The Insomnia Treatment and Problems (The iTAP Study)
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IRB# 2010684
NCT# 03627832
PI Miller

IRB USE ONLY
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CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Researcher's Name(s): Mary Beth Miller, Ph.D.
Project Number: 2010684

Project Title: Insomnia Treatment and Problems (The iTAP Study)

This form may contain words that do not make sense to you. Please ask the research assistant to explain any words or information that are not clear.

This research study is about the impact of insomnia treatment among young adults who drink alcohol. We are doing this study to better understand how and for whom insomnia treatment is effective. The knowledge gained from this study may lead to better treatments that improve people's health without the use of medications.

Please take as much time as you need to read this consent form. You can discuss it with your family, friends, or anyone you choose. If there is anything you do not understand, please ask us to explain. Then you can decide if you want to take part in the study or not.

The University of Missouri Research Board is providing the funding for this study.

WHAT SHOULD I KNOW BEFORE I DECIDE WHETHER TO PARTICIPATE OR NOT?

- Research studies help us to answer questions that may improve our understanding of human behavior, attitudes, beliefs, and interactions.
- Taking part in a research study is voluntary. You are free to say yes or no. You decide if you want to take part, and you can stop taking part at any time. You will not be penalized in any way if you choose not to take part in this study.
- We are doing this study to better understand how and for whom insomnia treatment is effective. The knowledge gained from this study may lead to better treatments that improve people's health without the use of medications.
- We invite you to be part of this study because you are 18-30 years old and reported experiencing symptoms of insomnia.
- About 52 people will take part in this study.
- If you take part in this study, you will come to the University of Missouri's Department of Psychiatry 6-9 times, depending on your treatment condition. We will ask you to complete questionnaires and engage in individual treatment for insomnia. We will explain these in detail later in this form.
- The total amount of time you could be in this study is about 12 weeks.
- Taking part in this study may or may not benefit you directly. We hope that the information we learn from this study will lead to better insomnia treatments.
- As with any research study, there are risks that we know about and there may be some we don't know about. We will explain these risks in this form.
- We will only include you in this study if you give us your permission first by signing this consent form.

WHY IS THIS STUDY BEING DONE?

You are invited to participate in a research study examining the impact of insomnia treatment among young adults who drink alcohol. The purpose of this study is to better understand how and for whom insomnia treatment is effective. The knowledge gained from this study may lead to better treatments that improve people's health without the use of medications.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you agree to participate, you will come to the University of Missouri's Department of Psychiatry. The study will take part in four phases:

1. **Screening and baseline assessment.** During this phase of the study, we will ask you to answer some questions and complete a brief interview with a research assistant. The research assistant will ask you about current difficulties with insomnia, emotions, trauma, and substance use. These questions will help us determine if you are eligible for the study. If you are eligible, we will ask you to complete several questionnaires about your personal characteristics, health behaviors, and use of alcohol and other drugs. We will also ask you to complete several short tasks on the computer.
   - This first session will take 60-90 minutes to complete.
2. **At-home assessment.** After the baseline assessment is complete, the research assistant will show you how to use an actiwatch (a wrist watch that monitors your movement). We will ask you to wear the watch all day every day (except while swimming or taking a shower) for one full week. During this time, we will also ask you to complete daily online surveys about the previous night's sleep. These surveys will help us make sure that your insomnia is severe enough for you to be included this study.
   - The online surveys are expected to take 5-10 minutes each day.
3. **Treatment.** If you are eligible and still interested in participating, we will randomly assign you to one of two insomnia treatment conditions. The group you are assigned to will be determined by chance, similar to the toss of a coin. In one of the two treatment conditions, you will receive feedback and general recommendations on how to improve your sleep. In the other, we will ask you to come back to the research lab once a week for six consecutive weeks to participate in individual treatment with a trained therapist. Each session will be 30-50 minutes, and we will ask you to practice what you learned in session at home. In both treatment conditions, we will ask you to continue completing the online sleep surveys every day.
   - Each treatment session will take 30-50 minutes.
4. **Follow-up.** Six and eleven weeks after the baseline assessment, we will ask you to return to the research lab to complete some of the questionnaires that you completed at baseline. Again, these questionnaires will ask your health behaviors, sleep patterns, and use of alcohol and other drugs; and we will ask you to complete several short tasks on the computer. We will ask you to wear the actiwatch again all day every day (except while swimming or taking a shower) for one full week.
   - Follow-up assessments will take 45-60 minutes.

HOW LONG WILL I BE IN THE STUDY?

The study is expected to take 12 weeks. The investigator may decide to take you off this study if you do not meet diagnostic criteria for insomnia.

CAN I STOP BEING IN THE STUDY?

Yes, you can stop being in the study at any time without giving a reason. Just tell the researcher or study staff right away if you wish to stop taking part.

The researcher may also decide to take you off this study at any time, even if you want to stay in the study. The researcher will tell you the reason why you need to stop being in the study, for example:

- If it is not in your best interest
- You do not meet eligibility criteria for the study
- You do not follow the study rules
- The whole study is stopped
- New information becomes available that indicates that the treatment will negatively impact you

ARE THERE ANY BENEFITS TO TAKING PART IN THIS STUDY?

You may or may not benefit personally from taking part in this study. Participants in the Cognitive Behavioral Therapy for Insomnia and Sleep Hygiene conditions may benefit from the sleep-related information provided. However, we cannot promise that your insomnia symptoms will improve. You may also benefit, to the extent that you are contributing to medical knowledge. We hope that the information learned from this study will benefit young adults with insomnia in the future.

ARE THERE ANY RISKS FROM BEING IN THIS STUDY?

The physical, psychological, and social risks associated with this study are minimal. Some include:

- Very mild, temporary worsening of insomnia as sleep/wake cycles change. When this occurs, it is typically early in the course of therapy and resolves within 1-2 weeks.
- Information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you. We will take steps to decrease the likelihood of this happening. For example, as part of the treatment protocol, we may send you an email with treatment-related materials (e.g., a brief relaxation recording). This email will be labeled using a generic subject line and will not include the name of the study, so that no one who opens or sees your email will connect it to this study.
- Risks that are unknown at this time. If other risks are identified during the protocol, they will be addressed immediately by research staff, in collaboration with MU's Institutional Review Board. If you have any worrisome symptoms, please notify the investigator immediately.

WHAT OTHER CHOICES DO I HAVE IF I DON'T TAKE PART?

Instead of being in this study, you may

- Not receive treatment for your sleep problems.
- Choose to receive treatment for your sleep problems at a Sleep Disorder Center.

WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

The information we collect about you will be stored in the researcher's electronic/computer or paper files. Computer files are protected with a password and the computer is in a locked office that only study team members can open. Paper files are kept in a locked drawer in a locked office that only study team members can open.

We will give your records a code number and they will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location. Information that may identify you may not be given to anyone who is not working on this study without your written consent, or if required by law.

We will do our best to make sure that your personal information from this study is kept private, but we cannot guarantee total privacy. We may give out your personal information if the law requires it. If we publish the results of this study or present them at scientific meetings, we will not use your name or other personal information. We will keep therapy progress notes throughout the trial, but these notes will be labeled using your code number, not your name or identifying information. Medical staff from the University of Missouri may review these notes to ensure that the Principal Investigator is adhering to current medical standards of care. However, these notes will not include personal information that could be used to identify you.

A **Certificate of Confidentiality from the National Institutes of Health** has been obtained for this project. This means that the researchers may not disclose or use information that may identify you in any action, suit, or proceeding or as evidence (for example, if there is a court subpoena). Researchers will not disclose information that may identify you unless (a) there is a federal, state, or local law that requires disclosure; (b) you tell us that you plan to harm yourself or someone else; (c) you tell us about the abuse or neglect of a minor, older adult, or individual with a disability; or (d) you give us permission. Please note that the Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate also cannot be used to refuse a request for auditing or program evaluation information from the University of Missouri, as the University of Missouri Research Board is funding this project.

To maintain the quality of the intervention delivered to you, we would like to audiotape all treatment sessions. The Principal Investigator will review these tapes to ensure that study therapists are administering the treatment correctly and effectively. You must give us permission to use the recordings we take of you during the study. You will be able listen to them before you give your permission for us to use them. Please notify the research assistant if you do not want your treatment sessions audiotaped or if you would like to listen to them before giving us permission to review the tapes. These audiotapes and all other information that could identify you will be destroyed upon completion of the study.

ARE THERE ANY COSTS TO ME IF I TAKE PART IN THE STUDY?
No, there is no cost to you if you take part in this study.

WILL I BE PAID FOR PARTICIPATING IN THE STUDY?
In return for your time and effort, you will be given up to $100. You will be paid $20 for the baseline assessment, $5 for on-time completion of each treatment week's daily sleep surveys (up to $30), $25 for the post-treatment assessment, and $25 for the follow-up assessment. You will also receive treatment at no cost.

WHAT HAPPENS IF I AM HURT BECAUSE OF THE STUDY?
The University of Missouri does not have a plan to offer any type of payment for injury. The University of Missouri does provide medical, professional, and general liability insurance coverage for any injury caused

by the negligence of its faculty or staff.

You do not give up your legal rights by signing this form. These statements are not an admission of liability by the University of Missouri.
If you believe you have been hurt because of this study, please contact these people right away:

- The researcher, Dr. Mary Beth Miller, at 573-882-1813
- The lab coordinator, Nicole Hall, at 573-882-8598
- The Risk Management Officer at 573- 882-1181. This person can review the matter with you and provide more information.

WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?
Taking part in this study is voluntary. If you do decide to take part, you have the right to change your mind and drop out of the study at any time. Whatever your decision, there will be no penalty to you in any way.

If the study investigator decides to take you off the study, she will explain the reasons and help arrange for your continued care by your own doctor, if needed.

We will inform you of any new information that might influence your health, welfare, or willingness to be in this study if it is discovered during the course of the study.

We will keep the information we collect from you for this study to use in future research without asking for your consent again. Information that could identify you will be removed from your research information so no one will know that it belongs to you

WHERE CAN I GET MORE INFORMATION ABOUT THIS STUDY?
A description of this clinical trial will be available on 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 may search this website at any time.

WHO CAN I CALL IF I HAVE QUESTIONS, CONCERNS, OR COMPLAINTS?
You may ask more questions about the study at any time. For questions about the study or a research-related injury, contact Dr. Mary Beth Miller at (573) 882-1813 or the research team at 573-882-8598.

The Institutional Review Board (IRB) is a group of people who review research studies to make sure the rights of participants are protected. You may contact the University of Missouri IRB (573-882-3181) if you:

- Have any questions about your rights as a study participant,
- Want to report any problems or complaints, or
- Feel under any pressure to take part or stay in this study.

If you want to talk privately about your rights or any issues related to your participation in this study, you can contact University of Missouri Research Participant Advocacy by calling 888-280-5002 (a free call), or emailing MUResearchRPA@missouri.edu.

We will give you a copy of this consent form. Please keep it where you can find it easily. It will help you

to remember what we discussed today.

SIGNATURES

Agreement to Participate in Research

By signing my name below, I confirm the following:

- I have read/had read to me this entire consent form.
- All of my questions were answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits were explained to me.
- I voluntarily agree to take part in this research study. I have been told that I can stop at any time.

Subject's Name *[please print]*	**Subject's Signature**	**Date**

Name of Witness (if applicable*)	**Signature of Witness**	**Date**

**The presence and signature of an impartial witness is required during the entire informed consent discussion if the short form process is used or the subject/legally authorized representative is blind or unable to read.*

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