Path To Better Sleep + Virtual Coaching: The Effectiveness and Implementation of Internet-Based Self-Management Program for Insomnia in a Regional Healthcare System

NCT05558475

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Verbal Consent Document
(For Patients Referred to the SleepEZ Program)

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to determine if telephone contact from a Coach added to a digital internet-based self-management program for insomnia (the SleepEZ program) is effective for treating insomnia. You are being asked to participate because you have expressed interest in the program been referred to the program by your provider. You don't have to join this study, but if you do join and later change your mind, you may quit at any time. You may continue to receive all other treatments through the VA in the future or at any time while you are enrolled in this study.

WHAT WILL YOU BE ASKED TO DO?

This is a 6-month study. This study is done at home and over the phone. If you agree to participate in this research study, you will be assessed over the phone at baseline, at 8 weeks, and at 6 months. These calls will last about 45 minutes. During the baseline assessment, you will be asked to answer questions about topic such as your personal characteristics (age, gender, etc.), sleep characteristics, insomnia levels, internet and technology use, mood and anxiety levels, alcohol use, and quality of life. Each time you visit the SleepEZ program, you will be asked to enter the program through a special site that will log the time you enter and your progress through the course. You may also be asked to participate in a phone interview with a research team member who will ask you to discuss your experience with the program and coaching. These interviews will take about 30 minutes and will be recorded and transcribed by a member of our qualitative research team located in VACWM using Microsoft Teams. Transcriptions will be de-identified during the transcription process by removing all identifiers including names, dates, references to locations, diagnoses, medications, and any other identifying data. No identifying information will be linked to the file.

RANDOMIZATION

After you complete the baseline assessment, you will be randomly assigned to one of two groups using a process similar to flipping a coin. You will have a 50% chance of being assigned to the Intervention (a group the receives telephone support from a Coach), and a 50% chance to be in the Control (a group that receives initial information about the SleepEZ program, but no Coaching). No matter what group you are assigned to, you will be able to use the SleepEZ program.

Telephone Coaching: If you are assigned to the intervention group, you'll receive at least three phone calls from a Coach; an initial on-boarding session and two follow-up support sessions. In addition, the coach will be available for as-needed contacts, and you will be given to coach's contact information. Each call will last about 20 minutes. At the end of 8 weeks and again at 6 months, you will complete a similar assessment over the phone to the one you completed at baseline. Your time of involvement is estimated as follows: about 1 hour for coach contacts (this may vary and will depend on how often you call the coach); 2.5 hours for phone assessments with the research team, and 30 minutes for an interview with the research team if you are selected.

Health Education Group: If you are randomized to the information but no coaching group, you will engage in the same procedures described above, with the exception you will NOT receive coaching calls. Your time of involvement is estimated as follows: 2.5 hours for phone assessments with the research team and 30 minutes for an interview with the research team if you are selected.

RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY

This research study consists of receiving coach telephone support, phone assessments, and participating in the Sleep EZ program. There are few known risks associated with these study procedures. However, there are some inconveniences and minor risks to research and we are unable to predict who might be affected by these risks. You may feel uncomfortable answering some questions asked as part of this research. You will be free to refuse to answer any questions that you do not wish to answer. Although every effort will be made to keep your information confidential, there is potential risk of loss of confidentiality.

BENEFITS FROM TAKING PART IN THIS STUDY

You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others with insomnia. If you do enroll in this study, you may learn strategies to improve your sleep.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, The Food and Drug Administration (FDA), the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. 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.

COST OF PARTICIPATION IN THIS RESEARCH STUDY

There will be no costs to you for any of the research treatment or testing done as part of this research study.

COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN STUDY

Study participants will be compensated for their participation as follows: $10 for each phone assessment and $25 for a phone interview. A participant completing all study activities will receive $55. Participants will not be compensated for incomplete assessment periods. Compensation will occur by either direct deposit or check in the mail. In addition to study research staff, a budget technician in our research center will need access to your name and social security number in order to process compensation.

REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY

Drs. XXX or XXX may take you out of the study without your consent if they decide that continuing your participation could be harmful to you or you fail to follow instructions of the research staff.

PROTECTION AND SECURITY OF RESEARCH DATA

As part of the study, Drs. XXX and XXX as well as their study team will record information about you containing your name and other personal identifiers. Study records that identify you will be kept confidential as required by law. Except when required by law (HIPAA) your identity will not be disclosed outside of the VA Medical Center. Electronic data will be stored on secure VA servers behind the VA firewall where folders can only be accessed by this study's research staff. Your calls with the telephone coach will be recorded for the purpose of quality control. No one but study staff will have access to these recordings.

ACCESS TO MY RESEARCH DATA

If results of this study are reported to others, you will not be identified without your specific consent.

LIMITS TO THE PRIVACY AND CONFIDENTIALITY OF MY RESEARCH INFORMATION

If during the study any information reveals suicidal intent, depression, or other major clinical findings, your primary healthcare provider will be notified. In addition, if you reveal current intent to harm yourself or someone else, we may be required to enact our safety plan to ensure your safety or the safety of others, as applicable.

AFFIRMATION FROM PARTICIPANT

I would now like to ask for agreement with the following statements.

"My rights as a research participant have been explained to me and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described to me on this call." Yes/No

“I consent to have my calls with the coach recorded for the purpose of quality control. If I do not consent to this, it will not affect my eligibility to participate.”

Yes/No

[Interviewer: “Yes” means that my consent to be recorded is given, and “No” means I do not consent to being recorded.]

“I consent to have my telephone interview with research personnel recorded for the of research If I do not consent to this, it will not affect my eligibility to participate.”

Yes/No

[Interviewer: “Yes” means that my consent to be recorded is given, and “No” means I do not consent to being recorded.]