ClinicalTrials.gov ID:

NCT03658954

Title:

Development of a Multimodal Sleep Intervention Using Wearable Technology to

Reduce Heavy Drinking in Young Adults

Document:

Informed Consent Form

Date:

6/3/2020

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 1 (2016-2)
YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: *Development of a Multimodal Sleep Intervention Using Wearable Technology to Reduce Heavy Drinking in Young Adults*
Principal Investigator: Lisa Fucito, PhD
Funding Source: National Institutes of Health

Invitation to Participate and Description of Project

You are invited to participate in a research study designed to test the effects of different sleep intervention components on sleep and alcohol use in young adults. The sleep intervention components include: (1) sleep hygiene advice, (2) sleep and alcohol use self-monitoring including the use of wearable devices to track sleep and alcohol consumption, and (3) personalized feedback about sleep and alcohol data. This study also seeks to compare the alcohol sensing capabilities of two alcohol trackers against one another.

You have been asked to participate because you are 18-25 years of age, reported ≥3 heavy drinking occasions in the last 2 weeks, reported having concerns about your sleep, and have a personal smartphone available for use along with the wearable sleep and alcohol devices provided in the study.

If you are eligible to participate, you would be one of 120 participants we are seeking at the SATU clinic of the Connecticut Mental Health Center (CMHC). SATU is located at 1 Long Wharf Drive in New Haven. Alternatively, you can complete visits at the CMHC main offices (34 Park Street in New Haven) or the Yale School of Nursing (400 West Campus Drive in Orange).

Description of Procedures

Participation in this study will consist of an initial, in-person intake appointment (Week 0), a 2-week daily sleep and alcohol monitoring period (Weeks 1-2), 2 in-person visits (End of weeks 1 & 2), and 3 follow-up visits (Weeks 4, 8, 12).

Your participation in the study will consist of:

Screening, Intake, and Randomization (Week 0): At the initial intake/screening appointment, you will be asked to complete a number of questionnaires and self-assessments that will ask you about your sleep, alcohol use, health behaviors, mood, and psychological characteristics, and you will complete two computer tasks. We will also ask for demographic information including age, race, socioeconomic and marital status, and educational and occupational levels. We will measure your height and weight. In addition, we will measure your breath alcohol level at this appointment and all other in-person visits. You will be asked to have a Breathalyzer test by blowing into a small tube for five seconds. We will also obtain a urine sample to check on drug use. If your urine sample

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indicates use of illegal drugs, you will be excluded from the study automatically and will not receive any pay. Your urine drug test results will be destroyed immediately after the screening visit. This visit will take about 2 hours.

If you are eligible for the study based on the screening visit, you will randomly be assigned to 1 of 3 treatment conditions (like the flip of a coin), which vary by the extent to which you will be asked to actively self-monitor your sleep and alcohol habits, as well as the type of feedback that may receive about your sleep and alcohol self-monitoring/tracker data. You will be told what treatment condition you received at the end of your participation. Regardless of assignment, all participants will receive sleep hygiene advice and will be asked to wear a Actiwatch (wrist-worn actigraph device) that records sleep, an Alcohol Monitoring Systems Sensor (ankle-worn blood alcohol tracker), and a Skyn Sensor (wrist-worn blood alcohol tracker) device.

Treatment Phase (Weeks 1-2): You will begin wearing the actigraph and blood alcohol tracker immediately after the intake every day for a seven-day period. In addition, those assigned to the 2 conditions that involve active sleep/alcohol diary self-monitoring will also complete daily mobile application-based sleep diaries. We will arrange to pick up the monitors from you at the end of the seven-day monitoring period. The next day you will be asked to return for an in-person visit (Week 1 visit). At this in-person visit, you will receive brief mobile application-based sleep hygiene advice and handouts summarizing the health tips. This process will be repeated for another seven-day period, leading to the next in-person visit at the end of week 2 where an end of treatment evaluation and exit interview will be completed (Week 2 visit). Both treatment phase visits will take about 30-45 minutes.

Follow-Up Phase: (Weeks 4, 8, 12): You will be asked to attend a follow-up visit at each of these time points for a total of 3 follow-up visits. At each follow-up visit, you will complete a number of questionnaires that will ask about and assess your sleep, mood, health behaviors, alcohol use, psychological characteristics, and you will complete a computer task. The first of these follow-up visits will take about 75 minutes and the others 30 minutes.

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.

Risks and Inconveniences

Friction of the ankle bracelet against your skin incurs risk of itching, sweating, skin marks, and benign skin irritation. Rarely, these can complicate into more severe skin irritation or redness, sores, bruising, or open wounds. To minimize these risks, we ask that you clean around and underneath the sensor each day as part of a shower, inspect the area each day for skin damage, and contact us if skin damage occurs (see In Case of Injury, page 5). Also, we will clean and disinfect the sensor before fitting it on you and adjust it to the correct size for your ankle so as to minimize undue friction or tightness.

There are no other physical risks associated with this study. However, there is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Benefits

There is a need to improve sleep among young adults. All participants in this study will receive brief evidence-based advice that may help them improve their sleep and their drinking. Many participants will also engage in active sleep and alcohol use self-monitoring that may help participants learn more about their sleep and sleep-related behaviors. Further, many participants will also receive personalized feedback about their sleep and alcohol use that may further increase behavior awareness and promote behavior change. All participants will be offered honoraria for their participation.

Readings derived from alcohol trackers may not be accurate and you should not make decisions about operating a vehicle based on these alcohol readings.

Economic Considerations

Participants will not be charged for any aspects of the treatment. Participants will be randomized to 1 of 3 mobile sleep intervention conditions that will be provided to them at no cost.

Participants will be paid $30 for completing the intake, $10 each for the week 1 and 2 in-person treatment visits, $50 for completing the week 4 follow-up visit, $55 for completing the week 8 follow-up visit, and $60 for completing the week 12 follow-up visit, for a total of $215. Participants will also be compensated for at-home monitoring activities: (1) $2 per day for wearing the Actiwatch and Alcohol Monitoring Systems Sensor alcohol tracker (14 possible days for a total of $28), (2) $1 per day for wearing the Skyn Sensor alcohol tracker (14 days for a total of $14) (3) $10 for returning the Actiwatch and Alcohol Monitoring Systems Sensor (2 possible occasions to return for a total of $20), (4) $10 for returning the Skyn Sensor (2 possible occasions to return for a total of $20), and (5) and $1 for completing each sleep diary (14 possible days for a total of $14). The total possible compensation for at-home monitoring is $96. Therefore, the total possible compensation for participants is $311.
I understand the Economic Considerations described above:

☐ Yes ☐ No Initials: _____

Participant Device Responsibility

During the study intervention, the study team are essentially loaning you this devices/research equipment to wear for two weeks. If you decide to withdraw from the study participation prematurely, the devices/research equipment **MUST** be returned to the study team in the original condition they were given to you and in a timely manner. These devices can be returned in either in person or via mail service to the address listed below.

Yale University
Attention Fucito, Lisa
Psychological Medicine Service
Deliver To Rm: Fitkin Memorial Pav, 6th Floor, Room 0619
789 Howard Ave
New Haven CT 06519

The devices/research equipment have no off-market value and do not work outside of the spectrum of the study. By signing your initials below, you are accepting responsiblity for the devices/research equipment. The consequences of not returning, damaging, or destroying the devices/research equipment may result in billing for the cost of replacements. Please maintain the devices/research equipment as they are expected to be returned to the study team in the same condition they were given to you.

I understand that I am responsible for the devices/research equipment that I am being loaned in order to collect data as part of the study. I understand that I am to maintain this devices/research equipment for the two week duration when I am responsible for them. I understand that I will have to return this devices/research equipment to after the two week study intervention or in the event of a premature withdrawl/completion of the study. Finally, I understand that I may be held responsible for the cost of replacing the devices/research equipment in the event that they are damaged, destroyed, or not returned to the study team.

☐ Yes ☐ No Initials: _____ Date: _____

Printed Name: _____

Treatment Alternatives/Alternatives

Alternatives to treatment in this study include evidence-based web-based treatment programs for sleep and/or alcohol use, some of which are available at a cost to the consumer.

Confidentiality

We are committed to protecting your privacy, but we are ethically obligated to disclose your identity in some cases. Examples of information that we may have to disclose include abuse of a child or elderly person, or certain reportable diseases. When the results of the research are

published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

Representatives from the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential. Furthermore, authorized representatives of the National Institutes of Health and the Department of Health and Human Services may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

In the course of your participation in this study, a research record will be established for you. The research record includes all questionnaires and measures you will complete to help us develop the intervention. This research record will be treated as confidential.

In order to strictly protect your confidentiality, your research record will be coded by number rather than your name. Your name will not be included in this data and questionnaires will be maintained according to your coded study number. None of the research questionnaires require that you provide information (e.g., name, address) that would identify you. We will keep a master list that connects coded study numbers to participant names and contact information. This is the only document that will link coded study numbers to participants' names and it will be kept in a locked file cabinet, where it can be accessed by senior level project staff. You may be contacted via email by study staff. At no time will any private health information about you be transmitted via email.

The data collected will be used without your name for the evaluation of the research and may be used in the future in related or other studies. These data may also be used in publications about the study. However, your name will not appear in any study reports or publications.

Your research data will be kept for 7 years. After that time, it will be destroyed anonymized, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study.

Other researchers may request the use of the data collected in this study. At the discretion of Dr. Fucito and her collaborators, data may be sent to outside researchers for the purposes of research, analysis, and statistical reporting. However, only anonymous information about you will be used in these circumstances. No identifying information will ever be sent to researchers using the data in this way.

Certificate of Confidentiality

If you decide to take part in this research study, as part of the research record, you will be required to give us information about your alcohol and drug use, consequences you have

experienced related to alcohol and drug use, along with other related behaviors and attitudes. We have obtained a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH) to protect information in our research records. The CoC is issued to protect the investigators on this study from being forced to tell people that are not connected with this study about your participation in this study, even under a subpoena. The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities.

Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your participation in the research, then we may not use the CoC to withhold this information.

With your consent, your exit interview at your in-person visit at Week 2 will be audio recorded. The purpose of recording these sessions is to help us better identify what sleep intervention components were most helpful. These recordings will be used for study analysis purposes only. You should understand that these recordings may contain spoken information about your health behaviors and/or your participation in the study. It is possible that the research staff member conducting the exit interview may use your first name during the session, but will never use your last name. By signing this consent form, you will waive any opportunity to review, inspect, or approve the recordings or any materials that may be used in conjunction with the recordings. You should also know that neither your last name, nor other direct identifying information will be recorded on the tapes. These recordings will be destroyed once they are used for the above reasons. You may decline taping without prejudice for continuation in the study, and are free to withdraw your consent for audiotaping of the counseling sessions at any time during the conduct of the study.

I agree to allow each session with the study counselor to be audiotaped:

☐ Yes ☐ No Initials: _____

In Case of Injury

If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. In the event of a medical emergency from 9:00AM to 5:00PM Monday through Friday, please contact the study Principal Investigator, Lisa Fucito, PhD, at (203) 200-1470, and after hours please contact the CMHC operator at (203) 974-7300 and ask for the SATU on call physician or contact your local emergency department/dial 911. You do not waive your legal rights by signing this form.

Voluntary Participation and Withdrawal

Your participation in this study is voluntary. You are free to choose whether or not you wish to participate. Refusing to participate will involve no penalty or loss of benefits to which you are

otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study. If you do choose to participate, you are free to withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments. You can choose not to answer specific questions on the pen and paper questionnaire that we ask you to complete, and this will in no way affect your study participation.

If you choose not to participate or withdrawn from the study before it is completed, it will not harm your relationship with your own doctors or with the Connecticut Mental Health Center or Yale University. You do not give up any of your legal rights by signing this form. At your request, we can refer you to a clinic or doctor who can offer you treatment.

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to Dr. Lisa Fucito, Yale New Haven Hospital, 20 York Street, Fitkin Building – F619, New Haven CT 06510.

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

The researchers may withdraw you from this study at any time. This could be because you have not followed our instructions or because the entire study has been stopped, or if we believe that it is not in your best interest. If you withdraw from the study, you do not have the right to withdraw the research data obtained from you during your participation.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

CONSENT FOR FORWARDING ADDRESS

In the event that the investigators cannot contact me at my current address and phone number, I give consent for the following persons to be contacted to obtain my forwarding address and phone number: (I will tell these persons that they may be contacted)

Name: _____ Name: _____

Relationship:_____ Relationship: _____

Address: _____ Address: _____

_____ _____

Phone: _____ Phone: _____

CONSENT TO RECONTACT

The research team may wish to contact you in the future, to clarify questions from the questionnaires or interviews, or to invite you to participate in other studies. Therefore, we ask your permission to contact you in the future. Giving your permission for the research team to contact you does not obligate you to answer any future questions, or to participate in any future research-- you always have the right to decline further participation in research. Please indicate your preference about future contact by writing your initials in one of the spaces below:

Initials: _____ I give the research team permission to contact me in the future.

Initials: _____ I do not give the research team permission to contact me in the future.

Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject:_____

Signature:_____

Relationship:_____

Date:_____

_____ _____

Signature of Principal Investigator Date

or

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_____ _____

Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator Lisa Fucito, PhD, 203-200-1470.

If, after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

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