Impact of Reduced Cannabis Use on Functional Outcomes

NCT03681353

Informed Consent Form

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Impact of Reduced Cannabis Use on Functional Outcomes

CONCISE SUMMARY

The purpose of this study is to assess the impact of reduced frequency and quantity of cannabis use on functioning. If you agree to participate in this study, you will be asked to attempt to quit or reduce cannabis use. You will attend three in-laboratory sessions. In the first, you will complete several self-report questionnaires, and be interviewed by a study team member about psychiatric symptoms and substance use disorders. After the screening visit, you will be asked to monitor your cannabis use at home for two weeks. You will be asked to complete electronic diary entries in the morning and evening. You will be asked to respond to alarms on the phone we loan you three times per day. Each time an alarm sounds, you will be asked to upload video recordings of yourself doing an oral saliva test.. You will be asked to wear a wristband activity monitor for eight weeks. After two weeks of monitoring, you will be asked to come in for your second visit. We will give you a urine test at that time. After that, you will continue home monitoring for six more weeks. After you have completed the home monitoring, you will be asked to attend a final laboratory session in which you will be interviewed regarding your experiences with home monitoring.

You may benefit by quitting or reducing your cannabis use. Risks to participating in the study include the risk of discomfort or distress in answering questions. Reduction of marijuana use can cause withdrawal symptoms. Symptoms can last for a few days to several weeks. These may include: headache, trouble sleeping, sweating, night sweats, anxiety and/or depression, nightmares or vivid dreams, irritability, and cravings for use. There is a risk of loss of confidentiality.

You are being asked to take part in this research study because you are a cannabis user. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Kimbrel's and his research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Kimbrel will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

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WHY IS THIS STUDY BEING DONE?
The purpose of this study is to assess the impact of reduced frequency and quantity of cannabis use on functioning.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 25 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will asked to sign and date this consent form. This study includes two laboratory visits and eight weeks of home monitoring. The first session determines if you are eligible to continue with the rest of the study. In this visit, you'll provide us a urine sample for a drug screen, and if you are a woman, a pregnancy test. Your urine sample will be sent to LabCorp, Inc., for further analyses. You'll also provide us with three spit samples as a measure of any recent marijuana use. Also in that session, you'll fill out some questionnaires and be interviewed by our study coordinator about psychiatric symptoms, anger, trauma history, sleep, and substance use history. You will be asked to do some computerized tasks to measure impulsivity. You will also complete some scales of the Wechsler Adult Intelligence Scale to measure your working memory. If you are having thoughts of suicide, you may be asked to develop a safety plan with a study staff member. You will be paid $75 for the screening visit. This visit will take up to four hours.

If you're eligible to participate in the study, we will loan you a mobile telephone, some saliva test strips, and a wrist activity monitor to take home for eight weeks. We will also give you a small scale to use to help you estimate how much marijuana you use.

You'll be asked to wear a wrist activity monitor, a Fitbit Charge 2, wrist activity monitor 24 hours per day. The Fitbit measures body movement and heart rate. While wearing the monitor, you will be reminded to do whatever activities you would normally do, except for bathing, strenuous exercise, and swimming. You can remove the Fitbit while bathing, swimming, or performing strenuous exercise. The mobile phone that we loan to you will be equipped with an application (app) developed by our study team. The app is an electronic diary. We will ask you to complete daily and nightly electronic diaries on the smart phone. If you do not complete at least ten nightly diaries during the first two weeks of your home monitoring, we will withdraw you from the study. This electronic diary will send three alarms per day to you, and we will ask you to respond to the alarm. Questions in the electronic diary will include items about urges to use cannabis, recent use of cannabis, and your surroundings (e.g., where are you, what you are doing). Each time an alarm sounds, you will be prompted to video-record yourself completing a saliva test. Then, you will upload it for the study team.

For the first two weeks, you will be paid for uploading a video regardless of whether or not the saliva reading shows you have been using marijuana. During this two-week period, you will also be asked to start an alarm reading if you are going to be using marijuana. You will start the reading immediately before consuming marijuana, and an alarm will sound an hour later. At this alarm, we will ask you to

video-record a saliva test and upload the results to the study team. You can earn up to $175.00 for uploading videos during this two week period.

We will pay you $400 for wearing the Fitbit and completing the diary (that is, $50 per week). We will also pay you a bonus of $25 each week if you miss less than one alarm per day during the week.

If you would like, we will send study-related text messages on your personal phone. Because text does not provide a completely secure and confidential means of communication, please do not opt in to texts to your personal phone if you wish to keep your communication with the study private. The following are examples of the type of text you might receive: "Time for a diary! Please fill out a [type of diary] diary.", "You missed an alarm. Remember to respond to the next one!", or "Contact [name of study coordinator] if you're having problems with your equipment." You can opt out of text messages now, or at any time during the study.

Please indicate your text messaging preference by circling an option and initialing:
I would like to receive text messages on my personal phone. **YES NO Initials: _____**

At the end of the two week period, we will ask you to come to the lab to provide a urine sample and spit samples. Your urine sample will be sent to LabCorp for analysis.

After this visit, you will continue your at-home monitoring. We will pay you $25 for providing this sample. From this time point until the end of the study, you will be paid for uploading your readings, and you will be paid a bonus for providing readings that suggest you have abstained from using cannabis on six out of seven days in the week. This period of monitoring will last six weeks. You can earn up to $1598.00 for this portion of the study.

After you have completed the eight weeks of monitoring, you will be asked to return to our lab to return the equipment. You will be asked to provide spit samples and a urine sample that will sent to LabCorp for analysis. A study team member will interview you regarding your experiences with home monitoring, and ask for suggestions for improvement. You will complete questionnaires regarding substance use, sleep, and psychiatric symptoms. If you were interviewed regarding PTSD symptoms during the screening visit, we will ask you to repeat this interview. We will pay you $150 for completing the interviews, and $50 for returning the equipment on time.

While you're in the study, you may find that you'd like to refer another person to participate. In order to encourage you to refer another person to the study, we'll give you a referral coupon that is marked with an identification number that is unique to you. You can give this referral coupon to any person you think might be interested in the study. If that person comes in for a screening visit and brings us his/her coupon, we'll offer you a $20 payment for taking the time to make the referral. Please note that we won't be able to tell you whether or not a specific person uses your coupon. We ask that you not discuss

with others whether you think/believe a person you have referred may be participating in the study. You can choose not to distribute the coupons we give you, and you can refuse to even receive the coupons.

HOW LONG WILL I BE IN THIS STUDY?
Your involvement in this study will last about nine weeks.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
There is a risk of discomfort or distress in answering questions in the interviews and questionnaires. However, distress and discomfort related to questionnaire completion and the psychiatric interview are usually temporary and well-tolerated. You may refuse to answer any questions while completing the questionnaires. Risks also include discomfort related to reducing cannabis use. Reduction of marijuana use can cause withdrawal symptoms. Symptoms can last for a few days to several weeks. These may include: headache, trouble sleeping, sweating, night sweats, anxiety and/or depression, nightmares or vivid dreams, irritability, and cravings for use.

There is a potential risk of loss of confidentiality. If you express feelings about wanting to harm yourself or others, we will need to refer you for appropriate care.

If you are loaned a Duke phone for use during this study and you use it for non-study related reasons, this could add your personal information onto the device and potentially result in it being sent to unauthorized persons. The device will be preset with security settings. Please do not alter these during the course of the study.

When you return the device at the end of the study, the device will be cleaned to remove any of your personal information. If the device is lost or stolen during the course of the study, please contact the study team immediately.

As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

If you are a woman who is able to become pregnant: Cannabis use may be unsafe during pregnancy, and women who are pregnant or are planning to become pregnant are advised not to use cannabis. Although the interventions being used in this study are themselves safe to use during pregnancy, the changes that happen to your body during pregnancy can affect some of the things we are measuring in this study, and therefore women who use cannabis who are pregnant or who are trying to become pregnant are excluded from participating. If you are a woman of childbearing potential (you have not had a hysterectomy or gone through menopause) and you are currently in a sexual relationship with a man who is capable of fathering a child, a urine pregnancy test will be done, and it must be negative

before you can continue in this study. If you are currently using a method of birth control, we strongly advise you to continue to use your current method. If you are not currently using a method and there is a chance that you might engage in sexual activity that might put you at risk of pregnancy, we advise you to use an effective method of birth control, such as hormonal methods (birth control pills, patches, implants, injections), or barrier methods (condoms or diaphragm with spermicide). If you do become pregnant during this study or if you have unprotected sex, you must inform your study physician immediately.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefit to you. You may benefit from quitting or reducing your cannabis use. We hope that in the future the information learned from this study will benefit other people with your condition.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
Instead of being in this study, you have the alternative of talking with our study team about other treatment for cannabis use. You can also talk with your personal doctor about other options for treatment.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

When you return the Fitbit wristband, the data on the device will be transmitted by the study coordinator to the Fitbit cloud servers. One of our study staff members will pull data from the Fitbit servers back to a Duke University secured server. The data collected by the device and sent to the Fitbit servers does not contain your name, medical record number, or another direct identifier. Data are encrypted on the device, while being transferred to Fitbit servers, and while being transferred back to Duke. A copy of the data will remain on the Fitbit servers.

Fitbit is a commercial company and they, or their business partners, may disclose information about you collected from the Fitbit device. Any information they disclose is not covered by the privacy regulations in this document.

Electronic diary data that you provide to us using the smart phone app will be downloaded directly to a Duke secured computer server from the phone via a direct USB connection.

DUKE UNIVERSITY HEALTH SYSTEM

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Impact of Reduced Cannabis Use on Functional Outcomes

As part of the study, results of your study-related laboratory tests, x-rays, and procedures may be reported to National Institutes on Drug Abuse (NIDA) and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of NIDA, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

All of the urine and saliva studies are being done only because you are in this study. The study results will not be provided to you OR sent to your physician.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to

outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Kimbrel or a member of his study team. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to $2691.00 for study participation. You will be paid $75 for the screening visit. You can earn up to $1771.00 for providing cannabis saliva readings during that portion of the study. We will pay you $400 for wearing the Fitbit and completing the diary (that is, $50 per week). We will also pay you a bonus of $25 each week (up to $200) if you miss less than one alarm per day during the week. We will pay you $25 for coming in to provide a urine sample after two weeks of monitoring. We will pay you $150 for completing the interviews in the follow-up session, and $50 for returning the equipment on time. You can receive $20 for referring another participant to the study. If you withdraw from the study, we will pay you for those parts of those study that you have completed.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by

Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Kimbrel at 919-384-8582, ext. 4054 during regular business hours and at 984-999-1633 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you withdraw from the research, we will ask you to return the study equipment. If you do decide to withdraw, we ask that you contact Dr. Kimbrel in writing and let him know that you are withdrawing from the study. His/her mailing address is Duke University Medical Center, Box 2969, Durham, NC 27705

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include if you are not able to complete study procedures. If this occurs, you will be notified and your study doctor will discuss other options with you. If you do not complete at least ten nightly diary readings during the first two weeks of your home monitoring, you will be withdrawn from the study.

Your study data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

A description of this clinical trial will be available on https://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.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Impact of Reduced Cannabis Use on Functional Outcomes

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Dr. Kimbrel at 919-384-8582, ext. 4054 during regular business hours and at 984-999-1633 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time