Nocturnal Hypertension and Sleep (Sleep BP Study)

NCT05062161

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1. Study Purpose and Rationale
The purpose of this study is to examine the impact that sleep duration has on blood pressure levels during sleep. We will examine the effect of an 8-week sleep hygiene/extension intervention vs. control on sleep blood pressure.

Background:
Blood pressure varies across the day, typically highest when awake and lower during sleep. Elevated nighttime blood pressure (nocturnal hypertension, defined as sleep blood pressure ≥110/65 mmHg) and reduced nighttime declines in blood pressure ("non-dipping") are linked to higher risks of cardiovascular disease, target organ damage, and mortality. These patterns are present in 30–45% of the general population, but optimal strategies to address them remain unclear.

Short sleep duration, defined as fewer than 7 hours per night, affects more than one-third of U.S. adults and is associated with obesity, diabetes, hypertension, and increased mortality. Prior studies show that insufficient sleep is linked to higher nighttime blood pressure and non-dipping patterns. Experimental sleep restriction raises blood pressure, but there is limited evidence on whether extending sleep improves nighttime blood pressure. Small clinical studies suggest potential benefits, but these were conducted in specialized settings and relied on less widely validated measures. This study will build on that work by testing whether sleep extension in daily life can lower nighttime blood pressure.

2. Study Design
Up to 66 participants will be enrolled following a two-step screening process: (1) completion of initial questionnaires, and (2) a two-week period of daily self-reported sleep assessments. Those meeting eligibility criteria will be consented and undergo a baseline visit. Baseline clinic blood pressure will be measured with a validated automated device after a 5-minute rest. All participants will complete questionnaires and be fitted with devices for sleep tracking, 24-hour ambulatory blood pressure monitoring, and 24-hour heart rate monitoring. Participants return the 24-hour devices and are then randomized 1:1 to either a sleep hygiene/extension education program or control education. Depending on group assignment, participants will attend a 60-minute educational session on either sleep hygiene/extension strategies or general sleep physiology. Over the 8-week study period, participants will receive weekly phone or video check-ins, complete questionnaires, and review progress and study materials. At the end of the study, participants will repeat the 24-hour blood pressure and heart rate monitoring before returning study devices.

3. Statistical Procedures
Sample size calculations used a two-sided alpha of 5% and 80% statistical power. Enrolling 66 participants will provide a final sample size of 52, assuming 10% attrition and 10% with incomplete data. With this sample size, we will have 80% statistical power to detect a change in mean sleep systolic blood pressure and diastolic blood pressure between participants randomized to sleep hygiene/extension intervention vs. control. Mean sleep systolic and

diastolic blood pressure will be calculated at baseline and follow-up for participants randomized to sleep extension and sleep maintenance, separately. The change in mean sleep blood pressure from baseline to follow-up (the difference between baseline and follow-up sleep blood pressure) will be calculated and compared across randomization arms using a t-test.

4. Recruitment: Participants will be recruited through multiple approaches (e.g., flyers, community events).

Inclusion Criteria:

- English speaking adults
- Age 18 and older
- Sleep duration < 7 hours per night as assessed via daily self-report of sleep hours

Exclusion Criteria:

- Inability to read or write in English
- Pregnant or plans to get pregnant within study period
- Arm circumference >50 cm
- Lymphedema of the arm or unable to wear ABPM device for 24 hours or sleep monitoring device for 8 weeks
- End-stage renal disease (ESRD) on dialysis
- Unreliable internet or phone/text access
- High risk of Obstructive Sleep Apnea (OSA) (using the Berlin Questionnaire or diagnosis of OSA or use continuous positive airway pressure device)
- High risk of insomnia (using the Insomnia Severity Index), or a known prior history of insomnia, and/or use of prescription sleep aides
- High risk of depression (using the Patient Health Questionnaire Depression Scale: PHQ-8)
- Perimenopausal women who have hot flashes (using the Menopause Rating Scale (MRS) questionnaire, administered only to females age 45-65)
- Plan to travel out of state and/or internationally during the study period