SOCIAL, BEHAVIORAL, and NON-CLINICAL RESEARCH PLAN

CPHS template v. 04172017

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Important Note: The CPHS Department (Chair & Scientific) Review Form is required with this application. Find the form in the RAPPORT Library or on the CPHS Website.

- **Respond to each item, even if to indicate N/A or not applicable**
- **Attach and/or upload this form as your 'Investigator Protocol' in Rapport**
- **If you are completing this form on a Mac, indicate your answer to any checkboxes by bolding or highlighting, or by deleting any incorrect options.**

1. Introduction and Background

Poor sleep is a risk factor of obesity. Meta-analyses have shown that short sleep duration is associated with higher body mass index (BMI) (Cappuccio et al. 2008; Chen, Beydoun, and Wang 2008). Experimentally induced sleep deprivation was found to be associated with greater caloric consumption (Brondel et al. 2010; Spaeth, Dinges, and Goel 2013). Sleep problems, late bedtime and high sleep duration variability were also found to be associated with higher BMI and obesogenic factors (Golley et al. 2013; Kjeldsen et al. 2014; Chan 2017; Baron et al. 2011) . Recent evidence suggests that good subjective sleep quality and morning chronotypes are associated with greater success in weight loss maintenance (Ross, Graham Thomas, and Wing 2016). Although evidence for the role of sleep in weight control is promising, prior findings were primarily cross-sectional or based on subjective reports of sleep. Moreover, few studies have examined changes of sleep during weight loss and weight loss maintenance.

2. Objectives and Hypotheses

The objectives of this study are to a) characterize subjective and objective sleep parameters in adults with obesity during weight loss and weight loss maintenance, b) examine the cross-sectional associations between sleep parameters and BMI in overweight and obese adults, and c) evaluate whether sleep parameters prospectively predict changes in BMI during weight loss and weight loss maintenance. We will also obtain data on a number of covariates and secondary outcomes including sleep disturbances, insomnia symptoms, risk of sleep apnea, circadian preferences, weight loss self-efficacy, emotional eating, mood and anxiety, executive functioning, loneliness and social isolation, and patients' beliefs about how sleep might impact their weight control or vice versa. Findings from this study will shed light on the impact of sleep on weight loss and weight loss maintenance and the potential therapeutic role of sleep in improving weight control.

3. Study Design

Describe all study procedures, materials, and methods of data collection:

This study is an observational study using a longitudinal data collection design with non-invasive measures.

Fifty participants who are about to begin the Healthy Lifestyle Program (HLP) at the Weight and Wellness Clinic (WWC) and another 50 participants who are about to complete HLP will be recruited to the study.

Participants will be consented to the study by a research staff in the PI's office in Heater Road prior to the 1st session. After informed consent is obtained, the patient will be asked to complete several questionnaires about sleep and wellbeing, which will take about 30 mins. The questionnaires will be administered using REDCap displayed on a tablet. Their height and weight will also be measured by the research staff. The patient will then be given a wrist-worn accelerometer (see description below) to wear for 16 weeks to measure their sleep and physical activity. They will be asked to complete the same set of questions at approximately the 8th and 16th week at a research visit. Also, the research staff will collect food consumption data continuously. Each patient in HLP is expected to track their food consumption daily. This daily data will be collected by the research staff. Data on existing diagnosis of sleep disorders will be extracted from the patients' electronic medical records. PHI request approval will be obtained prior to data extraction.

Measures:
The ActiGraph model wGT3X-BT will be used as a wrist-accelerometer to measure sleep and physical activity. The patient will be asked to wear this on the non-dominant hand throughout the day and during sleep except during showers or in situations where the accelerometer can be damaged. The model wGT3X-BT does not have an interface and does not provide feedback to patients. Data will be downloaded either remotely if the patient has a smartphone to install the ActiGraph mobile app for remote data retrieval or in-person when they attend their program visits. For in-person data download, the patient will return the accelerometer they used and be given another one at their program visit to minimize any waiting time needed for completing data retrieval.
Pittsburgh Sleep Quality Index (PSQI) will be used to assess a range of sleep disturbances including insomnia, sleep-related breathing difficulties, and use of sleep aids.
The Insomnia Severity Index (ISI) will be used to assess the severity of insomnia symptoms and subjective daytime impairments.
The STOP-BANG Questionnaire will be used to assess the patient's risk for sleep apnea.
The Morningness-Eveningness Questionnaire (MEQ) will be used to assess whether the patient's circadian rhythm produces peak alertness in the morning or the evening.
The Weight Loss Self-Efficacy Scale will be used to assess self-efficacy in one's ability to lose or maintain weight.
The Weight Control Strategies Scale will be used to assess strategies used to lose weight.
Questions about beliefs related to sleep and weight control
The Three Factors Eating Questionnaire will be used to measure emotional and disinhibited eating.
Mood and Anxiety symptoms will be assessed using the PHQ9 and GAD7.
Executive functioning will be assessed using the computerized delay discounting task and the response disinhibition task.
Loneliness and social isolation will be assessed using the PROMIS isolation scale.
Physical Activity Acceptance & Action Questionnaire (PA-AAQ) will be used to measure acceptance of physical and psychological discomfort in the context of physical activity.
Food Craving Acceptance and Action Questionnaire (F-AAQ) will be used to measure acceptance of food related cravings and urges.

4. Analysis

Describe any qualitative tests and measures as well as quantitative methods:

Mixed modeling will be used to model changes of weight and sleep during the 16 weeks of data collection and examine the associations between the changes of weight and sleep during weight loss and weight loss maintenance.

5. Study Progress Monitoring

Note: appropriate monitoring may include periodic assessment of the following:

- data quality
- timelines
- recruitment and enrollment

Provide a description of the methods which will be used to determine the progress of the study, including periodic assessments of data quality, timelines, recruitment, and enrollment as appropriate:

The principal investigator will meet with the research coordinator weekly to monitor recruitment, enrollment and data collection. The PI will conduct monthly assessment of data quality to ensure that the data collection The PI will meet with the Co-Is once every three months or as needed to discuss progress and any problems in recruitment and data collection.

6. Risks & Benefits

Note: Risks may be physical, psychological, social, legal, economic, to reputation, or others.

a. Describe any potential risks, their likelihood and seriousness:

To the best of our knowledge, this study will have very minimal risks to the participants. Some participants may find the wrist-worn actigraph uncomfortable or causing allergic skin reactions. These reactions are usually temporary and occur in a small proportion of the participants.

b. Confirm that risks to subjects have been minimized, by use of procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk:

If an allergic reaction occurs, we will obtain other wrist-bands that will not cause an allergic reaction. The participants will also be reminded that they could withdraw from the study at any point if they find the data collection process is causing undesirable effects.

c. Describe why all the risks to subjects are reasonable in relation to both anticipated benefits and the knowledge expected to be gained from the study:

The knowledge gained from this study will provide some insight into how sleep could be a potential therapeutic target in weight loss and weight loss maintenance. Given that the risks to participants are very minimal and cause no lasting harm, we believe that the anticipated benefits will overweigh the risks.

7. Unexpected Events or Incidental Findings

Note: It may be important to consider the potential for certain unanticipated events to occur, for example:

- finding an anomaly in a MRI
- discovering child abuse
- causing distress in interviews of a sensitive nature

Describe potential events and provide a plan of action:

With the sleep data collected, we may discover that a participant might likely have a sleep disorder. We will let the participant's PCP know and recommend making a referral to the Sleep Medicine Center.

8. Deception

Does any part of this study involve deception or withholding of information from participants?

☐ **Yes** ☒ **No**

If Yes, provide an explanation which addresses the following:

- A description of the deception being used
- Why the deception is necessary
- A plan for debriefing, or providing subjects with the pertinent information after participation

N/A

9. Equitable Participant Selection

a. Estimated number of participants at Dartmouth CPHS reviewed sites:

100

b. Provide a justification of the proposed sample size

The proposed *N* will allow adequate statistical power for detecting significant associations between sleep and weight.

c. Define the target population:

Adult overweight or obese patients who are enrolled in or who completed the Healthy Lifestyle Program at Weight and Wellness Center.

d. Vulnerable populations

Note: Certain populations are considered vulnerable to coercion and undue influence and are provided with additional protections when participating in a research study.

Identify any of the below populations which you plan to recruit for this study. In addition, complete the form(s) linked with each population as necessary and upload on the 'Supporting Documents' page in Rapport.

☐ Pregnant Women, Fetuses and Neonates

☐ Children

☐ People with impaired decision-making capacity

The following populations may also be considered vulnerable to coercion or other undue influence:

- Prisoners
- People who are economically disadvantaged
- The elderly
- People who are illiterate or do not speak English
- Students and employees

Describe any other potentially vulnerable population(s) and the additional protections provided to them:

N/A

10. Recruitment

Describe method(s) of recruitment. Associated advertisements and other materials to be used for recruitment should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport.

Patients who are about to begin or complete the Healthy Lifestyle Program (HLP) at Weight and Wellness Clinic (WWC) will be given a pamphlet about this study. Interested patients will be invited to contact our research staff and be scheduled for a research visit. Recruitment materials will include a flyer and a facebook page (see attached).

11. Informed Consent, Assent, and Authorization

All forms discussed in this section should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport

a. Please describe the consent and/or assent process, addressing the following:

- Who will obtain consent/assent from participants
- Where the consent/assent process will take place
- The timeframe for providing information potential participants about a study, having the consent form signed, and beginning study activities
- Any precautions taken to minimize the possibility of coercion or undue influence
- The forms which will be used as well as any aids used to simplify scientific or technical information
- How comprehension will be ensured

The PI and the research coordinator will obtain consent from participants. The consent process will take place in PI's office. The PI/research coordinator will explain the study to the patients and ask if they have any questions or need to discuss with their providers or family before making the decision to participate in the study or not. They will be given as much time as they need to decide before the 1st session of HLP or the last session of HLP. They will be given as much as one week to decide. To minimize the possibility of coercion or undue influence, the PI/research coordinator will emphasize that participation or not will not affect the care they receive. Based on the research team's experience, interested patients might be more inclined to fill out a survey and have the research team contact them than initiating contact with the research team. Hence, we will create a facebook page containing the information about the study (same information as in the flyer) and a link to a REDCap survey where interested patients will be asked to complete a few eligibility questions and enter their contact information (see attachment).

b. Waiver(s) or alteration(s) may be requested for research that involves no more than minimal risk.
Indicate requested waiver(s) or alteration(s) below. In addition, complete the corresponding section of the Waivers and Alterations Request Form and upload it to the 'Consent Forms and Recruitment Materials' page in Rapport.

☐ For the informed consent *process*
☐ For the *documentation* of informed consent
☐ For the HIPAA Authorization to use and/or disclose PHI
☐ For a waiver of the requirement for medical record documentation

12. Compensation or Gifts

Please describe any payments, gifts or reimbursements participants will receive for taking part in the study:

Each participant will receive up to 60 dollars in gas cards for taking part in the study. They will receive a gas card with a $20 value for completing the initial assessments in the 1st week. Then they will receive a gas card with a $20 value at the research visit at 8th week for completing the assessments again, and another gas card with a $20 value for completing the same assessments again at 16th week.

13. Privacy of Participants

Note: Methods used to obtain information about participants may have an effect on privacy. For example:

- Consent discussions or interviews held in public which concern sensitive subjects or behaviors
- Observations of behavior, especially illicit behavior, in quasi-public settings

Describe any activities or interactions which could lead to a breach of privacy and provide a plan to protect participant privacy:

Consent discussions and measurements of height and weight will all be conducted in the PI's office.

14. Confidentiality of Data

Note: Any person engaged in research collecting information that could cause financial, social or legal harm to participants may apply for a Certificate of Confidentiality. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They are intended to allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

a. If disclosed, could any of the data collected be considered sensitive, with the potential to damage financial standing, employability, insurability, or reputation?

☒ **No** ☐ **Yes**

If Yes, describe the data or information, the rationale for their collection, and whether a Certificate of Confidentiality will be obtained:

N/A

b. Describe the safeguards employed to secure, share, and maintain data during the study, addressing any of the following which may apply:

- Administrative, ie. coding of participant data
- Physical, ie. use of locked file cabinets
- Technical, ie. encrypted data systems

Each participant will be assigned a research ID. All assessments will be labeled with the research ID. The only link between the research ID and identifying information will be the written consent form. The consent forms will be stored separately from the assessments. All materials will be stored in locked cabinets in the PI's clinic and kept confidential. De-identified data that are stored electronically will be stored in encrypted data systems (REDCap, Dartmouth Webshare, and DH-drive).

c. Describe the plan for storage or destruction of data upon study completion:

All of the research data not included in the medical record will be stored for 6 years following the completion of the study. Three years after the completion of the study analysis, the identifying data

will be destroyed. The de-identified database will be stored indefinitely for any future scientific investigation.

References

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