Statistical Analysis Plan (SAP)

Study Title: Akashic Records and Mental Health Outcomes

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Administrative Information

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1. **Study Objectives**
   - 1.1. Primary Objective: To evaluate how two Akashic Records sessions impact self-reported symptoms of stress, anxiety, and depression, and/or resilience and connectedness.
   - 1.2. Secondary Objective: To explore participants' qualitative experiences of Akashic Records sessions through semi-structured interviews, and to integrate qualitative and quantitative findings.
2. **Study Design Overview**
   - 2.1. Design: Single-arm, mixed-methods, exploratory pilot study.
   - 2.2. Intervention: Two Akashic Records sessions (1 90 min, 1 50 min) facilitated virtually via HIPAA-compliant telehealth.
3. **Sample Size**
   - 3.1. Target enrollment: 100 participants.
   - 3.2. Assessment Points: T0 baseline before first session; T1 before second session; T2 after second session; T3 follow-up 60 days after final session.
4. **Analysis Populations**
   - 4.1. Full Analysis Set: All enrolled participants with at least one pre- and one post-intervention validated clinical scale.
   - 4.2. Per-Protocol Set: Participants completing both sessions and all required validated clinical scales.
   - 4.3. Qualitative Sample: First 30–50 participants completing interviews until saturation is reached.
5. **Quantitative Endpoints**
   - 5.1. Primary Clinical Endpoints: Change in DASS-21 Depression, Anxiety, and Stress scores from T0 (baseline) to T2 (post-second session).
   - 5.2. Secondary Clinical Endpoints: Change in DASS-21 Depression, Anxiety, and Stress scores from T0 to T3 (60-day follow-up). Change in CD-RISC-10 Resilience scores from T0 to T2 and T0 to T3. Change in WATTS Connectedness Scale scores from T0 to T2 and T0 to T3.
   - 5.3. Feasibility/Acceptability Endpoint: Participant satisfaction with Akashic Records sessions at T3, assessed with a 5-point Likert survey will be analyzed descriptively (means, SDs, frequencies) to assess feasibility and acceptability.
6. **Qualitative Endpoints**
   - 6.1. Semi-structured interviews (first 30–50 participants, until data saturation) will explore participant experiences across seven domains: motivation for participation, understanding

of the Akasha, perceived benefits, changes in view of problems,, integration of insights, use of suggested practices, and perceived challenges during and after the session.

6.2. Transcripts will be coded structurally to these domains and further analyzed using in vivo codes to capture participant language. Thematic analysis will identify recurrent patterns across domains, with expected themes including:

6.2.1. Insight and meaning-making

6.2.2. Experiences of connectedness and coping

6.2.3. Emotional release and integration challenges

6.2.4. Perceived benefits or limitations of the sessions.

6.3. The qualitative endpoint is thematic saturation across domains, with stable, recurrent themes representing participant experiences.

7. Statistical Methods

7.1. Descriptive Statistics: Continuous variables summarized with means, standard deviations, medians, and interquartile ranges. Categorical variables summarized with counts and percentages.

7.2. Primary Analyses: Pre-post comparisons from T0 to T2 on validated clinical scales will be conducted using paired t-tests if differences are normally distributed, or Wilcoxon signed-rank tests if non-normal. Effect sizes reported as Cohen's d or rank-biserial correlation.

7.3. Secondary Analyses: Repeated-measures linear mixed-effects models with time as a fixed effect and participant as a random effect will examine change across T0, T1, T2, T3. Correlations between changes in validated clinical scales (e.g., resilience vs stress, anxiety, depression) will be calculated using Pearson or Spearman methods. Sensitivity analyses will exclude participants with missing follow-ups.

7.4. Missing Data: Patterns of missingness will be described. Less than 5% missing will use complete case analysis. Five percent or greater missing will use multiple imputation with chained equations.

8. **Qualitative Analysis**

The analysis will proceed in four phases:

8.1. Phase 1: Orientation and Transcript Selection: All 50 transcripts will be reviewed once by volunteers and the co-investigator, scored using a sampling grid (narrative richness, clarity of change, session benefit, memo notes). Twenty-five transcripts will be selected for further in-depth thematic analysis.

8.2. Phase 2: Structural and In Vivo Coding: Structural codes will be applied based on the interview guide, with in vivo codes added to capture participant language. Coders will write 2–3 memos per transcript based on theme development, questions to review, and a summary of the interview. A collaboratively developed codebook will be refined iteratively in weekly meetings.

8.3. Phase 3: Thematic Coding and Episode Profiles: Second-cycle thematic coding will be conducted by the co-investigator. Volunteers will create Episode Profiles including demographics, pre/post experiences, outcomes, integration challenges, and exemplar quotes. Inter-rater reliability will be monitored, with a target of ≥80% agreement.

8.4. Phase 4: Theme Synthesis and Visual Finalization: The co-investigator will consolidate themes, select exemplar quotes, and create visual models. Volunteers will provide feedback and review drafts for accuracy.
Note: Inter-rater reliability will be ensured by having at least two coders independently review each transcript and meet for consensus. Data saturation will guide the final interview sample size.

9. Protocol Deviations

9.1. Deviations such as missed validated clinical scales, rescheduled sessions, or technical issues will be logged. Participants with at least one pre and one post measure included in FAS. Major deviations described in study reporting.

10. Integration of Data

10.1. Convergence coding matrix and joint displays will align qualitative themes with quantitative changes on validated clinical scales. Convergences and divergences highlighted to generate hypotheses.

11. Data Presentation

11.1. Tables will include demographics, validated clinical scale scores at each timepoint, paired comparisons, effect sizes, protocol deviations, and adverse events. Figures will include line graphs of trajectories, scatterplots of correlations, and thematic maps.

11.2. Quantitative analyses will be conducted using validated statistical software (SPSS v29 or R version 4.3 or later).

11.3. Qualitative analyses will be conducted using Dedoose

11.4. Demographic satisfaction survey results and feasibility metrics (e.g., recruitment and retention rates) will be reported alongside quantitative and qualitative findings

12. Risk of Bias and Conflict of Interest Mitigation

12.1. Because the Principal Investigator (PI) also serves as the interventionist and sponsor, safeguards have been implemented to minimize bias and ensure the integrity of data collection and analysis.

12.2. Quantitative Data Firewalls: All validated clinical scale data (DASS-21, CD-RISC-10, WATTS) are collected via Jotform and secured with restricted access. The PI will not have direct access to raw survey responses. Data management will be overseen by the research coordinator and independent statistician.

12.3. Qualitative Data Analysis: The PI will not participate in qualitative coding or thematic analysis. Semi-structured interviews will be conducted and coded by the co-investigator and trained volunteers. At least two coders will review each transcript independently, with consensus meetings to ensure inter-rater reliability.

12.4. Independent Analysis: Quantitative analysis will be performed primarily by an independent statistician, with oversight by the co-investigator. The PI will not serve as the primary reviewer of statistical outputs.

12.5. Transparency in Reporting: All deviations from protocol and potential sources of bias will be documented in the final study report and addressed in dissemination.

12.6. These procedures collectively ensure that participant data are analyzed independently from the PI's role as interventionist, thereby reducing risk of bias and supporting the credibility of the study's findings.

13. Data Storage and Confidentiality

13.1. All quantitative data (validated clinical scales and survey responses) will be collected via Jotform, a HIPAA-compliant platform.
13.2. Responses will be de-identified and linked only by unique participant ID numbers.
13.3. Qualitative data (session transcripts and interview recordings) will be stored in encrypted, password-protected drives with access restricted to authorized research team members.
13.4. The PI will not have direct access to raw quantitative survey data, as outlined in conflict of interest mitigation procedures.
13.5. Data will be retained for six years in accordance with institutional and ethical guidelines

14. Participant Safety and Monitoring

14.1. Clinical observation and assessment of participant adverse events will be monitored. This is defined as psychological distress during or after sessions.
14.2. Monitoring through team check-ins and referral protocols.
14.3. The research coordinator will send all participants referrals to ongoing mental health services at study completion per protocol.
14.4. All participants will have contact information of licensed clinicians for support during and after the study.

15. References

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