Title: Adapting a Mindfulness Intervention to Improve Sleep and Reduce Diabetes Risk Among a Diverse Sample in Atlanta (MINDS)

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Project Goal: The goal of the project is to conduct a pilot study to determine the feasibility of delivering a MBSR plus sleep education intervention to improve sleep and subsequently improve subclinical biomarkers for T2DM risk among a community sample of racially diverse adults (N=20) with poor sleep quality and pre-diabetes.

Rationale: T2DM is a growing problem that currently affects more than 30 million Americans,[1] thereby highlighting the need for novel and innovative interventions to reduce T2DM risk. The pathogenesis of T2DM is complex and involves both impairments in pancreatic insulin secretion as well as reductions in insulin sensitivity.[18] Evidence suggests that both the processes of insulin secretion and insulin sensitivity are influenced by sleep. Early experimental sleep restriction studies noted marked alterations in insulin secretion and glucose uptake after a sleep duration of only four hours, indicating decreased glucose tolerance during sleep loss.[19] Furthermore, the disposition index which is a product of acute insulin response to glucose and insulin sensitivity, was decreased by 37% in a state of sleep deprivation compared to a fully rested state,[19] thereby indicating that T2DM related metabolic perturbations can occur due to shortened sleep duration.

Inadequate sleep (e.g. short sleep duration, poor sleep quality, sleep disturbances) is a public health burden. One-third of US adults are not consistently getting adequate sleep.[20] In recent years, an increasing number of studies have reported an association between sleep duration and T2DM risk. A study following men without T2DM at baseline for 16 years noted that men reporting a sleep duration of 6 hours of sleep per night were twice as likely to develop T2DM compared to those who achieved 7 hours.[20] Similarly, a meta-analysis assessing the relationship between sleep and T2DM incidence found that those with a sleep duration of 5-6 hours per night were 1.3 times more likely to develop incident T2DM compared to those who slept on average 8 hours per night.[21]

While the evidence linking sleep loss to T2DM risk is mounting, traditional T2DM prevention trials have focused primarily on weight loss through diet and physical activity interventions.[4–7] In the Diabetes Prevention Program randomized clinical trial, T2DM incidence was reduced by 58% with intensive lifestyle modification after 3 years. However, after 10 years of follow-up the decrease in diabetes incidence was attenuated to 34% between the lifestyle intervention group and the placebo group,[22] thereby indicating declines in efficacy over time. Furthermore, attempts to translate weight loss focused T2DM prevention trials into real world settings have proven modest at best, in part because of the difficulty in sustaining weight loss over time.[8] Given the challenging nature of translating weight loss based interventions, as well as the association between shortened sleep and T2DM incidence, the translation of interventions to improve sleep present a novel method to reduce T2DM risk.

Racial minorities are disproportionately affected by both inadequate sleep as well as T2DM.[12,13,21,23] Data from the Multi-Ethnic Study of Atherosclerosis showed that black, Hispanic and Asian participants had a higher prevalence of short sleep compared to non-Hispanic whites.[13] Similar disparities are observed for T2DM.[12] Data from the National Health Interview Survey indicate that although suboptimal sleep duration (short and long) were associated with T2DM in black and white adults, the prevalence of T2DM was higher at any level of sleep in blacks.[24] These results underscore the importance of intervening on sleep to reduce T2DM risk, particularly among racial minorities. Although there is a lack of data among racial minorities, studies among general populations have shown that intervening on sleep can improve insulin sensitivity. In fact, a study among a healthy population found that extending sleep was correlated with improvements in insulin levels ($r = -0.60$, $P = 0.025$), and insulin sensitivity ($r = +0.76$, $P = 0.002$).[25] More evidence is needed to confirm whether sleep improvement impacts subclinical biomarkers for T2DM.

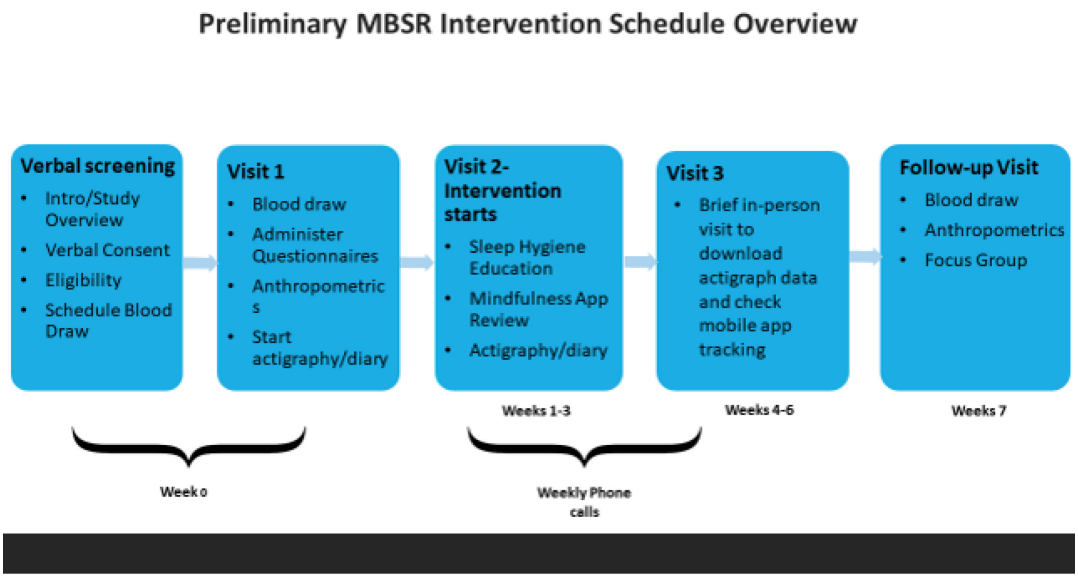
Psychosocial stressors remain a contributing factor to inadequate sleep,[26–29] and intervening on stress may result in sleep improvements. Mindfulness-based stress reduction (MBSR) is a evidenced-based intervention that focuses on mindfulness mediation, breathing, and other relaxing methods to reduce negative affect and improve vitality and coping. [30,31] MBSR is effective at reducing stress levels, ruminative thinking, and anxiety,[32] all contributors to poor sleep.[33] Results of a systematic review indicate that increased practice of mindfulness techniques is associated with improved sleep.[17] However more research is needed, particularly regarding the uptake of home practice.[34] Furthermore, evidence regarding the uptake of MBSR among populations most-at-risk for inadequate sleep and T2DM is lacking.

Hypothesis and Design: Our overarching hypothesis is *that the MBSR intervention will improve sleep quality, extend sleep duration and improve general sleep complaints and that that participants who complete the MBSR plus sleep education intervention will have improvements in glucose levels, lipid levels, blood pressure, and biomarkers associated with stress response.*

Project Design: Population: The target population is a racially diverse community sample of adults aged 18 years or older who reside in the Atlanta, GA area (N=20). Eligible participants will be proficient in English language, have a iPhone (for the purposes of the application), a sleep quality score ≥5 on the validated Pittsburgh Sleep Quality Index[35] and prediabetes. We will initially screen for high risk of prediabetes using the American Diabetes Association risk screener.[36] Those who are identified as high risk will be confirmed via venous blood test. Prediabetes will be defined as either fasting glucose between 100-125 mg/dL or HbA1c between 5.7-6.4%.[37] Participants will be recruited from the community via advertisements, community events and existing community partnerships. Potential participants will be screened by trained research assistants. Eligible participants will be contacted via phone and scheduled to attend a baseline visit to collect a blood sample and attend a sleep education session (see Aim 1). Co-PI, Dr. Johnson has an extensive experience recruiting from the community and will lead the recruitment strategies.

Overview: We aim to determine the feasibility of delivering a MBSR plus sleep education intervention to participants with prediabetes and poor sleep quality. The primary outcome is to improve sleep quality and duration, and secondarily improve subclinical biomarkers of T2DM risk such as glucose, HbA1c, blood pressure, and lipids. For Aim 1: we propose to deliver sleep education in a group setting, install MBSR app on the phones of participants, and monitor sleep patterns using wrist actigraphy for 7 weeks. For Aim 2, we will conduct focus groups among participants to determine usability of the app as well as barriers to obtaining optimal sleep. For Aim 3, we will analyze the biomarkers collected at baseline and follow-up and explore associations between stress, sleep and T2DM biomarkers. Participants of the proposed research will receive appropriate incentives (up to $265).

Determine the feasibility of delivering a mindfulness based stress reduction plus sleep education intervention to improve sleep health: We propose to conduct a 6-week MBSR intervention (See Figure 1). Eligible participants will be invited to a baseline visit at the Emory University Hospital branch of the Atlanta Clinical and Translational Science Institute where there will be a blood draw, anthropometry, questionnaires (e.g. stress, sleep, diet, exercise, medical



history, medications) and a sleep education session. Participants will receive a 1-hour session on sleep hygiene, highlighting the important components of healthy sleep: limiting naps, avoiding stimulants close to bedtime, exercise, establishing a bedtime routine, and optimal sleep environment (e.g. bedroom). Dr. Johnson, Co-PI will deliver the sleep hygiene. At the end of the session, participants will be asked to download the free headspace app (https://www.headspace.com/headspace-meditation-app). This app was selected based on the following available features: themed modules, varying meditation techniques, narrator selection, mindful moments, reminders, and journey tracking (i.e., run streaks, time meditated, sessions completed) The app features guided meditations on "Stress and Anxiety" that includes 3 "Basic" courses of 10 sessions each which teach the fundamentals of meditation and mindfulness; 6 themed courses of 10 sessions each such as "managing anxiety" which helps transform anxious thoughts, "letting go of stress" which focuses on reframing negative emotions, "restlessness" which aids in coping with a restless mind, "transforming anger" which emphasizes connecting with our anger and using it to train our minds, "navigating change" which focuses on being comfortable with change, and "reframing loneliness" which aids in feeling more connected to the world. The "Stress and Anxiety" module also features 3 advice sessions on the usefulness of putting down our phones, how to forgive ourselves, and the concept of loneliness. The module additionally features 6 SOS meditation sessions for panic attacks or anxiety, and 8 additional single meditation sessions for unwinding, restoration, stress, frustration, breaks, resetting, fear of flying, and alone time. Participants will undergo short mindfulness exercises daily via the app for 6 weeks. To optimize resources, we will implement the intervention in 4 groups of 5 individuals. Additionally, conducting the intervention in waves will allow us to make adjustments based on participant feedback. Following each wave, there will be a focus group session and blood draw to assess changes in biomarkers from baseline.

One week prior to the baseline visit, participants will receive a sleep monitor, which will objectively assess sleep patterns over a 7-week duration. A trained research assistant will instruct participants on wearing the sleep monitor (Spectrum, Philips Respironics, Murrysville, PA) on their non-dominant wrist for the next 7-weeks, and concurrently complete a brief log. Dr. Johnson, Co-PI, currently uses this device and has experience in the collection and analysis of the data.[39] The key sleep outcomes are average nightly sleep duration, sleep timing (mid-point, bed and wake times), sleep efficiency (sleep quality), wake after sleep onset, and night to night variability in sleep duration and timing (standard deviation). The actigraphy data will be complemented by validated sleep questionnaires. Participants will receive feedback reports and information for clinical evaluations, if interested.

Feasibility*:* Our main goals are to collect process measures that address the feasibility of the mindfulness intervention and identify components ('ingredients") that are most effective or have best uptake. We will quantify: recruitment yields, drop-out rates, adherence with app, returned actigraphs (sleep monitors), participant satisfaction via questionnaire and exit interviews, and ability to implement the intervention. We will describe the proportion of missing data. For measurements with more than 10% missingness, we will interview staff and participants to identify reasons (e.g., clarity, burden, etc.).

Conduct qualitative research to understand the uptake and usability of the mindfulness-based stress reduction intervention for sleep improvement

Qualitative data collection will be conducted via a series of focus groups in order to understand the uptake and usability of the mindfulness intervention for sleep improvement. Focus group discussions will be stratified by gender to facilitate discussion and provide characteristics for analytic comparison. We will conduct four focus group discussions (2 with men and 2 with women). Each group will consist of 6-8 participants, and will comprise diversity by race/ethnicity. Focus group discussions will be held at a location that is convenient to the participants such as a private conference room in the clinic or a meeting room at Emory University.

Focus group discussions will include the following key areas.

1) Perceived usability of the headspace application: topics will include ease of use of the application, barriers to use, and thoughts about how the application can be improved to increase mindfulness or usability.

2) Attitudes and beliefs towards sleep; understanding of the importance of healthy sleep practices/sleep hygiene, and barriers to following standard sleep health recommendations. We will also assess the impact of sleep-related impairments on following healthy lifestyle recommendations.

3) Facilitators and barriers (including a discussion on stress) to healthy lifestyle practices.

Data Analysis: Focus group discussions will be conducted in English by a trained moderator-note taker team. The team will be designed to match the focus group participant characteristics as closely as possible. This is important to achieve group homogeneity and foster open discussions among participants.[40] All focus group discussions will be audio-recorded and transcribed. Focus group recordings will be de-identified prior to analysis and transcribed verbatim. The MAXDA software will be used for analysis. Employing a thematic analysis, data will be coded separately by two individual coders. Codes will be compared between coders for validation, and key themes will be identified from the textual data. Structured comparisons between genders will be used to identify relevant issues.

Assess whether improving sleep through mindfulness-based stress reduction improves subclinical biomarkers associated with T2DM risk

Anthropometric measures will be assessed by trained staff, and fasting blood samples will be drawn by a trained phlebotomist. Height, weight, and waist circumference will be obtained according to standard procedures. After at least an 8-hour overnight fast, 100 mL of fasting blood will be drawn from a peripheral vein to measure fasting glucose, HbA1c, C-reactive protein and lipids. Blood samples will be processed and stored at -80 degrees C. Three seated blood pressure measurements will be made using an electronic sphygmomanometer. An average of the last two readings will be used to assess systolic and diastolic blood pressure. Smoking and alcohol use will be assessed via self-reported questionnaire. All measures will take place at the Emory University Hospital branch of the Atlanta Clinical and Translational Science Institute, and will be conducted at baseline as well as follow up. Participants will receive a $100 gift card at baseline and a $150 gift card at follow-up, as well as a detailed health report for their participation at the end of the study.

Data Analysis*:* Outcome variables will be the mean change in HDL cholesterol, triglycerides, fasting glucose, HbA1c, high blood pressure, and C-Reactive Protein. The means of each measure will be compared at baseline and follow up using analysis of variance (ANOVA) tests to assess whether significant changes occurred between pre and post intervention. Dr. Gujral (Co-PI) has extensive experience in the analysis of biomarkers related to T2DM risk and will conduct all related analyses.

In secondary analyses, we will test cross-sectional associations between sleep measures and subclinical biomarkers for T2DM risk, regardless of intervention adherence. The primary exposures will be average actigraphy defined sleep duration and sleep quality. Secondary sleep outcomes include: night to night standard deviation in sleep duration; sleep efficiency, sleep mid-point (timing; average and standard deviation of night to night differences); sleep debt (weekend-weekday sleep duration), and self-reported quality and daytime functioning (using the PROMIS scale). Sub-clinical outcomes will include mean changes in fasting glucose, HbA1c, C-reactive protein, and lipids.

Table 1. Study Measures and Sources

Measure	Source
Biochemical	
Fasting glucose	After at least an 8-hour overnight fast, 100 mL of fasting blood will be drawn from a peripheral vein. Fasting glucose will be assessed using the hexokinase method
HbA1c	Measured using the immunoturbidimetry assay from the fasting blood draw
C-Reactive Protein	Measured using the Immunoturbidimetric method from fasting blood
HDL-Cholesterol	Measured using the enzymatic method from fasting blood
LDL-Cholesterol	Calculated using the Fridenwald equation
Triglycerides	Measured using the enzymatic method from fasting blood
Sleep	
Sleep diary	Self-completion, home; Facilitates interpretation and assessment of actigraphy
7-day actigraphy	Identifies sleep/wake times, daytime naps, quality of sleep, sleep timing
Sleep questionnaire	Self-completion; Validated questionnaires to assess sleep duration, sleep quality (Pittsburgh Sleep Quality Index), snoring frequency, in bed activities, self-reported physician-diagnosed sleep disorders, insomnia (Insomnia Severity Index), PROMIS-measure of sleep quality
Psychosocial factors	
Stress	Validated questionnaires to assess perceived stress (Global Perceived Stress Scale), discrimination (Everyday Discrimination Scale)

Mood	Validated assessments of depression (Center for Epidemiological Studies Depression Scale), anxiety (State Trait)
Anthropometric	
Height	Measured using stadiomenter
Weight	Measured using a standing balance beam scale or digital weighing scale
Waist Circumference	Measured by trained study staff using a non-stretch tape measure at the site of maximum circumference halfway between the lower ribs and the anterior superior iliac spine. Two measures were taken and the average was used for analysis.
Blood Pressure	Three seated blood pressure measurements will be made using an electronic sphygmomanometer. An average of the last two readings will be used to assess systolic and diastolic blood pressure.

FUTURE PLANS

This pilot grant will serve as preliminary data for an NIH R-level application for translational research funding. For example, the National Institute of Diabetes and Digestive Kidney Diseases has an R01 entitled "Translational Research to Improve Diabetes and Obesity Outcomes." The proposed study will generate the information knowledge necessary to apply for such a funding mechanism. In particular, the results of the proposed study will help us to determine the needed sample size for the larger study. We will also gain critical feedback regarding the uptake of an app-based intervention. The future study will incorporate the focus-group data to develop a culturally relevant stress reduction intervention, thus allowing us to explore racial/ethnic disparities with the aim of reducing the inequity in diabetes.

PROJECT AS RELATED TO T2DM TRANSLATION RESEARCH

An area of translational research includes the process of applying discoveries generated during laboratory research or in preclinical studies to the development of interventions in target populations. Laboratory studies have shown that sleep deprivation can alter insulin secretion and resistance, and sleep interventions have been shown to improve subclinical markers of diabetes risk. However, these studies have been conducted in predominantly white populations in controlled settings. The aim of this study is to translate these findings into a mindfulness-based stress reduction intervention to improve sleep and subsequently improve subclinical markers for diabetes risk in a diverse sample of adults living in the Atlanta metro area.

COVID PRECAUTIONS

In response to the unprecedented COVID-19 pandemic and the resulting social distancing guidelines, the goals, design, and procedure of this study have changed for the safety of all involved.

Project Goal: The goal of the project is to conduct a pilot study to determine the feasibility of delivering a MBSR plus sleep education intervention to improve sleep and subsequently improve subclinical biomarkers for T2DM risk among a community sample of racially diverse adults (N=20) who are overweight/obese and experience poor sleep quality.

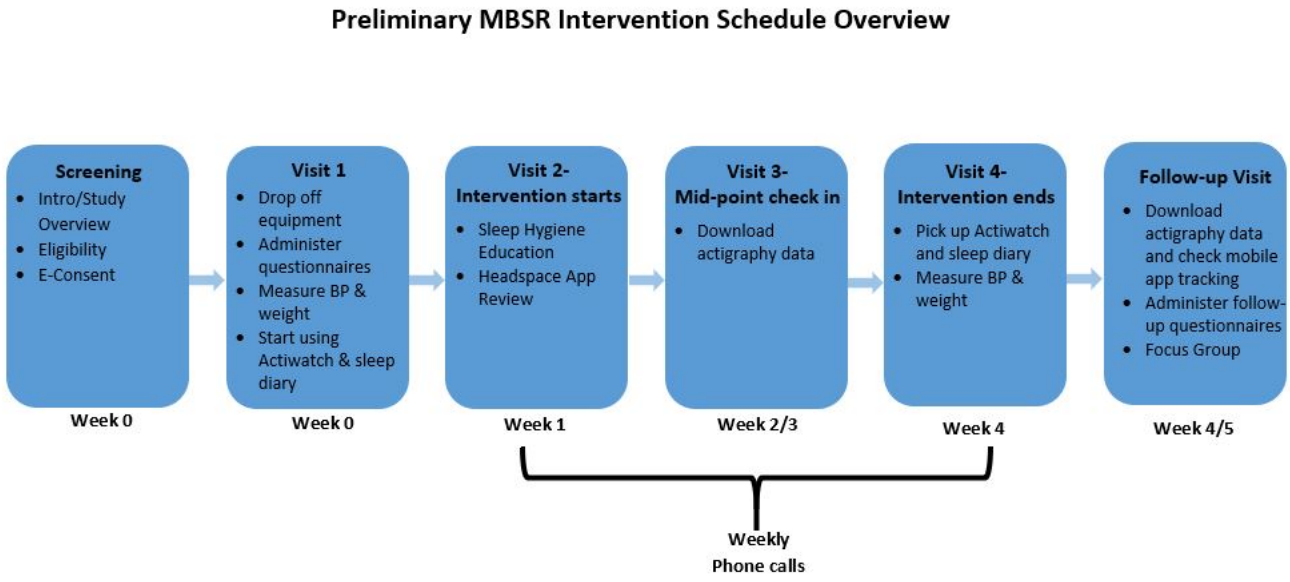
Hypothesis and Design: Our overarching hypothesis is *that the MBSR intervention will improve sleep quality, extend sleep duration and improve general sleep complaints and that participants who complete the MBSR plus sleep education intervention will experience improvements in blood pressure and weight.*

Project Design: Population: Eligible participants will be proficient in the English language, have a iPhone or Android (for the purposes of the application), a sleep quality score >5 on the validated Pittsburgh Sleep Quality Index[35] and overweight or obese. Participants will be recruited from the community via social media advertisements and flyer advertisements. Via an online questionnaire, we will screen for overweight or obesity defined by the CDC as a BMI of 25.0 kg/m2 or greater[41]. Those who are identified as overweight or obese will be contacted and given a blood pressure cuff and scale (RENPHO Digital Bathroom Scale). Consent will be conducted electronically for both participation in the intervention and focus group. Participants will be instructed on how to use both and record their morning weight and blood pressure reading before and after the intervention.

Overview: For Aim 1: we propose to deliver sleep education in a virtual group setting, ask participants to install MBSR app on their phones, and monitor sleep patterns using wrist actigraphy for approximately 35 days. The sleep device (Actiwatch), blood pressure cuff, and scales will be delivered to participants without contact. For Aim 2, we will conduct focus groups among participants to determine usability of the app as well as barriers to obtaining optimal sleep. Focus groups will be conducted over the phone/secure video conferencing (i.e. Zoom). For Aim 3, we will analyze changes in weight and blood pressure collected at the start of the study and at follow-up and explore associations between stress, sleep and T2DM biomarkers.

Determine the feasibility of delivering a mindfulness based stress reduction plus sleep education intervention to improve sleep health: We propose a 4-week MBSR intervention (See Figure 2.1). Questionnaires and sleep hygiene education will be provided over the phone/secure video conferencing (i.e. Zoom). Eligible participants will be provided with a blood pressure cuff, scale, and Actiwatch. Participants will also be remotely instructed by a trained research assistant on how to wear the sleep monitor. No physical contact will be made with participants over the course of the study.

Figure 2.1



Conduct qualitative research to understand the uptake and usability of the mindfulness-based stress reduction intervention for sleep improvement

Qualitative data will be collected over a series of focus groups that will take place over phone/secure video conferencing (i.e. Zoom).

Assess whether improving sleep through mindfulness-based stress reduction improves subclinical biomarkers associated with T2DM risk

Height and weight will be obtained according to standard procedures. Participants will take their own blood pressure as instructed with an at-home blood pressure monitor given to them. Smoking and alcohol use will be assessed via self-reported questionnaire. Participants will receive a $50 gift card at baseline, another $50 at the mid-point check in and a $100 gift card at follow-up, as well as a detailed health report for their participation at the end of the study.

Data Analysis*:* Outcome variables will be the mean change in weight and blood pressure. The means of each measure will be compared at baseline and follow up using analysis of variance (ANOVA) tests to assess whether significant changes occurred between pre and post intervention. Dr. Gujral (Co-PI) has extensive experience in the analysis of biomarkers related to T2DM risk and will conduct all related analyses.

In secondary analyses, we will test cross-sectional associations between sleep measures and subclinical biomarkers for T2DM risk, regardless of intervention adherence. The primary exposures will be average actigraphy defined sleep duration and sleep quality. Secondary sleep outcomes include: night to night standard deviation in sleep duration; sleep efficiency, sleep mid-point (timing; average and standard deviation of night to night differences); sleep debt (weekend-weekday sleep duration), and self-reported quality and daytime functioning (using the PROMIS scale). Sub-clinical outcomes will include mean changes in blood pressure and weight.

Table 1.1 Updated Study Measures and Sources

Sleep	
Sleep diary	Self-completion, home; Facilitates interpretation and assessment of actigraphy
Approx 35-day actigraphy	Identifies sleep/wake times, daytime naps, quality of sleep, sleep timing
Sleep questionnaire	Self-completion; Validated questionnaires to assess sleep duration, sleep quality (Pittsburgh Sleep Quality Index), snoring frequency, in bed activities, self-reported physician-diagnosed sleep disorders, insomnia (Insomnia Severity Index), PROMIS-measure of sleep quality
Psychosocial factors	
Stress	Validated questionnaires to assess perceived stress (Global Perceived Stress Scale), discrimination (Everyday Discrimination Scale)
Mood	Validated assessments of depression (Center for Epidemiological Studies Depression Scale), anxiety (State Trait)
Anthropometric	
Height	Self-reported
Blood Pressure	Three seated blood pressure measurements will be made using an electronic sphygmomanometer. An average of the last two readings will be used to assess systolic and diastolic blood pressure.

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