, time (treated categorically), and two-way interactions between each phase and time. For models of mechanisms and distal outcomes assessed with daily surveys, we accounted for the temporality of intervention components in relation to measurement occasions by fitting separate models for

Phase 1 and Phase 2 randomizations (e.g., Phase 2 intervention impacts observations occurring following Phase 2 randomization). Thus, Phase 1 models included daily-level observations collected over the entire 4-week period while Phase 2 models excluded observations from the initial two weeks. In addition to their respective intervention indicators, these daily-level Phase 1 and Phase 2 models included time (treated continuously) and Phase 2 models controlled for Phase 1 randomization. Models of daily-level mechanisms considered presence of suicidal ideation (yes/no) as a moderator given that specific mechanisms (e.g., safety plan use, coping) could be influenced by suicidal thoughts. Although, consistent with recommendations (Leon, Davis, & Kraemer, 2011), this pilot was not designed to be powered to measure intervention efficacy, Cox regression analyses were used to explore if Phase 1 and Phase 2 interventions (entered into Cox regressions simultaneously) predicted time-to-suicide attempt and, separately, time-to-suicidal behavior (actual, interrupted, and aborted suicide attempts) over the 3-month follow-up. Analyses were conducted using an intent-to-treat approach using SAS (version 9.4) (SAS Institute, Inc.).

Results

Baseline characteristics

Participants included 67.5% (n=54) female adolescents, with the mean age of 15.16 (SD=1.35). The racial distribution was (multiple categories could be selected): 83.8% (n=67) White, 6.3% (n=5) African-American/Black, 5.0% (n=4) Asian, 5.0% (n=4) American Indian or Alaska Native, 1.3% (n=1) Native Hawaiian or Other Pacific Islander, and 2.5% (n=2) Other. Nine (11.3%) participants self-identified as Hispanic. In terms of clinical characteristics, half of adolescents (n=40) previously attempted suicide, with over a third (37.5%, n= 30) attempting in the month before hospitalization. Moreover, 28 (35%) adolescents had multiple suicide attempt histories. The majority of adolescents (77.5%, n=62) endorsed lifetime NSSI. The overall baseline suicidal ideation severity, measured by C-SSRS (range 0-5), was 3.91 (0.90). Obtained via chart review, the majority of participants had a depressive disorder diagnosis, including major depressive or unspecified depressive disorder (86.3%; n=69). Approximately half of adolescents (53.8%; n=43) had at least one anxiety disorder diagnosis (social anxiety, generalized anxiety, or unspecified anxiety disorder). Those randomized to MI-SP versus MI-

SP+Texts in Phase 1 and those re-randomized to booster versus no booster conditions in Phase 2 were similar on demographic and clinical characteristics (Table S1).

Feasibility and acceptability of procedures

As shown in Figure 2, the vast majority of those meeting study eligibility criteria (87.2%) agreed to participate. Follow-up retention was high for parents (93.8 % at 1 month and 82.5% at 3 months) and adolescents (95.0% at 1 month and 91.3% at 3 months). The overall adherence to daily surveys among adolescents was 72.4% (1621 out of 2240).

Of the 80 randomized participants, 76 (95%) took part in the MI-SP individual and family sessions; the family session was not delivered to four parents due to scheduling difficulties. Of note, 15 parents took part in the family session by telephone when in-person attendance was challenging (e.g., childcare responsibilities, scheduling conflicts, travel barriers). For the majority randomized to booster calls in Phase 2 (n=36), both adolescents and parents participated in booster calls (n= 29; 80.6%); an additional three (8.3%) were completed by either parent (n=2) or adolescent (n=1) alone. On average, booster calls took place 20.47 (SD=2.51) days after discharge. Finally, none of the 40 adolescents randomized to Texts requested that messages be stopped. While the first text message of the day was sent automatically, the second daily message was actively requested ("pulls"); nearly all adolescents (n=36; 90%) requested the pull message at least once. Adolescents requested pull messages about a third of the time (33.8%), on 9.45 days (SD=9.01) on average. The likelihood of requesting messages decreased with time (odds ratio 0.86; CI = 0.84, 0.89; $p<.001$).

Mechanisms of change

Daily data. As shown in Table 1, adolescents initially randomized to MI-SP+Texts, compared to M-SP, reported significantly higher self-efficacy to refrain from suicidal action irrespective of time and presence of suicidal ideation (B=0.99, p=.007; Cohen's d[1]=0.46). There was a similar trend for those re-randomized to booster calls, versus no calls, in Phase 2 (B=0.82, p=.056; d=0.38). Significant differences also emerged for support seeking, but not for other coping strategies. First, irrespective of time, adolescents randomized to MI-SP+Texts, versus MI-SP

[1] *d* represents an effect size for mixed models analogous to Cohen's *d*, based on Westfall et al (2014).

reported greater likelihood of seeking support from professional sources on days when they experienced suicidal ideation (B=0.82, p=.039; OR=2.27), but not on days without ideation (B=0.02, p=.963; OR=1.02). Second, as indicated by a two-way interaction with time (B=0.17, p=.005), the probability of professional support-seeking was increasing with time among adolescents who were re-randomized to booster calls. Third, adolescents in the booster condition were significantly more likely to cope using personal sources of support (B=2.24, p<.001; OR=9.39), irrespective of time and suicidal ideation. Finally, with regard to safety plan use, there was a significant three-way interaction between Phase 1, time, and the daily suicidal ideation indicator (B=0.11, p=.037); adolescents in MI-SP+Texts, compared to MI-SP, had greater likelihood of sustaining safety plan use when suicidal ideation was present (B=0.11, p=.025), but not on days without ideation (B=0.002, p=.968); see Figure S1. Moreover, those re-randomized to booster calls, versus no calls, had greater likelihood of safety plan use across time and regardless of suicidal ideation (B=2.00, p=.022; OR=7.39).

Follow-up data. Results from models of mechanisms of change assessed at baseline and at the 1- and 3-month follow-up (Table 2) indicated a significant 2-way interaction between time and adolescents' coping self-efficacy for Phase 1 (p=.004); adolescents assigned to MI-SP+Texts, versus MI-SP, reported greater increase in coping self-efficacy at 1 (B=13.84, SE=4.93, p=.006) and 3 months (B=15.15, SE=5.00, p=.003). Finally, although not reaching statistical significance, there was a trend indicating greater increase in parental self-efficacy over time for parents in the booster condition in Phase 2.

Distal (suicidal ideation and behavior) outcomes

Daily data. As shown in Table 1, adolescents assigned to MI-SP+Texts, compared to MI-SP, reported significantly lower intensity of suicidal urges (B= -0.59, p=.018; d=0.39), although there were no differences in terms of suicidal ideation frequency or duration. For those randomized to booster calls, versus no calls, in Phase 2 there was a potential signal in terms of less frequent suicidal thoughts (B= -0.37, p=.057; d=0.17).

Follow-up data. As shown in Table 2, there were no differences between adolescents assigned to MI-SP versus MI-SP+Texts in Phase 1 with regard to decrease in suicidal ideation severity over time, nor between those assigned to booster calls versus no calls in Phase 2.

Finally, Table 3 provides frequencies of suicide attempts, suicidal behavior, and rehospitalizations at follow-up. Cox regressions for suicide attempts and suicidal behavior indicate the results were in the hypothesized direction. Specifically, adolescents initially randomized to MI-SP+Texts, versus MI-SP, had lower risk (albeit not statistically significant) of suicide attempts (Hazard ratio=0.30; 95% CI=0.06, 1.48; p=.139) and suicidal behavior (Hazard ratio=0.36; 95% CI=0.10, 1.37; p=.135). In Phase 2, adolescents randomized to the booster calls, versus no-calls, had lower risk (albeit not statistically significant) of suicide attempts (Hazard ratio= 0.65; 95% CI=0.17, 3.05; p=.654) and suicidal behavior (Hazard ratio=0.78; 95% CI=0.23, 2.67; p=.685).

Discussion

In this paper, we report results from a non-restricted pilot SMART conducted to guide the development of a future AI for suicidal adolescents transitioning from inpatient care. Although AIs have yet to be empirically developed to target suicide prevention in adolescents, the application of AIs in this context has the potential to improve the limited evidence base for intervening with these high-risk youths. The results from this pilot SMART suggest that study procedures for optimizing interventions for adolescents at elevated suicide risk were feasible and acceptable. Moreover, results indicate that specific intervention components and sequences influenced key mechanisms of change and have potential to reduce risk of suicidal behavior.

An important finding was that mechanisms of change were improved by initially augmenting MI-SP with Texts. For mechanisms assessed daily over a four-week period, this included sustained safety plan utilization in the presence of suicidal ideation, greater likelihood of contacting professional sources of support to cope with suicidal thoughts, as well as higher sense of self-efficacy to refrain from suicidal action. Consistently, adolescents who were assigned to receive MI-SP+Texts endorsed higher self-efficacy to engage in suicide-specific coping assessed across the 1- and 3- month follow-up. With regard to distal outcomes, MI-

SP+Texts showed a promising impact, in terms of effect size,[2] on reducing suicide attempt and suicidal behavior risk (hazard ratio of 0.30 and 0.36, respectively), providing initial evidence of meaningful clinical utility. Technology-augmented interventions may be well-suited to provide effective continuity of care strategy for suicidal adolescents, in line with results from an intervention development study for hospitalized adolescents incorporating a smartphone application (Kennard et al., 2018). Moreover, text-based interventions have been shown to influence different health behaviors (review by Berrouiguet, Baca-García, Brandt, Walter, & Courtet, 2016) and suicide attempts in adults (Comtois et al., 2019). It is worth noting that mobile-based interventions are not without challenges, such as declining engagement over time (Torous, Nicholas, Larsen, Firth, & Christensen, 2018). We similarly observed that adolescents were less likely to request the optional second message as time went on, indicating engagement warrants more attention in future work (Czyz et al., 2020a). Nevertheless, the promising findings, coupled with the fact that text-based interventions are relatively low-cost and scalable, call for additional research considering their benefit following hospitalization and during other high-risk periods.

Another noteworthy finding was that adding booster calls in Phase 2 had a positive impact on daily-level mechanisms of change for adolescents, regardless of which Phase 1 intervention was initially provided. This included adolescents being more likely to engage in support-seeking from personal and professional supports as well as greater safety plan use. While booster calls did not have an overall meaningful influence, in terms of effect sizes, on suicide attempts or suicidal behavior, the pattern of results suggests that boosters may have benefited those initially assigned to MI-SP+Texts; adolescents receiving this intervention sequence reported no suicide attempts or suicidal behavior. However, this pattern of results will require replication in a larger study. Moreover, given the non-restricted SMART design, it is important to emphasize that booster calls were offered to all adolescents re-randomized to this condition. A future SMART could restrict Phase 2 randomization based on early non-response status (only non-responders to Phase 1 are re-randomized). Ultimately, in an AI, treatment decisions are individualized based on tailoring variables, which identify conditions in which intervention should be provided or modified (Nahum-Shani et al., 2012). In the current context, this will

[2] Hazard ratio represents an effect size measure for time-to-event outcomes (Oliver, May, & Bell, 2017).

require investigating early predictors of an impending suicidal crisis and ascertaining their usefulness in classifying responders versus non-responders. While there is emerging evidence that tailoring variables can be derived by using intensive longitudinal data to detect early markers of suicidal crises following discharge (Czyz, Yap, King &Nahum-Shani, 2020b), more work in this area is needed.

Finally, while not less likely to experience daily-level suicide ideation, adolescents randomized to MI-SP+Texts, versus MI-SP, reported significantly lower intensity of suicidal urges. Providing text-based support may be linked with improved management of suicidal thoughts in daily life, also consistent with adolescents receiving post-discharge Texts reporting greater safety plan utilization and support seeking when suicidal ideation was experienced. Moreover, adolescents randomized to added booster calls in Phase 2 reported marginally less frequent daily thoughts of suicide. However, neither Phase 1 nor Phase 2 interventions showed significant effects on suicidal ideation severity assessed over the 3-month follow-up. While different aspects of suicidal ideation were likely captured using daily versus traditional assessments, the inconsistency may also be attributable to more adolescents disclosing suicidal thoughts using daily diaries, as found in previous research (Czyz, King, & Nahum-Shani, 2018). Here, significantly more adolescents reported suicidal ideation via daily diaries relative to 1-month follow-up (82.4% versus 51.4%). This highlights the value of incorporating ecological assessment paradigms that not only enable capturing highly dynamic suicide-related outcomes (Kleiman et al., 2017), but also assessing intervention response in a more fine-grained manner.

Findings from this study should be considered in light of its limitations, particularly a sample size that had reduced statistical power and a largely female and Caucasian adolescent sample that limits generalizability of results. The timing of follow-up components also raises the question if the pattern of results would be similar if phone boosters had been offered first. However, in keeping with the principle of stepped care, the ultimate goal of this pilot SMART is to inform an AI where the more resource-intensive support (e.g., booster calls) would be provided only when the initial and less costly intervention (Texts) is not sufficient. Despite limitations, the current pilot study demonstrates promising preliminary results warranting a full-scale SMART. In addition to examining the efficacy of initially augmenting MI-SP with Texts, there are other questions that could be addressed in a larger trial. For example, in a restricted full-scale SMART, will adolescents who are classified as early non-responders to either MI-SP

or MI-SP+Texts benefit from further support via booster calls, or what intensity of boosters would be optimal? Or, are initial adolescent characteristics (e.g., sex, attempt history) or time-varying factors (at the end of initial treatment) useful moderators that can guide further tailoring of initial and subsequent intervention options? Ultimately, a full-scale SMART is needed to validate and extend on the findings reported in this pilot SMART, leading to an optimal AI that can be compared against a suitable control in a standard randomized controlled trial (Almirall, Compton, Gunlicks-Stoessel, Duan, & Murphy, 2012).

Conclusions

Despite their potential to address the unique and changing needs of individuals in a resource efficient manner, AIs have been underutilized to improve suicidal adolescents' post-discharge outcomes. This pilot SMART was conducted to lay the groundwork for a full-scale SMART, to inform the development of an AI for suicidal adolescents transitioning from inpatient hospitalization. More broadly, the study sought to address an urgent need to develop efficacious interventions for this population. This study is the first to demonstrate that carrying out SMARTs is feasible in the context of informing AIs for adolescents at elevated suicide risk. Moreover, results suggest that augmenting MI-SP delivered during hospitalization with post-discharge Texts had a promising impact on hypothesized mechanisms of action (safety plan use, self-efficacy, coping by support seeking), as did providing booster calls regardless of whether or not initial MI-SP was accompanied by Texts. Additionally, results hinted at the potential benefit of MI-SP with Texts on suicidal behavior 3 months post discharge, and booster calls appeared to have additionally benefited those initially assigned to this group. A full-scale trial will be necessary to more definitely optimize the sequencing and adaptation of MI-SP, booster calls, and Texts, including how to further tailor intervention components (e.g., different intensity of booster calls) and for whom (e.g., early responders versus non-responders).

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article:

Figure S1. Probability of safety plan use by group (MI-SP versus MI-SP+Texts).

Table S1. Baseline sample characteristics.

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Table 1. Mixed effects models for mechanisms of change and distal outcomes assessed with daily surveys.

	Phase 1			Phase 2*		
Daily Mechanisms of Change	**n**	**Coefficient (SE)**	**p**	**n**	**Coefficient (SE)**	**p**
Safety plan use (yes/no)	1623	0.11 (0.05)[a]	**.037**	803	2.00 (0.87)	**.022**
Coping behavior						
Non-cognitive strategies (yes/no)	1617	-0.33 (0.62)	.594	801	1.31 (0.87)	.135
Cognitive strategies (yes/no)	1617	0.56 (0.66)	.400	801	1.06 (0.82)	.197
Personal support (yes/no)	1617	0.10 (0.58)	.859	801	2.24 (0.62)	**<.001**
Professional support (yes/no)	1617	0.80 (0.39)[b]	**.043**	801	0.17 (0.06)[c]	**.005**
Self-efficacy (0-10)	1624	0.99 (0.37)	**.007**	803	0.82 (0.43)	.056
Daily Distal Outcomes						
Suicidal ideation (SI)						
SI frequency (0-4)	1624	-.0.22 (0.20)	.269	803	-0.37 (0.19)	.057
SI duration (0-4)	631	-0.25 (0.20)	.202	276	0.34 (0.25)	.171
SI urge intensity (1-7)	631	-0.59 (0.25)	**.018**	276	-0.17 (0.36)	.641

Notes: Phase 1 and Phase 2 models include their respective phase (group) indicator and time; *all Phase 2 models adjust for Phase 1; as presence of SI could influence safety plan and coping use, daily mechanism models explore SI (yes/no) as a moderator; reference group is

MI-SP for Phase 1 and No Booster for Phase 2; coefficients for binary variables represent differences in log odds whereas coefficients for continuous variables represent differences on the raw scale.

[a] three-way interaction with group, time, and SI indicator; [b] two-way interaction with group and SI indicator; [c] two-way interaction with group and time; interpretation of interaction terms is described in results.

Table 2. Mixed effects models for mechanisms of change and distal outcomes assessed at baseline and at follow-up.

	Phase 1				**Phase 2***			
	Coefficient (SE)	**p**	**Coefficient (SE)**	**p**	**Coefficient (SE)**	**p**	**Coefficient (SE)**	**p**
Mechanisms of Change	1-month follow-up		3-month follow-up		1-month follow-up		3-month follow-up	
Adolescent coping self-efficacy	13.84 (4.93)	**.006**	15.15 (5.00)	**.003**	-1.77 (4.99)	.724	-1.32 (5.05)	.794
Parent self-efficacy	2.72 (2.24)	.226	-1.01 (2.34)	.667	3.78 (2.26)	.096	4.38 (2.36)	.065
Distal Outcome								
Suicidal ideation severity	-0.25 (0.38)	.511	0.15 (0.40)	.714	-0.71 (0.39)	.067	-0.58 (0.40)	.151

Notes: Mechanism of change and distal outcomes were assessed at baseline, 1,- and 3-month follow-up; all models include indicators for Phase 1 and Phase 2, time (with reference point of baseline), and two-way interactions between each phase and time; coefficients represent the difference in change from baseline between groups at each time point; reference group is MI-SP for Phase 1 and No Booster for Phase 2.

Table 3. Suicide-related outcomes assessed over the 3-month follow-up.

	N (%) of Suicide Attempts				HR (95% CI)	N (%) of Suicidal Behavior				HR (95% CI)	N (%) of Rehospitalizations				HR (95% CI)
Phase 1	**MI-SP**		**MI-SP+Texts**		0.30 (0.06, 1.48)	**MI-SP**		**MI-SP+Texts**		0.36 (0.10, 1.37)	**MI-SP**		**MI-SP+Texts**		0.77 (0.23, 2.51)
	6/34 (17.6%)		2/34 (5.9%)			8/35 (22.9%)		3/34 (8.8%)			6/38 (15.8%)		5/37 (13.5%)		
Phase 2	**Booster**	**No Booster**	**Booster**	**No Booster**	0.65 (0.17, 3.05)	**Booster**	**No Booster**	**Booster**	**No Booster**	0.78 (0.23, 2.67)	**Booster**	**No Booster**	**Booster**	**No Booster**	0.45 (0.12, 1.71)
	3/14	3/20	0/15	2/19		4/14	4/21	0/15	3/19		1/17	5/21	2/16	3/21	

Notes: HR = hazard ratio; CI = 95 % confidence interval; time-to-event comparisons were conducted for Phase 1 (MI-SP vs. MI-SP + Texts) and for Phase 2 (added booster vs. no booster) using censored data.

Figure 1. SMART Pilot Design

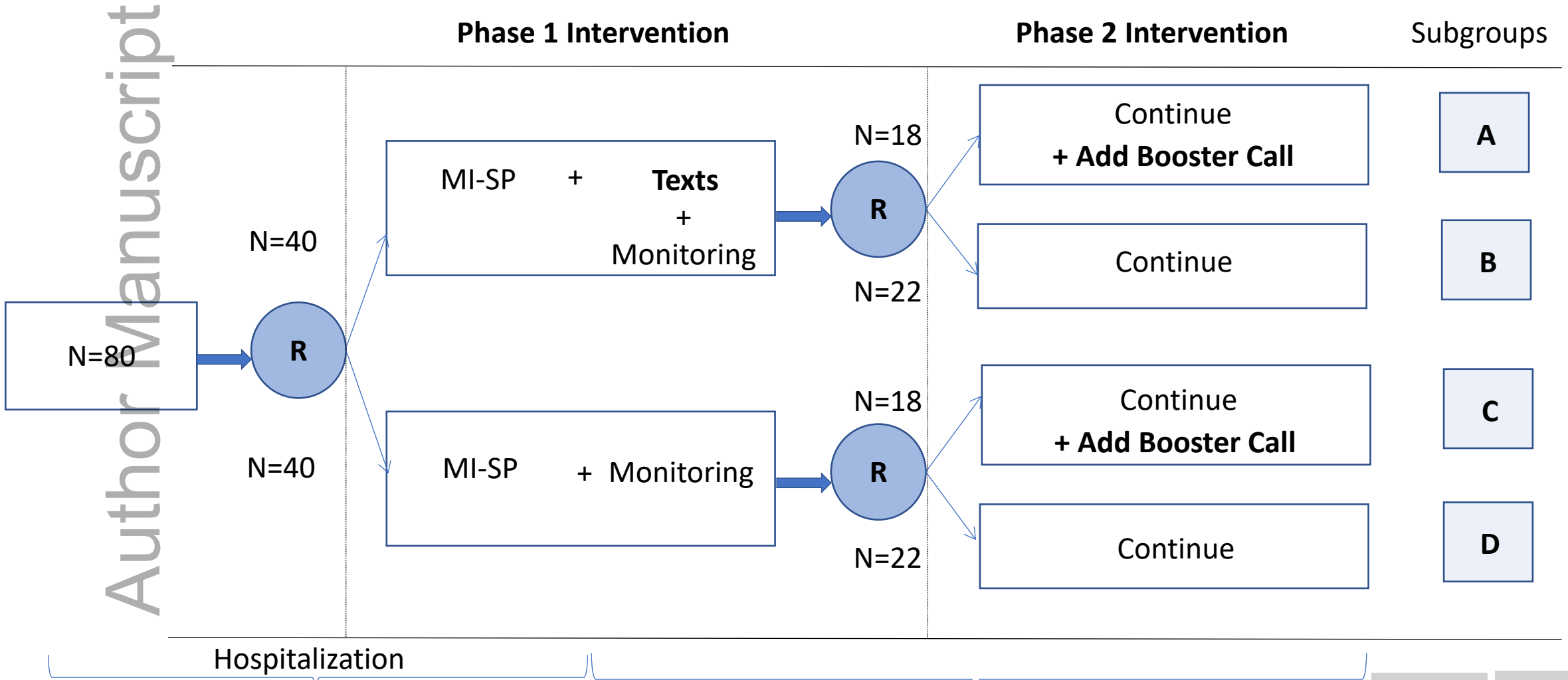

Figure 1. Consort Chart