Reducing cannabis use for sleep among adults using medical cannabis

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: CannSleep

Company or agency sponsoring the study: National Institutes of Health

Principal Investigators:
Mark A. Ilgen, Ph.D., Associate Professor, University of Michigan Department of Psychiatry
J. Todd Arnedt, Ph.D., Associate Professor, University of Michigan Department of Psychiatry
Study Coordinator: Haylie J. Stewart, University of Michigan Department of Psychiatry

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to provide your informed consent before you can start study-related activities. Before you do, be sure you understand what the research study is about.

Research studies hope to make discoveries and learn new information about certain conditions and how to treat them. You should consider the reasons why you might want to join a research study or why it might not be the best decision for you at this time.

Research studies don't always offer direct benefit. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study, such as amount of time required. In your decision to participate in this study, consider all of these matters carefully.

The purpose of this research study is to look at the effect of two different programs aimed at helping people manage insomnia. The program sessions focus on educational information about insomnia and strategies for managing sleep problems. We are looking to enroll people who have insomnia and use cannabis to improve their sleep to see if they could benefit from these programs. This research study will help us learn how we can improve current therapies to help manage insomnia for people who use cannabis to improve their sleep.

This research study is recruiting people who are having trouble sleeping and are using cannabis to improve their sleep. If you choose to take part, you will be asked to participate in a 6-week program delivered via video chat or telephone, as well as complete several surveys today and approximately 2 and 4 months after today. Today, we will ask you to complete a baseline survey and short interview. We will also ask some participants to put on a sleep monitoring watch and wear it continuously for at least seven days. Starting tomorrow, we will ask you to complete an on-line daily sleep and cannabis use

survey. The daily surveys will continue until you complete the study. You will also be randomly assigned to one of two programs for this approximate 4-month study.

Both programs include 6 one-on-one sessions with the study therapist. All sessions will last approximately 45 – 60 minutes. After the last session, we will ask some participants to wear the sleep monitoring watch for at least 7 more days, before we meet to complete your first follow up assessment, then again for at least 7 days before the final follow up assessment. Both will consist of a follow up survey and short interview, and a voluntary urine drug screen. The 6 sessions and follow-up interview will be audio-recorded (voice only). You can earn up to $200 in cash or gift cards and the study will last approximately 4 months.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include potential loss of confidentiality and discomfort when answering sensitive questions. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by allowing us to better understand how to deliver appealing and helpful programs related to insomnia and cannabis use. More information will be provided later in this document.

You can decide not to be in this study. Participation is completely voluntary.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this research study is to look at the effect of two different programs aimed at helping people manage insomnia. The program sessions focus on educational information about insomnia and strategies for managing sleep problems. We are looking to enroll people who have insomnia and use cannabis to improve their sleep to see if they could benefit from these programs. This research study will help us learn how we can improve current therapies to help manage insomnia for people who use cannabis to improve their sleep.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You can take part in this study if you are 21 years of age or older, are currently using cannabis and are having trouble sleeping, and have a telephone/laptop/tablet/computer that you can use during the study.

3.2 How many people are expected to take part in this study?

We expect up to 60 people to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to be in this research study, you will be asked to complete the following:

1. Complete a baseline survey and short interview
2. Some participants will receive and continuously wear a daily sleep monitoring watch for at least 7 days starting today
3. Receive and answer daily online sleep diary and cannabis use surveys starting the day after enrollment for about 7 weeks, then again approximately one week prior to the final follow up;
4. Participate in 6 remote program sessions via telephone or video chat over about 6 weeks, which will be audio recorded;
5. Some participants will receive and continuously wear a daily sleep monitoring watch for at least 7 days after you complete all program sessions and 7 days before your 4 month follow up assessment
6. Complete two follow up surveys, short interviews, and urine drug screens approximately 2 and 4 months after enrollment.

If you decide to be in this research study, you will be assigned to one of two groups that focus on sleep and cannabis use for this approximately 4-month study by staff opening an envelope to see what group you are assigned to. Both groups are one-on-one remote program sessions delivered by phone or video

chat, and are 6 sessions long. The study therapist will call or video chat with you once a week for about six weeks to talk about your sleep and cannabis use. You can talk to the therapist via phone or a video chat platform (BlueJeans, Skype for Business, or Zoom through the University of Michigan). These sessions will last about 45 – 60 minutes and will be audio-recorded. We will audio-record all sessions to be sure that that therapist is conducting the sessions the same way for everyone. These recordings will be used only for this research study. You may refuse to be audio recorded and still participate in this study.

For the first 7-10 weeks and for the week before your final assessment in this study, you will be asked to complete a daily online survey about your sleep and cannabis use. You will also be asked to complete two follow up assessments approximately 2 and 4 months after today, that will include a survey, a urine drug screen, and a short interview about any substance use. The results of urine drug screens will be kept confidential. Only our study staff will have access to the results of these urine drug screens.

If you are selected to wear the sleep monitoring watch, you will be asked to wear the watch for at least seven days at the start of your study participation, for at least seven days after completing the program sessions, and for at least 7 days at the end of your study participation. You may wear this watch while you shower or bathe, for up to 30 minutes. Please do not wear during other water activities, such as swimming. You will be given a brochure with more information if you are selected. There will be no additional compensation for wearing the watch. If you are selected, you have the option to choose not to wear the sleep monitoring watch and may still participate in the rest of the study.

4.2 How much of my time will be needed to take part in this study?
If you are eligible and decide to participate in the study, you will be asked to take a baseline survey and timeline follow back interview that may take up to 1 hour to complete. You will also be asked to complete daily online surveys that may take up to 10 minutes to complete. You will be asked to complete 6 remote program sessions delivered via video chat or telephone, each taking 45 minutes to 1 hour to complete. All participants will have two follow ups; one approximately 2 months after today, and another one approximately 4 months after today, both of which are expected to last 1 hour.

4.3 When will my participation in the study be over?
Your total study participation should take up to 4 months to complete. The entire study is expected to last about 3 years.

4.4 What will happen with my information and/or biospecimens used in this study?
Your collected information and biospecimen (urine) test results may be shared with the National Institutes of Health who is sponsoring this study.

Biospecimens will not be stored, or shared outside of the study. Urine test results will be immediately recorded and the sample promptly discarded by a member of our study staff or by you personally.

With appropriate permissions, your collected information and biospecimen test results may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers (meaning any information that would identify you, like name, address or phone number, would be removed) and used for future research

studies or distributed to another researcher for future research studies without additional informed consent. Urine samples will be destroyed upon collection.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Some of the questions that will be asked are about sensitive or personal information such as your cannabis use. These questions may make you feel uncomfortable or anxious. You may skip any question you don't want to answer and you are free to leave the study at any time. The daily sleep monitoring watch (Actigraph) is worn on the wrist like a regular wrist watch. It may cause discomfort and/or skin irritation. If you experience discomfort or irritation you may remove the sleep monitoring watch. Watches will be thoroughly cleaned and disinfected before and after each use.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. By participating in the program, you may learn more about strategies for managing insomnia, sleep, and other health behaviors. We hope this study will help us better understand how to deliver remote therapy sessions focused on cannabis and sleep.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

If you decide not to take part in the study, there will be no penalty to you. Participation in this study is voluntary. Choosing not to participate will not affect you in any way.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please email hayjay@med.umich.edu or tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

We do not expect that you would experience any harm if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study. Because the sessions will be done over the phone/video chat and surveys completed on-line, you may be charged costs for minutes or data used on your personal telephone bill. We will give you $30 to help cover any costs you may incur.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

To thank you for our time, you will receive: $40 for completing the baseline assessment, $40 for completing the follow-up assessments, $10 for completing at least four out of seven days of the daily online survey for every week before your first follow up, $10 for completing four out of seven of the daily online surveys for the week before your final follow up, plus an additional $20 for providing a urine drug screen sample at each follow up ($10 each). You will also receive $30 for any cost related to the use your technology. In total, you may receive up to $200 for completing all parts of the full study and this will be paid in the form of cash or gift card.

Study Activity	Amount
Baseline survey/interview ($40)	$40
Daily online survey ($20 for completing 4/7 days per week for weeks ~1-8)	$20
2 month survey/interview ($40), Urine drug screen ($10)	$50
Daily online survey ($10 for completing 4/7 days the week before final follow up at month ~4)	$10
4 month survey/interview ($40), Urine drug screen ($10), Technology use payment ($30)	$80
	Total: $200

8.3 Who could profit or financially benefit from the study results?
Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my information?
To keep your information confidential, we'll create a unique study ID number to use for your information, rather than your name or any other details that someone could use to identify you. Although we'll keep a list of all the people who participate in the study, no one outside our study team will be able to figure out who participated or which people gave which answers. Your name and other identifying information will be kept securely and separately from your research data. Audio recordings will be collected using a digital recorder and therapy sessions will be encrypted and immediately uploaded to a password protected UM server and deleted from the recorder.

The computerized surveys are designed and administered using the REDCap database (https://www.project-redcap.org/). REDCap is dedicated to protect all customer data using industry best standards. For more information, REDCap security and privacy statements can be found at https://www.iths.org/wp-content/uploads/About-REDCap-Vanderbilt.pdf

The program sessions, assessment interviews, and urine drug screen confirmations will be delivered remotely via telephone or a video conferencing platform. You will have the option to use a video chat platform of your choice (e.g., BlueJeans, Zoom, Skype for Business, etc.) to complete some of your study activities. Your confidentiality will be kept to the degree permitted by the technology being used. Although every reasonable effort will be taken, confidentiality during actual web-based or video chat communication procedures cannot be guaranteed.

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.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report a problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Mark A. Ilgen, Ph.D. Mailing Address: 2800 Plymouth Road, Ann Arbor, MI 48109 Telephone: (734) 845-3646 Email: marki@umich.edu	Study Coordinator: Haylie Stewart Mailing Address: 2800 Plymouth Road, Ann Arbor, MI 48109 Telephone: 734-222-7426 Email: hayjay@umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*
- Handouts related to the program session you are participating in
- Resource brochure
- ActiGraph watch brochure

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to audio recording solely for purposes of this research

This study involves audio recording.

_____ Yes, I agree to be audio recorded.

_____ No, I do not agree to be audio recorded.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____