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Informed Consent

Title: Sleep GOALS (Goal-focused Online Access to Lifestyle Support)

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Source of Support:
The National Heart, Lung, and Blood Institute

Why is this research being done?

We are doing this study to develop a novel weight loss intervention for postpartum people by providing strategies to improve sleep, diet, and physical activity. You are being asked to participate in this study because:

- you gave birth between 3±1 and 6±1 months ago
- and expressed interest in learning how to improve your sleep, diet, and physical activity and lose weight.

The study is designed so that you could receive one of two interventions:

- Educational brochures
- A 16-week online program

Both interventions will provide tips to sleep better, eat healthier, and increase physical activity.

What are you being asked to do?

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time." Briefly, the following is what to expect if you consent to being in the study.

During the first visit today, you will:

- have your height and weight measured with a portable scale and height board,
- complete several questionnaires to tell us about your demographic characteristics, weight history, mental wellness, social determinants of health, social support, infant sleep and feeding, diet, physical activity, and sleep,
- complete a 24-hour diet recall, and
- receive an Actigraph Link, a research-grade activity monitor to wear for 7 days. You will also complete a sleep diary each day for 7 days to help us interpret the Actigraph data. After 7 days, you will mail the Actigraph Link to us in a pre-paid postage envelope.
- During the 7-day actigraphy assessment period, you will also complete another 24-hour diet recall on a random day.

Once we receive the activity monitor, you will be randomly assigned (like a coin flip) to receive the educational brochures or the 16-week online program.

Educational Brochures: If you are randomly assigned to receive the educational brochures, we will email them to you immediately.

Online Program: If you are randomly assigned to the 16-week online program, we will email instructions on how to access the website. The online program is called Sleep GOALS. You will learn tips to improve your sleep to act as a starting point to help you eat healthier, increase physical activity, and lose weight. The program is entirely online. You can view the 15-to-20-minute informational videos at your own convenience. New videos will be made available each week. You will receive weekly email reminders when a new video is available. A lifestyle coach will also help you throughout the program. The coach will help by giving you feedback and encouragement, help you brainstorm solutions to specific challenges, and act as an accountability partner. You can ask the coach questions through our secure messaging system anytime. You will also receive a Fitbit and Aria wireless scale that is yours to keep to measure your sleep, diet, physical activity, and weight each week. Lastly, each week you will complete a short questionnaire to provide feedback on each lesson and your experience with the lifestyle coach. Your responses can help us improve the program.

After 16 weeks, you will have another visit, similar to today, where you will:

- be weighted on a portal scale,
- complete the same questionnaires and diet recall as today, and
- receive an Actigraph Link to wear for 7 days. You will also complete a sleep diary each day for 7 days to help us interpret the Actigraph data. After 7 days, you will mail the Actigraph Link and diary to us in a pre-paid postage envelope.
- During the 7-day actigraphy assessment period, you will also complete another 24-hour diet recall on a random day.

If you are assigned to the Sleep GOALS intervention, you will also complete a 30-to-60-minute interview to discuss your experiences in the program and how we can make it better. We will record the interview and upload the audio file to TranscribeMe, a secure online transcription service. TranscribeMe will type up your words and mine as we hear them on the audio file.

If scheduling an interview is challenging, you have the option to complete an evaluation survey instead. It will take 15-20 minutes. While we prefer interviews, the survey will also help us collect valuable feedback on your satisfaction with the intervention and identify potential improvements.

What are this research study's possible risks, side effects, and discomforts?

There are a few risks to participating in this study. These risks include:

Emotional discomfort: There is a chance that you might be uncomfortable completing the questionnaires or answering questions during the interview. To minimize this risk, you can skip as many questions as you would like. You may also stop participating in the interview at any time.

Breach in confidentiality: There is a rare risk of breach of confidentiality. We will do everything to prevent that from happening. All of your answers to the questionnaires will be stored on a secure online website called REDCap. Your names will not be included on the questionnaires. The questionnaires will have a unique study ID. Only the study team members will have access to a separate file that links your ID to you. When we record your interview, we will store the audio files on REDCap. If your name or any other name comes up in the interview, we will remove it from the transcribed file. We will delete all copies of the recording after we verify the accuracy of the transcribed file. Emails may not be encrypted during transmission or storage and may be intercepted and used by others not associated with the study.

Physical discomfort: There is a potential risk of discomfort. The activity monitor or Fitbit may cause discomfort (e.g., skin irritation) while wearing it. If you experience too much discomfort, you may stop wearing the monitor or Fitbit at any time and return it to us.

Intervention-Related Risk: You will be asked to do more physical activity for the 16-week program. Increasing physical activity can cause your body to feel sore or tired. Exercise may also cause injury to joints or muscles. In some cases, exercise may make any existing injuries worse. There is the possibility of experiencing shortness of breath, changes in your blood pressure, fainting, or other health problems. If you have existing

health conditions that could make exercise unsafe, we ask that you get approval from your doctor to be physically active. This will help lower your risk of experiencing problems from exercise. You should choose exercises that you feel safe doing. You are also able to message your lifestyle coach any time if you need advice on how to make exercises safer or modify them to your abilities.

What to do if you experience an injury related to the research procedures?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form.

Will my data remain confidential?

We may share data with researchers not a part of the study. None of the data we share will be identifiable. Authorized representatives from the University of Pittsburgh Office of Research Protections may review your identifiable data solely to monitor the conduct of this study. *If the researchers learn that you or someone you are involved with is in serious danger of harm, they will need to inform the appropriate agencies as required by Pennsylvania law*.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality

does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information."

What are the possible benefits of taking part in this study?

There are not any direct benefits expected from being in this study. You may find the tips to sleep better, eat healthier, and increase physical activity levels helpful. This research may help us develop better, future programs to help people like you.

Will I be paid if I take part in this research study?

There is no cost to you for participating in this study. You will receive $50 after completing the first assessment, $75 after completing the second assessment in 16 weeks, $50 after completing the interview, $15 after completing the evaluation survey instead of the interview, $7 for parking on the first visit, and lastly, $7 for parking on the second visit. You can receive a maximum of $189 to reimburse you for your time in the study. Should you complete the second assessment, you will be eligible for additional compensation, which will be randomly drawn. You will have a minimum of 1 in 40 chance to be chosen at random for one $200, one $100, or one $50. We will use a random number generator after all participants have a chance to complete the final assessment by approximately the end of January 2025. Each participant will only have one chance to be chosen; i.e., a participant chosen for $200 will not be eligible to be selected for $100 or $50. We will make three attempts to notify the chosen participants. The first attempt will be via email, the second through text, and the third and final attempt will be by phone. If we are unable to reach the chosen participants by the third attempt, we will remove their ID number from the random number generator and select a new participant. All of your payments will be put on a reloadable debit card. We must collect some information from you for tax purposes to receive your compensation. You will need to provide your name, address, and social security number. Suppose you choose not to provide your social security number. In that case, current IRB guidance indicates that the amount of tax withholding is 24%. This information will be released to the Accounting Office. If the total amount of money you get from research participation is over $600, the Internal Revenue Service (IRS) considers it as income.

Is my participation in this research study voluntary?

Your participation in this study is entirely your choice. You may stop participating in the study anytime and for any reason. To formally withdraw, you must submit a written request to the Principal Investigator, Dr. Marquis Hawkins. We will use the data collected until the time of your withdrawal. Participants may be removed if they become unable or unwilling to participate in the research procedures. Participants may also be removed if they no longer meet eligibility criteria (ie., reported pregnancy, begin taking medications that affect weight)

To whom do I contact if I have any questions about the study?

You can reach out to the study team with any questions or research-related problems with about the study by email or phone:

Email: momsleep@pitt.edu
Phone: 412-532-9476.

You can also reach out to the University of Pittsburgh's Human Subjects Protection Advocate office by phone (1-866-212-2668) to:

- discuss problems or concerns with the study,
- ask questions,
- obtain information,
- offer input,
- or discuss situations if the research team is unavailable.

Voluntary consent

You should contact the principal investigator to formally withdraw your consent for this study. Your formal withdrawal should be written and dated. The contact information is listed at the top of this form in the "To whom do I contact…" section.

All of this has been explained to me. All of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research at any point in the study. My future questions will be answered by the researchers listed on the first page of this form.

By signing this form, you formally agree to participate in this study.

_____
Date

_____
Printed Full Name of Participant

_____
Signature

Certification of Informed Consent

I certify that I have explained the nature and purpose of this research study to the individual named above (s) and discussed the potential benefits and risks of study participation. Any questions the individual(s) have about this study have been answered. We will always be available to address future questions, concerns, or complaints as they arise. I certify that no research component of this protocol was begun until after this consent form was signed.

_____
Date

_____
Printed Full Name of Person Obtaining Consent

_____

Signature of Person Obtaining Consent

_____

Role in the Study