Title of Study:

Individualizing Incentives for Alcohol in the Severely Mentally Ill

NCT number: NCT03481049

Date of Document: 4/6/2023

WASHINGTON STATE UNIVERSITY

Research Study Consent Form

Study Title: Individualizing Incentives

Study Researchers:

Michael McDonell, Ph.D., Professor, Washington State University, Elson S Floyd College of Medicine, (509) 368-6967, Principal Investigator
Sterling McPherson, Ph.D., Associate Professor, Washington State University Elson S Floyd College of Medicine, (509) 324-7459, Co-Investigator
Naomi Chaytor, Ph.D., Associate Professor, Washington State University, Elson S Floyd College of Medicine, (509) 368-6775, Co-Investigator
John Roll, Ph.D., Professor, Washington State University, Elson S Floyd College of Medicine, (509) 358- 7836, Co-Investigator
Oladunni Oluwoye, Ph.D., Postdoctoral Research Associate, Washington State University, Community Health, (509) 368-6805, Postdoctoral Researcher
Liat Kriegel, Ph.D., Postdoctoral Research Associate, Washington State University, Community Health, (509) 358-7794, Postdoctoral Researcher
Julianne Jett, Ph.D., Postdoctoral Research Associate, Washington State University, Community Health, (509) 590-7023, Postdoctoral Researcher
Douglas Weeks, Ph.D., Research Professor, Washington State University, Community Health, weeksdl@wsu.edu

Research Coordinators:

Sara Parent, Clinical Assistant Professor, Washington State University, Community Health, (509) 496-5325, Research Associate
Mohammad Keshtkar, Research Coordinator, Washington State University, Community Health, (509)-666-1745, Research Associate
Rachael Beck, Research Coordinator, Washington State University, Community Health (509) 818-7024, Research Associate
Paige King, Research Coordinator, Washington State University, Community Health, (206)-475-1676, Research Associate
Elizabeth Smith, Research Coordinator, Washington State University, Community Health, (509) 368-6952, Research Associate
Sophie Elliot, Research Assistant, Washington State University, Community Health, (509) 496-5325, Research Associate
Mariah Brigman, Technical Assistant, Washington State University, Community Health, (509) 496-5325, Research Associate
Diana Tyutyunnuk, Research Coordinator, Washington State University, Community Health, (509) 496-5325, Research Associate
Julia Paxton, Research Coordinator, Washington State University, Community Health, (509) 496-5325
Katharine Palmer, Research Coordinator, Washington State University, Community Health, (253) 363-0828
Hannah Sylvester, Research Coordinator, Washington State University, Community Health, (509) 638-2415
Debbie Vogel, Trainer, Learning and Design, Washington State University, Community Health,

(509) 496-5325, Research Associate

Introduction
You are being asked to take part in a research study carried out by Dr. Michael McDonell. This form explains the research study and your part in it if you decide to join the study. Please read the form carefully, taking as much time as you need. Ask the researcher to explain anything you don't understand. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. There will be no penalty or loss of services or benefits if you decide to not take part in the study or quit later. This study has been approved for human subject participation by the Washington State University Institutional Review Board.

What is this study about?
This first purpose of this study is to evaluate a reward-based treatment that may help decrease drinking. This treatment is called Contingency Management (CM). In CM a person is rewarded for not using alcohol or reducing their alcohol use by drawing for a chance to earn prizes. In this study we ask participants to provide urine and breath samples at study visits to assess whether or not they are drinking. The main purpose of the study is to figure out which type of CM is the most effective for alcohol problems for people who are heavy drinkers and have mental health problems. The second purpose of the study is to figure out which type of CM is the most effective at helping people with other problems, like drug use and mental health symptoms. The other goals of the study are to figure out which version of CM is the most cost-effective and to figure out what predicts a good response to CM. If you participate in this study, we also ask you to complete interviews and fill out questionnaires at your study visits.

The study has 4 phases: The Baseline Interview, the Warm-Up Phase, The Treatment Phase, and the Follow-Up Phase. You can continue to receive other treatments, like counseling and medication, for alcohol and mental health problems while you are in the study. We plan on enrolling a total of 430 subjects for the Individualizing Incentives parent study. Forty of those enrolled participants will also be recruited for the Social Network pilot sub-study, while thirty will be recruited for the stress-cue sub study.

Phase 1. Baseline Interview.
If you decide to participate, there will be an initial visit called a baseline interview. You will complete this interview after you fill out after this consent form. The baseline visit lasts about 4 hours. We will ask you to provide a urine sample to assess your recent alcohol use, fill out questionnaires, and sign a release of information that allows us to get information about the health care you have used. We will also ask you to complete some tests that measure your memory and attention. If you complete the baseline visit, you will earn a $60 gift card for your time.

You cannot be in the study if you are younger than 18 years old or over 65 years old. You also cannot be in the study if you are pregnant or trying to get pregnant. You cannot be in the study if the researchers determine that your personal safety may be in danger because of your symptoms of medical or psychiatric illness or you have a high risk for alcohol withdrawal symptoms.

Phase 2. Warm Up Phase
After you complete the baseline interview you will participate in the 4-week Warm Up Phase. During this phase you will come in twice per week to do urine tests and to provide breath samples. You will receive gift cards for providing these tests. You will receive these rewards even if your breath and urine test results say that you have used alcohol.

We will monitor your alcohol use and study attendance 2 times a week for the 4-week Warm Up Phase. You will get to draw for prizes even if you are using alcohol. Whether or not you are eligible to be in the Treatment Phase will be decided by whether or not you show up to study visits and the result of your alcohol tests. Not everyone who starts the study will get to be in the Treatment Phase. If you are not a good fit for the Treatment Phase we will give you contact information for other alcohol treatment providers. If you provide at least 1 urine sample during each of these 4 weeks you will receive a $20 gift card.

Phase 3. Treatment Phase
If you are eligible to continue to the Treatment Phase, you will be randomly placed (by chance like flipping a coin) in one of 3 treatments. The researchers have no control over what treatment you will be in. You will have an equal chance of being placed in one of the 3 treatments. You will be in the Treatment Phase for 16 weeks (4 months). You can continue to your other non-study treatments during the Treatment Phase.

During the Treatment Phase you will come in and give urine and breath samples 2 times a week for 16 weeks. After you give a urine sample, you will get electronic “prize draws" for prizes depending on results of your valid alcohol urine test. Each group will be different in the number of draws they get. But each time you get an electronic “prize draw” you will have a 25% chance that you will get a result that says, “Good Job.” The other 75% will say Small, Large, or Jumbo. You will have a 62.6% chance of getting a Small Prize token result ($2 prize). You will have a 12% chance of drawing a Large Prize token result ($20 prize). You will have a 0.4% chance of drawing a Jumbo Prize token result ($100 prize). You will have more than a 50% chance of getting a prize with each electronic “token draw”. All prizes will be gifted via electronic gift cards through Tango. You may decide which store/service your gift cards will be available for based on what Tango offers. You may not use the electronic or physical gift cards earned from participating in this study to purchase drugs, alcohol, firearms, ammunition or weapons.

The 3 treatments are:

Regular Rewards – If you are in this treatment you will get to make “draws” for prizes when your valid urine tests show no signs of alcohol use. You will get at least 5 electronic prize draws every time you submit a valid alcohol-negative urine sample. You will get one extra draw for every 2 times in a row that your samples show no signs of alcohol use. So, if you have not used alcohol during the 2nd week you will get 6 draws, the 3rd week you will get 7 draws. If you don’t use alcohol the number of draws you get will keep getting bigger. If you use alcohol again, you will go back to 5 draws. If you then have 2 tests in a row of not using alcohol, you will go back to the number of draws you had earned before you used.

High Rewards – If you are in this treatment you will get to make at least 15 electronic “token draws” for prizes each time your valid urine test shows no signs of alcohol use. You will get one extra draw for every 2 times in a row that your samples show no signs of alcohol use. So if you have not used alcohol during the 2nd week you will get 16 draws, the 3rd week you will get 17 draws for each alcohol negative urine sample. If you don’t use alcohol the number of draws you

get will keep getting bigger. If you use alcohol again, you will go back to 15 draws. If you then have 2 tests in a row of not using alcohol, you will go back to the number of draws you had earned before you used.

Reduced Drinking Rewards– If you are in this treatment you will get to make “draws” for prizes when your valid urine tests show light or no drinking during the first 4 weeks of treatment. So you don’t have to quit drinking to draw for prizes. After the first 4 weeks you will get rewards only when your urine samples show no sign alcohol use. You will get at least 5 draws each time your urine test results show that you had light or no drinking (first 4 weeks) or no drinking (weeks 5-16). You will get one extra draw for every 2 times in a row that your samples show either light drinking or no drinking (first 4 weeks), or no drinking only (weeks 5-16). Just like in the other interventions the longer you engage in light drinking or no drinking (first 4 weeks) or no drinking (weeks 5-16) the more draws you will get. If you drink a lot (first 4 weeks) or at all (weeks 5-16) your prize draws will be reset to 5. If you then have 2 tests in a row that show light or no drinking (first 4 weeks), or no drinking (weeks 5- 16), you will go back to the number of draws you had previously.

For participating in the entire study, you have the potential to earn approximately up to $240 in gift cards for completing interviews and up to $1000 in gift cards via electronic token draws for prizes. If you decide to quit the study, you will not receive any payment beyond any rewards already earned for any completed study visits. If you earn more than $600 in gift cards from the study in one calendar year, we will ask you to sign a tax form that states your earnings exceeded that amount.

Once each month in the 16 weeks of treatment, we will ask you questions about drug and alcohol use, medical history and services used, smoking, health risk behaviors and sexual partners, and mental illness symptoms. We will also ask you to complete tests that measure your attention and memory at some of these visits. You will receive $20 in gift cards for each of these visits that you complete. Each visit will take about 60 minutes. Even if you stop attending the weekly treatment phase study visits, we will still contact you for these monthly visits, and you will still receive $20 in gift cards for attending. At the end of the treatment phase, you will complete the cognitive assessments and for your time you will receive $30 in gift cards.

Attendance—You must attend visits and submit urine samples to earn rewards, so if you miss a visit, you will not receive prize draws for that visit. Most missed visits will result in resetting your prize draws to the original level, just like if you had a positive urine test. Some pre-arranged absences may be excused on a case-by-case basis. If you miss 8 consecutive study visits during the treatment phase, you will no longer be eligible receive prize draws. However, you may continue to participate in monthly and follow-up visits.

Follow-up Phase
After the Treatment Phase we will ask you to return 4 times to take part in Follow-Up interviews. The Follow-Up Phase will last 12 months. Everyone in the Treatment Phase will participate in the Follow- Up Phase. During the Follow-Up Phase we will ask you questions about drug and alcohol use, medical history and services used, smoking, health risk behaviors and sexual partners, and mental illness symptoms. At some of these appointments we will ask you to complete tests that measure your attention and memory. This will take about 1 hour. Follow-Up Phase interviews will be at 1, 3, 6, and 12 months after you complete the Treatment Phase.

What will I be asked to do if I am in this study?
If you take part in the study, you will be asked to do the following:

- COVID-19 Safety Compliance: Follow our current COVID-19 safety practices, which may include wearing a mask, answering questions about COVID-19 safety practices, and exposure or verify your vaccine status.
- Complete the baseline interview. This will take about 4 hours. Components of this visit may be conducted over the phone. You will be asked to fill out questionnaires and provide a urine sample (described in detail below).

- Attend two study visits per week for 20 weeks to provide urine samples. Each visit should take less than 60 minutes. You will also be asked to attend 4 follow-up interviews that will last about 60 minutes each. Components of these visits may be conducted over the phone.

- Provide a urine sample and a breath sample at each study visit (including the baseline interview). A urine test, ethyl glucuronide (EtG), will be used to detect the presence of alcohol at study visits. We will ask that you supply about ½ cup of urine into a cup. The sample will be labeled with a unique study ID number in order to protect your privacy and we will test your urine at our lab either in the clinic or at WSU Spokane. Providing samples is a condition of participating in the study. At any time, you may decide not to provide samples, however this may result in discontinuing your participation in the study. Urine samples will also be tested to see if they are valid. For example, your urine sample might be too dilute to get an accurate measure of your recent alcohol use. We may not be able to accept the urine sample or you may be asked to give another one.

- Answer questionnaires regarding alcohol, nicotine, and drug use; location of frequently used resources, and general physical and mental health. You may refuse to answer anyof these questions.

- Complete cognitive tests. These tests will be given on an iPad or computer and willassess your attention, memory, and your alcohol cravings.

- Sign a release of information. We will ask you to sign a release of information so that we can obtain your medical records and health care use information for 15 months before you start the study until 17 months after you start the study. This will help us see if the study treatments are cost-effective. We will also ask for you to sign a release of information so that we can confirm that you are receiving treatment services at either Sound or Frontier Behavioral Health.

- Safety Issues. For safety purposes, we ask that you do not attempt to drive to your study appointments if you are intoxicated or under the influence. If team members observe overt behaviors of intoxication, you will be asked to remain in our laboratory or office until your blood alcohol level (assessed by a breathalyzer) returns to below the legal limit. You will not be allowed to participate in any electronic token draws nor receive payments for appointment participation if you are intoxicated. If you appear intoxicated one hour before our office closes you will be asked to either call a friend or family member to pick you up or will be provided with a cab ride home. Participants who repeatedly come to study visits intoxicated may be asked to stop participating in the study. Participants will be required to find alternative modes of transportation (bus, cab, ride from relative or friend) if they are

under the influence of any substance. If you are unable to find transportation, we will assist in finding transportation for you. If you are experiencing symptoms of alcohol withdrawal or you may be asked to be evaluated by a medical professional. These procedures are to make sure that you and others are safe. Should a medical emergency occur at a study visit, the study team may call 911.

- Suicidal Ideation. We ask questions about suicidal thinking and behavior in our study because we want to know if people who reduce their alcohol intake are less likely to experience suicidal thinking. If you disclose that you are experiencing suicidal ideation, we will contact your case manager or a designated crisis manager to ensure you are receiving the support you need. This study is focused on alcohol treatment, as such, the research staff are not mental health clinicians and we will contact a mental health clinician in the event you are endorse suicidal ideation or behaviors. We want to make sure you are safe. If you report suicidal ideation or behaviors, we will ask you to speak to a clinician or call the crisis line before you leave. We will ask you to provide the name and relevant information of your mental healthcare provider on the contact information sheet.

Are there any benefits to me if I am in this study?
You will receive CM free at no cost to you. We know that CM can be effective treatment for alcohol problems. If you take part in this study, you may help others in the future. It is hoped that the results from this study will help develop more effective treatments for alcohol problems.

Are there any risks to me if I am in this study?
The following are some potential risks that may occur as a when taking part in this study. We also list how we will minimize these risks.

- There is a small risk that information you provide to the study will be seen by someone who is not allowed to see it. We will try to lower this risk by assigning all data you provide with a unique identifier (number) instead of your name.

- There is a small risk that you may encounter another study participant in the clinicwhich would result in a loss of your confidentiality. We will attempt to schedule participants at times that would prevent this from occurring.

- You may be asked some questions about your personal habits and history that make you feel uncomfortable. You may feel uncomfortable providing urine or breath samples. We selected questionnaires and sample collection procedures that are similar to those thatyou might be given at a regular clinic or doctor's appointment.

- If you earn more than $600 in gift cards from the study in one calendar year, we will ask you to sign a tax form that states your earnings exceeded that amount. If you receive more than $600 in gift cards from the study in one calendar year, the total amount of gift cards will be considered as income which you should consider for tax planning and any other income-based benefits you receive. There is no financial consultation being offered through this study regarding the gift cards earned and their impact on other possible benefits received outside of this study.

- You may experience alcohol withdrawal symptoms if stop drinking during the study. Examples of withdrawal symptoms are feeling like you need another drink to make you feel better, shaking uncontrollably, and sweating. We will try to lower this risk by evaluating your withdrawal symptoms at every study visit. If you score higher than 4 points on our

withdrawal scale, Dr. Michael McDonell will be contacted, and you may need to be evaluated by a medical professional.

- Should a medical emergency occur at a study visit, study staff will contact Dr. Michael McDonell and may call 911. Importantly, there is no compensation being offered throughthis investigation should a medical emergency occur while being part of this study.

Will my information be kept private?
Yes. Your information gathered in this study will be kept confidential to the extent allowed by law. All participants will be assigned a unique ID number that is stored separately from personal information. This number will be used on all data collection materials. All recorded data will be kept in a locked file cabinet in a locked research office that is only accessible by members of the research team. The unique ID number will also be used for the urine samples. Only research team members will have access to the study database storing participant information, which is saved on a firewall protected computer under password protection. The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous. If we cannot reach you during the study, we will try to contact you by calling the people that you list on the "Contact Information Form". We will tell them that you are participating in a study at Washington State University and that you gave us their name to help find you. We will not tell them anything else about you or the study.

If we are concerned about your safety, we will work with clinicians at Frontier Behavioral Health (Spokane), Sound (Seattle), or other crisis services to keep you safe. If keeping information private would immediately put you or someone else in danger, the investigators would release information to keep you or another person safe. If investigators learn about abuse to child or an elder, we will report that information to the proper authorities. Also, if the safety procedures described in this consent form are not followed, the police may be notified. We may need to report your information to the IRS if you earn more than $600 in gift cards in one year.

Certificate of Confidentiality
To help us protect your information, this research study has a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, the research team cannot be forced to provide your name or any identifiable research data or specimens in any Federal, state, or local proceedings unless you agree that we can share it. However, we still must report information to local authorities if we learn about child abuse or neglect, or intent to harm yourself or others.

Disclosure will also be necessary upon request from the Department of Health and Human Services (DHHS) or other federal agencies for audits or program evaluations.

The Certificate does not stop us from voluntarily giving out your identifiable information. We will give you your identifiable information, which may include your name, for the following reasons. Any of this information that is given out will not be protected by the Certificate of Confidentiality.

- To the National Institute on Alcohol Abuse and Alcoholism in an audit,
- To state or federal public health authorities to who certain contagious diseases (tuberculosis, HIV, anthrax, syphilis) are reported (if we observe such diseases in any subjects),
- To law enforcement authorities if we become aware of information that suggests the occurrence of child abuse, elder abuse, abuse of a disabled person or your intent to

harm yourself or others,

- To the WSU office that manages payment to participants: your name, Social Security number, address, and the name of this study,
- To state, federal, and institutional offices involved in auditing or compliance of research, risk management, patient safety, and financial controls.

The Certificate of Confidentiality will not prevent you or a member of your family from telling others about yourself or that you are in the study. If you give your written consent to an insurer, employer, or other person to receive research information about you, then we cannot use the Certificate to refuse to give that information.

The Certificate of Confidentiality is not an endorsement from the Federal Government for our research.

Are there any costs or payments for being in this study?
There are no costs to participate in this study. Payment for study participation is based on attendance and alcohol use. If you choose to participate, you will be eligible to receive about $1,000 in gift cards depending on what intervention you are in. If you decide to quit the study, you will not receive any payment beyond any rewards already earned for any completed study visits. If you earn more than $600 in gift cards from the study in one year, we may need to report your gift card earnings in the IRS.

What are the alternatives to taking part in this study?
If you do not want to participate in the study, it will not change your treatment at Sound or Frontier Behavioral Health. You do not have to be in this study to get treatment. Free 12-Step groups, like Alcoholics Anonymous might also help you.

Who can I talk to if I have questions?
If you have questions about this study or the information in this form, please contact the researcher, Dr. Michael McDonell at 412 E. Spokane Falls Blvd, Spokane WA 99202. (509) 368-6967; mmcdonell@wsu.edu.

If you have questions about your rights as a research participant, or would like to report a concern or complaint about this study, please contact the Washington State University Institutional Review Board at (509) 335-7646, or e-mail irb@wsu.edu, or regular mail at: PO Box 643143, Neill Room 427, Pullman, WA 99164-3143.

What are my rights as a research study volunteer?
Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part.
You may choose not to answer specific questions or to stop participating at any time.

What does my signature on this consent form mean?
Your signature on this form means that:

- You have been able to ask the researcher questions and state any concerns
- You understand the information given to you in this form
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risksthat are involved.
- You agree to not use the electronic or physical gift cards earned from participating in this study to purchase drugs, alcohol, firearms, ammunition or weapons

Where can I go to learn more about the results of this study?
You can go to ClinicalTrials.gov to find this study using our ClinicalTrials.gov number NCT03481049. There you can find more information about this study and results of the study once it has finished. For more information on the how to find our study please use the following link: https://clinicaltrials.gov/ct2/help/for-patient.

You may also contact the Dr. Michael McDonell or other research staff during the study for information.

Statement of Consent
I give my voluntary consent to take part in this study. I will be given a copy of this consent document for my records.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant
I wish to have my contact information stored and used to contact me about future studies. I understand that I can change my mind at any time. If at any point I change my mind I will notify study staff to destroy my contact information

☐ Yes ☐ No_____(please initial)

Statement of Person Obtaining Informed Consent
I have carefully explained to the person taking part in the study what he or she can expect.

I certify that when this person signs this form, to the best of my knowledge, he or she understands the purpose, procedures, potential benefits, and potential risks of participation.

I also certify that he or she:

- Speaks the language used to explain this research
- Reads well enough to understand this form or, if not, this person is able to hearand understand when the form is read to him or her
- Does not have any problems that could make it hard to understand what it means to take part in this research.

_____ _____

Signature of Person Obtaining Consent Date

_____ _____

Printed Name of Person Obtaining Consent Role in Research

Copies to: Subject

Investigator's File

Contact Information Form

In order to help us locate you, please provide your address, telephone numbers, and emails and the names, phone numbers, and emails for people who many know where you would be at that time. These can include friends and family members.

Name_____

Date of Birth_____/_____/_____

Primary Phone/cell (with area code) _____

Secondary Phone/cell (witharea code) _____

Text Message # (with areacode) _____

Email Address _____

Address _____

If we are unable to reach you, who else might we contact to get in touch with you?

List Clinical Contact here, if you have one.

Name_____

Relationship to you: _____

Primary Phone/cell (witharea code) _____

Email Address _____

Name_____

Relationship to you: _____

Primary Phone/cell (witharea code) _____

Email Address _____

Name_____

Relationship to you: _____

Primary Phone/cell (witharea code) _____

Email Address _____

WSU IRB #16326-047
Approved: 4/6/2023
Valid Until: 4/5/2024