# Cost Effectiveness of Combined Contingency Management and Cognitive Behavioral Therapy for Alcohol Use Disorder

NCT03987581

Informed Consent Form
Document Date: 5/23/2023

DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
**Cost Effectiveness of Combined Contingency Management and Cognitive Behavioral Therapy for Alcohol Use Disorder**

CONCISE SUMMARY

The purpose of this study is to examine the clinical effectiveness and cost-effectiveness of a treatment for alcohol use. The treatment combines an existing therapy, cognitive-behavioral therapy, with contingency management, in which people get paid to stop drinking.

If you are eligible to participate in this study, we will use a process like drawing a number out of a hat to assign you to one of four groups. No matter which group you are in, you will receive counseling sessions designed to help you quit drinking. Two of the study groups will receive the contingency management treatment in addition to counseling sessions, and two will not. If you are assigned to the contingency management group, you will be asked to make video recordings of yourself doing a breathalyzer test. Half of study participants will receive an incentive for being alcohol-free at the six-month visit, and half will not.

If you participate in the study, there may be a direct benefit to you. You may benefit from reducing or stopping your use of alcohol, but this benefit is not guaranteed. Risks of the study include alcohol withdrawal symptoms.

Your active participation in the study will last about 13 weeks. You will have three follow-up sessions. One will occur after completing study treatment, and the others are six and twelve months after your alcohol quit date. Altogether, your participation will last about one year.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you are a veteran and drink alcoholic beverages and wish to reduce or stop drinking alcohol. 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. Dedert's and his research team's salaries will be paid by this grant.

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## WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Dedert 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.

## WHY IS THIS STUDY BEING DONE?

The purpose of this study is to examine the clinical effectiveness and cost-effectiveness of a treatment for alcohol use. The treatment combines an existing therapy, cognitive-behavioral therapy, with contingency management, in which people get paid to stop drinking

## HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 250 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 be asked to sign and date this consent form. You will also be asked to sign and date a VA Health Care System consent form and HIPAA authorization. You will receive a signed copy of the consent form via email. Email is not a secure means of communication so there is a potential risk for loss of confidentiality. You will have the following tests and procedures to make sure that you are eligible:

- participate in an interview about your current mental health; and
- complete questionnaires about your current mental health and substance use. You can expect completing questionnaires will take about 45 minutes to an hour during visits.

All of your study sessions will occur in-person or remotely via a teleconferencing system like WebEx when in-person visits are not possible due to the COVID pandemic. The study coordinator will let you know if you will be allowed to attend visits in person.

You will be randomly assigned (like drawing numbers from a hat) to one of four study groups. No matter which study group you are assigned to, you will receive 12 sessions of cognitive-behavioral therapy (CBT) for alcohol cessation. This therapy is designed to help you quit drinking. The four study groups are:

1. Group 1: If you are assigned to this group, you will receive another treatment for quitting drinking called contingency management (CM). With CM, you will complete home breathalyzer monitoring for eight weeks. You will be paid for breathalyzer readings that suggest you have been abstinent from drinking. In addition, if you are assigned to Group 1, you will receive $300 if you are abstinent from drinking at a 6-month follow-up visit.
2. Group 2: If you are assigned to this group, you will receive the CM treatment described above. You will <u>not</u> receive $300 for being abstinent at the 6-month follow-up visit.
3. Group 3: If you are assigned to this group, you will receive CBT, but no CM. You will receive $300 if you are abstinent from drinking at a 6-month follow-up visit.
4. Group 4: If you are assigned to this group, you will receive CBT, but no CM. You will <u>not</u> receive $300 for being abstinent at the 6-month follow-up visit.

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The screening visit will take about 4 ½ hours, and you will be paid $50 for completing it.

After the screening visit, no matter what group you're in, you will be asked to participate in 12 weekly CBT sessions. Each session will last less than an hour. You will be asked to make a quit attempt at session 3. Each of your counseling sessions will be recorded using an iPad or iPhone. Some of your counseling sessions will reviewed by a study staff member to ensure that the counseling treatment is being done correctly. The recording will be moved from the recording device to a Duke secured server. At each counseling session, your study therapist will ask you some questions about suicide. If you are considered to be at high risk for suicide, the therapist or another staff member will work with you to get you appropriate care. You are not paid for participation in the counseling sessions.

If you are assigned to Groups 1 or 2, at your second counseling session, you will be given a breathalyzer and mobile telephone to take home for several weeks. You will use the equipment to monitor yourself taking breathalyzer readings when prompted by alarms from the mobile telephone, and upload them to the study team. The mobile telephone has a small video camera. You will be trained how to use the breathalyzer, and how to use the telephone to record yourself using the monitors. You will be trained how to upload the video to this study's website using a mobile application (called mCM) that will be on the study phone provided to you. You will practice monitoring for one week to make sure you have learned how to complete monitoring procedures. Each time you respond to an alarm on your phone by recording a practice video, you will use the phone app to scratch off a virtual lottery ticket. The ticket will indicate whether you have won a prize. Values of prizes are $1, $2, $5, $10, $20, and $100. Your chances of winning a lower value prize are higher. The video recordings are stored by the web platform InMotion Hosting Inc.

If you are in Groups 1 or 2, starting at counseling session 3 and lasting until session 10, you will be asked to record and upload your breath alcohol readings each time you hear an alarm on your phone. The study phone will send text messages to your personal cell phone each time that the alarm sounds. You can opt out of receiving text messages on your personal phone at any time. This will happen on average about ten times per week. When you upload your first breath alcohol reading that tests negative, you will use the phone app to scratch off a virtual lottery ticket. The ticket will indicate whether you have won a prize. Values of prizes are $1, $2, $5, $10, $20, and $100. Your chances of winning a lower value prize are higher. After this first negative breath alcohol reading, your number of scratch-off tickets will increase by one, up to a maximum of four, for each consecutive negative breath alcohol reading. If you miss a breath alcohol reading or you have a breath alcohol reading that suggests that you have been drinking alcohol recently, the number of scratch-offs you receive will be reset to one. The study area will allow you to see how many readings have been uploaded, and will provide information about monetary rewards for your readings. It is possible to earn about $611 for this monitoring if your readings all suggest alcohol abstinence.

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After you have completed monitoring, we will ask you to return the study equipment to the study staff. If you misplace the study equipment, or it is stolen while you have it, we ask you to tell a study staff member immediately. The telephone has tracking software on it, and we may be able to use the software to locate the phone, shut it down, and get all of the data you have stored on it. We will only use the tracking software if you report the telephone as lost or stolen, or you fail to return it to us at the end of the study. If your telephone or other equipment has been misplaced or stolen, and you still need the equipment to continue in the study, we will provide you with a replacement at no cost.

No matter what group you're assigned to, you will be asked to come in for three additional visits after your counseling treatment has ended. One visit will occur about one week after your counseling treatment has ended. The other visits will occur at 6 and 12 months after you started counseling. In each of these sessions, you will be asked to complete some questionnaires about your mood, suicidal thoughts, healthcare use, impulsivity, and substance use. At the 6- and 12-month follow-up visits, you will also be asked to provide a small blood sample by finger prick for a dried blood spot test. This test will allow us to determine if you have had an alcohol beverage recently. If these visits occur remotely, you will be asked to do the finger prick tests on your own and mail the test card back to us. The study team will work with you to demonstrate how the finger prick is done, and we will provide you with a safe way to mail back the test card.

If you are assigned to Groups 1 or 3, if you report long-term abstinence from alcohol use and your blood spot test indicates that you have been abstinent from heavy drinking, you will be paid an additional $300. You are not paid this money if you are assigned to Groups 2 or 4.

One important part of this study is evaluating whether or not this treatment is cost effective. In order to determine whether it is, we will need to collect information about your health-related care at the VA Health Care System. You will be asked to sign a VA consent form to allow us to access your medical record for the year prior to and the year after your first study visit.

**Optional Study Procedure:**

If you are assigned to Madison Tobin as your study therapist, we would like permission to share the video recordings of your therapy sessions with her supervisor. Ms. Tobin is seeking a professional counselor's license. As part of her training, she must have some sessions recorded and reviewed by an outside supervisor who is not affiliated with Duke. If you agree to being recorded, the video recording will be shared with Courtney White, MA, LPCS, a licensed supervisor. The video recording will be shared with her through Box@Duke, which is a cloud-based server to which only Ms. Tobin, Ms. White, and Dr. Dedert have access. After the video recordings are reviewed, they will be deleted from Box@Duke, and no recording will be retained.

Please note that this option is not a part of the research study. You can refuse to participate in this procedure and it will not impact your participation in the research study at all.

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I am willing to have my therapy session recordings shared with Courtney White for the purpose of providing supervision to Madison Tobin. I understand that the recording will be deleted after it is reviewed.

☐ Yes ☐ No Initials: _____

**HOW LONG WILL I BE IN THIS STUDY?**
Your active participation in this study will last about 13 weeks. You will have a follow-up session about one week after completing treatment. You will have two additional follow-up visits six months after you begin treatment, and again at one year after you begin treatment. Altogether, your participation will last about one year. 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.

Clinically relevant results of this research will be communicated with you.

**WHAT ARE THE RISKS OF THE STUDY?**
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Stopping alcohol use may cause withdrawal symptoms. Symptoms of alcohol withdrawal may include headache, insomnia, sweating, shakiness, and rarely, seizures or hallucinations.

There are no known risks associated with completing paper and pencil measures. There is a possible risk of temporary anxiety associated with discussing psychiatric symptoms. There is a potential risk for loss of confidentiality associated with using the mobile application(s).

**Blood Spot Collection**: At two sessions, you will be asked to provide a blood spot sample to assess drinking status. Blood will be taken from your index, middle, or ring finger with a very simple prick to your finger, collecting about 3mL of blood. The risks of having a blood puncture includes temporary pain for the needle stick, bruising, and rarely, infection. Some people may experience dizziness, possibly lightheadedness, or rarely, fainting. Should any of these symptoms occur, the collection process will stop and the collector will follow health and safety protocols as required.

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 reducing or stopping your use of alcohol. However, we cannot guarantee that you will stop drinking

during this study. We hope that in the future the information learned from this study will benefit other people who are trying to stop drinking.

**WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?**
Instead of being in this study, you could enroll in another alcohol cessation treatment program. There may be other treatment programs available to you in the community. Please talk to your doctor about these and other options.

**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.

If at any time during the study you are considered to be at high risk of suicide, the study team will work to get you appropriate care. This may include talking to a local emergency department or local police.

As part of the study, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Duke University Health System Institutional Review Board, National Institutes of Health, and/or the Office for Human Research Protections, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The mCM mobile application will upload the videos you take to InMotion Hosting, Inc. The data may be permanently kept by this group and/or their contracting partners. The mobile application was developed by a study staff member who is our partner at the Durham, NC Department of Veterans Affairs Medical Center.

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. We will limit some of the phone functions, like internet searching and emailing. You should not attempt to re-install those functions. You should not use the phone for personal use, for example, personal phone calls or taking pictures during the study. If you do so, this could add your personal information onto the phone and potentially result in it being sent to unauthorized persons. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others. When you return the device at the end of the

study, the device will be cleaned to remove all of your personal information. If the device is lost or stolen during the course of the study, please contact the study team immediately.

We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

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.

All of the blood sample studies are being done only because you are in this study. The study results will not be given to you to send OR sent to your physician to include in your 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.

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.

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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. Dedert 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.

**WHAT ABOUT COMPENSATION?**
You will be paid $50 for the study screening visit. You will be paid $50 for the end of treatment visit. You will be paid $100 for the 6-month follow-up visit, and $125 for the 12-month follow-up visit. If you are assigned to Group 1, you may earn up to $611 for providing breathalyzer readings that suggest you have been abstinent. You may also earn $300 at the 6-month follow-up visit if your blood stick test suggests that you have been abstinent from heavy drinking. If you are assigned to Group 2, you may earn up to $611 for providing breathalyzer readings that suggest you have been abstinent. If you are assigned to Group 3, you may earn $300 at the 6-month follow-up visit if your blood stick test suggests that you have been abstinent from heavy drinking. If you are assigned to Group 4, there will be no additional payments. Participants in Group 1 can earn up to $1237, participants in Group 2 can earn up to $926, participants in Group 3 can earn up to $625, and participants in Group 4 can earn up to $325.

Payment will be given to you in several installments. Payment will be requested for session 1 just after you have completed it. Payments during monitoring will be requested as frequently as weekly and

payment for the follow-up sessions will be requested just after you have completed them. After we request payment, it may take up to four to six weeks for you to receive payment.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual exceeds $600 in any one calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). Research subject payments to a non-employee of Duke University exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

**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. Dedert at 919-286-0411, ext. 134055 during regular business hours, or toll free at 1-888-878-6890 and ask the operator to contact Dr. Dedert at home 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 while you are in treatment, we will ask you some questions about your opinions about your therapist. Otherwise, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be used by the study team.

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 do decide to withdraw, we ask that you contact Dr. Dedert in writing and let him know that you are withdrawing from the study. His mailing address is Eric Dedert, Ph.D., Duke University Medical Center, Box 2969, Durham, NC 27705. You will be asked to return any study equipment you have been loaned.

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 failure to follow the instructions of the study staff, inability to complete the study

requirements, or inability to attend study visits as scheduled. If this occurs, you will be notified and your study doctor will discuss other options with you.

Your 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.

**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. Dedert at 919-684-9022 or 919-384-8582 x4055 during regular business hours, or toll free at 1-888-878-6890 and ask the operator to contact Dr. Dedert at home 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."

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