Pilot Microrandomized Trial of a Brief Digital Intervention for Suicidal Thoughts

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Abstract

Objective: The goal of this study was to conduct a pilot micro-randomized trial (MRT) to assess the feasibility and acceptability of a brief digital intervention aimed at promoting in-the-moment coping strategy use for suicidal thoughts after psychiatric hospitalization.

Method: 71 adults hospitalized for suicide risk (mean age = 31.94 years, 46.48% female, 78.87% White) were enrolled and included in analyses. Real-time reports of suicidal thoughts were collected for 28 days after discharge via ecological momentary assessment (EMA). Each time participants reported elevated momentary suicide urge or intent on an EMA survey, they were randomized to smartphone-based messages aimed at promoting use of evidence-based coping strategies (versus 'no message' control). Messages included either personalized or general coping strategy recommendations.

Results: 44 participants (57.89%) met criteria for randomization at least once and were randomized on average 11.48 times (SD = 23.38); 8.85% of completed EMAs met randomization criteria. Participants found the intervention messages feasible and acceptable. Most described the messages as helpful and preferred personalized (over general) messages. Statistical analyses revealed no group-level iatrogenic intervention effects. Following intervention (versus no intervention), participants were significantly more likely to report use of a coping strategy to manage suicidal thoughts, with stronger effects for personalized messages.

Conclusions: This pilot MRT supports the feasibility and acceptability of a brief digital intervention for promoting in-the-moment coping strategy use during episodes of suicidal thinking. Results inform the development of novel just-in-time adaptive interventions (JITAIs) for suicide prevention and the design of larger-scale MRTs to evaluate and optimize them.

Keywords: suicide, suicidal thoughts, micro-randomized trial, just-in-time adaptive intervention

Public health significance statement: This pilot study suggests that sending brief smartphone-based messages to promote in-the-moment use of coping strategies for suicidal thoughts is feasible and viewed as acceptable by adults during the high-risk period after psychiatric hospitalization. This brief digital intervention may also aid coping with suicidal thoughts.

Over the past 20 years, the suicide rate has increased by >30%,[1] with more than 49,000 Americans who died by suicide in 2023 alone.[2] Non-fatal suicidal thoughts and behaviors (STBs) are also prevalent.[3] For every suicide death in the U.S., there are three hospitalizations for suicide attempts or self-harm, eight emergency department visits related to suicide, 38 suicide attempts, and 265 people who seriously consider suicide.[4] STBs are a public health problem in need of urgent attention, particularly given the disproportionately low funding allocated to prevention research.[5]

The period after psychiatric inpatient hospitalization is widely known to be the highest-risk time for suicidal behavior. Approximately one-quarter of all suicide deaths occur among patients who are within three months of hospital discharge, with an outsized percentage occurring within the first month.[6,7] Recent meta-analyses underscored this critical high-risk period by showing that for hospitalized psychiatric patients, the suicide rate during the first three months after hospital discharge is over 100 times the global rate.[8,9] For the first month, the suicide rate is 200 times the global rate, and for the first week, 300 times.[8,9] Moreover, among those at elevated risk for suicide, suicidal thoughts and urges can fluctuate rapidly, on the order of hours or even minutes.[10–14] One study that delivered brief, momentary surveys up to 6x/day via smartphone to adult inpatients with STBs showed that 94% of participants had a change in their suicidal thought intensity ratings of more than one standard deviation over the course of hours, and more than a quarter of ratings differed by at least one standard deviation from one momentary survey to the next.[12]

Unfortunately, most existing psychological interventions are not well-matched to the dynamic nature of STBs. A recent review highlighted three main areas of mismatch: timing, accessibility, and personalization.[15] First, regarding timing, most treatments targeting suicide risk

are delivered at static, relatively infrequent intervals (e.g., weekly 45-minute sessions), and require patients to remember when and how to access coping strategies learned in therapy during or leading up to suicidal crises. Second, most psychological interventions that have been shown to effectively reduce STBs are not widely accessible. A large literature points to the relatively low rates of treatment access and utilization among people with STBs[16,17] due to both structural (e.g., cost, limited therapist availability) and psychological (e.g., stigma, distrust of mental health professionals, concerns about the consequences of disclosing suicidal thoughts to providers) barriers.[18–20] During the post-hospitalization period, care receipt is low, with roughly one-third of patients not attending a single mental health appointment after discharge.[21,22] Among those who do attend aftercare, the contrast between 24/7 care and monitoring received in the hospital and relatively infrequent contact with outpatient mental health providers is marked. During suicidal crises, current intervention delivery models require people in need to initiate seeking care or support (e.g., by contacting a professional or hotline) rather than by bringing interventions to them.[15] Lastly, increasing research points to the tremendous degree of heterogeneity in suicide risk, both across and within individuals.[12,23,24] This points to the need for different interventions, for different people, at different times, representing yet another mismatch with the general "one-size-fits-all" approaches of existing treatments.

Just-in-Time Adaptive Interventions (JITAIs)

Just-in-Time Adaptive Interventions (JITAIs) offer tremendous potential to help overcome the limitations of many existing psychological treatments for STBs. JITAIs are designed to provide the right amount and type of support to individuals at the right times.[25] A key to JITAIs is the adaptation of interventions to an individual's dynamically changing status and context, thereby delivering support both when the individual needs it the most *and* is most likely

to be receptive. JITAIs deliver automated intervention content (e.g., messages, reminders) through smartphones or wearable sensors, though intervention components may be delivered through other digital devices or direct human (e.g., clinician or coach) outreach. JITAIs have been developed and used to promote change in a wide range of health-related behaviors.[26–29]

JITAIs may help prevent suicidal urges from transitioning to behavior by promoting the implementation of evidence-based coping strategies – for example, the use of a coping skill for distraction or seeking social or professional support[23,30–33] while people are experiencing suicidal thoughts. Suicidal crises are characterized by diminished problem-solving capacity and high emotional arousal,[34–37] both of which can make it challenging to practice effective (and often effortful) behavioral strategies in-the-moment. Thus, it may be valuable to provide suggestions, reminders, or other forms of guided support or scaffolding during moments of suicidal thinking to promote real-time implementation of coping skills. Post-hospitalization, when care engagement is low and risk is high,[8,9,21,22] there is a need to augment traditional models of care with additional, scalable supports. JITAIs can help achieve this end while flexibly adapting to the ever-changing needs of individuals who experience suicidal urges. JITAIs that specifically seek to promote coping strategy use when needed could also enhance or reinforce existing evidence-based therapies[30,32,38] that emphasize coping effectively with suicidal thoughts and urges as a key component.

Micro-Randomized Trial (MRT) Experimental Design

The effectiveness of JITAIs can be tested using the micro-randomized trial (MRT) experimental design.[39–41] MRTs are designed to evaluate intervention effects on proximal outcomes by randomizing the delivery of the intervention (or different intervention components) multiple times (on up to hundreds or even thousands of occasions) within the same individual.

MRTs have the benefits of both maximizing statistical power and determining whether certain interventions work better than others, given an individual's constantly changing context.[40] *Decision points* dictate when and for whom to deliver a given intervention component, and usually rely on real-time data collected either *passively* (e.g., from a wearable biosensor) or *actively* (e.g., via self-report surveys) from an individual over time. Passively or actively collected contextual information can also be incorporated into decision rules as *tailoring variables*. MRTs assess both *proximal* and *distal outcomes*, with proximal outcomes conceptualized as mediators of change in distal outcomes. An MRT testing digital interventions aimed to promote effective coping with suicidal thoughts, for example, might assess the use of coping strategies in response to suicidal urges as the proximal outcome, with the expectation that more in-the-moment coping over time would reduce the risk of suicidal behavior (the distal outcome).

Current Study

The goal of this pilot study was to assess the feasibility and acceptability of brief digital intervention messages aimed at promoting in-the-moment coping strategy use for suicidal thoughts using an MRT design during the four weeks after psychiatric hospitalization. We hypothesized that the intervention would be perceived as feasible and acceptable based on participants' responses to validated self-report questionnaires and qualitative interview data. Although our primary focus was feasibility and acceptability, we also explored the effects of the intervention on coping strategy use and momentary suicidal thought intensity (proximal outcomes), as well as potential differential intervention effects by message type and contextual moderators, to identify aspects of the intervention that require modification. Our longer-term aim was to use the findings from this pilot MRT to inform the development and upcoming evaluation

(in a larger-scale trial) of a multi-component JITAI that sequences and adapts different forms of both digital and clinician-delivered support during the high-risk period following psychiatric hospitalization.

Method

We report how we determined our sample size, all data exclusions (if any), all manipulations, and all measures in the study.

Participants

Participants in this pilot MRT were all adults enrolled between July 5, 2023, and May 8, 2024 in a large, ongoing ecological momentary assessment (EMA) study aimed to improve short-term suicide risk prediction during the post-hospitalization period (the "parent" EMA study). Participants were recruited from adult inpatient psychiatry units at two large urban hospitals. Primary inclusion criteria were: (1) age 18+ years old; (2) English fluency; (3) presentation with STBs at inpatient admission (per study staff review of the admission note in the electronic health record); (4) smartphone ownership; and (5) willingness to provide at least one collateral contact person. Exclusion criteria included any factor that impaired the individual's ability to understand study procedures or provide informed consent, as determined by the inpatient clinical team or study staff. All participants provided written informed consent. As this was a pilot study focused primarily on feasibility and acceptability, our sample size was determined based on the number of participants enrolled in the parent EMA study while the MRT portion was active.

Procedure

All study procedures were approved by the Institutional Review Board at the Massachusetts General Hospital (under protocol #2015P000598) with reliance agreements

(under SMART IRB protocol #2255) and data use agreements with other involved institutions. This trial was prospectively registered, before data were collected, on ClinicalTrials.gov (NCT05791643).

Inpatient period. During the study enrollment/baseline visit, which occurred as close to inpatient admission as possible, a research assistant downloaded a survey app (MetricWire Catalyst) on participants' smartphones. Immediately following enrollment, participants began receiving prompts to complete EMA surveys six times a day for the duration of their hospital stay. Each EMA survey took under five minutes to complete and included questions assessing suicidal thoughts (see *Measures*) and a range of affective, cognitive, and contextual factors. The first and last survey of the day occurred at one of a few different times that the participant could choose (6AM, 8AM, or 10AM for the first survey and either 10PM or 11:59PM for the last survey), with other prompts sent randomly between predetermined intervals (10AM – 9:30PM, 12PM – 11:30PM, or 2PM – 11:30PM), with a minimum of 2 hours between prompts and surveys expiring after 2 hours. Participants were compensated $1 for each EMA survey completed. Prior to discharge, a research assistant collaboratively developed a personalized safety plan with each participant. The study safety plan template used a modified, simplified format from that of Stanley & Brown,[37] consisting of three (instead of six) categories: (1) relaxation or distraction strategies; (2) people for support or distraction; and (3) professional/crisis resources. Research assistants who developed the study safety plan were trained (via an interactive workshop) and supervised (via at least weekly small group and/or individual supervision meetings) by the lead author, a licensed clinical psychologist with prior formal training in the Stanley-Brown safety planning intervention.[37] When a previously developed (e.g., by inpatient clinical staff) safety plan was available, research assistants worked

with participants to collaboratively select content from the existing plan to include in the simplified study template. Content from the study safety plan was used for the just-in-time messages and entered in the MetricWire app for the participant to access at any time after discharge. Participants hospitalized for more than eight weeks were withdrawn from the study, as our primary focus was on the post-discharge period.

Post-discharge period. Prompts to complete the same 6x/day EMA surveys continued for 28 days after inpatient discharge. On the day of discharge, the MRT portion of the study began; of note, EMA data collected during the inpatient period were not used to inform the MRT protocol or just-in-time interventions implemented only after discharge. Each time an EMA survey response met criteria for micro-randomization, the participant was randomized to either receive or not receive a series of automated messages aimed to promote in-the-moment coping strategy use (see *Interventions*). After each randomization, a very brief (~5-item) "follow-up" EMA survey to assess proximal outcomes (see *Measures*) was prompted 15 minutes later and remained open for 4 hours (with prompted reminders to complete it, if not yet completed, 1- and 2-hours after the initial EMA survey). Participants were not paid for the post-randomization follow-up surveys. At the end of the post-discharge study period, participants were contacted to complete a 30-minute audio-recorded qualitative phone interview with a research assistant to obtain feedback about the intervention, for which they were paid $30. Participants who had received at least one intervention were also asked to complete two brief self-report questionnaires (see *Measures*) on intervention feasibility and acceptability at the end of the study.

After two consecutive days of no study data, a research assistant attempted to contact participants to troubleshoot issues with the technology and encourage re-engagement with the

EMA surveys. If the study participant continued not providing data after this initial contact, four more attempts at contact were used to try to re-engage study participants. After five unanswered contacts (and no data provided) over two weeks, participants were considered lost to follow-up (though still able to re-engage in the study at any point up until 28 days post-discharge). After participants were considered lost to follow-up, the automated app-based prompts to complete EMA surveys continued, but no more contact attempts were made to re-engage them.

Measures

A subset of specific EMA items from the parent EMA study was used for this pilot MRT.

Suicide urge. Suicide urge was assessed with the item: "Right now, how strong is your urge to kill yourself?" Participants responded on a 0 (not at all) to 10 (very strong) scale. This item was used in both the 6x/day EMA surveys and the post-randomization follow-up surveys.

Suicidal intent. Suicidal intent was assessed with: "Right now, how strong is your intention to kill yourself today?" Participants responded on a 0 (I am definitely not going to kill myself today) to 10 (I am definitely going to kill myself today) scale. This item was used in both the 6x/day EMA surveys and the post-randomization follow-up surveys. Ratings of ≥ 8 on the suicidal intent item triggered the study risk assessment protocol, which involved a study clinician contacting the participant by phone for a brief risk assessment and delivery of a range of potential clinically indicated interventions (e.g., reviewing a safety plan, enacting emergency procedures).[42] Participants were made aware during informed consent that a study clinician may contact them after leaving the hospital if their EMA responses suggested they were at imminent risk of suicide.

Coping strategy use. The post-randomization follow-up EMA survey assessed coping strategy use with a series of items. Each follow-up survey was tailored to the intervention content

the participants received following the most recent initial EMA survey (if randomized to intervention). Follow-up surveys after randomization to intervention asked, "Since the last survey, did you:" followed by each coping strategy recommendation previously presented. Participants first selected "Yes" or "No", and if "Yes", on the next screen, they then indicated which of the suggested strategies they tried. If "No", the next item asked, "Have you done anything else to feel better since the last survey?" and if "Yes" to this item, participants were asked to describe what they did in an open-ended text box. Following randomization to no intervention, the corresponding follow-up survey item on coping asked, "Since the last survey, did you try anything to help cope with your feelings?" followed by, if "Yes", an open-ended text box to describe what they did.

Feasibility of Intervention Measure. The Feasibility of Intervention Measure (FIM) is a 4-item self-report questionnaire used to assess participant's perspectives on the sustainability of the intervention messages. On the original scale, each item uses a "[INSERT INTERVENTION]" placeholder; for the present study, we used "messages". At the start of the survey, we also displayed two example just-in-time messages to ensure participants answered the FIM items with respect to the intervention. Participants were asked to answer two of the four FIM questions ("The messages seem doable" and "The messages seem easy to use"), as the other two items ("The messages seem possible" and "The messages seem implementable") were less relevant for recipients of the messages, as opposed to clinicians, for example. Only the participants who received an intervention during the study period were sent this survey at the end of the study. Each item is scored from 1 (Completely disagree) to 5 (Completely agree), and the final score is the average of the items with higher scores indicating higher feasibility.

Acceptability of Intervention Measure. The Acceptability of Intervention Measure (AIM) is a 4-item self-report questionnaire used to assess intervention acceptability. The specific items were: "The messages meet my approval", "The messages are appealing to me", "I like the messages", and "I welcome the messages". These questions were sent in the same survey as the FIM; higher total scores indicate higher perceived acceptability of the intervention.

Qualitative interview. A semi-structured interview guide was used to facilitate the phone-based interviews aimed to collect qualitative information about acceptability and solicit feedback on the intervention. All initial interview questions were open-ended, and the research assistants conducting the interviews were trained to follow up with probing or clarifying questions as needed. Topics included: perceived helpfulness of the messages (and their specific components), feedback on message content, wording, included images, and frequency, and the specific contexts when messages were more or less helpful and relevant. The interview guide also included a question about the burden of the post-randomization follow-up surveys and solicited any other suggestions. For participants who had received at least one intervention during the study, the research assistant began the interview by showing the participant example messages (via a web-based link shared immediately before the interview) to jog their memory about the study intervention. For those who never received an intervention, the research assistant started the interview by both sharing an overview of the messages and presenting them with examples via the same web-based link. The wording of interview questions was also modified to be about hypothetical intervention delivery (e.g., "When *could* these messages be more or less helpful to you?" instead of "When *were* these messages more or less helpful to you?").

Interventions

Here we define key components of the intervention and its delivery within the pilot MRT. Additional details about the intervention protocol is available from the first author upon request.

Decision point. The decision point for intervention delivery was endorsement of high (≥ 8 of 10) suicide urge or non-zero but not high (> 0 but < 8) suicidal intent; as described above, high (> 8) intent triggered the study's standard risk assessment protocol. Using this particular threshold to indicate high suicide urge was somewhat arbitrary; however, we chose ≥ 8 out of 10 due to our primary interest in the effects of the interventions during periods of more elevated and potentially distressing suicidal thinking, during which there was at least some intent to act and participants thus may be more likely to identify as in need of intervention (thus potentially increasing message receptivity). We also did not want to set too low of a threshold for intervention delivery given concerns about both overburdening participants in the context of the parent EMA study and the potential for habituation to messages. Lastly, this decision point was chosen because the intent criterion covered a relatively wide range of suicidal thought intensity ratings, and we were interested in exploring whether effects varied as a function of pre-randomization suicidal thought intensity. Data from previous participants in the parent study indicated that we could expect about 10% of all completed surveys to fall within the range for this decision point.

Decision rule. Whenever a participant provided a response (to one of the 6x/day EMA surveys) of high (≥8) urge or non-zero but not high (>0 but <8) intent, randomization occurred immediately in the app. There were no additional tailoring variables. 50% of the time, participants were randomized to no intervention, and 50% of the time, they were randomized to an intervention. When randomly assigned to intervention, the probability of a personalized versus general intervention was also 50/50 (see *Intervention components*). There were three

possible personalized intervention messages (each delivered randomly with an 8.3% probability) and six possible general messages (each delivered randomly with a 4.2% probability). See **Figure 1** for a design overview.

Intervention components. Prior to starting the pilot MRT within the parent EMA study, example intervention messages and post-randomization follow-up surveys were shown to n=4 parent study participants. Brief "think aloud" interviews were conducted and resulted in feedback including: minor suggestions to word choice in both intervention messages and response options; shortening of text overall; and a preference for assessing the more objective outcome of coping strategy use (versus intervention helpfulness) in the follow-up surveys. This feedback informed refinements to the wording and illustrations used in the intervention messages as well as the content of the follow-up surveys used to assess proximal outcomes in the subsequent pilot MRT.

The intervention consisted of a series of interactive digital messages delivered within the MetricWire app at the end of each EMA survey meeting randomization criteria. The overall intervention goal was to recommend the use of specific strategies for coping with suicidal thoughts. The coping strategies recommended were either (1) *personalized* (drawn from the individual's safety plan) or *general* (common across other participants' safety plans), and either (2) *internal* (i.e., strategies for relaxation or distraction) and/or *external* (i.e., people for support or distraction). We used both personalized and general messages in order to maximize variety in message content to potentially increase engagement and avoid habituation, and given the potential for the effectiveness of personalized versus general messages to differ at both the individual (e.g., those with higher quality safety plans may prefer to see content drawn from their own safety plan, whereas those newer to psychotherapy may prefer seeing other common

evidence-based strategies) and momentary level (e.g., the accessibility of personalized coping strategies may vary by context).

General coping strategies were developed by study staff coding the content of n = 439 de-identified study safety plans from previous participants and taking the most common internal coping strategies. Intervention messages included *internal* and/or *external* coping strategies. Of the 6 total general messages, one focused on *external* coping only ("external"), one consisted of the most common *internal* coping strategies (across all subtypes of internal coping strategies, *internal – all subtypes*), and one included the most common internal coping strategies (all subtypes) plus external coping (*internal and external*). The remaining 3 general messages consisted of the most common coping strategies in each of 3 internal coping subtypes: *relaxation, distraction,* or *physical activity*. The general *relaxation*, *distraction*, and *physical activity* coping strategy messages did not overlap in content with the general *internal – all subtypes* and *internal and external* messages. These combinations (personalized X general, internal X external) resulted in 9 total intervention types: *personalized (external), personalized (internal), personalized (internal and external), general (external), general (internal – all subtypes), general (internal and external), general (relaxation), general (distraction),* and *general (physical activity)* (**Figure 1**).

The series of interactive digital messages followed a predetermined decision tree. At the end of EMA surveys randomized to intervention, an initial screen suggested one or more coping strategies. For example, the *personalized (external)* message stated, "You had listed these people as being helpful supports: [person 1] | [person 2] | [person 3]. Would it be helpful to reach out to any of them now?" and the *general (distraction)* message read, "For some people, distraction can be helpful when feeling suicidal, for example: Read | Play a game | Hold ice. Would any of these

distraction tools be good to try now?"; see **Supplemental Material** for all initial messages. Simple illustrations (developed by a graphic designer) corresponding to the specific coping strategies recommended were included on each initial intervention screen.

On this initial screen, participants were able to select which (if any) of the recommended strategies they would like to try, or they could select "Maybe/I'm not sure" or "No, none of the above." If they selected one or more specific strategies, on the next screen they were notified that we would check back in with them in a few minutes. If they selected "Maybe/I'm not sure" or "No, none of the above" in response to a personalized message, they were asked on the next screen: "No problem. What could/will get in the way?" with the following response options: "It may/will take too much time/effort," "It may/will not help," "Might not/don't need a strategy", "Thoughts may/will pass on their own," "I'm busy," "I may/will try something else," "I don't like the suggestions," and "Other reason." Participants could select multiple reasons, and if they endorsed "Other", they were asked on the next screen to elaborate in an open-ended text box. If participants selected "Maybe/I'm not sure" or "No, none of the above" in response to a general message, the next screen suggested alternative coping strategies (within the same category as the initial message). If the participant again selected "Maybe/I'm not sure" or "No, none of the above," they were asked what could/will get in the way on the next screen, and then notified to expect a brief follow-up survey. If participants selected that they would like to try one of the alternative strategies, they were then notified to expect a brief follow-up survey on the final intervention screen. See **Supplemental Material** for an example of the flow of the intervention messages.

Analytic Strategy

Descriptive analyses. For feasibility, we calculated the mean, standard deviation (SD), and range of total scores on the FIM. We also calculated the percentage of enrolled participants who completed (i.e., were not lost to follow-up or withdrawn during or prior to) the 28-day post-discharge period, percentage of prompted EMA surveys completed post-discharge, percentage of completed EMA surveys that met micro-randomization criteria and were randomized, percentage of participants randomized at least once, and the mean, SD, and range of number of randomizations across those who were randomized at least once. We calculated the percentage of randomized surveys assigned to intervention versus no intervention and the percentage of prompted post-randomization follow-up surveys completed.[1] For acceptability, we calculated the mean, standard deviation (SD), and range of total scores on the AIM.

Qualitative data. Transcripts from the interviews were summarized by trained research assistants. We used rapid coding procedures, which are designed to quickly produce actionable results to inform ongoing intervention development and have been shown to produce valid results similar to gold-standard in-depth analyses for qualitative data.[43–45] Using a draft structured template corresponding to the interview guide, at least two research assistants extracted key themes from an initial set of three transcripts. Multiple meetings between the coders and lead author were convened to review themes from this initial set of transcripts and revise the structured template. Once the template was finalized, the full set of transcripts[2] was coded independently using the template by one of four total research assistants trained on coding procedures for this study. Finally, themes were combined in two overall summary tables (one for

[1] Due to the study app not storing data on partially-completed EMA surveys, we were not able to determine how often participants began, but did not complete progressing through, the series of automated intervention message screens potentially presented within the randomly timed EMA surveys.

[2] Of the 53 total interviews, 3 did not have transcripts available due to issues with the audio recording process. For these 3 interviews, detailed notes taken by the interviewer during the interview were coded instead of transcripts.

participants who received at least one intervention during the study and one for those who did not).

Statistical analyses. Although the primary focus in this pilot MRT was feasibility and acceptability, we also assessed intervention effects on proximal outcomes with two main objectives. First, we wanted to determine whether there were iatrogenic effects (at the group level, given the relatively small sample) of the intervention, differential effects across intervention types (e.g., personalized versus general messages), or contextual moderators of intervention effects (e.g., levels of pre-randomization suicide urge or intent). Statistical analyses were meant to supplement the descriptive analyses on feasibility and acceptability and help inform decisions about potential future changes to the intervention or rules for triggering its deployment. Second, given the complexity of statistical analyses for MRTs, we wanted to use data from this pilot MRT to test out the implementation of key analytic procedures and ensure that any issues that arose would be addressed in future MRT study designs. Specifically, we wanted to confirm our operationalization of key proximal outcome, control, and potential moderator variables in this set of statistical analyses and establish how to handle missing data in these three different types of variables.

For statistical analyses, the *primary proximal outcome* was a binary variable indicating use of a coping strategy since the prior survey (i.e., the most recent survey triggering randomization). For follow-up surveys after intervention assignment, a "Yes" response to *either* the item assessing whether they used any of the specific coping strategies recommended in the prior survey (which were displayed again in the follow-up survey) *or* the item assessing if they used any other coping strategies since the last survey resulted in a "1" (indicating coping strategy use since the prior survey) for this binary item. For follow-up surveys after assignment to no

intervention, a "Yes" response to the item assessing if any coping strategies were used since the last survey resulted in a "1". All other follow-up surveys were assigned "0" (indicating no coping strategy use) on this binary variable. *Secondary proximal outcomes* were momentary suicide urge and suicidal intent, both also assessed (on a semi-continuous 0 to 10 scale) in the post-randomization follow-up survey.

The *primary pilot analysis* compared any intervention to no intervention on the primary proximal outcome. We used a generalization of regression analysis that ensures unbiased estimation of causal effects of time-varying intervention messages in mobile health settings.[46,47] Time-varying longitudinal data across all analyzed participants was pooled in these analyses. The causal effect of intervention on coping strategy use for suicidal thoughts is expressed on the log-relative risk scale, a scale that measures the probability ("risk") of using a coping strategy in the time between receiving the intervention and the follow-up survey. A log-relative risk greater than 0 implies the intervention had a positive effect on the probability of coping strategy use. The effect at each decision point is defined among participants who met criteria for micro-randomization.

Secondary pilot analyses compared any versus no intervention on secondary proximal outcomes. Data were analyzed using similar methods to those reported above but modified to assess the causal effect of any intervention on suicide urge or intent on the linear scale. A causal effect of less than 0 implies that the intervention reduced momentary suicide urge or intent relative to no intervention. *Additional pilot analyses* addressed intervention contrasts and contextual moderators. For intervention contrasts, we explored the effects of personalized versus general intervention messages on coping strategy use. For contextual moderators, we explored the effects of any versus no intervention on coping strategy use at *high* (intensity ratings of 6-10)

versus *low* (0-5 intensity) pre-randomization (from the EMA survey triggering randomization) levels of suicide urge (as suicide urge rating < 8 could still trigger randomization as long as intent was non-zero) and *high* (5-7 intensity) versus *low* (0-4 intensity) pre-randomization suicide intent.

Regarding the modeling strategy, for each analysis, we specified a parametric working model for the expected value of the binary (primary proximal) or semi-continuous (secondary proximal) outcomes. The regression analysis used this working model in a set of estimating equations that allow for consistent causal estimates regardless of working model correctness.[47] For semi-continuous outcomes, the estimating equations were based on the weighted and centered least squares,[46] where centering ensures robustness of causal estimates to incorrect working model specification. For the binary outcome, estimating equations were based on the EMEE approach,[48] which are similar to log linear model score functions but are robust to incorrect working model specification. All models controlled for pre-randomization suicide urge and intent, as well as the number of days since hospital discharge. Missing data on proximal outcomes (from the 18.61% of prompted post-randomization follow-up surveys that were not completed) were excluded. Our pilot does suggest the use of missing data strategies such as multiple imputation[49] and augmented inverse-probability of missingness weights (AIPW)[50] as part of sensitivity analysis in future MRTs that build from this pilot work to address potential biases in complete case analysis.

Transparency and Openness

We report all data exclusions, manipulations, and measures in the study, and we follow JARS.[51] Analysis code for this study are available from the corresponding author upon request;

data sharing may also be possible upon reasonable request to the corresponding author. Data were analyzed using R, version 4.3.0 and MRTAnalysis[52] and geepack[53] packages.

Results

Participant Characteristics

A total of 87 participants enrolled in the parent EMA study from June 2023 to May 2024. The average age was 32.94 years (SD = 13.43, range = 18 to 70). 46.51% identified as women, 44.19% men, 6.98% non-binary/gender non-conforming, as 1.16% transgender men, and 1.16% other. 75.58% identified as White, 8.14% Black, 5.81% Asian, 1.16% American Indian/Alaskan Native, 1.16% Native Hawaiian/Pacific Islander, and 6.98% other (participants could select multiple); 16.28% identified as Hispanic/Latine. At baseline, 54.65% of participants reported a lifetime suicide attempt; of these, 15.11% had made a suicide attempt in the past month.

Feasibility

Of the 87 participants enrolled in the parent EMA study, 12 (13.79%) were withdrawn (either self-initiated by the participant due to no longer wanting to participate for various reasons [n = 8; 9.20%] or withdrawn by the investigators [n = 4; 4.60%] while still hospitalized due to either not being discharged after 8 weeks in the study or logistical problems such as being unable to download the study app). A total of 4 participants (4.60%) were lost to follow-up. None of these n = 16 withdrawn or lost to follow-up participants (18.39% of those enrolled) ever met criteria for randomization (and thus never received the intervention) during their time in the study and were excluded from all MRT analyses. There were no statistically significant differences in either demographic characteristics or prior suicide attempt between the N = 87 participants enrolled in the parent study and the n = 71 included in the MRT analyses to follow (the "MRT sample").

Participants in the MRT sample completed a total of 5,708 EMA surveys (47.85% of all prompted surveys). Of all completed surveys, 505 (8.85%) met randomization criteria and were randomized (248 [49.11%] to intervention and 257 [50.89%] to no intervention). A total of 44 participants (57.89%) met criteria and were randomized at least once during the study. Among those randomized at least once, the mean number of randomizations per participant was 11.48 [SD = 23.38], range = 1 to 127). A total of 411 (81.39% of all prompted) follow-up surveys were completed. Among the n = 37 who completed the FIM (only n = 44 who met randomization criteria at least once were sent the FIM and AIM at the end of the study, resulting in an 84.10% completion rate[3]), the mean score (on a scale of 1 to 5) was 3.82 (SD = 0.70; range 2.00 to 5.00).

Acceptability

Among the n = 37 participants who completed the AIM, the mean score (on a scale of 1 to 5, with higher scores indicating greater acceptability) was 3.75 (SD = 0.69; range 2.50 to 5.00). A total of 53 participants (74.6%) did the end-of-study interview, 33 (62.3%) of whom were randomized to potentially receive an intervention at least once and 20 (37.7%) of whom were never randomized during the study. Below we present summaries of themes for each subgroup.

Participants who were randomized at least once. Most (69.6%; 23 of 33) participants who were randomized at least once during the study reported finding the messages helpful overall. It was most common to note that the messages served as reminders of "healthy" coping strategies available and helped motivate them to engage in coping activities when needed (e.g., during "crisis" moments when it is "hard to know what to do next" and "good to have

[3] We tested for differences in baseline characteristics of those who did and did not complete the AIM/FIM. Age, gender, ethnicity, and suicide attempt history were not significantly different. There was a significant ($p < .05$) difference by race, with a higher proportion of White participants who did not complete the AIM/FIM than other racial groups. These findings should be interpreted with caution given the small cell sizes for several groups.

suggestions of something to do"). Fewer (30.3%; 10 of 33) participants did not find the messages particularly helpful, noting primarily that they either already do the suggested strategies or know the content on their safety plan so they do not need reminders. Two participants stated that they could use more help bolstering motivation to use the strategies (rather than only being reminded of them).

Specific aspects of message content that participants generally liked included: the variety of messages and coping strategies provided, clear and concise wording of messages, and the format. Feedback on the illustrations was mixed. Of the 20 participants who expressed a preference for personalized or general messages, 16 (80.0%) preferred messages containing personalized coping strategies from their safety plan (versus general coping strategy recommendations). Another 9 (27.3%) participants pointed to the combination of both message types being helpful, both to maximize variety and because they may be more likely to do personalized recommendations from their safety plan, but more helpful to see "new" general coping strategy suggestions they may not have previously considered. The remaining four participants (12.1%) did not share a preference for personalized or general messages. One participant suggested adding the option for participants to update message content over time. In terms of the specific contexts when messages were helpful, it was most common for participants to indicate that the messages were especially helpful during moments of more intense suicidal thoughts or emotional distress, generally because those are the times when reminders are more needed. Others, however, indicated that the messages were more helpful when "less suicidal," generally because coping strategies are easier to implement during those moments. It was also common to describe messages as more helpful in the evening (when suicidal thoughts tend to be more intense and it may be more feasible to do the strategies recommended versus, for example,

when at work) and when alone (versus around others). Participants generally indicated that message frequency was not burdensome, although a couple suggested sending messages at a fixed cadence (e.g., once daily or weekly).

Participants who did not receive an intervention. Among those who did not receive an intervention during the study, most (90%; 18 of 20) reported thinking that the messages would be helpful, largely to remind them of coping strategies (e.g., "when someone is experiencing strong thoughts of suicide or panic attacks, it is really hard to think of coping strategies") and as an indication that they are cared for (e.g., providing "support in your pocket"). Of note, two participants noted that the messages would be more helpful for people who are less experienced or familiar with using their safety plan. Feedback was more mixed regarding when the messages would be more or less helpful, with some indicating that the messages would be more helpful when feeling more suicidal (including because there is no need for coping skills if "feeling fine") and others indicating that they would be more receptive to coping strategy recommendations when feeling less suicidal or overwhelmed. Specific aspects of message content that participants liked included: "casual" wording, images, colors used, and format/layout. Again, most participants (14 of 20; 70.0%) preferred personalized messages. Notably, two participants suggested including more motivational statements or "affirmations" in the messages, as well as the option to update personalized messages with new coping strategies over time. Participants again suggested sending messages at night (because they are more likely to be alone, not busy/distracted, and feeling worse). These participants generally suggested sending messages between 1-3x/day. One individual suggested allowing people to choose how often to receive them and another suggested sending messages more often during the initial days after discharge and then scaling back.

Proximal Outcomes

Results from statistical analyses are shown in **Table 1** and **Figure 2**.

Primary analysis. After the intervention (versus no intervention), participants were significantly more likely to have used a coping strategy for suicidal thoughts since the last survey (as evidenced by a positive log-relative risk [log RR]; log RR = 0.38 [95% CI: 0.07, 0.68], $p < .05$). No iatrogenic effects were observed at the group level.

Secondary analyses. Change in momentary suicide urge from pre- to post-randomization when assigned to intervention was not significantly greater than the change when assigned to no intervention (as evidenced by a non-statistically significant linear risk [LR]; LR = -0.13 [95% CI: -0.44, 0.18], $p = 0.41$). Change in momentary suicide intent was also not significantly different (LR = -0.19 [95% CI: -0.63, 0.26], $p = 0.40$). No group-level iatrogenic effects were observed.

Additional analyses. The effect of personalized messages (versus no intervention) on the primary proximal outcome (coping strategy use) was significant (log RR = 0.33 [95% CI: 0.11, 0.55], $p < .01$), whereas the effect of general messages (versus no intervention) was not (log RR = 0.44 [95% CI: -0.01, 0.89], $p = .06$). The differences in intervention effects for high versus low pre-randomization suicide urge (log RR = -0.03 [95% CI: -1.08, 1.02], $p = 0.95$) and high versus low intent (log RR = -0.06 [95% CI: -2.38, 2.49], $p = 0.96$) on coping were not significant.

Discussion

We conducted the first-ever, to our knowledge, micro-randomized trial (MRT) to test a just-in-time adaptive intervention (JITAI) for those experiencing suicidal thoughts after psychiatric hospitalization. There were three main findings. First, we found that it is feasible to send brief smartphone-based messages that remind people of coping strategies (either from their own safety plan developed in the hospital or common evidence-based coping strategies) in

response to real-time reports of suicidal thoughts. Second, people receiving these messages following their experience of suicidal thoughts reported that this was an acceptable intervention. Third, the intervention significantly increased coping strategy use, with personalized messages overall having a stronger effect than general messages. Below, we discuss these findings in detail.

Feasibility

We found that it was feasible to deliver (randomly assigned) automated smartphone-based intervention messages aimed to promote in-the-moment coping strategy use in response to real-time reports of suicidal thoughts. Although there are no validated cut-off scores available for the FIM, the mean score in this study (3.82 on a 1 to 5 scale) corresponds to an average response of "agree" to each statement about intervention feasibility, suggesting that overall, participants found it feasible to receive the messages. Regarding objective feasibility data, over 80% of those enrolled in the MRT completed the 28-day post-discharge monitoring period. Notably, none of the participants who were withdrawn or lost to follow-up met criteria for randomization or received a just-in-time intervention during the study, rendering it highly unlikely that participant-initiated withdrawal or dropout was due specifically to the intervention. Just over half (58%) of participants reported elevated suicide intent or high suicide urge on an EMA survey during the study and thus met criteria for randomization. Among participants who were randomized at least once during the study, just under 10% of completed surveys met randomization criteria, as expected given our previous data from the parent study with EMA alone. The fact that a substantial minority (42%) of participants never had the opportunity to receive the intervention and the vast majority (91% among those randomized at least once) of completed surveys did not exceed the threshold for randomization is consistent with recent work showing the zero-inflated

nature of real-time data on the intensity of current suicidal thoughts,[14,42] even in an extremely high-risk group. This, coupled with other qualitative and quantitative data we return to below, suggests that in future work it may be reasonable to lower the threshold of suicidal thinking severity used to trigger the intervention.

It is possible that some people who were never randomized experienced intense suicidal thoughts during the study period but did not report them via EMA, and among those who received interventions at some point during the study, certain moments of intense suicidal thinking went uncaptured. There are potential benefits and costs of making intervention deployment contingent on patient self-reports of suicidal thoughts. Although this approach ensures that the intervention is only sent during moments of elevated suicidal thinking and may help maximize receptivity to intervention, an obvious downside is that it hinges on in-the-moment self-report of suicidal thoughts. The hesitance and barriers to self-disclosure of suicidal thoughts are well-known (e.g.,[54–56]), and our recent qualitative interview research (in n = 100 recently discharged adult inpatients) suggests that at least some individuals are less likely to complete EMA surveys when feeling more distressed:[57] the moments, of course, when intervention may be most critical. Deploying real-time interventions based on individuals' self-reported personalized warning signs may offer a way to deliver support without requiring disclosure of suicidal thoughts, aligning with the emphasis of the Stanley-Brown safety plan[37] on using one's warning signs to prompt coping. Future JITAIs aimed at reducing proximal suicide risk may also explore other alternative (or additional) methods of triggering intervention delivery. For example, such JITAIs could potentially be deployed based on passive sensing data capturing states relevant to mental health such as physiological arousal[58] or changes in physical activity or patterns of social interaction.[59] Deploying suicide prevention JITAIs based on passive

data, however, faces challenges, both related to recent findings that call into question the utility of passive data for detecting or predicting states of suicide risk[58,60] and the technical barriers associated with processing passive data to trigger interventions in real-time or very close to it. We view the intervention delivery model used here, which relies on patient self-report of current suicidal thoughts, as one step toward potentially more advanced and lower burden frameworks for ascertaining dynamic information about suicide risk during high-risk periods in the future. In the interim, based on qualitative interview data from a subset of n=100 participants in the parent EMA study (who participated before the MRT) addressing the desired frequency of EMA surveys, 3 or 4 surveys per day was perceived as more acceptable than 6.[57] In our currently ongoing MRT research, we are now prompting 4 surveys/day in part based on this feedback.

Acceptability

The mean score on the validated AIM (3.75 on a 1 to 5 scale) corresponds to an average response of "agree" to statements about intervention acceptability, indicating that overall, participants rated the intervention acceptable. During qualitative interviews, roughly three-quarters of participants either described the messages as helpful to them or, if they never received an intervention, that the messages would be helpful to others. In terms of why the interventions were helpful, participants generally indicated that the messages reminded them of coping strategies available to them during emotionally challenging and overwhelming moments. In terms of what was not helpful, some indicated that they did not need in-the-moment reminders of coping strategies because they either already do or know the coping strategies available to them. A small number of participants noted that the messages could be more helpful if the content focused more on bolstering motivation to actually do the strategies. Refinements to the intervention may include expanding the messages to include more content or interactive

exercises based on principles of motivation enhancement,[61,62] which may maximize the perceived relevance and helpfulness of the messages. It is likely that the most potent message content will differ across individuals; whereas some may find timely reminders of coping strategies helpful, others may prefer or be more likely to benefit from messages targeting specific psychological (e.g., motivational) or logistical barriers to using coping strategies during suicidal crises. The most preferred and ultimately beneficial message content may vary not only across individuals, but also within a given person over time. The degree of personalization in the intervention content tested here (individualized safety plan content) was limited. One could envision future JITAIs with more personalization (for example, by targeting individualized barrier(s) to coping strategy use for suicidal thoughts) and updating over time based on information collected about individuals' preferences and needs. Work toward this end is ongoing by our team and will be implemented in future larger-scale MRT designs.

Regarding frequency and timing, participants generally described receiving messages once daily (or even up to a few times per day) as acceptable, indicating that the intervention was not perceived as overly burdensome in its current form. Message frequency may also be a component of future JITAIs that could vary based on an individual preference, consistent with feedback received during the qualitative interviews. In terms of the times when messages were (or could be) most helpful, participants commonly indicated that the messages were (or could be) more helpful at night, when suicidal thoughts are more intense[63] and they are more likely to be alone and not engaged in work/other tasks that could reduce receptivity or lessen the feasibility of doing a coping strategy. Time of day could thus be considered as a tailoring variable in future JITAIs. Participants also overall expressed that the messages were (or would be) more helpful when suicidal thoughts were more intense, when being emotionally overwhelmed can impede

one's ability to remember and implement coping strategies. A minority of participants, however, pointed out that it can be easier to actually implement coping strategies when feeling less distressed and overwhelmed. This qualitative feedback provides additional support for lowering the threshold used to trigger the intervention in the future. In our team's upcoming larger-scale MRT, which includes random assignment to either clinician outreach or another (more intensive) digital intervention at higher levels of suicidal thinking, we will also be deploying a version of the automated messages tested here at low-to-moderate levels of suicide urge. For at least some, this strategy may not only be acceptable but also maximize receptivity and effectiveness on proximal and distal outcomes. In line with other qualitative feedback received in this pilot study, we will also be giving participants the option to update the content of the automated messages receive over time in upcoming work.

Effects on Proximal Outcomes

Sending messages encouraging people experiencing suicidal thoughts to use coping skills had no iatrogenic effects on proximal outcomes at the group level and instead significantly increased the use of a coping strategy (primary proximal outcome). Intervention effects on suicide urge and intent (secondary proximal outcomes) were in the desired direction, but not statistically significant. Given the low-burden and scalable nature of these messages, these encouraging findings (especially for coping strategy use) may be interpreted as another indicator of intervention acceptability and suggest that future large-scale efficacy and effectiveness studies – including those powered to test the distal outcome of suicidal behavior – are warranted. Recent data show that although coping strategy use is associated with reduced suicidal thinking and risk of suicidal behavior,[33,64–66] safety plan and coping strategy use after hospital discharge are relatively low.[67,68] The content of the automated messages tested here was straightforward,

included relatively little individual-level tailoring, and was static over time (with no updating of message content or format based on data collected from individual participants). This bodes well for more tailored and dynamic future JITAIs that incorporate the messages examined here as one component.

Our analyses also point to two other primary considerations for future work. First, we observed stronger overall effects on coping strategy use for messages that contained coping strategies from an individual's safety plan (versus general coping strategy recommendations). This is consistent with qualitative feedback that personalized messages were generally more helpful. In our future larger-scale MRT work, we plan to focus primarily on personalized coping strategy recommendations across both digital and clinician-delivered intervention components, although general messages may still have promise for certain individuals and in specific contexts. Second, intervention effects on coping strategy use did not vary as a function of suicidal thought intensity. This result may be interpreted as consistent with qualitative feedback that although messages are most helpful when suicidal thoughts are more intense, messages may be more actionable when suicidal thoughts and emotional distress are less intense. This finding may also be in part due to the restricted range of suicide urge (8, 9, or 10 on a 0 to 10 scale) ratings at which randomization occurred in this pilot MRT. Even though a wider range of suicide urge ratings prompted randomization (1 through 7, or 0 when urge was $\geq$ 8), similar to our other EMA studies, levels of suicidal intent were highly zero-inflated, perhaps at least in part due in part to using extreme anchors on this item with a "today" timeframe (e.g., 10 = I am definitely going to kill myself *today*) or making participants aware at the start of the study that EMA responses indicating high immediate risk of suicide may result in clinician outreach (e.g., potential reactivity).[42] Future JITAIs that deploy other clinician-delivered or automated

intervention components at high suicide intent are also worth testing, given that such high-risk moments may be when accessible and scalable intervention is most critical. Pinpointing the precise points in time leading up to or during suicidal crises at which deploying interventions aimed to promote effective coping must continue to be a focus of suicide prevention JITAI development. For some individuals, sending digital messages earlier on, when suicidal urges are just beginning to build or as we noted earlier in the presence of an individual's personalized warning signs, may be most helpful, whereas others may be more receptive or perceive a need for support during more intense suicidal thinking. Moreover, personalizing JITAIs (pJITAIs),[69,70] in which decision rules continually learn and improve as data are collected from each individual over time, are a promising direction for future work in this area.

Limitations

The findings from this pilot MRT must be considered in the context of several limitations. First, due to the relatively small sample included and the low base rate of suicidal behavior (even in this very high-risk population), we did not test intervention effects on the distal outcome of suicide attempt. This is a key next step for future larger-scale work. Second, participants were paid a small amount ($1) for each random EMA survey completed, rendering it unknown whether engagement with the surveys used to trigger the intervention would decrease substantially in the context of "real world" service delivery when compensation may not be feasible. This will also be a focus of our upcoming work in this area. Third, nearly 80% of the sample was White and only 13% identified as Hispanic/Latine. Thus, results may not generalize to more racially and ethnically diverse populations. Tailoring the content of this (and other) intervention components to the needs of specific minoritized groups at elevated risk for suicide is needed in future JITAI work.

Fourth, our primary proximal outcome did not distinguish between whether the coping strategy used was specifically a recommended strategy or not; future research could examine more granular proximal outcomes (e.g., type of strategy used), which may provide additional information about differential message effects. It is possible, however, that by prompting individuals to use a given set of specific coping strategies can still help motivate the use of another – potentially more accessible or helpful – coping strategy and achieve the same end goal (reduction of risk). Fifth, in the specific EMA protocol used, it is possible that two randomly timed EMA surveys could have been completed and met randomization criteria before the corresponding follow-up survey(s), which could have led to participant confusion about which "last survey" the follow-up survey(s) referred to. This timing issue only occurred twice across all data collected in this pilot; however, in our ongoing MRT work, we have reduced the number of random prompts per day and shortened the follow-up survey window to mitigate this risk. Another limitation is that the EMA app does not store information about partially-completed but never submitted surveys, so we were unable to determine whether participants ever abandoned an EMA survey during the potentially embedded series of intervention message screens: another potential acceptability metric. Last, we did not include additional assessments of psychological constructs that may serve as mechanisms of intervention effects, such as coping self-efficacy. Identification of mechanisms may aid in additional intervention optimization and refinement.

Conclusions

The findings from this pilot MRT support the feasibility and acceptability of a brief digital intervention for promoting in-the-moment coping strategy use during episodes of suicidal thinking after psychiatric hospitalization. Given the urgent need for scalable solutions to help reduce suicide risk, especially during critical care transition periods, future research that

rigorously evaluates intervention efficacy and effectiveness and seeks to optimize this (and other) strategies that focus on delivering timely and tailored support to individuals at high risk for suicide is warranted.

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