Protocol

Development of PRECISE, a Data-Driven Personalized Suicide Prevention Intervention: Protocol for an Intervention Refinement Pilot and Randomized Controlled Trial

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Abstract

Background: Suicidal thoughts and behaviors (STBs) are heterogeneous in their causes and course, yet most interventions rely on nomothetic, one-size-fits-all models. Dialectical behavior therapy (DBT) is an evidence-based treatment for STBs, but its standard year-long format is resource-intensive and difficult to access. Ecological momentary assessment (EMA) combined with idiographic (person-specific) statistical modeling offers a way to identify which emotion regulation processes are driving an individual's risk, and in turn to select the DBT skills most relevant for that person.

Objective: This protocol describes the refinement (aim 1) and preliminary evaluation (aim 2) of PRECISE (Personalized Clinical Intervention for Suicidal Events), an 8-week, EMA-informed, idiographically tailored adjunctive treatment for adults with active suicidal ideation.

Methods: In aim 1, an existing PRECISE treatment manual and clinician dashboard will be iteratively refined with a mentorship and advisory panel and tested for feasibility and acceptability in a small, randomized pilot study (n=10; n=5 per arm), comparing high- and low-intensity personalization schedules. In aim 2, 60 adults with active suicidal ideation will be randomized to a high-intensity (weekly idiographic model updates across all 8 EMA-monitored weeks) or low-intensity (single idiographic model generated after an initial 2-week EMA burst) version of PRECISE. Both arms will receive coach-delivered DBT skills selected according to each participant's idiographic model, which will be generated using the group iterative multiple model estimation (GIMME) algorithm. Primary outcomes include usability, retention, EMA adherence, acceptability, and fidelity; secondary and exploratory analyses will examine trajectories of suicidal ideation and a within-person mediation model linking emotion regulation to STBs.

Results: The trial registration record (ClinicalTrials.gov) was first posted on February 5, 2025, and enrollment began on November 14, 2025. The study is currently recruiting. Estimated total enrollment across aim 1 and aim 2 is 70 participants. Primary and final data collection are anticipated to be complete by March 2030. The study was funded in May 2025, and data collection began in November 2025. As of November 9, 2026, 7 participants had been enrolled. Results are expected to be published in approximately the beginning of 2030.

Conclusions: PRECISE is, to our knowledge, the first idiographically personalized, EMA-informed adjunctive treatment developed specifically for STBs. This trial will provide feasibility, acceptability, and preliminary efficacy data to inform a subsequent fully powered efficacy trial.

Trial Registration: ClinicalTrials.gov NCT06809348; https://clinicaltrials.gov/study/NCT06809348

International Registered Report Identifier (IRRID): DERR1-10.2196/109277

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KEYWORDS

suicide prevention; ecological momentary assessment; idiographic; personalized intervention; dialectical behavior therapy; digital health; randomized controlled trial protocol

Introduction

Suicide is a leading cause of death in the United States [1], and a substantial minority of adults report serious suicidal ideation each year [2]. Reducing suicidal thoughts and behaviors (STBs) is a public health priority [3], and precision approaches to mental health care, including tailoring intervention content to the individual rather than applying a uniform protocol, have been identified as a strategic objective for suicide-focused research [4].

Theoretical models converge on the role of negative emotion and emotion dysregulation in the onset and maintenance of STBs [5-8]: negative affect tends to rise before a self-injurious or suicidal event and to fall afterward, consistent with a negative reinforcement account of why these behaviors persist [9-13]. Dialectical behavior therapy (DBT) directly targets this pathway and is among the most well-supported treatments for STBs [14,15]. However, standard DBT requires roughly a year of weekly individual therapy, weekly group skills training, and between-session coaching, a level of intensity that limits access. Evidence that a skills-only version of DBT can match outcomes from full-model DBT [16] suggests that briefer, skills-focused adaptations [17] may retain much of DBT's active ingredients [18,19].

A second, related problem is that most STB interventions are built from between-person (nomothetic) models [20-22], despite growing evidence that the emotional and behavioral processes preceding STBs vary substantially across individuals [23-25]. Our prior work using ecological momentary assessment (EMA) in youth recently discharged from hospitalization for suicide risk [26] applied idiographic (person-specific) analyses (eg, group iterative multiple model estimation [GIMME] [27]) and found substantial between-participant heterogeneity in how coping behaviors relate to suicidal thoughts: some individuals showed strong associations between suicidal thoughts and reaching out to family, while others showed weak or no such association. This heterogeneity argues for tools that can identify an individual's own risk pattern and route them to the specific skills most likely to help.

Personalized treatments developed for other conditions have shown promising effects relative to nonpersonalized care, including for mood and anxiety symptoms [28] and eating disorder severity [29], with a recent meta-analysis of randomized trials finding personalized treatments outperformed nonpersonalized ones across mental health symptoms generally [30], consistent with the broader recognition that psychiatric presentations are heterogeneous [31]. However, this approach has not yet been applied to STBs. We developed PRECISE (Personalized Clinical Intervention for Suicidal Events) to fill this gap. PRECISE is an adjunctive, blended digital health treatment that uses EMA and an idiographic algorithm to identify each participant's within-person emotional and behavioral correlates of STBs and uses this information to select which DBT skills [32,33] a coach teaches, alongside safety planning [34].

Because withholding personalization from a comparison arm would raise ethical and equipoise concerns in an elevated-risk population, and because the more clinically urgent open question is not whether personalization helps but how much ongoing data collection and retailoring is required to realize its benefit, PRECISE's primary comparison is between high- and low-intensity personalization schedules rather than personalized versus nonpersonalized care. A further barrier to implementing data-driven personalized approaches in routine care is that the average clinician lacks the statistical training, infrastructure, and interpretive tools to translate EMA data into treatment decisions. Personalization tools must therefore be designed for direct clinical usability and efficiency from the outset, rather than layered on afterward.

This protocol addresses 2 aims and one exploratory aim. In aim 1, we will refine the PRECISE treatment manual and clinician dashboard through iterative, stakeholder-informed development, and establish the feasibility and acceptability of the refined protocol in a small, randomized pilot study (n=10; n=5 per arm) comparing high- versus low-intensity personalization. In aim 2, we will conduct a randomized controlled trial (n=60) to evaluate the feasibility, acceptability, and preliminary clinical outcomes of PRECISE, comparing a high-intensity (continuous weekly retailoring) versus low-intensity (single initial tailoring) personalization schedule. Finally, in an exploratory aim, we will test—within the high-intensity arm—whether within-person increases in effective emotion regulation strategy use mediate the association between negative affect and STBs.

Methods

Trial Design

This is a 2-phase, single-site study conducted in partnership with the University of California San Diego (UCSD) Health System. Aim 1 uses an iterative development and refinement design followed by a small randomized controlled feasibility pilot study (n=10; n=5 per arm; 1:1 allocation to high- versus low-intensity personalization). Aim 2 is a 2-arm, parallel-group randomized controlled trial (n=60; 1:1 allocation to high- versus low-intensity personalization) with assessments at baseline, 8 weeks (end of treatment), and 32 weeks (6 months after treatment). The low-intensity condition approximates the static, intake-based tailoring typical of treatment as usual, whereas the high-intensity condition tests PRECISE's central innovation of continuous, data-driven retailoring in response to a participant's ongoing gains or setbacks.

Participants, Eligibility, and Setting

Participants will be recruited in collaboration with UCSD Primary Care, Outpatient Psychiatry, San Diego County Mental Health System, and walk-in urgent care clinics, as well as through community and online sources. Potentially interested

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individuals will be made aware of the study through (1) referrals from clinicians and staff at these partner sites, who will share a brief description of the study and study team contact information with patients who may be eligible; (2) flyers posted in partner clinics, on the UCSD campus, and in community settings; and (3) online advertisements (eg, Reddit, Craigslist, and university research webpages). These channels mirror those used in our open trial of PRECISE, in which online advertisements, referrals from university counseling and mental health services, and posted flyers accounted for most enrollments [35]. Interested individuals will be screened for eligibility, scheduled for an initial visit, and asked to provide written informed consent before any study procedures begin.

Eligible participants must be aged 18 years or older, fluent in English, and experiencing active suicidal ideation, defined as a score >2 on the Columbia Suicide Severity Rating Scale (C-SSRS) or thoughts of killing oneself or a suicide attempt within the past month. Participants must also be willing to provide contact information for a key support person as part of the risk and safety plan. Participants will be excluded if they have had exposure to DBT within the past year (assessed by self-report); have a moderate to severe substance use disorder within the past 30 days, assessed using the Structured Clinical Interview for DSM Disorders (SCID); have dementia, moderate cognitive impairment, or traumatic brain injury affecting participation, screened using the Montreal Cognitive Assessment; or lack the capacity to consent to research, including being under conservatorship. Capacity to consent will be assessed by clinician judgment during the informed consent process. After reviewing the consent form, the consenting clinician will ask the individual to describe, in their own words, the purpose of the study, what participation involves (including EMA monitoring and coaching sessions), the main risks and safety procedures, and the fact that participation is voluntary and can be stopped at any time. Individuals who are unable to accurately describe these study procedures will not be enrolled.

Eligibility criteria were selected to maximize within-person statistical power (recent elevated risk), reduce confounding from prior DBT skills exposure, and ensure that participants can safely and meaningfully participate. Consistent with the National Institute of Mental Health (NIMH) Research Domain Criteria framework, eligibility is defined dimensionally (elevated suicidal ideation) rather than by *Diagnostic and Statistical Manual of Mental Disorders* diagnosis, targeting the negative valence and emotion regulation domains. To characterize the generalizability of the sample, the demographic and clinical characteristics of individuals who are approached and decline before screening will be compared with those of individuals who are approached and proceed to screening, regardless of subsequent eligibility, consent, or enrollment status.

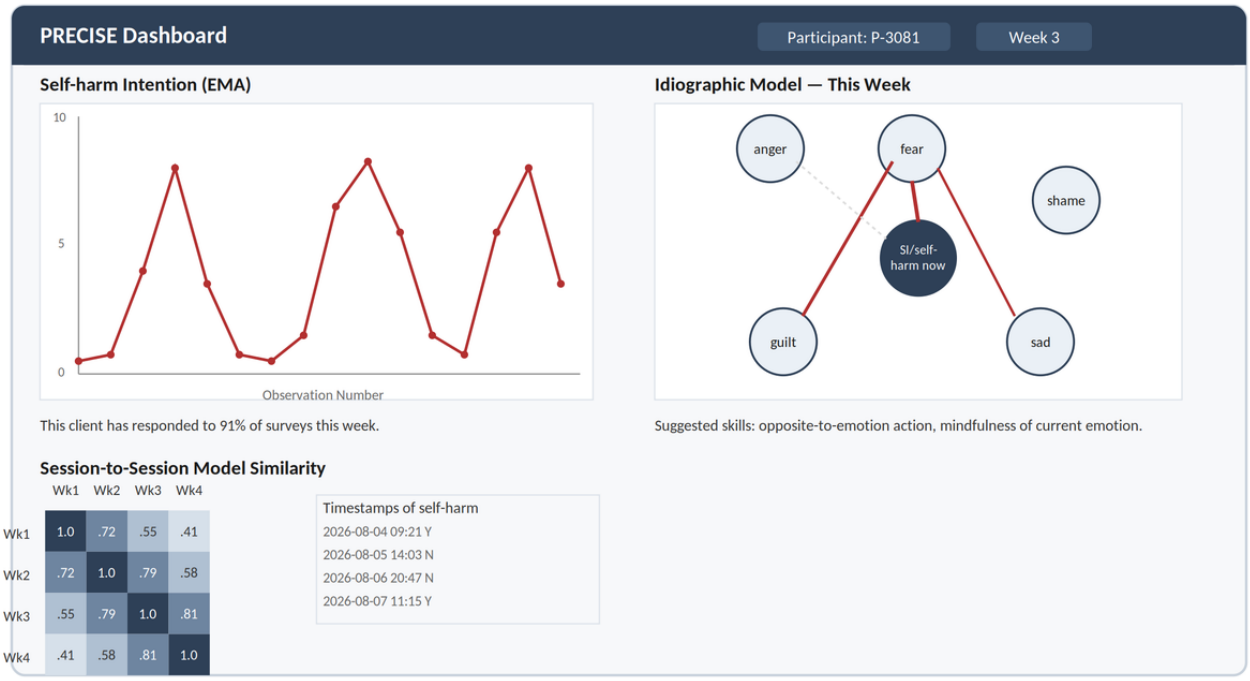
The PRECISE Intervention

PRECISE is an 8-week, coach-delivered, adjunctive treatment combining safety planning and DBT skills training with EMA-informed idiographic tailoring. At the initial visit, staff will train participants to complete smartphone-based EMAs. Participants will receive prompts (via a texted hyperlink, delivered through the Inclivio platform) 5 times per day, at least 2 hours apart, and may also complete event-contingent surveys; a reminder will be sent 30 minutes after an unanswered prompt, and surveys will remain open for 2 hours.

Participants will complete an initial 2-week “learning period” of EMA assessing emotions, emotion regulation strategies, and STBs. These data will be processed through a real-time, preprogrammed cleaning and analysis pipeline and modeled using GIMME [27], an idiographic algorithm that identifies each participant’s own within-person associations among emotions, coping behaviors, and suicidal thoughts [36]. The resulting person-specific model will be displayed on a clinician-facing dashboard (prototype shown in Figure 1) and used as the starting point for a coach-led functional behavioral analysis—identifying vulnerability factors, antecedents, and consequences of a participant’s STBs [12].

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Figure 1. Prototype PRECISE (Personalized Clinical Intervention for Suicidal Events) clinician dashboard for reviewing idiographic models and self-harm intention over time. Shown are a participant's ecological momentary assessment (EMA)–reported self-harm intention across observations, the current idiographic (group iterative multiple model estimation) network model, and week-to-week model similarity; mock data are shown for illustration.



The 2-week learning period yields up to 70 prompted observations per participant (5 prompts per day over 14 days), or approximately 52 at the 75% adherence benchmark, in addition to any event-contingent reports. Suicidal ideation fluctuates substantially within and across days in EMA studies of adults at elevated risk [37], and eligibility requires active suicidal ideation within the past month, increasing the likelihood that within-person variability in suicidal ideation is observed during this window. A 2-week period may nonetheless capture too few episodes for individuals whose suicidal ideation is more sporadic, reducing the precision of their initial idiographic model. Whether a single 2-week model is sufficient is the central question the aim 2 comparison is designed to answer: the high-intensity arm continues EMA and reestimates each participant's model before every session across all 8 weeks (up to 280 prompted observations), whereas the low-intensity arm relies on the initial 2-week model. In both arms, the idiographic model serves as the starting point for a collaborative functional analysis rather than being applied mechanically (Table 1), and event-contingent surveys and in-session chain analyses of flagged events provide additional information about infrequent episodes. The number of completed observations and the within-person variability in suicidal ideation during the learning period will be reported for each participant as part of the feasibility evaluation.

Table 1. Illustrative tailoring rules linking person-specific idiographic correlates to skill selection[a].

Illustrative case	Suicidal thoughts and behaviors correlate (idiographic model)	Tailoring logic
Person A	Positive correlation with fear (increased fear is associated with increased SI[b]) and negative SI autocorrelation (SI at T–1 is associated with decreased SI at T)	• If fear is justified: STOP[c] skill, self-soothing, problem-solving, distraction, and mindfulness of current emotion • If fear is unjustified: approach the feared situation and reduce vulnerability (opposite-to-emotion action)
Person B	Positive correlation with shame (increased shame is associated with increased SI) and positive SI autocorrelation	• If shame is justified: problem-solving and mindfulness of current emotion • If shame is unjustified: act confidently (opposite-to-emotion action) and use distress tolerance skills

[a]Table adapted from prior idiographic tailoring work; coaches use the pattern of correlates identified in each participant's group iterative multiple model estimation as the starting point for a collaborative functional behavioral analysis, rather than applying either case mechanically.

[b]SI: suicidal ideation.

[c]STOP: stop, take a step back, observe, and proceed mindfully.

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The EMA battery intentionally focuses on emotions, emotion regulation strategies, and STBs, the constructs that the DBT skill selection logic directly targets (Table 1). Contextual variables, such as interpersonal conflict, loneliness, or being alone, were not included as EMA items to limit participant burden across up to 8 weeks of prompting 5 times per day, given evidence that longer EMA questionnaires increase perceived burden and reduce compliance and data quality [38]. Instead, interpersonal and situational context is assessed in each coaching session through behavioral chain analysis of flagged events, which explicitly identifies prompting events, vulnerability factors, and consequences [12] and can directly inform skill selection (eg, interpersonal effectiveness skills [33]). Brief contextual EMA items will be considered for the subsequent efficacy trial.

Following the 2-week EMA learning period, participants will meet with their coach weekly for six 60-minute sessions (concluding the 8-week treatment period). Each session will follow a consistent structure: review of EMA data since the previous session (including time stamps of any suicidal thoughts or behaviors and the current idiographic model), a collaborative behavioral chain analysis of any flagged events, instruction in and practice of new or generalized DBT skills informed by the participant's idiographic profile, and updating of the individualized safety plan, concluding with an assigned between-session practice task.

Illustrative tailoring logic is shown in Table 1. For example, a participant whose model shows suicidal thoughts co-occurring with justified fear may be taught self-soothing, problem-solving, and mindfulness of current emotion skills, whereas a participant whose fear appears unjustified may instead be taught approach-based strategies and opposite-to-emotion action strategies. Tailoring rules will be documented and iteratively refined based on aim 1 feedback, and the anonymized data, data processing scripts, and treatment manual will be made publicly available to support replication.

Treatment proceeds through four phases: (1) pretreatment and orientation; (2) active tailoring and skill acquisition; (3) refining and practicing skills; and (4) consolidation, relapse prevention, and referral to ongoing care.

Aim 1 Procedures: Manual and Dashboard Refinement and Feasibility Randomized Pilot Study

An initial PRECISE manual and a working prototype clinician dashboard (already in use in a related pilot project) form the starting point for aim 1. The study team will refine the manual in consultation with the mentorship team, outlining core intervention elements and sample dialogue for each treatment phase. The draft protocol will then be reviewed by an expert advisory group comprising the mentorship team, individuals with lived experience of suicidal ideation (n=2), and administrators from local behavioral health facilities (n=2). The dashboard will then undergo a user-centered design refinement process [39], incorporating feedback from participants and clinicians.

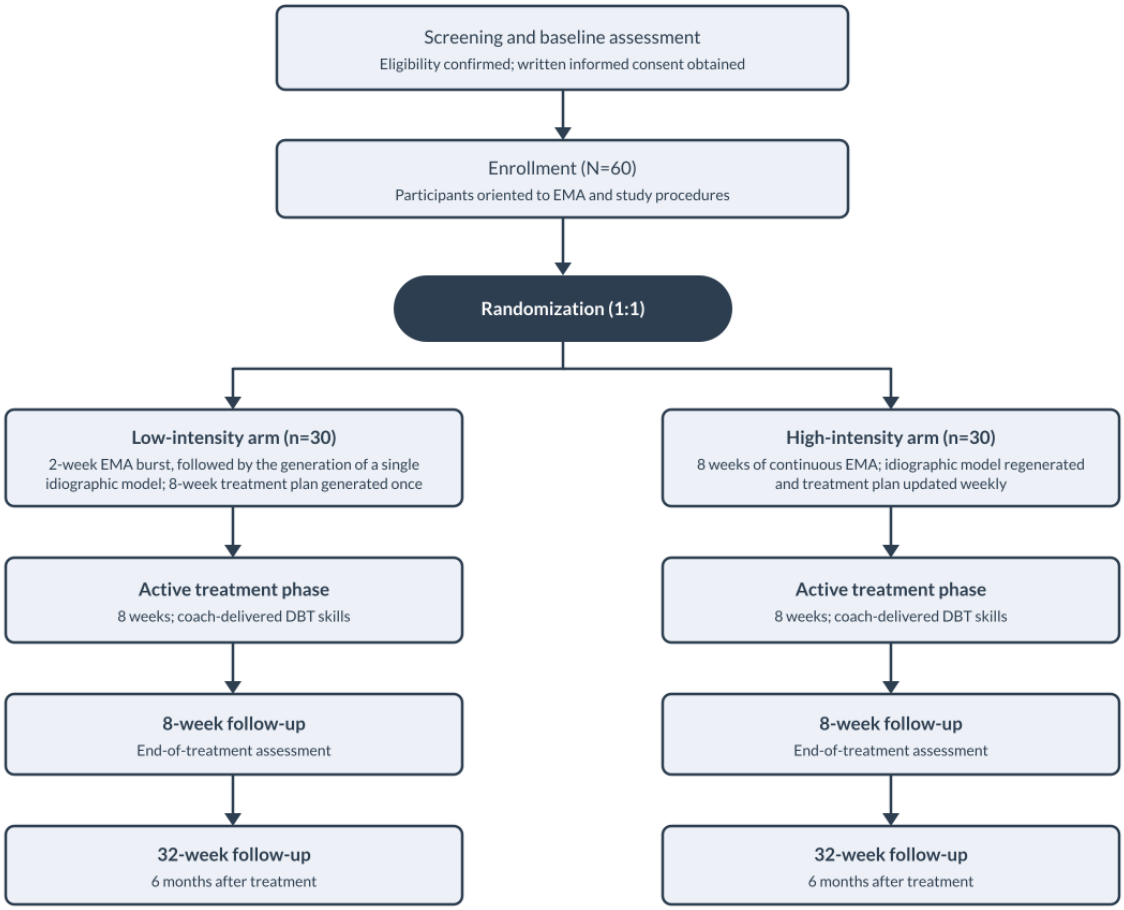
The protocol will first be tested in a small, randomized pilot study: 10 participants will be randomized 1:1 (n=5 per arm) to the high- or low-intensity personalization schedule described in aim 2 below, using the same randomization and blinding procedures, to obtain initial feasibility and acceptability data under conditions that approximate aim 2. Sessions will be audio-recorded, and open-ended participant feedback on satisfaction and suggested changes will be collected. Quantitative and qualitative data will be synthesized using thematic content analysis [40], supervised by a user-centered design expert, against prespecified benchmarks (mean acceptability >4.0 out of 5; EMA adherence >75%; retention >75%; and adequate fidelity). Where benchmarks are not met, qualitative interview data will guide targeted protocol revisions, which will be presented to the mentorship team before finalizing the aim 2 protocol.

Aim 2 Procedures: Randomized Controlled Trial

Sixty eligible participants will be enrolled, complete baseline assessments, and be randomized 1:1 to a high-intensity (n=30) or low-intensity (n=30) personalization schedule. All participants will be oriented to EMA procedures at baseline. In the low-intensity arm, GIMME modeling will be run once, after an initial 2-week EMA burst, and the resulting idiographic model will inform the full 8-week treatment plan. In the high-intensity arm, EMA will continue across all 8 weeks, with idiographic models regenerated and treatment plans updated before each of the remaining sessions. This design allows a direct comparison of how much ongoing personalization is needed to identify appropriate emotion regulation targets. Follow-up assessments will occur immediately after treatment (8 weeks) and at 6 months (32 weeks) after treatment (Figure 2).

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Figure 2. Aim 2 study flow diagram: screening and baseline assessment, randomization, 8-week active treatment phase, and follow-up assessments at 8 and 32 weeks, by high- versus low-intensity personalization arm. EMA: ecological momentary assessment; DBT: dialectical behavior therapy.



Randomization for both the aim 1 pilot study and the aim 2 trial follows the same procedure: a standard simple randomization approach in which a computer-generated list of randomly ordered participant allocation identifiers will be created prior to enrollment and used to assign participants sequentially to a condition. Coaches will also be randomized to deliver only one condition (high- or low-intensity personalization) throughout the trial, rather than delivering both, reducing the risk of cross-condition contamination in intervention delivery. The principal investigator will generate the allocation sequence and administer assignment; allocation will therefore not be concealed from study staff enrolling participants, a limitation of this pilot-scale design (refer to the Limitations section). The trial is single-blind: outcome raters are blinded to condition assignment throughout data collection and scoring, but coaches delivering the intervention are not blinded, as delivery of the high- versus low-intensity personalization schedule requires them to know which condition a participant has been assigned to.

Coach Recruitment, Training, and Treatment Fidelity

Five master's-level trainees (eg, from social work, marriage and family therapy, and clinical psychology programs) will be recruited as PRECISE coaches from local psychology training programs in San Diego. Required qualifications include at least second-year training status and prior applied experience with DBT or another evidence-based therapy (eg, prolonged exposure [41], behavioral activation, cognitive processing therapy, and motivational interviewing); prior volunteer or clinical experience in suicide prevention is preferred. Coaches will complete a 3-day training led by the principal investigator covering safety planning, use of the coach dashboard, and DBT skills, including expert-led instructional video review and behavioral rehearsal with individualized feedback. Ongoing weekly group supervision will be provided throughout the trial.

Fidelity will be monitored using a modified DBT Adherence Checklist [42], completed by coaches after each session. All sessions will be audio- and video-recorded, and a random 50% sample will be independently coded for fidelity by the study's clinical supervisor during weekly supervision meetings, with corrective feedback provided to coaches as needed.

Safety Management

Given the elevated-risk study population, a comprehensive suicide risk monitoring and response plan has been developed, aligned with NIMH guidance on conducting research with persons at elevated risk for suicide. Incoming EMA responses are monitored in real time through an automated notification system that alerts study staff if a participant reports intent to end their life. Flagged participants will be contacted within 24 hours to complete a risk assessment, update their safety plan, and receive a referral to a higher level of care if indicated. These procedures have been used successfully in prior EMA studies of high-risk individuals conducted by the study team.

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Outcome Measures

Feasibility outcomes (aims 1 and 2) and clinical outcomes (aim 2) are summarized in Tables 2 and 3.

Table 2. Feasibility outcome measures (aims 1 and 2).

Domain	Measure
Usability	System Usability Scale [43]
Retention	Number of participants retained at 8 and 32 weeks
Ecological momentary assessment adherence	Proportion of prompted surveys completed
Acceptability	Acceptability of intervention measure [44]
Fidelity	Modified DBT[a] Adherence Checklist [42]

[a]DBT: dialectical behavior therapy.

Table 3. Aim 2 primary and secondary outcome and target measures.

Category	Measure	Construct
Primary outcome	Scale for Suicide Ideation [45]	Severity of suicidal ideation
Target	Emotion Reactivity Scale [46]	Emotion sensitivity, intensity, and persistence
Target	Cognitive Emotion Regulation Questionnaire [47]	Emotion regulation strategies

Additional assessments at baseline, 8, and 32 weeks include depression (Patient Health Questionnaire-9) and anxiety (Generalized Anxiety Disorder-7) symptoms, treatment history, medication use, self-injurious behavior (C-SSRS) [48], and psychiatric diagnoses (Mini International Neuropsychiatric Interview). Treatment co-occurrence, data literacy, and socioeconomic status will be examined as moderators, given their likely influence on intervention uptake and their relevance to social determinants of health in suicide risk and treatment engagement.

Sample Size and Feasibility Rationale

Aim 1 (n=10; 5 per arm) is designed to establish initial feasibility and acceptability rather than to detect a clinical effect. The aim 2 sample size (N=60; 30 per arm) was set based on prior recruitment feasibility in comparable EMA and digital health suicide studies [35-37,49-52] and is adequately powered to detect large within-person changes in negative emotion intensity and emotion regulation strategy use, though it is underpowered to detect small between-group effects, consistent with its role as a preliminary, hypothesis-generating trial rather than a definitive efficacy trial.

Statistical Analysis Plan

Feasibility analyses (aim 2.1) will summarize central tendency for usability, retention, EMA adherence, acceptability, and fidelity against prespecified benchmarks (>75% EMA adherence and retention; mean fidelity >4 out of 5). Clinical outcome analyses (aim 2.2) will first characterize patterns of missing data (missing completely at random, missing at random, and missing not at random) by examining associations between missingness and time or outcome variables. Bayesian multilevel models will then be used to model trajectories of suicidal ideation over time, with participant-level random intercepts (and random slopes for time, where supported by the data) and time modeled as a fixed effect; linear versus quadratic growth will be compared using leave-one-out cross-validation and the widely applicable information criterion, selecting the better-fitting functional form for the primary model. A time-by-condition (high- vs low-intensity) interaction will test whether trajectories differ by personalization intensity; evidence for this and all other effects will be summarized using posterior median estimates with 95% credible intervals, the probability of direction, and the proportion of the posterior distribution falling within a prespecified region of practical equivalence around the null, rather than null-hypothesis significance tests. Model convergence will be confirmed using the potential scale reduction statistic $\hat{R} \leq 1.01$ and adequate effective sample size. Standardized, within-person effect sizes will also be reported for primary contrasts to aid interpretation and comparison with the existing DBT literature.

An exploratory analysis, restricted to the high-intensity arm (for which EMA data are available continuously across the study), will use multilevel structural equation modeling to test whether within-person increases in effective emotion regulation strategy use mediate the association between negative affect and STBs [53,54].

The study will recruit approximately equal numbers of men and women in both arms and will test for sex differences in primary outcomes and targets, consistent with National Institutes of Health expectations regarding sex as a biological variable. Research staff will complete annual training and reliability review, with separate leadership for coaches and blinded outcome raters, and independent data and safety oversight.

Ethical Considerations

This study was reviewed and approved by the UCSD Institutional Review Board via full-board review (IRB 811796). All participants will provide written informed consent prior to any study procedures. Given the elevated-risk population, the safety monitoring procedures described above will be implemented throughout data collection, and the trial was

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registered on ClinicalTrials.gov (NCT06809348) prior to enrollment of the first aim 2 participant. Participants will be compensated in cash: US $30 for completing the baseline assessment and US $30 for each of the 2 follow-up assessments (end of treatment and 6 months after treatment), for a total of up to US $90.

Results

Enrollment began on November 14, 2025, and the study is currently recruiting. Total estimated enrollment across aim 1 and aim 2 is 70 participants. The estimated primary completion date and overall study completion date are both March 2030. The study was funded in May 2025. As of November 9, 2026, 7 participants had been enrolled (7 in aim 1 and 0 in aim 2). Data analysis has not yet begun. Results are expected to be published at the beginning of 2030.

Discussion

Principal Expected Findings

PRECISE addresses 2 persistent gaps in suicide-focused intervention research: the reliance on nomothetic models that may not reflect an individual's own risk processes and the limited accessibility of intensive, evidence-based treatments such as standard DBT. By pairing EMA-derived idiographic modeling with brief, coach-delivered DBT skills training, PRECISE aims to deliver a more efficient and individually relevant version of an established treatment. The high- versus low-intensity comparison in aim 2 is designed to identify how much ongoing data collection and retailoring is needed, which has direct implications for the scalability of any idiographically personalized intervention.

Comparison With Prior Work

Personalized treatments have shown promise for mood and anxiety disorders [28] and eating disorders [29], and a meta-analysis of randomized trials found that personalized psychological interventions outperformed nonpersonalized ones across mental health outcomes [30]. In suicide research, idiographic studies have documented substantial person-to-person heterogeneity in the emotional and behavioral processes that accompany suicidal thoughts [20,26,36], and scholars have called for a more personalized suicidology [22]. Our proof-of-concept case series [52] and open trial [35] laid the methodological groundwork for PRECISE; to our knowledge, this is the first randomized trial of idiographic, EMA-informed treatment tailoring for STBs. Unlike many existing digital phenotyping tools that operate largely outside of clinical care [55], and smartphone-based DBT supports that deliver skills content without person-specific modeling [19,56], PRECISE embeds real-time idiographic modeling directly into an evidence-based treatment (DBT) that already relies on structured self-monitoring [32,33]. PRECISE is also complementary to just-in-time adaptive interventions for suicide prevention, which primarily tailor when support is delivered [57]; PRECISE instead tailors which skills are taught.

Limitations

Anticipated limitations include the modest sample size, which limits power to detect small between-group differences, and the relatively demanding 8-week EMA burden, which the study team will mitigate through coach engagement strategies and daily adherence monitoring using motivational interviewing principles. As a single-site pilot and preliminary trial, generalizability to other settings and populations will also be limited pending a larger, fully powered efficacy trial. Additionally, because the principal investigator both generates and administers the randomization sequence in this single-site pilot study, allocation is not concealed from enrolling staff, which introduces a risk of selection bias that a fully powered trial should address through independent sequence administration. Finally, the 2-week learning period may yield imprecise initial models for participants whose suicidal ideation is infrequent, and the EMA battery does not include contextual (eg, interpersonal) items; context is instead captured qualitatively through in-session chain analysis (refer to The PRECISE Intervention section).

Conclusions and Future Directions

Findings from this trial are intended to inform 2 subsequent lines of work: a sequential multiple assignment randomized trial comparing PRECISE with an active treatment such as Collaborative Assessment and Management of Suicidality [58] among nonresponders to low-intensity care and development of a just-in-time adaptive intervention [57] incorporating wearable sensor data for real-time risk detection.

Funding

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Generative AI Use

Generative AI was not used to draft the original manuscript. Claude (Opus 5.5; Anthropic) was used as a coding assistant to develop the clinician dashboard and the data processing and analysis code for this study. During revision, Claude was used to help reformat references to journal style and to draft revised text in response to editorial comments. The authors reviewed and edited all AI-assisted code and text and take full responsibility for the content of this manuscript.

Authors' Contributions

Conceptualization: KK, CD
Data curation: KK

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Funding acquisition: KK
Investigation: KK
Methodology: KK, CD, KTF, RM
Project administration: KK
Resources: CD, RM
Software: KK
Supervision: CD, RM
Validation: KK
Visualization: KK
Writing—original draft: KK, CD, KTF, RM
Writing—review and editing: KK, CD, KTF, RM

Conflicts of Interest

RM is a cofounder of KeyWise AI and holds equity in the company. This arrangement has been reviewed and managed by the University of California San Diego in accordance with its conflict-of-interest policies. All other authors declare no conflicts of interest.

Multimedia Appendix 1

Summary statement for K23 application.
[PDF File (Adobe PDF File), 137 KB-Multimedia Appendix 1]

Multimedia Appendix 2

SPIRIT checklist.
[PDF File (Adobe PDF File), 344 KB-Multimedia Appendix 2]

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Abbreviations

C-SSRS: Columbia Suicide Severity Rating Scale
DBT: dialectical behavior therapy
EMA: ecological momentary assessment
GIMME: group iterative multiple model estimation
NIMH: National Institute of Mental Health
PRECISE: Personalized Clinical Intervention for Suicidal Events
STB: suicidal thoughts and behavior
SCID: Structured Clinical Interview for DSM Disorders
UCSD: University of California San Diego

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