HHS Public Access

Author manuscript

Int J Yoga Therap. Author manuscript; available in PMC 2022 March 18.

Published in final edited form as:

Int J Yoga Therap. 2021 January 01; 31(1): . doi:10.17761/2021-D-20-00004.

A Closer Look at Yoga Nidra: Sleep Lab Protocol

Erica Sharpe, PhD[1], **Alison Lacombe, PhD**[2], **Matthew P. Butler, PhD**[3], **Douglas Hanes, PhD**[4], **Ryan Bradley, ND, MPH**[5]

[1]National University of Natural Medicine, Portland, Ore.; and State University of New York at Canton, Canton, N.Y

[2]National University of Natural Medicine, Portland, Ore.; and U.S. Department of Agriculture, Produce Microbiology Research Unit, Berkley, Calif.

[3]Oregon Health & Science University, Portland, Ore.

[4]National University of Natural Medicine, Portland, Ore.

[5]National University of Natural Medicine, Portland, Ore.; University of California, San Diego, La Jolla, Calif.; and Australian Research Centre in Complementary and Integrative Medicine, Faculty of Health, University of Technology Sydney, Ultimo, NSW, Australia.

Abstract

Extended sleep onset latency (SOL), or “sleep onset insomnia,” can decrease total sleep time, increasing risk for many health conditions, including heart disease, stroke, and all-cause mortality. Sleep disorders persist in the United States despite current behavioral/pharmaceutical remedies, with 10% to 15% of the population suffering from insomnia. Mind-body therapies offer additional solutions, as meditation has been correlated with decreased SOL. More research on use of mind-body practices for insomnia is needed. This study investigates the guided meditation practice of *Yoga Nidra* (yogic sleep) as a promising intervention for sleep disorders because of its purported ability to induce mental, physical, and emotional relaxation. In this pilot study, we address the feasibility of Yoga Nidra for insomnia, appropriateness of our selected measurement systems, and effect of Yoga Nidra on brainwaves, sleep onset, and the autonomic nervous system. Our study sample includes 22 adults, ages 18–45, with insomnia. The design includes two clinic visits (V1, lying quietly for 90 min; V2, randomization to 90-min lying quietly vs. 30-min Yoga Nidra plus 60-min lying quietly), taking place 1 to 14 days apart. Outcomes measured during/after Yoga Nidra (vs. control) include sleep onset, electroencephalography (EEG) power, heart rate variability (HRV), and respiratory rate. Self-reported mood and anxiety will be measured before/after each visit. Resulting physiological, psychological, and feasibility data will be used to inform future clinical studies of Yoga Nidra for sleep and relaxation. *Sharpe et al. Int J Yoga Therapy 2021(31). doi: 10.17761/2021-D-20-00004.*

Correspondence: esharpe@nunm.edu.

Conflict-of-Interest Statement

There are no conflicts of interest, financial relationships, copyrights, patents, relationships, or activities that could influence the content of this submitted work.

Keywords

Yoga Nidra; electroencephalography (EEG); heart rate variability (HRV); PANAS; STAI; sleep onset latency; insomnia

Introduction

Up to 15% of the U.S. population has difficulty falling asleep at night.[1] This disorder, known as "sleep onset insomnia," increases risk for many negative outcomes (48% increase in CHD deaths, 15% increase in strokes, and 12% increase in all-cause mortality).[2] Current approaches to decreasing the time it takes to fall sleep, or sleep onset latency (SOL), include prescription drugs, supplements, and cognitive behavioral therapy for insomnia (CBT-I).[3] Hypnotic sleeping pills, which offer little benefit,[4,5] can be costly and carry risks, including death from overdose, depression, and automobile crashes.[4–6] Melatonin supplements, which are processed by the CYP liver enzyme, may interact with drugs processed by the same enzyme (including caffeine and birth control); this may increase plasma melatonin. Melatonin may also interact with hypnotics to cause psychomotor and memory impairment. The paucity of long-term human studies means that long-term effects are not known and these supplements cannot be recommended for those who are pregnant/breastfeeding.[7] Behavioral approaches, which include diet and lifestyle change (modifying caffeine and alcohol consumption, practicing sleep hygiene, and increasing exercise),[8,9] require significant willpower, commitment, and time investment.[10,11]

CBT-I remains the gold standard for treating insomnia, yet it is costly, may be difficult to access,[3,12] and can take roughly 1 month to begin working.[3] There are efforts to make CBT-I more accessible[13] (including telehealth,[14] app-based CBT-I,[15] and brief behavioral treatment of insomnia [BBTI][16]), yet some individuals' insomnia does not remit with CBT-I.[17] For example, in one study, 30% to 40% of the sample did not report insomnia remission (Insomnia Severity Index scores < 8) following 6 or more months of traditional CBT-I.[18] Thus, continued exploration of insomnia intervention options could be valuable to the sleep community, particularly if these interventions could be used as a complement to gold-standard CBT-I (simultaneously, as an entry-point intervention in a stepped care model,[13] or for those who did not respond to CBT-I and are still seeking help with insomnia). Such an intervention could help patients to engage with CBT-I and enact cognitive and behavioral change while, importantly, providing acute relief of insomnia by improving sleep and daytime functioning.

Unlike pharmaceuticals, which bring immediate relief from symptoms but do not enhance effectiveness of CBT-I,[18] mind-body techniques may hold potential for encouraging positive response from CBT-I because of their likely ability to increase self-efficacy[19] and self-regulation.[20] Mind-body techniques such as yoga[21] and mindfulness[22] have been studied in relation to insomnia,[10,23–27] yet knowledge gaps on their effectiveness remain.[1,12] Furthermore, these studies show the strongest changes in self-reported measures of sleep rather than objective polysomnographic outcomes (monitored by electroencephalography [EEG]),[21,22] and few mechanistic studies have been done to understand their effects.[28]

Interestingly, there is also evidence that mindfulness meditation can create a state of hyperawareness,[29] which may counter the intended effects of a pre-bedtime, sleep-oriented practice.

We introduce here a meditative practice that is seemingly most appropriate for addressing insomnia but has yet to be studied in this context: *Yoga Nidra* (yogic sleep or psychic sleep).[30,31] This practice naturally produces a hypnogogic state (indicated by alpha brainwaves[30,32–35]), without the use of hypnotic drugs. Yoga Nidra represents a distinct limb of yoga called *pratyahara,* or sense withdrawal, and is a scripted (and therefore reproducible) group of activities (rationalized in Table 1). With practice, these mental activities may produce the unique state of yoga nidra, wherein an individual is physiologically asleep (producing all sleep stages), yet maintains a subtle internal and external awareness[30,35,36] that allows for profound transformations within the conscious and unconscious mind.[30,31] This practice therefore has excellent potential as both an independent insomnia treatment and alongside CBT-I; Yoga Nidra is not only purported to improve sleep but is traditionally used for self-learning and improvement of self-control, outcomes that could be highly influential in the effort to improve responsiveness to CBT-I.

The goal of our proposed mechanistic research is to investigate the physiological and psychological effects of a single Yoga Nidra practice and assess the feasibility of Yoga Nidra as an intervention for insomnia. Outcomes will be used to inform future research designs related to Yoga Nidra and sleep onset.

Objectives

The overarching objective of this work is to assess feasibility of Yoga Nidra for use in insomnia, as well as to determine its effects on sleep, the brain, and the autonomic nervous system. To accomplish this objective, we define three specific aims to be measured over the course of two visits, taking place 1 to 14 days apart.

Specific Aim 1

Specific Aim 1 is to measure patterns of electrical brain activity via EEG (Thought Technologies EEG device attached to frontal lobe [F3], central lobe [C3], occipital lobe [O1], eyes [EOD], and chin sites) before, during, and after the practice of Yoga Nidra, compared to a control condition of lying quietly, to determine:

- **1.a:** if Yoga Nidra induces changes in brainwave activity measurable by our EEG system.
  - **H0:** There are no differences in patterns of brain electrical activity between Yoga Nidra and control, indicating that (1) the EEG system we have selected is not sensitive enough for use in this intervention, (2) changes produced do not occur in the electrode sites we have selected, or (3) Yoga Nidra does not induce changes in brainwave activity.

  - **H1:** There are mean differences in EEG power in alpha, theta, beta, and/or delta bands originating in the frontal, occipital, and/or central lobes between Yoga Nidra and control groups.

- **1.b:** if sleep can be detected using our EEG measurement system and analysis of raw data by registered polysomnographic technicians at Sleep Strategies.
  - **H0:** Sleep is not detected, indicating (1) our system is not capable of detecting sleep, or (2) our intervention does not induce sleep.
  - **H1:** Sleep is detected in the intervention group and/or the control condition.
- **1.c:** if time to sleep onset (SOL: minutes from the start of the intervention to when a persistent stage 2 brainwave pattern begins) differs between intervention and control.
  - **H0:** There is not a significant difference in mean SOL between intervention and control.
  - **H1:** Mean SOL is decreased with the intervention relative to the control.

Specific Aim 2

Specific aim 2 is to measure patterns of respiratory rate via the wireless Spire device and heart rate variability (HRV) via the wireless Bodyguard 2 electrocardiogram (ECG) device before, during, and after Yoga Nidra, compared to a control condition of lying quietly, to determine:

- **2.a:** if Yoga Nidra induces changes in HRV and respiratory rate that are measurable by our selected system.
  - **H0:** There are no differences in patterns of respiratory rate or HRV between Yoga Nidra and control, indicating that (1) Yoga Nidra produces no changes to respiratory rate or HRV, or (2) our measurement system is not sensitive enough.
  - **H1:** Mean respiratory rate decreases, high frequency (HF) HRV parameters increase, and/or root mean square of successive differences (RMSSD) in HRV parameters increase with intervention versus control.
- **2.b:** if it is feasible to use these devices in our clinic to measure changes in HRV and respiratory rate during and after Yoga Nidra, and if data from these devices can be successfully extracted and analyzed.
  - **H0:** One or both of these devices pose challenges that cause them to be impossible to use for collection of data or impossible to use because of challenges in retrieving or analyzing the data gathered.

- **H1:** Both devices can be successfully applied and used for measurement during this study, and our study team is able to retrieve and analyze relevant data from these devices.

Specific Aim 3

Specific aim 3 is to assess the feasibility of our intervention to determine:

- **3.a:** if our intervention is viewed as credible for supporting healthy sleep within our sample, indicated in the postintervention survey by experience of benefit ratings on a slider scale (range *not beneficial* to *very beneficial*).
  - **H0:** The intervention is not credible for the proposed use, indicated as all ratings below 50%.
  - **H1:** The intervention is viewed as credible for use in decreasing SOL in our selected sample, indicated as one or more ratings above 50%.
- **3.b:** if intervention conditions are acceptable as indicated by recruitment and retention rates.
  - **H0:** Conditions are not acceptable, indicated by an inability to recruit 22 participants for our proposed study within 3 months and/or a dropout rate greater than 50%.
  - **H1:** Conditions are acceptable, indicated by a dropout rate below 50% and ability to recruit 22 participants within 3 months.

Trial Design

In this randomized controlled trial, we will explore the physiological effects of Yoga Nidra, in comparison to lying quietly before sleep, using a 1:1 allocation ratio between intervention and control groups.

Methods

Participants will complete both visits at our academic medical center, the Helfgott Research Institute, in Portland, Ore. This institute is part of the National University of Natural Medicine (NUNM).

Eligibility and Screening

Inclusion and exclusion criteria are described in Table 2. Prospective participants will complete a phone screening and, if eligible, a screening visit.

Initial eligibility is confirmed during the phone screening if participants score between 8 and 21 on the Insomnia Severity Index (ISI), indicating subclinical insomnia to clinical insomnia of moderate severity. Those who score above 21 will be read a medical referral. Additional inclusion/exclusion criteria (Table 2) will be discussed during this screening.

Two additional surveys (the patient health questionnaire PHQ-9 and the sleep apnea screener STOP-BANG, described in Table 3) require in-person administration and will be administered at the screening visit, Visit 1. These surveys will be completed after signing the consent form and will be used to exclude candidates with a likelihood of sleep apnea (STOP-BANG score ≥ 3) and/or moderate depression (PHQ-9 score ≥ 10). If participants are excluded during Visit 1, they will be given a referral for medical management and contact information for our clinical coinvestigator. If suicidality is perceived, they will immediately be given the number for a helpline.

Interventions

Participants act as their own baseline control by lying quietly for 90 minutes at Visit 1.

Half of the participants will be randomized to the experimental group and will listen to a Yoga Nidra recording during the first 30 minutes of the 90-minute measurement period at Visit 2. This two-visit design with randomization at Visit 2 (1–14 d after Visit 1) creates a subgroup of participants who perform the same activity at V1 and V2, allowing us to explore and account for any "first-night" effects (wherein a participant may feel more comfortable at the second visit due to familiarization with the environment).

The Yoga Nidra recording was made using scripts from Swami Satyananda Saraswati's *Yoga Nidra* book, following his guidelines for use in insomnia,[30] and with input from collaborators in the fields of Yoga Nidra, yoga therapy, and EEG analysis.[34]

Withdrawal/Discontinuation

The study is completely voluntary. Participants can leave the study at any time and do not have to give a reason. If a participant is an NUNM student or employee, deciding not to take part or deciding to leave will not affect their relationship with NUNM.

Adherence

As soon as the participant schedules their first visit, they will receive an email confirming their date/time and thanking them for joining the study. A similar email will be sent after Visit 1, thanking them for completing their visit and confirming the date for Visit 2. The study coordinator or principal investigator (PI) will call all participants the day before their visit and send a reminder email 1–2 days before the visit to ensure that participants are aware of their scheduled appointment. We will also reschedule dates as needed to accommodate unexpected schedule changes.

Concomitant Care

We ask participants during the phone screening and in our visit reminders not to make any lifestyle changes with respect to substance use (sleeping medication, alcohol, stimulants, etc.) and/or mind-body practices (including yoga and meditation) during the time as a participant in our study. We also ask that they do not use any over-the-counter sleep aids, allergy medicine, or home remedies for sleep (including CBD or melatonin) within 48 hours

of the visit. Additionally, we ask participants to avoid coffee and alcohol after 10:00 am on the day of each visit.

Outcomes and Comparators

Table 3 describes outcomes and measurement tools used, and Table 4 outlines the timeline for our study.

Individuals with insomnia typically have chronically elevated respiratory rate[37] and sympathetic nervous system activity,[37,38] both of which may contribute to difficulties falling asleep. Yoga Nidra may decrease SOL by lowering both respiratory rate and sympathetic activity while facilitating the transition into an alpha brainwave state that immediately precedes sleep. Thus, the following comparators are used during our intervention.

- **HRV (RMSSD and HF parameters):** One previous study has shown Yoga Nidra to increase HRV when practiced after Hatha Yoga and when practiced without Hatha Yoga movements beforehand.[39] Thus, as a measure of autonomic nervous system response to our Yoga Nidra intervention, we are measuring HRV, specifically root mean square of successive differences between RR intervals (RMSSD), and HF HRV parameters, which have been correlated with relaxation.[40]
- **Respiratory rate:** As a measure of autonomic nervous system response to Yoga Nidra, we are measuring respiratory rate, which has been shown to decrease during meditation.[41]
- **Alpha and theta brainwave frequencies from O1:** We will measure alpha, beta, theta, and delta brainwave frequencies from O1, C3, and F3 locations, representing all frequency ranges and the occipital (O), central (C), and frontal (F) lobes, respectively; however, our focus is on alpha and theta at O1 because these frequencies were shown by previous researchers to increase significantly during meditation.[27,32,34,41–43] EEG brainwave data will also be used to detect sleep. Sleep parameters of interest include whether sleep occurs during the intervention, time to sleep onset, and sleep efficiency.
- **Positive and Negative Affect Schedule (PANAS):** This questionnaire is used to measure mood (positive and negative affect) before and after the intervention.
- **State-Trait Anxiety Inventory (STAI):** This survey measures self-reported anxiety before and after the intervention.

Sample Size

We have calculated our sample size considering changes in EEG power for alpha frequency bands measured by other researchers studying meditation and brainwave activity. In one study of 34 novice meditators exposed to mindfulness meditation versus listening to podcasts, a 10% increase in alpha power was observed in the occipital lobe (29 (μV)2/Hz change: 300.37, control vs. 329.13, intervention), with a pooled standard deviation (SD) of

19 (μV)2/Hz) (6%, relative to control).[41] This increase in alpha activity during meditation and Yoga Nidra agrees with previous reports.[30,41,42]

Assuming our intervention will at least match this 10% power increase and allowing for the same measurement error (6%), a 90% power, and a 5% alpha, our sample size was calculated using the following equation: $n = 2((1.96 + 1.2816)^2(19)2)/(29)^2$. This yields a sample size of 9 individuals per study arm. With a predicted 20% dropout rate, we plan to recruit 11 individuals into each of two study arms, requiring 22 participants.

It should be noted that change in theta power has also been largely observed during meditation.[27,42,44] The above-referenced study[41] detected a 70% increase in theta power during mindfulness meditation in novice meditators. Using our proposed sample size of 11 per arm and the pooled SD for theta values found by Ahani et al.[41] (13%, relative to control), a change of 66% theta power could be detected using an 80% power. With this sample size, our study is well-powered to detect clinically significant, previously observed changes in EEG power in the alpha and theta bands generated from the occipital lobe during meditation and Yoga Nidra.

Recruitment and Retention

Participants will be recruited using online advertising, fliers, and newspapers distributed throughout the NUNM campus and the city of Portland. Other advertising methods will be used as needed. Our study team will also contact and screen participants from a previous yoga trial at NUNM who consented to being recruited for future studies. Compensation ($75/visit) will be advertised as well.

In addition to compensation, our retention strategy involves timely and effective communication with participants in the form of visit reminders and thank-you follow-ups. We keep open lines of communication for questions and concerns and do our best to reschedule or make accommodations when necessary.

Assignment of Interventions

Participants will be randomized using one block and 30 participants, designed so that in case of dropouts group sizes would remain equal.

Groups will be written inside of sealed envelopes by a third party. Envelopes will be stored in a locked filing cabinet until Visit 2, when the study coordinator or PI will open one, in front of the participant, to reveal the group. On the back of the envelope, the study coordinator will then sign, date, and write the group name (Yoga Nidra or Control). The group name and number will also be entered into the study Research Electronic Data Capture (REDCap) database at this time.

Our biostatistician will create a randomization sequence for 1:1 allocation between intervention and control groups. The study coordinator and PI will enroll participants and reveal groups at the beginning of Visit 2.

Our biostatistician will analyze the data for this trial. Participant groups will be indicated using a number in REDCap. Without knowing which group the numbers represent, the statistician will perform statistical comparisons between the two groups with respect to all outcome measures described. When analysis is complete, the identity of each group will be revealed.

Data Collection, Management, and Analysis

Instruments used for the following data collections are detailed in Table 3.

Self-Report Data

PANAS, STAI, and pre-/postintervention questionnaires will be completed before and after the intervention at Visits 1 and 2. Each participant will complete these surveys within REDCap on an iPad while alone in the clinic room. The postpractice survey will also include an open-ended comment box asking about participant experience during the practice, with the intention of phenomenologically exploring[28] any possible awareness occurring during sleep states[45] that may describe the state of yoga nidra.[35]

Objective Data

EEG, HRV, and respiratory rate will be collected continuously throughout the 90-minute measurement periods at both visits. The EEG montage used complies with the American Academy of Sleep Medicine guidelines for detecting sleep using EEG[46] and includes electrodes attached to one frontal lobe location (F3), a central lobe location (C3), an occipital lobe location (O1), both eyes (EOD), and the chin. A grounding electrode will be attached to the ears, and a reference will be placed on one mastoid bone (M2, behind the ear). At all visits, before measurements, an impedance check will be performed and sensors will be adjusted as needed to ensure that all EEG electrodes are collecting high-quality data. Then, baseline measurements (5 minutes eyes open and 5 minutes eyes closed) will be taken.

Data Management

All participants will be assigned a number when they join the study. This number will be used on all forms and all electronic data. Any paper forms, including W-9 forms for payment as well as adverse event (AE) report forms, will be kept in a locked filing cabinet, in a locked room, only accessible to investigators at Helfgott. All digital surveys will be administered through the secure REDCap server, and telephone screen and case report data will be entered directly into REDCap.

Every effort will be made to ensure confidentiality and to keep any shared personal health information (PHI) confidential. We will protect PHI by limiting use of identifying data. We will make an effort to ensure confidentiality by limiting where names and identifiers are stored. Identifiers will only be recorded in necessary locations such as our file matching names to numerical codes used in the study.

The first time the participant ID (the code that will replace the name) appears is on the telephone survey, the only connection in REDCap between identifying information and the

ID code. This information will not be shared outside of our study team and will only be accessed on a case-by-case basis, for example, for withdrawals. Names, assigned numbers, and contact information will also be stored as a backup in a password-protected Excel sheet, saved only by the study coordinator on an encrypted computer.

Data Analysis

All data will be stored in REDCap and exported and analyzed by our biostatistician. We acknowledge that because our sample size was based on statistical change in EEG measures, it is more likely to see meaningful change in these parameters than in the others (e.g., respiratory rate, HRV).

Specific Aim 1: EEG

Data preprocessing:

EEG data will be exported and sent to our collaborators at the University of Manitoba and the State University of New York at Canton for conversion from text file to European Data Format (EDF). EDF files will be sent to Sleep Strategies for detailed sleep scoring (sleep onset, sleep staging, sleep efficiency, etc.).

Before our analysis of changes in EEG power, the raw data will be autoprocessed according to a protocol created by the PI prior to beginning data collection. For each frequency band (beta: 13–35 Hz, where sigma can be seen between 12 and 16 Hz; alpha: 8–12 Hz; theta: 4–7.5 Hz; and delta: 0.5–3.5 Hz), the amplitude of all waves in that category are automatically averaged during each of several steps of the Yoga Nidra practice (indicated as various time intervals during the first 30 minutes) and in 5-minute intervals for the hour following the practice. The instrument will output mean EEG amplitude for each frequency band (alpha, beta, theta, and delta) for each indicated step of the 90-minute measurement period. All amplitude measurements will then be converted to power by squaring the amplitude and dividing by the median frequency of the brainwave band of interest (alpha, beta, theta, or delta). Auto-artifact removal will be performed by eliminating data points above or below 2 SD from the mean value of the individual's 90-minute session. These mean EEG power values will be exported to Excel and directly uploaded into REDCap by the PI for the following analyses. We note that although this technique was based on previous reports of the utility of similar approaches for removal of clear outlines from EEG data,[47] auto-artifact removal may not account for certain subtle physical movements.

Outcome 1:

For each individual, we will compute and compare the differences between mean EEG power values (at each of three locations and for each of four frequency bands) recorded during the entire 30-minute baseline of lying quietly (Visit 1) and the first 30 minutes of Visit 2. These differences between the treatment and control groups will be compared using independent *t* tests and analysis of covariance (ANCOVA) models adjusted for Visit 1 values.

For an exploratory analysis, this same procedure will be applied to each of the 5-minute time intervals recorded during the 90-minute session (indicating all steps of Yoga Nidra, and the hour following the practice, broken into 5-minute intervals). Control group data will further be examined for any significant changes in the participants' brainwave patterns between Visits 1 and 2 that would indicate temporal changes independent of the intervention.

All measures will be assessed for normality and transformed prior to analysis as required. If any extreme outliers are detected, we will attempt to determine whether these might have been due to measurement errors or movement artifacts and discard the outlier if this is the case. If no cause for the outlier can be detected, we will compare the main analysis with a sensitivity analysis conducted without the outlier.

Outcome 2:

We will document whether each participant fell asleep during each visit. Sleep and sleep stages (NREM and REM) will be identified by Sleep Strategies experts, following analysis of our raw EEG data. We will calculate percentage of participants who fell asleep during any point of their measurement period for each visit. Using only those individuals who fell asleep, we will also calculate: (1) average percentage of time spent in REM, NREM 1, NREM 2, and NREM 3 for each visit; and (2) percentage of people who first fell asleep during the intervention (Yoga Nidra or lying quietly) versus during the hour afterward. Mean (SD) total sleep time and % sleep efficiency will be also be computed for each of two visits for those who fell asleep. Percentage of individuals with any sleep will be compared between conditions using a chi-square test of proportions. Mean sleep time will be compared between groups using zero-inflated linear models, with sleep duration = 0 for individuals who did not fall asleep.

Outcome 3:

We will compare time to sleep onset (i.e., SOL) between control and intervention groups. SOL is measured from the start of the measurement period to persistent stage 2 sleep (as determined by experts at Sleep Strategies using our raw EEG data). SOL is measured in minutes and will be presented in terms of mean and SD for each visit. SOL will be compared between groups using a Cox regression, with onset of sleep coded as the event. This outcome will be examined more closely in a larger future clinical trial investigating the effects of Yoga Nidra on sleep latency.

Specific Aim 2: Respiratory Rate and HRV

Data preprocessing:

Respiratory rate data will be obtained by contacting the Spire Company to retrieve raw data from one device to be used by all 22 participants throughout the course of our trial. Clinic visit times (including start time for each measurement) will be carefully noted in REDCap to accurately extract average respiratory rate data, by participant, for each step of our intervention during Visits 1 and 2. The PI will calculate mean respiratory rate values for each time point in Excel, then upload these values to REDCap for analysis by our biostatistician.

H RV data will be uploaded using the FirstBeat Uploader and then analyzed using Kubios. Artifacts (due to movement of the sensor, etc.) will be removed using the program's settings for low, medium, or high error, depending on the PI's interpretation of results. She will also work with the medical technician at Heart Math to determine appropriate artifact settings for each session. Data will then be manually processed for each time interval throughout the 90-minute session. Results will be processed in Excel and uploaded into REDCap for further analysis.

Outcome 1:

The same analysis technique described in "specific aim 1, outcome 1" for EEG values (within- and between-group comparison of intervention and control groups from Visit 1 to Visit 2, by time interval) will be applied to respiratory rate and HRV data. These comparisons will reveal whether a significant (1) decrease in respiratory rate or (2) increase in HRV parameters can be detected at any point during Yoga Nidra, or during the hour afterward, relative to control.

Specific Aim 3: Feasibility (Credibility and Intervention Conditions)

Outcome 1:

Feedback given using the continuous slider-scale questions on the pre-/postintervention surveys will be converted in REDCap to a quantifiable value between 1 and 100. Results will reveal how positive our sample was that they would experience mental, physical, or emotional relaxation and whether it could help them fall asleep. Results of expectancy analysis will be presented as % positive expectancy before our intervention versus afterward for each parameter of mental, physical, and emotional relaxation, as well as for ability of the practice to help them fall asleep at night.

Outcome 2:

In addition to expectancy, intervention acceptability will be assessed using recruitment (goal: target sample size within 3 months) and retention (< 50% goal) outcomes. During the postintervention questionnaire, slider scales will also be used to assess comfort level and intervention tolerability. Slider-scale questions will be scored and reported in the same way as the expectancy questions above (specific aim 3, outcome 1). Multiple-choice options are provided for questions inquiring about challenges and distractions appearing during each visit. Results will be presented as % of the sample that answered in each way. An open-ended comment box is also included in the postintervention survey. These responses will be analyzed using qualitative approaches to determine trends, consider areas for improvement, and explore participant experiences of possible awareness during sleep.

Acute changes at each visit (exploratory):

Momentary anxiety (STAI-Y6) and mood (PANAS) will be analyzed before and after the measurement period of each visit. Data will be analyzed using directions on each survey. The primary analysis will be a between-group comparison of change in pre-to-post difference from Visit 1 to Visit 2 using independent *t* tests and ANCOVA models, as above. Within-group analyses will also be conducted for each group (intervention and control).

Pre/post change in anxiety and mood scores will be compared for Visits 1 and 2 using a two-tailed paired *t* test. This analysis will assess whether Yoga Nidra affects anxiety and/or mood differently than lying quietly; in the control group, we will obtain information on changes in these measures corresponding to repeat performance of the control visit.

Methods for Imputation and/or Consideration of Protocol Nonadherence

Although our aim is to collect all outcomes for every participant at each visit, in the case that a participant does not complete a survey or our devices or visit coordinators fail to collect physiological data, missing data points will be omitted from analysis. When computing average measures over a time interval, we will allow use of an average of nonmissing values from an individual as long as at least 80% of measures are available within that interval. Cases of deviation from protocol will be documented within our study folder and will be reported to the institutional review board (IRB) during annual continuing reviews or sooner if the AE is serious or requires a change in protocol. The PI will have responsibility for reporting to the NUNM IRB as required.

Monitoring and Adverse Event Reporting

This is a largely noninvasive and minimal-risk study. The PI and clinical coinvestigator will monitor safety of this study. Any safety concerns will be discussed, and protocol changes will result as needed, after clearance with the IRB, through a protocol-amendment approval process. AEs will be documented within our study folder and will be reported to the IRB at the annual continuing review or earlier if needed.

Possible risks of this study include the following:

- Minimal risk of loss of confidentiality.
- Bringing up possibly upsetting memories or emotions.
- If suddenly woken, participants may become startled, dizzy upon standing, and/or disoriented.
- There may be minimal discomfort from the gel and electrodes worn on the top and back of the head, the eyes, and the chin, with a grounding electrode on the ear and a reference electrode behind the ear.
- Minimal discomfort or distraction from wearing the adhesive heart rate variability device on the chest.

Possible study benefits include the following:

- Participation will help us learn more about Yoga Nidra as a possible intervention to address insomnia in adults.
- Participation will be useful for assessing feasibility of this intervention and devices.
- Participants may receive mental, physical, and emotional benefits from the practice of Yoga Nidra, including relaxation, emotional release, and mental relaxation.

AEs reported by participants or observed by the study coordinator or PI at any time will be recorded on the Standardized Adverse Events Questionnaire: Spontaneous Reporting form. This form captures the source of the AE report, the severity/grade of the report (mild/moderate/severe), any clinical actions taken, and the current state of the AE. Following a spontaneous report, the study team will develop a response plan. All AEs and response plans will be recorded in the adverse event log for this study and reported as noted above. If a participant believes they have suffered an AE due to participation in the study, they are encouraged to report it. Our study team and NUNM will determine whether compensation or support is required.

Table 5 outlines the data-auditing plan.

Ethics

Approval and Amendments

The protocol for this study has been approved by the NUNM IRB.

The NUNM IRB will continue to review all protocol amendment forms as needed to ensure adequate safety and effectiveness of the trial, as well as reach recruitment and retention goals.

Consent or Assent

At the beginning of Visit 1, participants will be given a consent form that outlines the research and the information we aim to gain from this study. They will be given ample time to read this form and offer their signature if they wish to participate. The study coordinator or PI, to the best of their abilities, will answer any questions. Further questions about participant data or safety will be forwarded to the IRB.

We do not collect biological samples that could be reused; however, we do obtain consent from participants if they would like us to maintain their contact information for recruitment into future studies.

Confidentiality

We make every effort to ensure privacy and confidentiality of study participants. The study team has been trained in human subjects research, responsible conduct of research, and the U.S. Health Insurance Po rtability and Accountability Act (HIPAA). Participants will be informed of our intent to maintain confidentiality. Our team will not request data beyond what is stated on the informed consent form.

Each participant will be assigned a unique alphanumeric ID upon screening. All survey and physiological data will be saved by participant number to protect participant confidentiality. The REDCap database for this project will only be accessible by members of our study team including the PI, clinical coinvestigator, biostatistician, and study coordinator.

Only the PI, coinvestigator, and biostatistician will have access to study data in REDCap, while the study coordinator will only have access certain surveys to be completed at clinic

visits. Deidentified data will be backed up on a secure R-Drive accessible only to Helfgott personnel. The password-protected recruitment spreadsheet with participant information will be stored in this location and accessible only by the PI and study coordinator.

Dissemination

Final results from this study will be shared in clinicaltrials.gov no later than the time of the first publication of the data. In addition, protocol designs and preliminary results will be shared at local, national, and international conferences.

Individuals who contributed to the protocol design, data analysis and interpretation, or writing and editing of the manuscript will be invited to be authors.

Our protocol is available on clinicaltrials.gov (identifier NCT03685227). We will publish relevant data and results and share them with journal editors and other investigators upon request.

The informed consent form is available from the corresponding author of this article (ES).

Acknowledgments

We acknowledge the contributions of Gandhar, Kate, and Vishwas Mandlik (a student of Satyananda Saraswati) toward the development of the Yoga Nidra script used in this study.

This article represents protocol 10.3.2018, version 1.7

This trial was funded by the R90 BRIDG Program, supported by grant 5R90AT00892403 from the National Center for Complementary and Integrative Health of the U.S. National Institutes of Health.

Author ES is the principal investigator; RB is co-clinical investigator; AL and MB are coinvestigators; and DH is the biostatistician. Trina Soileau, National University of Natural Medicine, is the study coordinator. ES will be responsible for trial operations, regulatory requirements, IRB reporting, leading study visits, and ensuring proper data collection/input.

References

1. Neuendorf R, Wahbeh H, Chamine I, Yu J, Hutchison K, & Oken BS (2015). The effects of mind-body interventions on sleep quality: A systematic review. Evidence-Based Complementary and Alternative Medicine, 2015, 902708. 10.1155/2015/902708 [PubMed: 26161128]
2. Cappuccio FP, & Miller MA (2017). Sleep and cardio-metabolic disease. Current Cardiology Reports, 19(11), 110. 10.1007/s11886-017-0916-0 [PubMed: 28929340]
3. Asnis GM, Thomas M, & Henderson MA (2015). Pharmacotherapy treatment options for insomnia: A primer for clinicians. International Journal of Molecular Sciences, 17(1). 10.3390/ijms17010050
4. Kripke DF (2016). Hypnotic drug risks of mortality, infection, depression, and cancer: But lack of benefit. F1000Research, 5, 918. 10.12688/f1000research.8729.3 [PubMed: 27303633]
5. Kripke DF (2000). Chronic hypnotic use: Deadly risks, doubtful benefit. Sleep Medicine Review, 4(1), 5–20. 10.1053/smrv.1999.0076
6. Petrov ME, Howard VJ, Kleindorfer D, Grandner MA, Molano JR, & Howard G (2014). Over-the-counter and prescription sleep medication and incident stroke: The REasons for Geographic and Racial Differences in Stroke study. Journal of Stroke and Cerebrovascular Diseases, 23(8), 2110–2116. 10.1016/j.jstrokecerebrovasdis.2014.03.025 [PubMed: 25113086]
7. Andersen LP, Gögenur I, Rosenberg J, & Reiter RJ (2016). The safety of melatonin in humans. Clinical Drug Investigation, 36(3), 169–175. 10.1007/s40261-015-0368-5 [PubMed: 26692007]

8. Chou TL, Chang LI, & Chung MH (2015). The mediating and moderating effects of sleep hygiene practice on anxiety and insomnia in hospital nurses. International Journal of Nursing Practice, 21(suppl. 2), 9–18. 10.1111/ijn.12l64 [PubMed: 26125570]
9. Irish LA, Kline CE, Gunn HE, Buysse DJ, & Hall MH (2015). The role of sleep hygiene in promoting public health: A review of empirical evidence. Sleep Medicine Review, 22, 23–36. 10.1016/j.smrv.2014.10.001
10. Schroeck JL, Ford J, Conway EL, Kurtzhalts KE, Gee ME, Vollmer KA, & Mergenhagen KA (2016). Review of safety and efficacy of sleep medicines in older adults. Clinical Therapeutics, 38(11), 2340–2372. 10.1016/j.clinthera.2016.09.010 [PubMed: 27751669]
11. Mack LJ, & Rybarczyk BD (2011). Behavioral treatment of insomnia: A proposal for a stepped-care approach to promote public health. Nature and Science of Sleep, 3, 87–99. 10.2147/NSS.S12975
12. Swedish Council on Health Technology Assessment. (2010). Treatment of insomnia in adults: A systematic review. Swedish Council on Health Technology Assessment (SBU).
13. Koffel E, Bramoweth AD, & Ulmer CS (2018). Increasing access to and utilization of cognitive behavioral therapy for insomnia (CBT-I): A narrative review. Journal of General Internal Medicine, 33(6), 955–962. 10.1007/s11606-018-4390-1 [PubMed: 29619651]
14. McCurry SM, Guthrie KA, Morin CM, Woods NF, Landis CA, Ensrud KE, … LaCroix AZ (2016). Telephone-based cognitive behavioral therapy for insomnia in perimenopausal and postmenopausal women with vasomotor symptoms: A MsFLASH randomized clinical trial. JAMA Internal Medicine, 176(7), 913–920. 10.1001/jamainternmed.2016.1795 [PubMed: 27213646]
15. Koffel E, Kuhn E, Petsoulis N, Erbes CR, Anders S, Hoffman JE, … Polusny MA (2018). A randomized controlled pilot study of CBT-I Coach: Feasibility, acceptability, and potential impact of a mobile phone application for patients in cognitive behavioral therapy for insomnia. Health Informatics Journal, 24(1), 3–13. 10.1177/1460458216656472 [PubMed: 27354394]
16. Gunn HE, Tutek J, & Buysse DJ (2019). Brief behavioral treatment of insomnia. Sleep Medicine Clinics, 14(2), 235–243. 10.1016/j.jsmc.2019.02.003 [PubMed: 31029189]
17. Trauer JM, Qian MY, Doyle JS, Rajaratnam SM, & Cunnington D (2015). Cognitive behavioral therapy for chronic insomnia: A systematic review and meta-analysis. Annals of Internal Medicine, 163(3), 191–204. 10.7326/m14-2841 [PubMed: 26054060]
18. Morin CM, Vallières A, Guay B, Ivers H, Savard J, Mérette C, … Baillargeon L (2009). Cognitive behavioral therapy, singly and combined with medication, for persistent insomnia: A randomized controlled trial. JAMA, 301(19), 2005–2015. 10.1001/jama.2009.682 [PubMed: 19454639]
19. Gouw VXH, Jiang Y, Seah B, He H, Hong J, & Wang W (2019). Effectiveness of internal qigong on quality of life, depressive symptoms and self-efficacy among community-dwelling older adults with chronic disease: A systematic review and meta-analysis. International Journal of Nursing Studies, 99, 103378. 10.1016/jdjnurstu.2019.06.009 [PubMed: 31450083]
20. Sullivan MB, Erb M, Schmalzl L, Moonaz S, Noggle Taylor J, & Porges SW (2018). Yoga therapy and polyvagal theory: The convergence of traditional wisdom and contemporary neuroscience for self-regulation and resilience. Frontiers in Human Neuroscience, 12, 67. 10.3389/fnhum.2018.00067 [PubMed: 29535617]
21. Khalsa SB (2004). Treatment of chronic insomnia with yoga: A preliminary study with sleep-wake diaries. Applied Psychophysiology and Biofeedback, 29(4), 269–278. 10.1007/s10484-004-0387-0 [PubMed: 15707256]
22. Ong JC, Manber R, Segal Z, Xia Y, Shapiro S, & Wyatt JK (2014). A randomized controlled trial of mindfulness meditation for chronic insomnia. Sleep, 37(9), 1553–1563. 10.5665/sleep.4010 [PubMed: 25142566]
23. Kligler B, Teets R, & Quick M (2016). Complementary/integrative therapies that work: A review of the evidence. American Family Physician, 94(5), 369–374. [PubMed: 27583423]
24. Chiu HY, Chiang PC, Miao NF, Lin EY, & Tsai P S. (2014). The effects of mind-body interventions on sleep in cancer patients: A meta-analysis of randomized controlled trials. Journal of Clinical Psychiatry, 75(11), 1215–1223. 10.4088/JCP.13r08918

25. Shealy RC (1979). The effectiveness of various treatment techniques on different degrees and durations of sleep-onset insomnia. Behaviour Research and Therapy, 17(6), 541–546. 10.1016/0005-7967(79)90097-4 [PubMed: 393245]
26. Wang X, Li P, Pan C, Dai L, Wu Y, & Deng Y (2019). The effect of mind-body therapies on insomnia: A systematic review and meta-analysis. Evidence-Based Complementary and Alternative Medicine, 2019, 9359807. 10.1155/2019/9359807 [PubMed: 30894878]
27. Shapiro DH Jr., & Giber D (1978). Meditation and psychotherapeutic effects: Self-regulation strategy and altered state of consciousness. Archives of General Psychiatry, 35(3), 294–302. 10.1001/arch-psyc.1978.01770270044003 [PubMed: 365121]
28. Ong JC, & Smith CE (2017). Using mindfulness for the treatment of insomnia. Current Sleep Medicine Reports, 3(2), 57–65. 10.1007/s40675-017-0068-1 [PubMed: 30294523]
29. Britton WB, Lindahl JR, Cahn BR, Davis JH, & Goldman RE (2014). Awakening is not a metaphor: The effects of Buddhist meditation practices on basic wakefulness. Annals of the New York Academy of Sciences, 1307, 64–81. 10.1111/nyas.12279 [PubMed: 24372471]
30. Saraswati SS (2013). Yoga nidra (6th ed.). New Delhi: Thomson Press (India) Limited.
31. Mandlik V (2008). In Huddart VPL (Ed.), Yoga sopan (easy way to health: physical and mental). Naskih, Maharashtra, India: Yoga Chaitanya Prakashan.
32. Davidson JM (1976). The physiology of meditation and mystical states of consciousness. Perspectives in Biology and Medicine, 19(3), 345–379. [PubMed: 958856]
33. Tanaka H, Hayashi M, & Hori T (1996). Statistical features of hypnagogic EEG measured by a new scoring system. Sleep, 19(9), 731–738. [PubMed: 9122561]
34. Mandlik V, Jain P, & Jain K (2009). Effect of yoga nidra on EEG [unpublished report]. Nasik, Maharastra, India: Yoga Vidya Gurukul University.
35. Parker S, Bharati SV, & Fernandez M (2013). Defining yoga-nidra: Traditional accounts, physiological research, and future directions. International Journal of Yoga Therapy, 23(1), 11–16. [PubMed: 24016819]
36. Parker S (2019). Training attention for conscious non-REM sleep: The yogic practice of yoga-nidra and its implications for neuroscience research. Progress in Brain Research, 244, 255–272. 10.1016/bs.pbr.2018.10.016 [PubMed: 30732840]
37. Bonnet MH, & Arand DL (1998). Heart rate variability in insomniacs and matched normal sleepers. Psychosomatic Medicine, 60(5), 610–615. [PubMed: 9773766]
38. Tobaldini E, Nobili L, Strada S, Casali KR, Braghiroli A, & Montano N (2013). Heart rate variability in normal and pathological sleep. Frontiers in Physiology, 4, 294. 10.3389/fphys.2013.00294 [PubMed: 24137133]
39. Markil N, Whitehurst M, Jacobs PL, & Zoeller RF (2012). Yoga nidra relaxation increases heart rate variability and is unaffected by a prior bout of hatha yoga. Journal of Alternative and Complementary Medicine, 18(10), 953–958. 10.1089/acm.2011.0331 [PubMed: 22866996]
40. McCraty R, Atkinson M, Tomasino D, & Bradley RT (2009). The coherent heart—Brain interactions, psychophysiological coherence, and the emergence of system-wide order. Integral Review, 5(2).
41. Ahani A, Wahbeh H, Nezamfar H, Miller M, Erdogmus D, & Oken B (2014). Quantitative change of EEG and respiration signals during mindfulness meditation. Journal of NeuroEngineering and Rehabilitation, 11, 87–87. 10.1186/1743-0003-11-87 [PubMed: 24939519]
42. Cahn BR, & Polich J (2006). Meditation states and traits: EEG, ERP, and neuroimaging studies. Psychological Bulletin, 132(2), 180–211. 10.1037/0033-2909.132.2.180 [PubMed: 16536641]
43. West M (1979). Meditation. British Journal of Psychiatry, 135, 457–467.
44. Lou HC, Kjaer TW, Friberg L, Wildschiodtz G, Holm S, & Nowak M (1999). A 15O-H2O PET study of meditation and the resting state of normal consciousness. Human Brain Mapping, 7(2), 98–105. [PubMed: 9950067]
45. Dor-Ziderman Y, Berkovich-Ohana A, Glicksohn J, & Goldstein A (2013). Mindfulness-induced selflessness: A MEG neurophenomenological study. Frontiers in Human Neuroscience, 7, 582–582. 10.3389/fnhum.2013.00582 [PubMed: 24068990]

46. Berry R, Brooks R, Gamaldo C, Harding S, Lloyd R, Marcus C, & Vaughn B (2017). The AASM manual for the scoring of sleep and associated events: Rules, terminology and technical specifications (v. 2.4). American Academy of Sleep Medicine.
47. Delorme A, Makeig S, & Sejnowski T (2001). Automatic artifact rejection for EEG data using high-order statistics and independent component analysis. In Proceedings of the 3rd International Independent Component Analysis and Blind Source Decomposition Conference, San Diego, Dec. 9–12.
48. Kocak M, Ulmer JL, Sahin Ugurel M, Gaggl W, & Prost RW (2009). Motor homunculus: Passive mapping in healthy volunteers by using functional MR imaging—Initial results. Radiology, 251(2), 485–492. 10.1l48/radiol.2512080231 [PubMed: 19261925]
49. Sallés L, Gironès X, & Lafuente JV (2015). Organización motora del córtex cerebral y el papel del sistema de las neuronas espejo. Repercusiones clínicas para la rehabilitación [The motor organization of cerebral cortex and the role of the mirror neuron system. Clinical impact for rehabilitation]. Medicina Clinica, 144(1), 30–34. 10.1016/j.medcli.2013.12.013 [PubMed: 24613375]
50. Lee EH, Lee SJ, Hwang ST, Hong SH, & Kim JH (2017). Reliability and validity of the Beck Depression Inventory-II among Korean adolescents. Psychiatry Investigation, 14(1), 30–36. 10.4306/pi.2017.14.1.30 [PubMed: 28096872]
51. Kroenke K, Spitzer RL, & Williams JB (2001). The PHQ-9: Validity of a brief depression severity measure. Journal of General Internal Medicine, 16(9), 606–613. 10.1046/j.1525-1497.2001.016009606.x [PubMed: 11556941]
52. Sargento P, Perea V, Ladera V, Lopes P, & Oliveira J (2014). Measurement properties of a screening questionnaire of obstructive sleep apnea risk: Little information, great prediction? Sleep Science, 7(2), 89–95. 10.1016/j.slsci.2014.09.008 [PubMed: 26483909]
53. Carvalho HW, Andreoli SB, Lara DR, Patrick CJ, Quintana MI, Bressan RA, … Jorge MR (2013). Structural validity and reliability of the Positive and Negative Affect Schedule (PANAS): Evidence from a large Brazilian community sample. Revista Brasileira de Psiquiatria, 35(2), 169–172. 10.1590/1516-4446-2012-0957 [PubMed: 23904023]
54. Quek KF, Low WY, Razack AH, Loh CS, & Chua CB. (2004). Reliability and validity of the Spielberger State-Trait Anxiety Inventory (STAI) among urological patients: A Malaysian study. The Medical Journal of Malaysia, 59(2), 258–267. [PubMed: 15559178]
55. Dear BF, Titov N, Sunderland M, McMillan D, Anderson T, Lorian C, & Robinson E (2011). Psychometric comparison of the generalized anxiety disorder scale-7 and the Penn State Worry Questionnaire for measuring response during treatment of generalised anxiety disorder. Cognitive Behaviour Therapy, 40(3), 216–227. 10.1080/16506073.2011.582138 [PubMed: 21770844]
56. Zhong QY, Gelaye B, Sánchez SE, & Williams MA (2015). Psychometric properties of the Pittsburgh Sleep Quality Index (PSQI) in a cohort of Peruvian pregnant women. Journal of Clinical Sleep Medicine, 11(8), 869–877. 10.5664/jcsm.4936 [PubMed: 25845902]
57. Schnall R, Liu J, Cho H, Hirshfield S, Siegel K, & Olender S (2017). A health-related quality-of-life measure for use in patients with HIV: A validation study. AIDS Patient Care and STDs, 31(2), 43–48. 10.1089/apc.2016.0252 [PubMed: 28051875]
58. Aliverti A (2017). Wearable technology: Role in respiratory health and disease. Breathe, 13(2), e27–e36. 10.1183/20734735.008417 [PubMed: 28966692]
59. Mandryk RL, & Atkins MS (2007). A fuzzy physiological approach for continuously modeling emotion during interaction with play technologies. International Journal of Human-Computer Studies, 65(4), 329–347.
60. Mandryk RL, Inkpen KM, & Calvert TW (2006). Using psychophysiological techniques to measure user experience with entertainment technologies. Behaviour & Information Technology, 25(2), 141–158.
61. Parak J, & Korhonen I (n.d.) Accuracy of Firstbeat Bodyguard 2 beat-to-beat heart rate monitor. Industry white paper retrieved from https://assets.first-beat.com/firstbeat/uploads/2015/11/white_paper_bodyguard2_final.pdf

Table 1.

Steps of Yoga Nidra

Step	Time (s)	Description	Rationale
Introduction	166	Instructions to lie supine, hands apart	Physical relaxation
Antar mouna (inner silence)	54	Awareness of sounds (moving from far away to nearby)	Beginning of *pratyahara* (sense withdrawal)
Visualize body	62		
Awareness of body and space	35	"I will not sleep"	
Awareness of meeting points between body and floor	103		
Resolve	44	Establish a personal goal	Creating intention
Rotation of consciousness	197	Awareness of each body part	Pratyahara achieved by rapidly shifting awareness from one body part to another and finally away from the body; release of physical tension; release of mental tension[a]
Natural breath and *nadi shodhana* instructions	106	Alternate-nostril breathing	*Pranayama* (controlled breathing); pratyahara achieved by shifting awareness away from body parts to the breath
Nadi shodhana independent practice	269		
Opposites: heaviness	40	Recollecting experiences of opposite sensations	Emotional release; systematic arousal of feeling, sensation, and experience
Opposites: lightness	39		
Opposites: cold	34		
Opposites: hot	41		
Opposites: pain	31		
Opposites: pleasure	36		
Checking that the person is still focused on the recording	16	"Are you awake?"	Awareness of tiredness/sleepiness
Visualizations	211	Guided imagery	Mental relaxation; pratyahara achieved through focus on imagined scenes and emotions rather than the physical body
Resolve	35		Regaining focus on the personal goal
Awareness of body/breath	31		Bringing awareness back to the body and present moment
Omkar chanting	22		
Mental Omkar chanting	10		
Awareness of surroundings/room	16		
Closing	6	"Adjust your body for comfort"	Permission to sleep

Int J Yoga Therap. Author manuscript; available in PMC 2022 March 18.

Step	Time (s)	Description	Rationale
	5	"Stop listening, let your mind go"	
	3	"Yoga Nidra is now complete"	
Total time	27 min		

[a]It is proposed that sending a signal from body to brain following the same pattern as this neuronal map progressively relaxes the mind.[30](p. 261),48,49

Table 2.

Exclusion Criteria and Rationale

Inclusion Criteria (Rationale)	Exclusion Criteria (Rationale)
• Age 18–45 (adults, premenopause) • Can hear (intervention is a recording) • Can understand English (recording in English) • Insomnia Severity Index (ISI) score of 8–21 (subclinical to moderately severe clinical insomnia) • Can lie on a massage table for 90 min (lying meditation)	• Regular mind-body practice within 6 mo (may affect response) • Sleeping pills (masking of intervention effects) • Cannabis within 30 d (masking intervention effects) • Smoke cigarettes (interference with relaxation) • Sleep apnea STOP-BANG score ≥ 3 (interference with sleep) • Moderate depression, PHQ-9 score ≥ 10 (interference with sleep) • Stimulant, opioid, or illegal drug use (disrupted sleep) • Shift work (irregular sleep) • > 14 alcoholic drinks/wk (interference with REM sleep) • Unavoidable disruptions to sleep (e.g., new baby, pet, or other dependent; insomnia may not be the issue)

Considerations: Participants who are unable to lie supine can assume another comfortable position. General anxiety will be documented in our population using the Generalized Anxiety Disorder (GAD-7) survey upon intake. Comorbidities, including any diagnosed disease/disorder, will be documented along with any regular substance use that is not grounds for exclusion from this study (alcohol use, caffeine use, medications, etc.).

Table 3.

Measurement Tools/Forms and Their Purposes

Measurement Tool	Standardization	Recall Period	Purpose
Patient Health Questionnaire (PHQ2/PHQ9)	Y: correlates well ($r = 0.75$)[50] to the Beck Depression Index (depression in the present moment); Cronbach's alpha = 0.89[51]	2 wk	Depression screener used in recruitment (Visit 1)
Insomnia Severity Index (ISI)	Y	14 d	Insomnia assessment (telephone screen)
Baseline intake	N (in house)	General	To gather information on contact details; demographics (age, gender, menopause, ethnicity, language, ability to hear); substance use (alcohol, stimulants, sleeping pills, cannabis); lifestyle (disruptions to sleep, shift work, mind-body practice); and comorbidities (a diagnosis of fibromyalgia, sleep apnea, insomnia, or depression)
Sleep apnea screener (STOP-BANG)	Y: with minimal information requested, it is adequate for use in informal diagnosis; Cronbach's alpha = 0.74[52]	General	To predict sleep apnea at Visit 1 based on: snoring, tiredness, observations of interrupted breathing, blood pressure, BMI, age, neck circumference, and gender
Positive and Negative Affect Schedule (PANAS)	Y: Cronbach's alpha = 0.87 (negative affect) and 0.88 (positive affect)[53]	Moment	Assessment of mood (20 questions) before/after visit
State-Trait Anxiety Inventory Y-6 (STAI-Y6)	Y: Cronbach's alpha = 0.89 for total scores[54]	Moment	Anxiety measurement (6 questions) before/after visit
Consent form (CF)	N (in house)	General	Confirmation of participant willingness to participate in the study
Preintervention survey (PreI)	N (in house)	Moment	Assessment of participant perceptions about the intervention before they experience it
		1 d	Documentation of behavior and substance use in the last 24 hours (exercise, alcohol, caffeine intake, sleep quality, tiredness and restedness)
Generalized Anxiety Disorder Survey (GAD-7)	Y: correlates moderately with the Penn State Worry Questionnaire ($r = 0.51–0.71$); Cronbach's alpha = 0.79–0.91[55]	2 wk	Anxiety assessment (7 questions) at intake
Pittsburgh Sleep Quality Index (PSQI)	Y: scores ≥ 5 indicate poor sleep quality; this survey correlates with other surveys used here (PHQ-9 [0.49] and GAD-7 [0.46]); Cronbach's alpha = 0.57[56]	30 d	Sleep quality assessment at intake
Patient-Reported Outcomes Measurement Information System (PROMIS-29)	Y: Cronbach's alpha = 0.87–0.97[57]	7 d	Assessment of disturbed sleep, depression, anxiety, pain, and other health outcomes at intake
Respiratory rate (RR) monitor (Spire)	This device is popularly used and attracting research interest[58]	Real-time, continuous	To gather data on breathing rate; Spire is a wearable, wireless sensor clipped to a belt
Electroencephalograph (EEG) (ProComp Infiniti device with BioGraph Infiniti software)	This device has been used in research for measurement of various physiological parameters[59,60]	Real-time, continuous	To gather data on brainwave patterns and sleep
Heart rate variability (HRV; BodyGuard2)	Validated against a clinical ECG with offline R-wave detection; Bodyguard 2 has a high beat detection rate and	Real-time, continuous	To gather data on HRV; the device is a wearable, wireless sensor placed on the chest

Measurement Tool	Standardization	Recall Period	Purpose
	provides accurate HRV analysis in many conditions (sitting, lying, standing, walking, etc.)[61]		
Postintervention exit survey (PE)	N (in house)	2 h	To gather perceptions of the intervention after experiencing it (credibility/acceptability/tolerability) and feedback about intervention conditions (comfort, challenges, other)

Table 4.

Intervention Outline/Schedule

	Consent	Arrival Surveys	Physiological Measurements			Exit Surveys		
Schedule	**CF**	**STOP-BANG,* PreI, PHQ-2 to PHQ-9,* GAD-7,* PSQI,* PROMIS-29,* PANAS, STAI-Y6**	**RR**	**EEG**	**ECG**	**PANAS**	**STAI-Y6**	**PE**
Checkin	Visit 1 only	*Visit 1 only						
Prepractice baseline: 5-min eyes open; 5-min closed								
During practice[a] (first 30 min) Visit 1: lying quietly Visit 2[b]: Yoga Nidra or lying quietly								
Naptime (final 60 min)								
Checkout								

[a]Study coordinator will turn out lights and leave the room during measurements. A sound monitor will be in the room in case assistance is needed.

[b]Participants will be randomized using one block and 22 subjects. For allocation concealment, groups will be written inside of sealed envelopes by a third party. Envelopes will be stored in a locked filing cabinet until Visit 2, when the study coordinator opens them to reveal the group.

See Table 3 for measure abbreviations.

Table 5.

Data-Auditing Plan

Data Type	Frequency of Review	Reviewer
Subject accrual (including compliance with protocol enrollment criteria)	Weekly	PI
	Monthly	Study team
Status of all enrolled subjects, as of date of reporting	Weekly	PI
Data-entry quality-control checks	Each visit Per occurrence	PI PI
SAEs (unexpected and related)	Per occurrence	PI
SAEs (expected or unrelated)	Per occurrence	PI
Unanticipated problems	Per policy	IRB

PI = principal investigator (ES); SAE = serious adverse event; IRB = institutional review board.