STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Prepared for submission to ClinicalTrials.gov

Sleep Treatment for Teens:

A Two-Site Open Pilot Trial of Digital Cognitive Behavioral Therapy for Insomnia (dCBT-I; Sleepio™) in Suicidal Adolescents with Co-Occurring Insomnia During the Post-Hospitalization Period

Short title	Sleep Treatment for Teens (Open Pilot)
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Multiple Principal Investigators	Evan M. Kleiman, Ph.D. (Rutgers University — lead site); Catherine (Cassie) R. Glenn, Ph.D. (Old Dominion University — via reliance agreement)
Participating sites	Rutgers University / Rutgers University Behavioral Health Care (UBHC); Old Dominion University / Children's Hospital of the King's Daughters (CHKD, recruitment only)
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Document organization

This document contains two parts. Part A is the Study Protocol. Part B is the Statistical Analysis Plan (SAP). The two parts may be uploaded to ClinicalTrials.gov as a single combined document or separated into two uploads (Study Protocol and SAP) as preferred; the SAP begins on its own page and is self-contained.

Note on scope. This document describes the open pilot only — a single-arm, open-label study in which all enrolled adolescents receive Sleepio plus post-hospitalization treatment-as-usual (TAU). There is no randomized control arm in the pilot. The planned, separately powered randomized controlled trial (RCT) comparing dCBT-I to TAU is referenced where relevant but is not the subject of this protocol.

PART A — STUDY PROTOCOL

1. Protocol Synopsis

Design	Two-site, single-arm, open-label pilot feasibility/effectiveness trial with intensive longitudinal (daily and weekly) assessment.
Population	Adolescents 14–18 years old, recently hospitalized for suicide risk, with co-occurring clinically significant insomnia, during the high-risk post-discharge period. One parent/legal guardian per adolescent also enrolls.
Sample size	20 adolescents (10 per site) and their parents.
Intervention	Sleepio™ (Big Health Ltd.), a fully automated 6-session digital CBT-I, delivered over 6–10 weeks, plus post-hospitalization treatment-as-usual (TAU).
Duration (per participant)	Approximately 12 weeks (range 10–14): ≤ 2-week baseline window after discharge, 6–10-week treatment phase, and a 1-month post-treatment follow-up.
Primary objective	Establish feasibility and acceptability of delivering Sleepio to this high-risk population (Aim 1).
Secondary objectives	Estimate preliminary within-person change in insomnia severity (Aim 2) and suicidal ideation (Aim 3) during treatment and at 1-month follow-up.
Primary outcomes	Enrollment and retention rates; EMA and actigraphy adherence; treatment acceptability (MARS, IIUQ, qualitative interview).
Secondary outcomes	Insomnia Severity Index (ISI; weekly, primary insomnia measure); actigraphy and sleep-diary parameters; SIQ-Jr (weekly, primary suicidal ideation measure).
Analysis	Linear mixed-effects (growth curve) models for within-person change; intent-to-treat; descriptive feasibility/acceptability summaries. The pilot is not powered for confirmatory efficacy testing.

2. Background and Rationale

Suicide is a leading cause of death among adolescents, and rates have risen over the past decade. The period immediately following discharge from acute psychiatric care is among the highest-risk windows for suicidal behavior and rehospitalization, and access to follow-up care during this transition is frequently disrupted. Insomnia symptoms—the most common sleep problem in youth—are transdiagnostic and have been linked, uniquely and beyond depression, to suicidal thoughts and behaviors (STBs) in adolescents.

Cognitive behavioral therapy for insomnia (CBT-I) is a brief, empirically supported treatment with medium-to-large effects on insomnia and benefits for psychiatric symptoms including suicidal ideation in adults. Digital CBT-I (dCBT-I) appears comparably effective to face-to-face delivery and can be scaled to reach youth who would not otherwise access care. Sleepio™ is a

fully automated dCBT-I program delivering the core components of in-person CBT-I via smartphone or web.

Rationale for an open pilot. dCBT-I has not been tested in high-risk suicidal youth with co-occurring insomnia during the post-hospitalization period, and feasibility and acceptability cannot be assumed to generalize from lower-risk samples. This single-arm open pilot is designed to establish feasibility, acceptability, and preliminary signal, and to generate the parameter estimates (retention, adherence, variance components, and candidate effect sizes) needed to design and power a subsequent randomized controlled trial.

Preliminary data from the investigators' prior intensive EMA study with high-risk suicidal youth during the post-hospitalization month showed that poorer sleep quality and quantity predicted next-day increases in suicidal ideation, directly motivating a test of whether reducing insomnia can reduce suicidal thinking in this population.

3. Objectives and Endpoints

3.1 Aim 1 (Primary): Feasibility and Acceptability

Examine the feasibility and acceptability of delivering Sleepio to suicidal adolescents with co-occurring insomnia during the post-hospitalization period.

- **Feasibility endpoints:** enrollment rate (proportion of eligible adolescents who enroll), retention rate, EMA prompt-completion rate, weekly-survey completion rate, actigraphy wear adherence, and Sleepio session completion.
- **Acceptability endpoints:** Mobile App Rating Scale (MARS; weekly app-specific items and full post-treatment MARS), Internet Intervention and Utility Questionnaire (IIUQ), daily acceptability/usage and interference items, and post-treatment qualitative interviews with adolescents and parents.

3.2 Aim 2 (Secondary): Preliminary Effectiveness for Insomnia Severity

Examine preliminary within-person change in insomnia severity during and after treatment.

- **Aim 2a:** change in insomnia severity across the treatment phase.
- **Aim 2b:** maintenance of gains across the 1-month follow-up.
- **Primary measure:** Insomnia Severity Index (ISI), assessed weekly. Secondary: actigraphy-derived sleep parameters (e.g., sleep efficiency) and daily sleep-diary parameters.

3.3 Aim 3 (Secondary): Preliminary Effectiveness for Suicide Outcomes

Examine preliminary within-person change in suicidal ideation during and after treatment.

- **Aim 3a:** change in suicidal ideation severity across the treatment phase.
- **Aim 3b:** maintenance across the 1-month follow-up.
- **Primary measure:** Suicidal Ideation Questionnaire-Junior (SIQ-Jr), assessed weekly. Secondary: daily EMA suicidal ideation. Exploratory: suicide attempts and suicide-related rehospitalizations (EMA and medical-record abstraction).

4. Study Design

This is a two-site, single-arm, open-label pilot trial. All enrolled adolescents receive Sleepio plus post-hospitalization TAU; there is no control arm. The study uses an intensive longitudinal design with daily smartphone-based EMA, weekly self-report surveys, and continuous wrist actigraphy, structured into three phases:

1. **Baseline (pre-treatment):** conducted within two weeks of hospital discharge; includes diagnostic interviews, baseline questionnaires, device orientation, and safety planning.
2. **Treatment phase (6–10 weeks):** delivery of the six Sleepio sessions (one per week, up to 10 weeks to complete), with daily EMA (up to 4×/day), weekly surveys, and continuous actigraphy; a post-treatment phone interview concludes the phase.
3. **Follow-up (1 month post-treatment):** continued daily EMA and actigraphy, weekly surveys, and a final phone interview to assess maintenance of gains.

5. Study Population

5.1 Inclusion Criteria

4. Age 14–18 years.
5. Recent hospitalization due to suicide risk (suicide attempt, aborted/interrupted attempt, or suicidal ideation with intent and/or plan), assessed with an abbreviated C-SSRS; baseline must be completed within 14 days of discharge.
6. Clinically significant insomnia symptoms (Sleep Condition Indicator [SCI] score ≤ 16).
7. Motivation to engage with treatment (each of the motivation items rated ≥ 5 on a 0–10 scale).
8. Parent/guardian willing to provide permission (for minors) and to consent to their own participation.

5.2 Exclusion Criteria

9. Prior CBT-I treatment (indicating lack of response to an adequate prior dose).
10. High risk for obstructive sleep apnea (modified STOP-BANG); these adolescents are referred for non-study polysomnography screening.
11. Bipolar disorder (sleep restriction components of CBT-I may be risky).
12. Substance use disorder primary to insomnia (would require alternative treatment).
13. Factors that may reduce ability to consent or complete procedures (e.g., current psychosis, other-directed violence, severe cognitive impairment, non-English speaking).
14. Unwillingness to wear wrist actigraphy or to complete EMA surveys.

Eligibility is not based on sex, gender identity, race, or ethnicity; these variables are recorded to compare eligible and ineligible individuals.

5.3 Recruitment and Feasibility

Adolescents are identified by study staff from inpatient and crisis-service census/EMR review and clinical team referral, supplemented by self-referral flyers. To minimize perceived coercion,

the clinical treatment team is generally not involved in recruitment, and recruitment proceeds via study staff. Across the two sites, the target of 20 adolescents represents fewer than 5% of the eligible patient flow during the recruitment period, supporting feasibility.

6. Study Intervention

6.1 Sleepio (dCBT-I)

Sleepio™ (Big Health Ltd.) is a brief, fully automated dCBT-I delivered via iOS app or website. It comprises six 20-minute sessions covering the core components of in-person CBT-I: (1) psychoeducation about sleep and treatment orientation; (2) sleep hygiene; (3) sleep scheduling and stimulus control; (4) cognitive therapy and relaxation; (5) additional techniques (mindfulness, thought blocking); and (6) treatment summary and relapse-prevention planning. Sessions are ideally completed one per week over six weeks; adolescents are allowed up to 10 weeks. To protect a high-risk population with emotion-regulation difficulties, the program does not restrict sleep below 7 hours.

Parents receive an orientation to Sleepio and have access to the program as a resource. Significant parental involvement is not required, to avoid making treatment inaccessible to adolescents whose parents cannot participate substantially.

6.2 Treatment-as-Usual (TAU)

All participants continue any post-hospitalization treatment they receive in the community. Other treatment received is tracked weekly via EMA (provider contacts, treatment type, and psychiatric medication use).

7. Study Procedures and Schedule of Assessments

Treatment is delivered on participants' own smartphones (or tablet/computer). EMA surveys are delivered via MetricWire, a HIPAA-compliant EMA platform, with up to four brief (1–3 minute) prompts per day within pre-specified windows that avoid sleep and school periods, plus weekly surveys of major outcomes. Sleep–wake patterns are measured continuously with the Philips Actiwatch Spectrum Plus, worn on the non-dominant wrist throughout the treatment and follow-up phases. The schedule of assessments is shown in Table 1.

Table 1. Schedule of Assessments.

Procedure / Measure	Screen	Baseline	Treatment (daily/weekly)	Post-tx	1-mo F/U
Informed consent / assent	X				
Eligibility (C-SSRS screen, SCI ≤16, motivation, STOP-BANG)	X				
Sociodemographics / SES		X			
MINI-Kid (DSM-5 diagnoses; adolescent + parent)		X			

Procedure / Measure	Screen	Baseline	Treatment (daily/weekly)	Post-tx	1-mo F/U
C-SSRS (full; adolescent, parent-confirmed)		X		X	X
Insomnia Severity Index (ISI) — primary insomnia outcome		X	Weekly	X	X
Sleep Condition Indicator (SCI)	X	X		X	X
Children's Morningness-Eveningness; PROMIS sleep		X			
SIQ-Jr — primary suicidal ideation outcome		X	Weekly	X	Weekly
Daily EMA (4×/day): sleep diary, mood, SI, intent, behaviors			Daily		Daily
Wrist actigraphy (Philips Actiwatch Spectrum Plus)		X (orient)	Continuous		Continuous
Sleepio (dCBT-I) session completion			6 sessions		
MARS (app-specific items weekly; full MARS post-tx)			Weekly	X	
IIUQ; qualitative acceptability interview				X	
Other-treatment-received survey			Weekly		Weekly
Safety plan review / risk assessment		X	As triggered	X	X
Medical-record abstraction (ED visits, rehospitalization)			←— up to 1 year post-enrollment —→		
Compensation		X	X	X	X

X = administered once at that phase; "Daily," "Weekly," and "Continuous" denote repeated measurement during that phase. Medical-record abstraction covers ED visits and psychiatric admissions for up to one year after enrollment.

8. Outcome Measures and Instruments

8.1 Insomnia and Sleep

- **Insomnia Severity Index (ISI):** 7-item measure of insomnia severity; primary insomnia outcome, administered weekly across treatment and at follow-up.
- **Sleep Condition Indicator (SCI):** 8-item DSM-5 insomnia screen (≤ 16 indicates probable insomnia); used at screening and repeated.
- **Actigraphy:** objective sleep–wake parameters (e.g., sleep efficiency) from the Philips Actiwatch Spectrum Plus; cleaned and feature-extracted with Philips Actiware.

- **Daily sleep diary:** brief morning EMA report of prior-night sleep quantity/quality and sleep-aid use.

8.2 Suicide Outcomes

- **Suicidal Ideation Questionnaire-Junior (SIQ-Jr):** 15-item measure of recent suicidal ideation severity; primary suicidal-ideation outcome, administered weekly.
- **Columbia Suicide Severity Rating Scale (C-SSRS):** semi-structured interview of ideation and behavior, at baseline, post-treatment, and follow-up.
- **Daily EMA:** suicidal ideation, suicide intent, and suicide-related behaviors; suicide attempts and suicide-related rehospitalizations (exploratory; also via medical-record abstraction).

8.3 Acceptability

- **MARS:** app-specific items weekly; full MARS at post-treatment.
- **IIUQ:** perceptions/utility of the digital intervention at post-treatment.
- **Qualitative interviews:** brief post-treatment interviews with adolescents and parents.

8.4 Characterization and Mechanisms

MINI-Kid (DSM-5 diagnoses), sociodemographics/SES, Children's Morningness-Eveningness Scale, and PROMIS sleep measures characterize the sample. Daily EMA also captures candidate proximal mechanisms (e.g., fatigue, mood, cognitive flexibility) as pilot data for the planned RCT.

9. Safety Monitoring and Risk Management

9.1 Daily Risk Monitoring

Because participants are a high-risk sample assessed during a high-risk period, suicidal thoughts and behaviors are anticipated and monitored throughout. Daily EMA includes a suicide-intent item (0–10) and items on suicide-related behaviors (active planning, aborted/interrupted attempt, attempt). Responses are reviewed daily by trained study staff supervised by the site PI. The specific monitoring time is not disclosed to adolescents.

9.2 Suicide-Risk Response Procedures

- **Low–moderate risk (intent 0–7):** an in-app pop-up provides clinical and personalized safety-plan resources; confidentiality is not broken.
- **High/imminent risk (intent ≥ 8 or reported high-risk behavior):** in addition to the pop-up, the participant is notified that the team will follow up within 24 hours; a trained team member conducts a phone risk assessment and takes appropriate steps (contacting the parent, connecting to the outpatient provider, referral for acute care), with parent follow-up within 24 hours.

Participants and parents are informed during consent that current-risk information is monitored and may be shared with parents and providers if there are serious safety concerns, and that EMA responses are not monitored 24/7 and must not be used to obtain emergency help. Safety

plans are developed at baseline, made available in the app, surfaced at elevated risk, and reviewed at study end.

9.3 Withdrawal Criteria

Every effort is made to retain participants. Study-initiated withdrawal occurs only if there is clinically significant worsening of insomnia attributable to participation (a ≥ 6-point ISI increase) or if significant distress is determined to result from participation. Participants are not withdrawn for suicidal behavior alone, as they are the population the study aims to help; participants who stop Sleepio but continue EMA are retained. A participant is withdrawn for inability to access their device for study procedures for 7+ days following an ED visit or rehospitalization.

9.4 Adverse Events and DSMB

Adverse events (AEs) and serious adverse events (SAEs) are classified by relatedness (not related / possibly related / related). Given the population, some rehospitalizations and attempts are expected and recorded as secondary suicide outcomes. Reporting follows institutional and NIH timelines (study-related death or SAE within 24 hours to the IRB; SAEs to NIH within 10 business days; other AEs, protocol deviations, and noncompliance per institutional/annual reporting). An independent Data and Safety Monitoring Board (DSMB; one chair and two members, independent of the study) monitors safety and advises on inclusion/exclusion/withdrawal criteria, AEs/SAEs, risk-monitoring procedures, stopping rules, and pilot-to-RCT transition. A Certificate of Confidentiality from NIH further protects participant data.

10. Data Management and Confidentiality

Participants are identified by a de-identified study ID; identifiers are stored separately from study data via a secure linking file. Self-report/consent data are collected in Qualtrics (Business Associate Agreement with Rutgers); EMA data are collected via MetricWire (security agreement with Rutgers) and stored on secure Rutgers cloud storage; actigraphy data are downloaded to a secure computer. All research data are encrypted, de-identified, and maintained on secure institutional storage (e.g., Rutgers Connect/SharePoint) with access limited to key personnel. Diagnostic and self-harm interviews are audio-recorded for reliability and stored on a secure server labeled only with study IDs. Per NIMH policy, de-identified data are submitted to the NIMH Data Archive (NDA) using Globally Unique Identifiers (GUIDs).

11. Human Subjects Protection

The study is conducted under a single IRB via a SMART IRB reliance agreement. Parental permission is obtained for minors (14–17) and consent for participants who are 18; minors provide assent; parents consent to their own participation. Consent/assent may occur in person or remotely (phone/Zoom/Teams) depending on whether the adolescent is still hospitalized, in a private setting, and includes comprehension checks. Participants who reach the age of majority during the study are re-consented. Participation is voluntary and may be withdrawn at any time without affecting clinical care. Mandatory-reporting obligations (child abuse/neglect) and

imminent-risk procedures are disclosed during consent. Adolescents and parents can earn up to $215 total for completing all study components.

12. Dissemination and Registration

The study is registered on ClinicalTrials.gov; consent posting and results reporting will comply with applicable Clinical Trial Registration and Results Reporting requirements. Individual results are not returned to participants; aggregate results will be posted to the lab website and disseminated through peer-reviewed publications, presentations, and follow-up grant applications, with fully de-identified data.

PART B — STATISTICAL ANALYSIS PLAN

13. SAP Overview and Design Recap

This SAP describes the planned analyses for the open pilot. The design is single-arm and open-label: all enrolled adolescents receive Sleepio plus TAU, with intensive longitudinal assessment (daily EMA, weekly surveys, continuous actigraphy) across a baseline window, a 6–10-week treatment phase, and a 1-month follow-up. Because there is no randomized comparator in the pilot, all effectiveness analyses estimate within-person change over time rather than between-group differences.

Relationship to the planned RCT. The between-group power analysis prepared for the future RCT (treatment vs. TAU; Cohen's d) does not apply to this single-arm pilot and is not used here as a sample-size justification. Instead, the pilot is sized for feasibility and to generate the descriptive estimates—retention, adherence, means, variances, intraclass correlations, and within-person trajectories—required to design and power that RCT.

14. Estimands, Objectives, and Hypotheses

The pilot is primarily descriptive (Aim 1) and estimation-focused (Aims 2–3). Hypotheses are directional and treated as preliminary; the pilot is not powered for confirmatory hypothesis testing.

- **Aim 1 (primary):** estimate enrollment, retention, adherence, and acceptability, with 95% confidence intervals, against pre-specified benchmarks.
- **Aim 2 (secondary):** estimate the within-person slope of ISI on time during treatment (expected negative/improving), and characterize the follow-up trajectory (expected maintenance).
- **Aim 3 (secondary):** estimate the within-person slope of SIQ-Jr on time during treatment (expected decreasing), and characterize the follow-up trajectory.

15. Endpoint Definitions

15.1 Primary (Feasibility/Acceptability)

- **Enrollment rate:** number enrolled ÷ number eligible.
- **Retention rate:** proportion completing the post-treatment and 1-month follow-up assessments.
- **EMA adherence:** proportion of delivered daily prompts completed; weekly-survey completion computed separately.
- **Actigraphy adherence:** proportion of valid wear days.
- **Sleepio completion:** number of the six sessions completed.
- **Acceptability:** MARS and IIUQ scores; daily acceptability/interference items; qualitative themes.

15.2 Secondary (Preliminary Effectiveness)

- **Insomnia:** ISI (weekly, primary); actigraphy sleep efficiency and sleep-diary parameters (secondary).
- **Suicidal ideation:** SIQ-Jr (weekly, primary); daily EMA suicidal ideation (secondary).

15.3 Exploratory

Suicide attempts and suicide-related rehospitalizations (EMA + medical-record abstraction); candidate proximal mechanisms (fatigue, mood, cognitive flexibility); associations between acceptability and adherence; and site as a descriptive covariate.

16. Analysis Populations

- **Intent-to-treat (ITT; primary):** all enrolled adolescents who provide at least one post-baseline assessment, analyzed regardless of Sleepio session completion or number of EMA responses. Likelihood-based mixed models use all available observations.
- **Feasibility population:** all enrolled adolescents, for enrollment/retention/adherence summaries.
- **Completer/per-protocol (sensitivity):** adolescents completing ≥ 4 of 6 Sleepio sessions, used to assess robustness of effect estimates.

17. Sample-Size Justification

The planned sample is 20 adolescents (10 per site). This is a pilot feasibility study; the sample size is justified by feasibility and parameter-estimation goals rather than by power to detect a treatment effect. Consistent with established guidance for external pilot trials, a sample of this size is adequate to (a) estimate feasibility parameters (enrollment, retention, adherence) with usable precision, (b) surface practical and procedural problems before the definitive trial, and (c) estimate the means, variance components, intraclass correlations, and candidate within-person effect sizes needed to power the planned RCT. Inferential statements about efficacy are therefore framed as preliminary, with emphasis on point estimates and confidence/credible intervals rather than on null-hypothesis significance tests. With up to 12 weeks of daily and weekly assessment per participant, the intensive longitudinal design yields a large number of within-person observations, which supports estimation of within-person change despite the small number of individuals.

18. General Analytic Principles

- **Software:** R; linear mixed-effects (growth curve) models fit with lme4 (REML for variance components; ML for nested model comparisons). Bayesian re-estimation (e.g., brms/Stan) may be used as a sensitivity analysis and to provide stable interval estimates given the small n.
- **Estimation focus:** report point estimates with 95% confidence (or credible) intervals; where p-values are reported, α = .05, two-sided, and they are interpreted as descriptive given the pilot scope. No multiplicity adjustment is applied to these

exploratory/preliminary tests; the number and direction of effects are reported transparently.

- **Descriptives:** continuous variables summarized by mean (SD) or median (IQR); categorical variables by n (%). Feasibility/acceptability metrics summarized with exact binomial (Clopper–Pearson) CIs for proportions.
- **Time metric:** day number (continuous) is the primary time variable for daily/continuous outcomes; week number for weekly outcomes. Time is centered at the start of the treatment phase.
- **Site:** with only two sites, site is examined as a fixed-effect covariate/moderator in sensitivity analyses (not modeled as a random effect).

19. Aim 1 Analyses (Feasibility and Acceptability)

Feasibility analyses are descriptive. Enrollment, retention, EMA prompt completion, weekly-survey completion, actigraphy wear, and Sleepio completion are summarized as proportions with 95% CIs and compared to pre-specified benchmarks drawn from the team's prior work in this population:

- Enrollment ≥ 65% of eligible;
- EMA prompt completion > 60%;
- Actigraphy wear > 80% of days.

Acceptability is summarized via MARS and IIUQ scores and daily acceptability/interference items; qualitative interviews are analyzed thematically and integrated descriptively. As an exploratory aim, the association between within-person acceptability (weekly MARS) and within-person adherence (weekly proportion of assessments completed) is examined with a mixed-effects model.

20. Aim 2 Analyses (Insomnia Severity)

20.1 Aim 2a — Change During Treatment

A two-level linear mixed-effects (growth curve) model is fit to repeated ISI measures during the treatment phase, with observations (level 1) nested within persons (level 2):

$$ISI_{ti} = \gamma_{00} + \gamma_{10}(\text{Time}_{ti}) + u_{0i} + u_{1i}(\text{Time}_{ti}) + e_{ti}$$

The fixed slope (γ_{10}) on time is the parameter of interest; a negative slope indicates improving insomnia. Random intercepts and random slopes for time capture between-person variability in starting severity and rate of change. A piecewise (spline) specification with knots at treatment-week boundaries is also fit to characterize non-linear change across treatment. Secondary models substitute actigraphy sleep efficiency and daily sleep-diary parameters as outcomes.

20.2 Aim 2b — Maintenance at Follow-Up

Using data from the full study (treatment + follow-up), a piecewise growth model estimates separate slopes for the treatment and follow-up phases. Maintained gains are indicated by a non-significant follow-up slope (no return toward baseline); a continued-improvement slope

indicates residual gains. The treatment-phase and follow-up-phase slopes are contrasted within the same model.

21. Aim 3 Analyses (Suicide Outcomes)

Aim 3 mirrors Aim 2, substituting suicidal ideation as the outcome. The primary outcome is the weekly SIQ-Jr; the secondary outcome is daily EMA suicidal ideation. The same two-level growth and piecewise specifications are used: Aim 3a estimates the treatment-phase slope (expected decreasing ideation), and Aim 3b estimates and contrasts the follow-up-phase slope to assess maintenance. Distributional features of EMA ideation (zero-inflation, skew) are accommodated as needed (e.g., appropriate link/family or a two-part model), with the modeling choice documented in the analysis log.

Exploratory suicide outcomes—suicide attempts and suicide-related rehospitalizations from EMA and medical-record abstraction—are summarized descriptively (counts, rates, and timing) over the treatment and follow-up phases; formal modeling is not planned given expected low event counts.

22. Exploratory and Mechanistic Analyses

- Candidate proximal mechanisms (daily fatigue, mood, cognitive flexibility) summarized and explored as time-varying covariates/mediators in mixed models, to inform mechanism hypotheses for the RCT (not confirmatory).
- Site explored as a fixed covariate/moderator of trajectories.
- Acceptability–adherence and adherence–outcome associations explored descriptively and with mixed models.
- Dose–response: association between number of Sleepio sessions completed and change in ISI/SIQ-Jr (descriptive).

23. Missing Data

Likelihood-based mixed-effects models use all available observations and are valid under a missing-at-random (MAR) assumption, which is plausible given the rich set of measured covariates in an intensive longitudinal design; no imputation is required for the primary models. Missing-data patterns and rates are reported by phase and measure. Sensitivity analyses may include covariate-dependent missingness models or multiple imputation; departures from MAR (e.g., dropout related to worsening symptoms) are examined descriptively. Intent-to-treat is preserved: participants are analyzed regardless of session completion or response count.

24. Safety Analyses

Safety data are summarized descriptively: frequencies of AEs and SAEs by relatedness category; counts and timing of suicide-related events (ED visits, rehospitalizations, attempts); and frequencies of triggered high/imminent-risk response procedures. No formal inferential safety testing is planned for the pilot; safety summaries are provided to the DSMB.

25. Reporting and Deviations

Analyses are reported in accordance with applicable pilot/feasibility reporting guidance (e.g., CONSORT extension for pilot and feasibility trials). Any deviations from this SAP, including changes to model specifications necessitated by data features (e.g., convergence problems, distributional issues), will be documented with rationale in the statistical analysis log and disclosed in resulting reports and publications. The primary feasibility focus and the preliminary, estimation-oriented nature of the effectiveness analyses are stated explicitly in all dissemination.

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