Study Protocol SL2026-003

1. STUDY PROTOCOL

BRANY PROTOCOL TEMPLATE – SBER

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1) STUDY (PROTOCOL) TITLE

A Pilot Two-Arm Randomized Controlled Trial Comparing an AI Mental Health Tool and Psychoeducational Control

2) OBJECTIVES

The purpose of this pilot randomized controlled trial is to evaluate whether personalized, conversational access to an AI-delivered mental health tool (Ash) reduces depressive symptoms more than a psychoeducational control delivered through the same application over 4 weeks among adults with at least moderate depressive symptoms. The study compares two conditions: (a) full access to Ash, including conversational chat, memory, and personalized content; and (b) a psychoeducational control condition consisting of 12 static psychoeducational modules released three times per week over 4 weeks in the same Ash interface, without conversational chat or personalization. The primary hypothesis is one of superiority: that the Ash arm will show greater reduction in depressive symptoms than the psychoeducational control at Week 4. The primary analysis population and the statistical approach are pre-specified in the study's preregistration and statistical analysis plan (SAP). Consistent with its pilot designation, the study also characterizes feasibility and the precision of the between-arm estimate to inform the design and powering of a future definitive trial.

Specific aims:

Primary aim: Evaluate whether Ash produces greater reduction in depressive symptoms (PHQ-9) than the psychoeducational control from baseline (Week 0) to Week 4. The between-arm difference in PHQ-9 change (Ash vs. Psychoeducation) will be estimated with a two-sided 95% confidence interval and tested for superiority at a two-sided alpha of 0.05. Within-arm change from baseline to Week 4 will also be estimated for each arm.

Secondary aims: (1) Estimate within-arm change and the between-arm difference in anxiety symptoms (GAD-7) using the same framework; (2) estimate within-arm change and the between-arm difference in functional impairment (WPAI-GH), global health (PROMIS Global Health), sleep quality (SQS), behavioral activation (BADS-AC), perceived stress (PSS-4), worry (PSWQ-3), and PTSD symptoms (PC-PTSD-5); (3) evaluate the feasibility of recruitment, in-app consent, randomization, retention, and survey completion.Exploratory aims: (1) Characterize the therapeutic alliance with Ash (WAI-3) among participants while they have active Ash access (both arms), and explore associations between alliance and symptom change; (2) characterize healthcare utilization, chronic-condition self-management, social support, and concomitant care initiation across arms; (3) explore additional candidate mechanisms of change — worry (PSWQ-3), behavioral activation (BADS-AC), and perceived stress (PSS-4) — by examining whether changes in these processes are associated with changes in clinical outcomes within and between arms.

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3) BACKGROUND

Slingshot AI is the developer of Ash, a conversational AI mental health tool designed to provide accessible, evidence-informed support for adults experiencing common mental health concerns such as low mood, anxiety, stress, and sleep difficulties. Ash is accessed via mobile and web applications on users' personal devices.

Common mental health concerns are highly prevalent in the United States, and access to traditional psychotherapy remains constrained by cost, geography, and clinician supply. Digital tools such as Ash may extend the reach of mental health support. A central open question is how much of any observed benefit is attributable to the personalized, conversational, and adaptive properties of the tool, as opposed to the psychoeducational content and the structure, cadence, and expectancy that any well-designed digital program provides. Psychoeducation alone has documented effects on depressive symptoms, so a psychoeducational comparator delivered in the same interface, at the same cadence, and with the same reminder schedule isolates the contribution of personalized conversational support. A superiority framework directly addresses this question.

This protocol establishes a pilot two-arm, superiority randomized controlled trial comparing two conditions over a 4-week period in adults with moderate or higher symptoms of depression: full access to Ash, and a psychoeducational control delivered in the same application. Participants randomized to the Ash arm receive 9 months of free Ash access beginning at randomization, with conversational chat and personalized features available immediately. Participants randomized to the Psychoeducation arm receive 12 static psychoeducational modules released three times per week across the 4-week intervention window, with Ash conversational chat deferred until after the Week 4 primary endpoint, at which point their 9 months of free Ash access begins. Both arms receive an identical cadence of reminders and notifications. This design preserves a clean comparison of personalized conversational support versus static psychoeducational content during the intervention window while ensuring that every participant ultimately receives the same study benefit. The study is designed to inform product development, clinical-care pathways, and the design of a future definitive trial.

4) INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria:

- Adults aged 18 years or older
- Residents of the United States
- New Ash users with active accounts at the time of recruitment
- English-speaking
- Able to provide informed consent
- At screening: PHQ-9 total score ≥ 10 (indicating at least moderate depressive symptoms)
- During onboarding, indicated that they are willing to share their data and are interested in being contacted about and participating in research

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Exclusion criteria:

- Currently engaged in individual therapy or counseling
- ASRM total score ≥ 6 at screening (positive screen for mania)
- PRIME-5 positive at screening, defined as ≥ 1 item rated 6 (Definitely Agree) OR ≥ 3 items rated 5 (Somewhat Agree) (positive screen for psychosis-spectrum symptoms)
- Self-reported heavy episodic drinking at a frequency of weekly or more often on the NIAAA single-item alcohol screen (past 12 months)
- Self-reported nonmedical drug use at a frequency of weekly or more often on the NIDA single-item substance use screen (past 12 months)
- Any change to psychiatric medications in the 6 weeks prior to screening (any response other than "No changes to my meds in the past 6 weeks")
- Currently in inpatient, residential, intensive outpatient (IOP), or partial hospitalization (PHP) mental health treatment
- Suicidality — PHQ-9 item 9 score of 3

Special populations: No minors are enrolled. Adults unable to consent are not enrolled. Pregnant women are not excluded. Prisoners are not targeted; the recruitment channel — an in-app prompt to consenting adult Ash users — is not anticipated to reach incarcerated populations, and prisoners will not be knowingly enrolled.

5) VULNERABLE POPULATIONS

This study does not target populations identified as vulnerable under 45 CFR 46 Subparts B, C, or D. Participants are adult Ash users who have actively expressed willingness to share data and interest in research participation. Individuals with severe psychiatric presentations at screening — active mania, positive psychosis screen, weekly or more frequent heavy substance use, or recent psychiatric medication changes — are excluded to ensure participation does not compete with appropriate higher-acuity clinical care.

6) SETTING

The Ash platform is accessed by users on their personal devices. All study onboarding — the study-interest prompt, informed consent, and the baseline screening and assessment survey — occurs in-app.

Randomization and study contact. All study procedures are asynchronous and take place in-app or by survey. Randomization occurs automatically when an eligible respondent submits the in-app baseline survey.

Psychoeducational control condition. The psychoeducational modules are delivered to participants in the Psychoeducation arm within the Ash application on their own devices. No separate platform, account, or download is required.

Follow-up surveys are administered remotely via a secure survey platform (Typeform). No in-person procedures occur.

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7) RESOURCES

Principal Investigator: Caitlin Stamatis, PhD (Slingshot AI Head of Research). Dr. Stamatis is a clinical psychologist with extensive experience in designing, implementing, and analyzing trials of digital interventions. She will oversee all research activities conducted under this protocol.

Co-Investigator: Derrick Hull, PhD (Slingshot AI Clinical R&D Lead). Dr. Hull is a clinical psychologist with expertise in the design and execution of trials evaluating text-based treatments for mental health. Dr. Hull will collaborate with the PI on study design, execution, and interpretation of findings.

Clinical Research Manager: Elizabeth Kroll, MEd (Slingshot AI). Ms. Kroll will support study operations, including participant communications, safety monitoring workflows, and data quality oversight.

Infrastructure: Slingshot AI maintains secure cloud-based data infrastructure including Google Cloud Platform (AlloyDB, Firestore) and Mixpanel, Statsig, and BigQuery analytics. All systems employ encryption at rest (AES-256) and in transit (TLS 1.2+), role-based access controls, and audit logging.

Personnel: Research activities may be conducted by members of the Slingshot AI research and data science team under the supervision of the PI and Co-Investigator. 8) NUMBER OF SUBJECTS

Target enrollment is approximately 500 adults, randomized 1:1 to Ash (approximately 250) and Psychoeducation (approximately 250). The enrollment target is derived from a superiority power calculation using nuisance parameters estimated from Slingshot AI's own real-world evidence cohort of Ash users with baseline PHQ-9 ≥ 10: a PHQ-9 standard deviation of approximately 5.0 at follow-up and a baseline-to-follow-up correlation of approximately 0.42, giving a residual standard deviation of approximately 4.5 after adjustment for baseline PHQ-9. At a two-sided alpha of 0.05 and 80% power, 500 randomized participants provide the ability to detect a between-arm difference of approximately 1.6 PHQ-9 points (standardized effect approximately 0.32) at 50% retention of the Week 4 primary endpoint, and approximately 1.8 points at 40% retention. The design effect size is informed by published meta-analytic estimates for conversational agents against information or attention controls and for psychoeducation against control, as documented in the SAP. Because Week 4 retention in a paid, consented trial population has not previously been observed by this study team, the SAP pre-specifies a blinded sample size re-estimation at a fixed interim: the pooled (arm-blinded) variance and the observed retention rate are examined, and the enrollment target is revised if either differs materially from these assumptions. Because the re-estimation is blinded to arm assignment and does not examine the between-arm difference, it does not inflate the Type I error rate and requires no alpha adjustment.

9) MULTI-SITE RESEARCH

N/A — single site.

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10) RECRUITMENT METHODS

Recruitment channel: Eligible Ash users are invited through an in-app flow. After a user downloads Ash and indicates that they are willing to share their data, they are shown an in-app prompt asking whether they are interested in participating in a research study. The prompt describes the study and its two arms (Ash and Therapy). Users who decline continue using the app normally and see no further study messaging.

Consent and screening: Users who indicate interest are presented with the informed consent form in-app. A user who does not consent receives a brief message thanking them for their interest and continues using the app normally.

A user who consents proceeds immediately to an in-app baseline survey that begins with the eligibility screening questions (PHQ-9, ASRM, PRIME-5, NIAAA single-item, NIDA single-item, current therapy participation, state of residence, and recent psychiatric medication changes). After completing the eligibility items, any ineligible respondent receives a brief message thanking them for their interest, along with mental health resources, and continues using the app normally. Respondents who pass all screening items complete the remaining baseline assessments and provide demographic and contact information.

Contact methods: Subjects who consent may be contacted by text message and email throughout the study to provide study instructions, send survey reminders, deliver group-assignment information, notify participants that a new psychoeducational module is available, confirm free Ash access details, conduct safety follow-up, and re-engage if contact is lost. The cadence of reminders and notifications is identical in both arms. Both channels are used because some participants do not regularly check email.

11) STUDY TIMELINES

- Protocol duration: Approximately 12 months from IRB approval, encompassing recruitment, follow-up, analysis, and dissemination.
- Individual subject participation: approximately 9 months from randomization (Week 0 through the Week 36 follow-up). Consent, eligibility screening, the baseline survey, and randomization all occur in a single in-app session; there is no interval between consent and randomization.
- Free product access (by arm): Ash arm — 9 months of free Ash access, including conversational chat, beginning on the date of randomization. Psychoeducation arm — 12 psychoeducational modules released three times per week over the 4-week intervention window, with Ash conversational chat deferred until after the Week 4 primary-endpoint window; the participant's 9 months of free Ash access then begins at that Week 4 unlock.
- Anticipated start date: 9/8/2026
- Anticipated completion date: 9/9/ 2027

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12) PROCEDURES INVOLVED

Study design: Two-arm, parallel-group, open-label, superiority randomized controlled trial with 1:1 allocation to Ash (approximately 250) and Psychoeducation (approximately 250). The Ash arm receives 9 months of free Ash access, including conversational chat and personalized features, beginning at randomization.

The Psychoeducation arm receives 12 static psychoeducational modules released three times per week over the 4-week intervention window, delivered in the same Ash interface, with Ash conversational chat deferred until after the Week 4 primary endpoint. Both arms receive an identical cadence of reminders and notifications.

Because the Psychoeducation arm does not have conversational Ash access during the 4-week intervention window, the Week 4 primary comparison reflects personalized conversational AI support versus static psychoeducational content. Participants and research staff are not blinded to arm assignment; blinding of participants is not feasible given the nature of the comparison. The primary endpoint is the between-arm difference in PHQ-9 change at Week 4, tested for superiority.

Allocation concealment: The allocation sequence is computer-generated and the arm assignment is generated by the study system only after the respondent submits the baseline survey. No member of the study team views, selects, or influences an assignment, and no assignment is visible before it is generated, so allocation concealment is complete.

Data sources:

- In-app informed consent records
- In-app baseline screening and assessment survey responses

- Follow-up survey responses (Typeform) administered at Weeks 2, 4,8, and 36
- Psychoeducational module delivery and engagement data (modules released, modules opened, time in module)
- Ash in-app usage metadata (session counts, message counts, feature-use timestamps) during periods of active Ash access
- Ash conversation transcripts during periods of active Ash access

Procedures (chronological):

- In-app recruitment. After downloading Ash and indicating willingness to share data, eligible users see an in-app prompt describing the study and its two arms.
- In-app consent. Interested users review and complete the informed consent form in-app before any study questions are presented.

- In-app screening and baseline survey. Consenting users complete an in-app baseline survey that begins with the eligibility screening items. All eligibility items are administered before an eligibility determination is made; ineligible users then receive a

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thank-you message with resources and return to normal app use. Eligible users complete the full baseline assessment battery.

- Randomization. Randomization occurs automatically when an eligible respondent submits the in-app baseline survey. Eligible participants are randomized 1:1 to Ash or Psychoeducation using a computer-generated allocation sequence.
- Arm-specific onboarding. Immediately after randomization the participant is shown their arm assignment in-app, together with the arm-specific onboarding described below, and the same information is sent by text and email.

- Intervention period (Weeks 1–4).
  - Psychoeducation participants receive 12 static psychoeducational modules in the Ash interface, released three times per week across the 4-week window. Modules cover evidence-informed content on mood, behavioral activation, sleep, stress, and related topics, and are identical in content and release schedule for every participant in this arm. Ash conversational chat remains locked for this arm during the 4-week intervention window. Participants receive the same cadence of reminders and notifications as the Ash arm.
  - Ash participants may use Ash freely; use is not directed or restricted.
- Follow-up surveys. Administered via Typeform at Weeks 2, 4, 8, and 36. Survey content and cadence are summarized in the table below.

- Deferred-access unlock (Psychoeducation arm). After the Week 4 primary-endpoint window, the Psychoeducation arm's Ash conversational chat unlocks and their free Ash access runs for 9 months.
- Safety monitoring. PHQ-9 item 9 responses are flagged automatically at every administration; transcript streams are monitored as described below and in Section 16.

- Study end. Each participant's free Ash access runs for 9 months from its start date (randomization for the Ash arm; after the Week 4 unlock for the Psychoeducation arm); thereafter participants may continue to use Ash as ordinary paying users.

Arm-specific onboarding and flow:

Ash arm. On randomization, Ash chatting unlocks in-app immediately and the participant is shown a confirmation screen stating that 9 months of free Ash access begins that day and that the research team reviews Ash conversations on a scheduled basis and when the app flags content suggesting the participant may need support, as described in the consent form. The same information is sent by text and email.

Psychoeducation arm. On randomization, the psychoeducational module track activates in-app and the first module is released immediately. The participant is shown a screen explaining that they will receive 12 short psychoeducational modules over the next 4 weeks, released three times per week, that they will be notified as each becomes available, and that Ash conversational chat unlocks for them after the Week 4 survey window, at

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which point their 9 months of free Ash access begins. The same information is sent by text and email.

Psychoeducational module delivery. The 12 modules are static, identical across participants, and authored in advance; no module content is generated, adapted, or personalized in response to a participant's inputs. Modules are released on a fixed schedule of three per week across the 4-week intervention window, independent of whether prior modules were opened. The following apply:

- Module release is automated and identical for every participant in the arm.
- Participants receive a notification when each module is released
- Participants may open, re-open, or skip any module. Module engagement is recorded but does not affect enrollment, the release schedule, or any study benefit.
- Modules contain no conversational, interactive, or adaptive elements and do not collect free-text input from participants.
- No transcripts are generated by the psychoeducational track. Engagement data are limited to module release, open, dwell-time, and completion events.

Safety monitoring. PHQ-9 item 9 responses are flagged automatically at every administration; see Section 16 and the Appendix (Safety Protocol and Resource List) for the full safety response protocol. In addition to survey-based monitoring, the study team reviews Ash app conversation transcripts for participants during periods of active Ash chat access (the Ash arm from randomization; the Psychoeducation arm after its Week 4 unlock), monitored via automated safety classifiers with PI or Co-Investigator review of flagged content within one business day. Because the psychoeducational track is non-conversational and collects no free-text input, no transcript stream exists for the Psychoeducation arm during the intervention window; for that arm during those 4 weeks, safety monitoring rests on scheduled survey administration, the automated PHQ-9 item 9 pathway, and a participant-initiated support option available within the psychoeducational track at all times. If risk of suicide, self-harm, or other acute harm is identified in any of these channels, a clinically trained member of the study team contacts the participant within 24 hours to provide crisis resources and assess need for referral. All safety events are documented in the Safety Log per the Appendix.

Participant compensation. Participants receive gift card compensation via Tremendous for completing study surveys: $10 for the in-app baseline survey and $15 for each of the four follow-up surveys (Weeks 2, 4, 8, and 36), for a total of up to $70 if all five surveys are completed.

The $10 baseline payment is earned by submitting the in-app baseline survey, including where the survey's skip logic ends the survey early because an ineligibility criterion was met. The payment is issued after the baseline survey is submitted.Follow-up survey payments are issued within 24 hours of survey completion.

Compensation is tied to survey completion only; free Ash access and, in the Psychoeducation arm, the psychoeducational modules, are provided to enrolled

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participants regardless of survey completion. The amounts are intended to reasonably compensate participants for their time (approximately 10 minutes for baseline and 10–15 minutes per follow-up) without constituting undue influence.

Survey content and cadence

Survey content and cadence

Measure / domain	W0	W2	W4	W8	W36
Demographics & contact info	✓				
Concomitant care	✓	✓	✓	✓	✓
Med changes	✓	✓	✓	✓	✓
PHQ-9 (depression)	✓	✓	✓	✓	✓
ASRM	✓		✓		✓
PRIME-5	✓		✓		✓
NIAAA	✓		✓		✓
NIDA	✓		✓		✓
GAD-7 (anxiety)	✓	✓	✓	✓	✓
WPAI-GH	✓	✓	✓	✓	✓
PROMIS Global Health	✓	✓	✓	✓	✓
SQS	✓	✓	✓	✓	✓
BADS-AC	✓	✓	✓	✓	✓
PSS-4	✓	✓	✓	✓	✓
PSWQ-3	✓	✓	✓	✓	✓
PC-PTSD-5	✓	✓	✓	✓	✓
WAI-3 (alliance)		✓	✓	✓	✓
DSSI	✓		✓		✓
healthcare utilization	✓		✓		✓
chronic conditions	✓		✓		✓

ASRM, PRIME-5, NIAAA, and NIDA are administered at baseline both for eligibility determination and to provide a baseline reference; they are re-administered at Weeks 4 and 36 to monitor for emergent symptoms.

Protection against risk: Standard data-protection procedures described in Section 14.4 mitigate the principal risk of breach of confidentiality. Psychological discomfort risks are mitigated by allowing participants to skip questions, a defined safety protocol for PHQ-9 item 9 endorsement (Section 16), and a referral pathway for participants who develop new acute symptoms during the study.

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13) SPECIMEN BANKING

N/A. No biological specimens are collected or analyzed.

14) DATA MANAGEMENT

14.1 Data Analysis

- Both an intention-to-treat (ITT) population (all randomized participants analyzed in their assigned arm regardless of intervention exposure) and a per-protocol (PP) population are pre-specified. The ITT population is the primary analysis population for the superiority comparison; per-protocol analyses are reported as sensitivity analyses. Participants randomized to the Psychoeducation arm who do not open any module remain in the ITT population and are classified as non-adherent for the per-protocol analysis.
- Primary outcome (PHQ-9 change from Week 0 to Week 4): mixed-effects model for repeated measures (MMRM) with arm, time, and arm-by-time interaction as fixed effects, baseline PHQ-9 as a covariate, and an unstructured residual covariance. The adjusted between-arm difference in PHQ-9 change at Week 4 (Ash vs. Psychoeducation) will be estimated with a two-sided 95% confidence interval and tested for superiority at a two-sided alpha of 0.05. The primary result is reported as the adjusted between-arm difference in PHQ-9 points with its confidence interval; a standardized effect size is reported alongside it for comparison with the published literature. Where the unstructured covariance model fails to converge, a structured covariance (Toeplitz, then first-order autoregressive) is substituted in the order pre-specified in the SAP.
- Secondary continuous outcomes (GAD-7, PROMIS-10 GPH/GMH T-scores, SQS, BADS-AC, PSS-4, PSWQ-3, WPAI-GH): analogous MMRM models.
- Count and categorical outcomes (PC-PTSD-5 positive screens, healthcare utilization counts): generalized linear models with appropriate link functions.
- Sensitivity analyses: per-protocol analyses restricted to participants meeting an a priori adherence threshold (to be pre-specified in the SAP; for example, a minimum number of psychoeducational modules opened in the Psychoeducation arm and a minimum level of Ash engagement in the Ash arm); analyses adjusted for concomitant care initiation.
- Missing data: MMRM accommodates missingness under MAR. App engagement indicators are included as auxiliary variables in imputation models because they predict both missingness and outcome. Multiple imputation and delta-adjusted tipping-point analyses are pre-specified as sensitivity analyses, and retention is reported by arm.
- Subgroup and moderator analyses by baseline symptom severity, PC-PTSD-5 status, and demographic factors will be exploratory and pre-specified in the SAP.
- Enrollment-flow reporting (CONSORT) will include the number of users shown the study prompt, the number who consented, the number who completed the in-app baseline survey, the number found eligible, and the number randomized.

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- Where AI tools (e.g., LLMs) are used to support text or data analysis, such use is read-only, restricted to de-identified data, and outputs are reviewed by the research team before being incorporated into any findings. See the Data Management Plan for additional detail.

14.2 Study Endpoints

- Primary endpoint: change in PHQ-9 total score from baseline to Week 4, evaluated as the between-arm difference (Ash vs. Psychoeducation) and tested for superiority.
- Secondary endpoints: change in GAD-7, PROMIS Global Health GPH and GMH T-scores, SQS, BADS-AC, PSS-4, PSWQ-3, and WPAI-GH outcomes from baseline to Week 4, with trajectory estimates across all timepoints.
- Exploratory endpoints: WAI-3 alliance score and association with outcomes; associations between change in candidate mechanism measures (PSWQ-3, BADS-AC, PSS-4) and change in clinical outcomes; DSSI changes; healthcare utilization counts (ER, urgent care, hospital admissions, outpatient visits); chronic-condition self-management indicators; concomitant care initiation.
- Feasibility endpoints: proportion of consenting users who complete the in-app baseline survey; proportion of Psychoeducation-arm participants who open at least one and at least eight of the twelve modules; survey completion rate at each timepoint, reported by arm.
- Safety endpoint: incidence and severity of PHQ-9 item 9 endorsement; reportable events.

14.3 Data Quality

- In-app survey and Typeform skip logic and validation rules applied at data entry. Enrollment is limited to one participant per Ash account, and the fraud-prevention controls already operating in the Ash application apply to study respondents as they do to all users. Duplicate or fraudulent enrollments identified through account-level review are excluded from the analytic dataset, with the exclusion and its reason reported in the enrollment-flow diagram.
- Automated daily extracts to research datasets with completeness and out-of-range checks.
- Independent code review of analytic pipelines prior to results reporting.
- A pre-specified statistical analysis plan (SAP) will be finalized prior to database lock.
- All measures used are published and validated; standard scoring algorithms apply.

14.4 Confidentiality

Review pathway: This study was approved under 45 CFR 46.110, expedited review categories 6 and 7, with the digital and brief behavioral intervention components situated within minimal-risk research. The changes in this amendment do not alter the risk level or the review pathway.

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De-identification plan:

- Direct identifiers (name, email address, phone number, IP address, device identifiers) are collected at consent for operational purposes (study communications, scheduling, payment) and stored in operational systems separately from analytic datasets.
- Each participant is assigned an opaque, randomly generated study identifier at enrollment. Analytic datasets contain only the study identifier — not direct identifiers.
- The key mapping between direct identifiers and study identifiers is maintained in an access-controlled operational system; the research team conducting outcome analyses does not have access to the mapping while conducting those analyses.
- Free-text survey responses are reviewed and, where necessary, redacted of any inadvertently disclosed PII before analysis.

Data storage and security:

- Operational identifiable data (contact information, scheduling) are stored in Slingshot's Google Cloud Platform infrastructure (AlloyDB, Firestore) with AES-256 encryption at rest and TLS 1.2+ in transit.
- Analytic de-identified datasets are stored in an access-controlled GCP project distinct from production systems.
- Role-based access controls and audit logging apply to all systems.
- All research personnel have completed CITI human subjects research training.

Data access: The PI, Co-Investigator, and authorized members of the Slingshot AI research and data science team, operating under the PI's supervision, have access to de-identified research data. Access to identifiable operational data is limited to the PI, the Co-Investigator, and the Clinical Research Manager. No external collaborators are currently planned; if external collaborators are added, a Data Use Agreement will be executed prior to any data sharing.

Data retention: De-identified analytic datasets will be retained for a minimum of 3 years following publication of results, consistent with federal data retention recommendations. After the retention period, datasets may be archived in cold storage or deleted at the PI's discretion.

14.5 Future Use of Data

De-identified analytic datasets may be re-used by the Slingshot research team for related secondary analyses without further IRB review, provided such analyses are within the general scope of evaluating Ash's effectiveness, safety, and engagement. Use of these data for purposes outside that scope, or sharing with external collaborators, will be submitted to BRANY as a protocol amendment or new submission, as appropriate.

15) PROTECTING THE PRIVACY OF SUBJECTS

- All onboarding, consent, baseline screening, and surveys are completed on participants' personal devices in private settings of their own choosing.

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- Personnel handling identifiable data are limited to those with an operational need; the analytic team works exclusively from de-identified data.
- Free-text fields are reviewed for inadvertent disclosure of PII prior to inclusion in analytic datasets.
- Recontact occurs only via the contact methods provided by the participant.

16) ENSURING THE SAFETY OF SUBJECTS

The probability and magnitude of harm or discomfort anticipated in this research are not greater than those ordinarily encountered in daily life or during routine psychological assessment. The full safety response plan, including role assignments, response timelines, outreach procedures, documentation requirements, and the participant-facing resource list, is provided in the Appendix (Safety Protocol and Resource List).

Safety protocol for PHQ-9 item 9 (thoughts of suicide)

- Any non-zero response to PHQ-9 item 9 triggers an in-survey resource screen presenting national crisis resources (988 Suicide and Crisis Lifeline; Crisis Text Line, text HOME to 741741) and a brief safety message, displayed within the same session as the response.
- A response of 1 or 2 ("several days" or "more than half the days") triggers an automated follow-up email and text message from the research team within one business day, including national and (where available) local resources and an invitation to contact the study team.
- A response of 3 ("nearly every day") triggers a same-business-day outreach attempt by a clinically trained member of the study team via the participant's stated preferred contact methods, with provision of resources and an offer of referral to higher-acuity care as appropriate.
- All item-9 endorsements are logged and reviewed weekly by the PI or Co-Investigator.

Emergence of mania, psychosis, substance-use, or other safety concerns during the study

Participants who develop new positive screens on the ASRM, PRIME-5, NIAAA, or NIDA at Week 4 or Week 36, or who report serious adverse events at any time during the study, will be flagged to a clinically trained member of the study team, provided with appropriate referral resources, and offered support in connecting with higher-acuity care. Such participants are not automatically withdrawn from the study; their data remain in the analytic dataset under intention-to-treat principles.

Transcript safety monitoring

The study team collects and reviews Ash app conversation transcripts for participants during periods of active Ash chat access (the Ash arm from randomization; the Psychoeducation arm after its Week 4 unlock). The Ash app applies automated safety classifiers to flag messages indicating potential self-harm, suicidal ideation, or acute psychiatric risk in real time. When an Ash transcript safety flag is triggered, the PI or Co-Investigator reviews the flagged content within one business day.

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The psychoeducational track is non-conversational and generates no transcripts, so no transcript-based monitoring is available for the Psychoeducation arm during the 4-week intervention window. For that arm and window, safety monitoring rests on the automated PHQ-9 item 9 pathway at each scheduled survey administration, on the crisis resources displayed within the psychoeducational track, and on a participant-initiated support option available at all times within that track, which surfaces crisis resources and offers to notify the study team. This is a narrower monitoring channel than the Ash arm has during the same period, and the study accepts that asymmetry as a necessary consequence of the comparison being tested; it is disclosed to participants in the consent form.

If risk of suicide, self-harm, or other acute harm is identified in any monitoring channel, a clinically trained member of the study team contacts the participant by email, phone, and/or text within 24 hours to provide crisis resources (including the 988 Suicide and Crisis Lifeline) and assess the need for higher-acuity referral. Participants are informed in the consent form and onboarding materials that their Ash conversations, during periods of active Ash chat access, may be reviewed by the research team for safety purposes.

Reportable events: Serious adverse events, unanticipated problems involving risks to subjects or others, and protocol deviations will be reported to BRANY in accordance with BRANY's reportable-events policy. 17) WITHDRAWAL OF SUBJECTS

Consented respondents who are not enrolled (screen failures). Randomization is the enrollment event in this study. A respondent who consents in-app but does not meet the eligibility criteria on the in-app screening items is a screen failure and is not enrolled. These individuals are not “withdrawn,” as they were never randomized. For them:

- No study surveys are sent and no intervention is delivered.
- They continue using Ash
- They receive the standard resource list and a message confirming that they were not enrolled.
- They are paid the $10 baseline compensation (Section 12).
- They cannot be re-screened or re-enrolled at a later date. This rule is applied uniformly so that every enrolled participant completed identical steps in an identical window with a baseline of identical recency, and it is disclosed to participants in the consent form and in the in-app copy before they schedule the call.
- Their in-app screening and baseline responses are retained in de-identified form and used only for enrollment-flow (CONSORT) reporting and the feasibility aims. Identifiable data are deleted on request.

Withdrawal of enrolled participants. Participants may withdraw from the study at any time without penalty by replying to any study communication, calling, or texting the study team. Upon withdrawal:

- Survey administration ceases.
- Free Ash access continues for its scheduled 9-month duration if the participant wishes; participants may also request that their Ash account be returned to its prior state.
- Data already collected are retained in the analytic dataset under intention-to-treat principles unless the participant specifically requests deletion of their identifiable data.

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De-identified data already incorporated into analytic datasets cannot feasibly be removed.

Investigator-initiated withdrawal: Participants may be withdrawn at the PI's discretion if continued participation is judged to be unsafe (for example, if a clinical picture develops that requires higher-acuity care incompatible with study participation). Such withdrawals are documented and reported per BRANY's reportable-events policy when applicable.

18) RISKS TO SUBJECTS

The probability and magnitude of harm or discomfort anticipated in this research are not greater than those ordinarily encountered in daily life.

AI-specific risks: Research has documented that AI systems used in mental health contexts can misinterpret user disclosures, generate inaccurate content (hallucinations), reinforce cognitive distortions, or respond inconsistently to crisis language. Some studies have documented harmful outputs such as affirming delusions or reinforcing maladaptive coping mechanisms. To mitigate these risks, Ash employs comprehensive safety guardrails that have been validated to block unsafe outputs and consistently surface appropriate crisis resources (Hull et al., 2025). Participants are informed that Ash is a wellness support tool and is not a substitute for licensed clinical care.

Breach of confidentiality: As with any study collecting personally identifiable contact information and self-reported mental health data, there is a residual risk of unauthorized disclosure. This amendment removes the audio-video recording of therapy sessions and the retention of session transcripts, which were the most identifiable data elements previously created by this study. Remaining mitigations are described in Section 14.4.

Psychological discomfort: Some survey items (e.g., PHQ-9, PC-PTSD-5, PSS-4) ask about symptoms of depression, trauma, and stress that some participants may find uncomfortable. Participants may skip any question and stop at any time. Crisis resources are presented alongside sensitive items where appropriate.

Disclosure of acute risk: Endorsement of PHQ-9 item 9 may indicate suicidal ideation. The safety protocol in Section 16 mitigates this risk through immediate in-survey resource delivery and clinician outreach for higher responses.

Not being enrolled after consenting: Because consent precedes eligibility screening, some consenting respondents will be found ineligible and will not be enrolled. Some may find this disappointing. This is disclosed in the consent form and in the in-app copy before the respondent begins the screening questions; all such respondents receive the standard resource list, retain unchanged access to their Ash account, and are paid the $10 baseline compensation.

Deferred Ash chat access (Psychoeducation arm): Participants randomized to the Psychoeducation arm do not have Ash conversational chat during the first 4 weeks; their chat access unlocks after the Week 4 primary endpoint, at which point their 9 months of free Ash access begins. During those 4 weeks they receive 12 psychoeducational modules rather than no content. This deferral is a foreseeable inconvenience rather than a withholding of established care: Ash is a wellness support tool, all participants retain

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access to their usual sources of care, and crisis resources are provided throughout. Participants may seek therapy or other care at any time.

19) POTENTIAL BENEFITS TO SUBJECTS

Direct benefits: Participants may experience improvement in mental health symptoms through Ash use (in the arms and periods with active access) and through the psychoeducational content (Psychoeducation arm). Direct benefit is not guaranteed; whether and to what extent it occurs is the question being studied.

Indirect benefits: Participants contribute to scientific knowledge about whether personalized conversational AI support produces greater benefit than static psychoeducational content delivered on the same schedule, which may inform future products and care models.

20) COMMUNITY-BASED PARTICIPATORY RESEARCH

N/A.

21) SHARING OF RESULTS WITH SUBJECTS

Individual-level results are not shared with subjects. Aggregate findings will be disseminated through peer-reviewed publication and/or conference presentation; participants may opt in to receive a plain-language summary of results upon study completion.

22) PRIOR APPROVALS

No additional approvals are required beyond IRB review. This protocol does not involve external sites, federal agencies, or school systems.

23) COMPENSATION FOR RESEARCH-RELATED INJURY

N/A. This research is minimal risk with no anticipated research-related injury.

24) ECONOMIC BURDEN TO SUBJECTS

There are no costs to participants for taking part in this study. Free Ash access (per the arm-specific schedule), the psychoeducational modules, and any technology required for participation (other than the participant's own personal device and internet connection) are provided by the research team. Participants are responsible only for their own device and connectivity.

Participants receive gift card compensation via Tremendous for completing study surveys, as described in Section 12: $10 for the in-app baseline survey and $15 for each of the four follow-up surveys (Weeks 2, 4, 8, and 36), for a total of up to $70 if all five surveys are completed. The $10 baseline payment is issued within 3 business days of survey submission and is not contingent on being found eligible or on being enrolled. Compensation is tied solely to survey completion and is not contingent on continued use of Ash or on engagement with the psychoeducational modules.

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25) CONSENT PROCESS AND DOCUMENTATION

Informed consent is obtained from all participants in-app prior to any study procedures (including the baseline screening survey and randomization). After a user indicates interest in the study, the informed consent form is presented in-app; the participant must affirmatively select “I agree” to indicate consent before any screening or baseline questions are displayed. Participants do not sign the consent form. A waiver of documentation of informed consent is requested under 45 CFR 46.117(c)(1)(ii): the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Informed consent is obtained from every participant; only the signature requirement is waived.

Because consent precedes eligibility screening, some consenting users will be found ineligible during the in-app screening survey and will not be enrolled; the consent form makes clear that completing consent does not guarantee enrollment.

The consent form covers purpose, procedures, duration, randomization to one of two arms (Ash or Psychoeducation) on submission of the baseline survey, 9 months of free Ash access beginning at randomization for the Ash arm and after the Week 4 primary-endpoint window for the Psychoeducation arm, the 12 psychoeducational modules and their release schedule, the superiority comparison, risks, benefits, compensation and its timing, confidentiality, conflict-of-interest disclosure, voluntary participation and withdrawal, and contact information.

Comprehension and questions: The consent form invites participants to contact the study team with any questions before consenting. Study staff are available by email and by reply to any study text message to discuss the consent form, and will arrange a telephone call with a participant on request.

Documentation: Consistent with the requested waiver of documentation of informed consent, no signature (paper or electronic) is obtained. Each participant's "I agree" selection is recorded with a date and a time stamp and stored in the operational system with restricted access. An unsigned copy of the consent form is available to participants in the app at any time and is emailed on request.

26) DRUGS OR DEVICES

N/A. This research does not involve drugs or devices. Ash is a digital wellness and behavioral support tool, not an FDA-regulated medical device. The psychoeducational modules are static informational content and are not an FDA-regulated medical device.

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