

Title of project: Breath of Resilience: Evaluating the Impact of SKY Breath Meditation on Stress, Well-being, and Connection in College Students – A Pilot Randomized Controlled Trial

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PROTOCOL TITLE: Breath of Resilience: Evaluating the Impact of SKY Breath Meditation on Stress, Well-being, and Connection in College Students – A Pilot Feasibility Randomized Controlled Trial

INSTRUCTIONSⁱ:

- Use HRP-503a - *TEMPLATE SBS PROTOCOL* to prepare a document with the information from the following sections.
- Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “NA”. For example, research involving a retrospective chart review may have many sections with “NA.” For subsections, like 1.x or 8.x, you can delete it if it’s not applicable.
- When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.
- As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.
- For submission of a protocol specific to a participating Site as part of a Multi-Site Study, use HRP-508 – *TEMPLATE - SITE SUPPLEMENT*

PROTOCOL TITLE:

Include the full protocol title. Breath of Resilience: Evaluating the Impact of SKY Breath Meditation on Stress, Well-being, and Connection in College Students – A Pilot Feasibility Randomized Controlled Trial

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VERSION NUMBER/DATE:

Include the version number and date of this protocol.

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

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1.0 Study Summary

Protocol Information	Description
Study Title	Breath of Resilience: Evaluating the Impact of SKY Breath Meditation on Stress, Well-being, and Connection in College Students – A Pilot Feasibility Randomized Controlled Trial
Study Design	This is a Pilot feasibility study with a randomized controlled trial (RCT) design
Primary Objective	<ul style="list-style-type: none">• To evaluate the feasibility and acceptability of this RCT by implementing an 8-week SKY Breath Meditation intervention for university students and examining participant recruitment and retention rates, intervention adherence, and stakeholder satisfaction.• To evaluate the preliminary efficacy of an 8-week SKY Breath Meditation program on the changes in amount of physical activity among university students in the intervention group as compared to that of the participants in control group from baseline to post-intervention phase.
Secondary Objective(s)	<ul style="list-style-type: none">• To evaluate the preliminary efficacy of an 8-week SKY Breath Meditation program on psychological outcomes of <i>perceived stress</i>, <i>anxiety</i> and <i>resilience</i> among university students by comparing the changes in these outcomes between the intervention group and control group participants from baseline to post-intervention phase.

	<ul style="list-style-type: none"> To assess the changes in social connectedness and cognitive focus of university students receiving SKY Breath Meditation Program from before to after the intervention phase.
Research Intervention(s)	SKY breath Meditation for three days in person and then twice weekly online practice sessions.
Study Population	Approximately 56 participants will be recruited from a local university, including both undergraduate and graduate students. Participants will be assigned to either the intervention group (SKY Breath Meditation) or active control group with equal allocation. Recruitment will adhere to clearly defined inclusion and exclusion criteria as outlined below.
Sample Size	56 University of Alabama students (Graduate or undergraduate)
Study Duration for individual participants	8 week
Study Specific Abbreviations/ Definitions	<p>Sudarshan Kriya Yoga (SKY)</p> <p>perceived stress scale (PSS)</p> <p>Generalized Anxiety Disorder (GAD-7)</p> <p>Social Connectedness Scale-Revised (SCS-R)</p> <p>Mindful Attention Awareness Scale (MAAS)</p> <p>International Physical Activity Questionnaire – Short Form (IPAQ-SF)</p>

2.0 Objectives

- 2.1 *To evaluate the preliminary efficacy of an 8-week SKY Breath Meditation program on the changes in amount of physical activity among university students in the intervention group as compared to that of the participants in control group from baseline to post-intervention phase.*
- 2.2 *evaluate the feasibility and acceptability of this RCT by implementing an 8-week SKY Breath Meditation intervention for university students and examining participant recruitment and retention rates, intervention adherence, and stakeholder satisfaction*
- 2.3 *To assess the changes in social connectedness and cognitive focus of university students receiving SKY Breath Meditation Program from before to after the intervention phase*
- 2.4 *To evaluate the preliminary efficacy of an 8-week SKY Breath Meditation program on psychological outcomes of perceived stress, anxiety and resilience among university students by comparing the changes in these outcomes between the intervention group and control group participants from baseline to post-intervention phase.*

3.0 Background

Mental health and well-being among university students have become a critical concern nationwide, with rising levels of stress, anxiety, and depression significantly impacting academic performance and overall well-being (American College Health Association [ACHA], 2023). Healthy Minds Study 2022-2023 Data Report (2023) and American College Health Association (2023) indicated that 76% college students reported psychological distress on the healthy minds survey, with 36% students reporting anxiety, 28% students experiencing depression, and 53% students reporting loneliness and feeling of isolation. Recent studies suggest lowest mental health and poor mental well-being is related to highest academic stress (Barbayannis et al., 2022). The same study indicated the relationship between the mental well-being and academic stress are negatively correlated, signifying that positive mental well-being is a possible pathway to lower academic stress; whereas, negative or poor mental well-being leads to higher academic stress (Barbayannis et al., 2022). Such levels of stress, anxiety, and disconnection not only impair academic performance but also strain campus counseling resources. There is an urgent

need for accessible, preventive interventions that can improve students' coping skills and resilience before problems escalate (Seppälä et al., 2020).

Introducing healthy coping strategies can assist students in managing challenges effectively leading to reduction in perceived stress and increased academic adjustment (Teixeira et al., 2022). A strategy widely researched in recent years is mindfulness-based interventions.

Mindfulness-based interventions, particularly breathwork meditation techniques, have emerged as promising strategies to mitigate stress and enhance psychological resilience among college students (Fincham et al., 2023; Seppälä et al., 2020). A 2025 meta-analysis of breathwork-based interventions further confirms that controlled breathing techniques can meaningfully lower self-reported stress and improve mental health outcomes (Ganesan et al., 2025). Specifically, the Sudarshan Kriya Yoga (SKY) Breath Meditation program integrates rhythmic breathing exercises, meditation, and gentle yoga, demonstrating effectiveness in reducing perceived stress, anxiety, and improving emotional resilience and mindfulness in multiple populations (Korkmaz et al., 2024; Seppälä et al., 2020). Prior randomized controlled trials have shown that SKY Breath Meditation significantly enhances emotional regulation, reduces anxiety symptoms, and promotes social connectedness in university students (Seppälä et al., 2020).

Given the promising evidence, evaluating the effectiveness of SKY Breath Meditation within a university student population aligns with institutional priorities to proactively support student mental health and promote academic success through evidence-based, preventive strategies (Chung et al., 2021; Fincham et al., 2023). The purpose of this study is to (a) test the feasibility and acceptability along with (b) preliminary efficacy of a structured, 8-week SKY Breath Meditation program on physical activity and psychological outcomes (stress, anxiety, and resilience), social connection, and the cognitive focus of university students randomly assigned

to intervention group receiving the SKY Breath Meditation program as compared to those assigned to an active control group receiving an informational booklet about meditation and yoga, and monthly check-in calls. We will also evaluate any changes in overall mental well-being, and academic performance among the participants in the intervention group compared to that of the participants in the control group..

4.0 Study Endpoints

4.1 Same as objectives listed above

5.0 Study Intervention

5.1 Intervention - SKY: The SKY Program has following components:

- I) **Three-Day In-Person Retreat:** The SKY program begins with a three-day intensive retreat, held Friday evening and during the daytime on Saturday and Sunday of the same weekend, totaling approximately 12 hours. Certified instructors will teach participants a structured sequence of yogic breathing techniques, meditation, and gentle yoga. A core component is the Sudarshan Kriya (SKY) breathing practice, characterized by cyclical breathing patterns involving slow, medium, and fast breaths, designed to induce calm and emotional release (Ganesan et al., 2025). Additional breathing practices include ujjayi (victorious breath) and bhastrika (bellows breath), as well as guided meditation and group exercises that enhance emotional awareness and social connection. Interactive discussions covering stress management, neuroscience of breathing, and positive psychology skills, such as gratitude exercises, will align with the standardized SKY Campus Happiness curriculum utilized in previous research (Seppälä et al., 2020). Overall, the multi-component approach of SKY—combining breathing techniques, physical movement, meditation, and community support—is hypothesized to produce broad psychological benefits demonstrated in earlier trials (Seppälä et al., 2020).

To encourage attendance and foster a retreat-like atmosphere, healthy catered meals (breakfast, lunch, and snacks) will be provided on each 4-hour retreat day. Offering meals ensures participants remain onsite throughout each day and serves as acknowledgment of their commitment. Depending on additional funding, participants will receive a \$20 gift card upon completing the study and the post-test data collection.

II) **Weekly Virtual Sessions (Weeks 2–8):** Following the retreat, SKY participants will continue weekly instructor-guided virtual sessions (30 minutes) and engage in independent SKY practice (approximately 20 minutes, 3 times weekly). Participants will log practice frequency and duration in provided journals, which will be collected at study completion and analyzed to assess adherence as a key feasibility and acceptability endpoint. Session attendance will also be tracked to evaluate participant engagement with the intervention. All sessions will be led by certified SKY instructors, such as those affiliated with the SKY Campus Happiness program. This will be a shorter guided meditation and breathwork practice along with opportunity for Q&A and check-in. Participants will receive instruction on safe breathing practices, avoiding overexertion, and logging adherence.

III) **Home Practice:** Participants will be encouraged to integrate brief daily practices on their own. Following the standard SKY protocol, they will be asked to practice the SKY breathing technique and meditation at least 3 times per week at home, for approximately 20 minutes per session. Participants will be encouraged to utilize daily log to record their practice frequency, which instructors will review to monitor adherence. Although daily practice is strongly encouraged for maximum benefit, no participant will be removed for

non-compliance; all data will be primarily analyzed by assigned group regardless of actual practice amount in an intent-to-treat approach.

IV) The SKY Breath Meditation retreat and weekly virtual sessions will be conducted specifically for the purposes of this research study and are not part of any program or event that would occur independently of the research. The active control group series is also created solely for the study.

The SKY intervention is group-based, fostering peer support and social connection. We anticipate that group bonding during the retreat (which involves some group discussions and enjoyable activities) will carry forward, potentially contributing to improved social connectedness – an outcome we will measure. The emphasis on *self-compassion* and non-judgment in the program may also positively influence participants' self-kindness and resilience.

Control Group: Participants in the active control group will be assigned to follow a pre-selected series of online yoga videos, without breath-based meditation, for 30 minutes at least 3-5 times per week, over 8 weeks. They will log yoga sessions and receive weekly reminders, mirroring the structure and frequency of the SKY Breath Meditation group after the 3-day SKY retreat.

As an ethical courtesy, once the 8-week trial is over and all post-test data is collected, the active control group participants will receive information regarding opportunity to attend a SKY retreat later at no cost. **Data Collection:** We will assess multiple outcomes spanning feasibility and standardized questionnaires. Feasibility metrics include recruitment rate, retention, and adherence to SKY practice (Ganesan et al., 2025).

Participants will be informed in the consent form that they will be randomly assigned to either the SKY Breath Meditation intervention group or the active control group. No deception is used, and no debriefing procedure is required.

6.0 Procedures Involved

Design: This is a Pilot feasibility study with a randomized controlled trial (RCT) design.

We will obtain the IRB approval from the University of Alabama. The study will use a two-arm, parallel-group, RCT design over an 8-weeks follow-up period to evaluate the effects of SKY Breath Meditation compared to an active control condition. Participants will be aware of their assigned group, but research staff responsible for data management and analysis will remain blinded to group allocations. The trial will be pre-registered in ClinicalTrials.gov and conducted in accordance with CONSORT guidelines to ensure transparency and methodological rigor.

Data Analysis:

Sample characteristics and study outcome measures will be assessed by randomized arm to check for imbalance. The frequency and percent meeting feasibility and acceptability benchmarks will be estimated along with their 95% confidence intervals (CIs). Before conducting the further analyses for preliminary efficacy outcomes, summary statistics will be generated and adjustments to our measures and statistical models will be made to address any potential violations of the assumptions underlying the models. Internal consistency reliability will be assessed with coefficients alpha and omega. Missing data will be inspected for their amounts and patterns, and if prevalent, sensitivity analyses conducted using multiple imputation with at least 100 imputations using a fully conditional specification. Primary analysis to evaluate study aims and related hypotheses will be conducted using analysis of covariance (ANCOVA) of post-intervention measures explicitly controlling for baseline levels when evaluating intervention vs. active control group mean differences. Additional control variables such as group, cohort, time slot or student demographics will be adjusted for if they affect the estimate of the intervention vs. active control effect by $\geq 10\%$. All analyses will be performed using SAS (SAS

Institute, Cary, NC and IBM SPSS (Armonk, NY) statistical software with primary findings based on an intent-to-treat approach. A two-sided p -value < 0.05 will be considered statistically significant and reported in tandem with measures of precision (95% CIs).

The effectiveness of the SKY intervention will be evaluated by comparing the pre-to-post change in outcomes between the intervention group and active control group. The primary outcomes, perceived stress and resilience will be tested first to determine if the intervention yields significant improvements relative to control.

For continuous self-report outcomes (PSS, GAD-7, etc.), we will assume approximate normality; if distributions are skewed; for example, GAD-7 might be skewed low in a healthy sample, we can apply transformations or use alternative group comparisons via Median or Gamma regression.

We will similarly analyze other preliminary efficacy outcomes (self-compassion, mindfulness facets, physical activity, social connectedness) with the same approach. We expect positive changes, such as increased SCS-R score, in SKY group relative to control group. Effect sizes (e.g., standardized mean difference/Cohen's d) along with their 95% CIs will be estimated for future trial design consideration.

Exploratory analyses: We will explore correlations between the amount of home practice (20 minutes at least 3 times per week, as reported in participant practice logs) and outcome changes within the SKY group to examine potential dose–response patterns. Because completion of practice logs may vary, adherence itself will also be evaluated as a feasibility endpoint. In addition, we will calculate the proportion of participants in each group who demonstrate clinically significant improvement on primary outcomes (e.g., ≥ 5 -point reduction on the Perceived Stress Scale, or a shift from moderate to low distress category). These exploratory

analyses are intended to illustrate the potential practical impact of the intervention and to inform design considerations for a larger, adequately powered trial.

1. Pre-test online questionnaires (20–25 minutes):

- Perceived Stress Scale (PSS)
- GAD-7
- Social Connectedness Scale-Revised (SCS-R)
- Mindful Attention Awareness Scale (MAAS)
- IPAQ-SF
- Brief Resilience Scale
- Demographics questionnaire

2. Random assignment:

Participants will be randomly assigned (1:1) to the SKY intervention or active control group.

Intervention Group Procedures:

3. Three-day in-person SKY Retreat (total ~12 hours): Participants attend a guided program including breathing practices, meditation, light yoga, and group activities.

4. Weekly virtual SKY sessions (30 minutes each week): Instructor-led breathwork and meditation.

5. Home practice sessions (20 mins sessions at least 3 times a week)

6. Home Practice logs (5–10 minutes per week to complete logs): Participants complete daily or weekly logs documenting SKY practice frequency and duration. Logs will be collected at post-test.

Control Group Procedures:

6. 30-minute online yoga video sessions, 3–5 times/week for 8 weeks: Participants log their participation in weekly practice logs (5–10 minutes per week).

7. Monthly check-in call (5–10 minutes).

8. Post-test online questionnaires (20–25 minutes):

Same measures as pre-test plus intervention feedback items.

Audio/video recordings:

No SKY sessions, control sessions, or study procedures will be audio- or video-recorded.

7.0 Data and Specimen Banking

All the data and the records from study participants will be treated as private healthcare records and will be stored on an encrypted network server and an encrypted cloud drive (UA BOX) shared between study investigators. All participant data will be obtained electronically and saved electronically to the UA Box. Data will be used in de-

identified format in any presentation, publication, or report from this project. All personnel involved in this project will complete HIPAA certification and receive training in Human Subjects Protections (CITI).

8.0 Sharing of Results with Subjects

8.1 *N/A*

9.0 Study Timelines

9.1 *Describe:*

- **Individual participation lasts approximately 8 weeks. Enrollment is expected to take 2–3 months, depending on recruitment flow. Data collection will be completed within the same semester as enrollment.**

10.0 Subject Population

- Approximately 56 participants will be recruited from a local university, including both undergraduate and graduate students. Participants will be assigned to either the intervention group (SKY Breath Meditation) or active control group with equal allocation. Recruitment will adhere to clearly defined inclusion and exclusion criteria as outlined below.
- ***Only adults (18+) may participate.***

11.0 Vulnerable Populations

- *N/A*

12.0 Local Number of Subjects

56 participants

13.0 Recruitment Methods

Attached flyer to the IRB application will be distributed to the colleges at UA to be added to the college wide newspapers at each university level.

14.0 Withdrawal of Subjects

Participation in the research study is voluntary, and participants may withdraw at any time during the study.

If a participant withdraws, the data collected before withdrawal will not be utilized.

15.0 Risks to Subjects

This intervention poses minimal risk. SKY is a structured breathing meditation with no invasive procedures. The greatest foreseeable risks are minor and transient, such as lightheadedness or slight hyperventilation effects during practice, muscle soreness from posture, or occasional emotional release. All breathing sessions will be taught and supervised by trained instructors, who will monitor for discomfort. In case of any adverse reaction, participants can pause the exercise or seek medical attention. No serious adverse events related to SKY are expected based on prior studies, SKY has a strong safety record and is generally considered low-risk.

16.0 Potential Benefits to Subjects

The primary potential benefit of the proposed research is the potential to improve in physical activity and mental well-being and cognition and reduce stress.

17.0 Data Management and Confidentiality

- All the data and the records from study participants will be treated as private healthcare records and will be stored on an encrypted network server and an encrypted cloud drive (UA BOX) shared between study investigators. All participant data will be obtained electronically and saved electronically to the UA Box. Data will be used in de-identified format in any presentation, publication, or report from this project. All personnel involved in this project will complete HIPAA certification and receive training in Human Subjects Protections (CITI).
- All collected data will be de-identified using unique participant ID codes. A separate, password-protected linkage file connecting names to ID codes will be stored on an encrypted server accessible only to the PI. Identifiers will be removed before analysis. No names or direct identifiers will appear in datasets used for analysis.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This section is required when research involves more than Minimal Risk to subjects.

- .N/A

19.0 Provisions to Protect the Privacy Interests of Subjects

Participants will be informed that all the data and the records from study participants will be treated as private healthcare records and will be stored on an encrypted network server and an encrypted cloud drive (UA BOX) shared between study investigators. All participant data will be obtained electronically and saved electronically to the UA Box. Data will be used in de-identified format in any presentation, publication, or report from this project. All personnel involved in this project will complete HIPAA certification and receive training in Human Subjects Protections (CITI).

Select all identifiers that will be collected at any time as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:

- x Names
 - ☐ Geographic Locators Below State Level
 - ☐ Social Security Numbers
 - ☐ Dates (year alone is not an identifier)
 - ☐ Ages over 89 (age under 89 is not an identifier)
- x Phone Numbers
 - ☐ Facsimile Numbers
- x E-mail Addresses
 - ☐ Medical Record Numbers
 - ☐ Device Identifiers
 - ☐ Biometric Identifiers
 - ☐ Web URLs
 - ☐ IP Addresses
 - ☐ Account Numbers
 - ☐ Health Plan Numbers
 - ☐ Full Face Photos or Comparable Images
 - ☐ License/Certification Numbers
 - ☐ Vehicle ID Numbers
 - ☐ Other Unique Identifier

- ☐ Employee #
 - ☐ No Identifiers

20.0 Compensation for Research-Related Injury

N/A

21.0 Economic Burden to Subjects

N/A

22.0 Consent Process

- *Consent will be collected prior to the start of the first in-person session.*
- **Participants will be informed in the consent form that they will be randomly assigned to either the SKY Breath Meditation intervention group or the active control group. No deception is used, and no debriefing procedure is required.**
- **Consent will be obtained electronically using an online consent form, without a handwritten signature. Participants will indicate consent by clicking an “I agree to participate” button.**
- We will be following HRP-090 - SOP - Informed Consent Process for Research. HRP-502 attached to the IRB application.

Non-English Speaking Subjects

N/A

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

- N/A – we will obtain the consent.

Subjects who are not yet adults (infants, children, teenagers)

- *College students, who are 18 and above are eligible to participate in the study. Hence, we will not need parental consent.*

Cognitively Impaired Adults

- N/A

Adults Unable to Consent

- N/A

23.0 Process to Document Consent in Writing

23.1 *Yes, we will be following HRP-091 - SOP - Written Documentation of Consent. If not, describe whether and how consent of the subject will be documented in writing.*

24.0 Setting

The initial 3-day, 4 hours each day, SKY Breath Meditation retreat will be conducted **in person** at a large space at the University of Alabama campus; for example, a ballroom in the student center, following campus safety protocols and allowing adequate space for yoga and breathwork practices. To accommodate students' schedules and maximize participation, the SKY retreat will be offered in **two parallel intervention groups, 8am to 12pm in the morning and 12:30pm to 4:30pm in the afternoon**, for three days, light snacks along with breakfast for morning session and lunch for afternoon session will be served. Participants randomized to SKY can choose a morning or afternoon retreat slot, each cohort capped at approximately 15 students, with a total of 28 in the SKY intervention group. This flexible scheduling is recommended for group interventions to reduce barriers to attendance.

25.0 Resources Available

25.1 *Describe the resources available to conduct the research: For example, as appropriate:*

- *We plan to recruit 56 undergraduate and graduate students at the university of Alabama. What percentage of those potential subjects do you need to recruit?*
- *The research will be implemented in Feb through April of 2026.*
- *We plan to utilize assistance of sky campus student organization on campus to reserve room in student center for in person session.*
- *Research protocol will be reviewed prior to the implementation of the intervention to ensure all team members are on aware of the research guidelines.*

26.0 Multi-Site Research (Delete this section if this is not a Multi-Site Research Study.)

N/A

ⁱ This template satisfies AAHRPP elements 1.7.B, 1.8.B, I-9, II.2. A, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D-F, II.4.A, III.1.C-F, II.2.D