Extending long-term outcomes through an adaptive aftercare intervention

NCT02143063

Consent Form

IRB Approval Version: 11/19/2018

IRB Review
IRB NUMBER: 14-090H-2
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INFORMED CONSENT FORM

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Co-Investigators: Carla Rash, Ph.D., UConn Health

Title of Research Study: Extending long-term outcomes through an adaptive aftercare intervention

Expected Duration of Subject's Participation: 18 months

IRB Number: 14-090H-2

Funder: National Institute on Drug Abuse

Name of Research Participant: _____

What Is The Purpose Of This Research Study?

The purpose of this study is to compare different forms of treatment for substance abuse. This study will involve a type of treatment called contingency management in which patients receive incentives (prizes) for not using drugs. This study will compare two forms of contingency management to standard treatment that does not involve incentives. The results could lead to better methods of treating substance abuse.

Why Am I Invited To Participate?

You are invited to participate in this study because you are beginning outpatient treatment for substance abuse.

How Many Other People Will Participate?

In total, up to 280 people will participate in this study.

Is Participation Voluntary?

Participation in this study is voluntary. Read this consent form carefully. Ask any questions you have. Then decide whether or not to participate. If you choose to participate in the study, you are free to withdraw at any time. If you choose not to participate or you withdraw from the study, your choice will not affect your care at this clinic or your medical care at UConn Health/John Dempsey Hospital. There will be no penalty or loss of benefits to which you are otherwise entitled.

How Long Will My Participation In This Study Last?

This study lasts 18 months. This study includes interviews that will happen today and in about 1, 3, 6, 9, 12, 15 and 18 months from today.

What Will I Be Asked To Do?

Research Interviews:

If you take part in this study, a research assistant will interview you up to 8 times. You will be asked questions about drug and alcohol use, high-risk behaviors, prior treatment, and medical, employment, legal, psychiatric and social problems. You will provide a breath sample that will be tested for alcohol use and a urine sample that will be tested for cocaine, amphetamine, methamphetamine, opiates, marijuana and benzodiazepines. You will receive a $35 gift card for completing today's interview. This interview may be split up over two days. You will receive $50 for each other interview you complete, for a total of $350. At today's interview and interviews about 3, 6 and 18 months from now, you will also have the chance to win up to $5 (on average) in your choice of gift cards based on your response to certain

tasks. Around the time of today's interview as well as the interviews at 3 and 6 months from now, you will receive $25 in gift cards for completing computer tasks that take about 1 hour, for a total of $75.

You may participate in the interviews even if you stop coming to the clinic for treatment. We encourage you to complete all interviews, even if you withdraw or are discharged from treatment. You will be asked to give names of at least 3 people you expect to have contact with over the next 18 months. Research staff need this information so they can find you if your phone or address change. No information about you (not even whether or not you are in treatment) will be given to these people. If you do these interviews over the phone or by mail rather than in person, you will receive $30 for each interview.

The interviews and study treatment may be audiorecorded. Audiorecordings will be listened to only by other staff members. Staff members listen to make sure the research assistant is doing the interviews and interventions correctly. If you decide you do not want your sessions audiorecorded, you can still take part in the research study. Please make a choice by initialing one option below.

Initials: _____ **Yes**, I agree. My assessments and study treatment can be audiorecorded.

Initials: _____ **No**, I do not want my assessments and study treatment to be audiorecorded.

If you are incarcerated during the study, you can still complete the questionnaire portion of the follow-up interviews. The interviews can be delivered to you. A stamped and addressed return envelope will also be provided. If you complete and return the interview, you will get $30 for the interviews at months 1, 3, 6, 9, 12, 15 and 18. You will get your payment after your release from incarceration, or you may designate a person to whom it should be sent during your incarceration. Your participation in this study while incarcerated will have no effect on your eligibility for parole. Please make a choice by and initialing one option below.

Initials: _____ **Yes**, if I become incarcerated during the study, I would like the interview delivered to me in prison.

Initials: _____ **No**, if I become incarcerated during the study, I do not want the interview delivered to me in prison.

After today's interview, you will be randomly assigned (like a flip of a coin) to one of three treatment groups. The reason you will be randomly assigned to a treatment, rather than you choosing a treatment, is so that researchers can determine which treatment works best.

***Treatment*:**
Group A (60 participants): If you are assigned to Group A, you will receive standard treatment at the clinic. In addition, you will be scheduled to meet regularly with research staff to provide breath and urine samples for 24 weeks. These visits will take about 5 minutes. Submission of urine samples may be observed by a same-sex staff member.

During weeks 1-3, you will be asked to give breath and urine samples twice a week. You can choose your schedule from: Mondays and Thursdays, Mondays and Fridays, or Tuesdays and Fridays. During weeks 4-24, you will be asked to give samples on days that are selected

from your testing days. Some weeks, you will be asked to come in on both your testing days. Some weeks, you will be asked to come in and give a sample on just one of the days. Some weeks, you may not be asked to come in at all. You should plan to come in each of your testing days, but some days you will not need to. You will receive $2 per requested sample submitted regardless of results, plus a $20 bonus if you submit all requested samples in a four week period. In the case of an excused absence, you can come in the next day to submit a sample to avoid forfeiting the $20 bonus.

For up to 24 weeks, you will get a study cell phone. This phone will have unlimited texting and calls. You can use the phone to call and text others as long as you answer study calls and come in for testing when asked. Research staff will call or text you (your choice) on the morning of each of your testing days. They will tell you if you need to come in and leave a sample that day. Before loaning you the study cell phone, we need a copy of a state-issued identification card (e.g., driver's license). The cell phone is state-owned equipment. We cannot lend it to you until we have proof of your name and address. If you prefer, you can use your own cell phone. If you use your own cell phone, you will get $25 for each month to help pay your cell phone bill. You will receive this $25 for each 30-day period that you give urine samples when asked, up to $150. If you miss more than one test in a row, you will not get $25 for that month.

Similarly, if you use the study cell phone, you must not miss more than one test in a row. If you miss two samples in a row, we will turn off the study cell phone. We will not turn the phone back on until you give a breath and urine sample.

If ever you do not give a sample when asked, you will need to come in to your next two testing days in a row. For example, if you did not leave a sample when asked on a Tuesday, you will need to leave a sample that Friday and the next Tuesday. If you miss two samples in a row, you will lose your $25 that month, or your cell phone will be turned off until you give a sample. If you need to change your testing days, you can. You need to ask the research staff at least one week ahead of time to change your testing days. In weeks 1-3, you will be asked to give 6 samples. In weeks 4-24, you will be asked to give between 15 and 35 samples.

Group B (110 participants): If you are assigned to Group B, you will receive standard treatment at the clinic and a study cell phone. If you already have a cell phone, you can get $25/month toward your cell phone bill. If you miss more than one testing day in a row, your study cell phone will be turned off (or you will lose your $25 that month).

You will be asked to give breath and urine samples twice weekly for 24 weeks, for a total of 48 samples. You can choose your testing schedule: Mondays and Thursdays, Mondays and Friday, or Tuesdays and Fridays. You can change your schedule with one week's notice. You will receive $2 per requested sample submitted regardless of results, plus a $20 bonus if you submit all requested samples in a four week period. In the case of an excused absence, you can come in the next day to avoid forfeiting the $20 bonus.

Each time you give a urine sample that is negative for cocaine, amphetamine and methamphetamine, you will get to draw a slip of paper from a bowl. With each draw, you get the chance to win a prize. You will get one draw for your first negative sample. You will get two draws if you leave two negative samples in a row. For each negative sample in a row, the number of draws will increase by one, up to a maximum of 5 draws.

The bowl contains 500 cards, and 50% of them are winning cards. Of these, 204 are small prizes (for example, your choice of $1 coupons, food items, or bus tokens), 45 are large prizes, worth up to $20 in value (for example, your choice of movie theater tickets, CDs, kitchen supplies, or a watch), and one is a jumbo prize worth up to $100 (for example, your choice of small stereo, television, or five large prizes). A variety of prizes will be available. You can also suggest prizes. The bowl is restocked after each draw.

If any of your samples test positive or you do not provide a sample on a testing day, your draws will reset to one the next time you give a negative sample. In total, you can earn about 229 draws if you give all 48 samples over 24 weeks and all test negative.

Group C (110 participants): If you are assigned to Group C, you will receive standard treatment at the clinic. You will also receive a study cell phone (or $25 per month toward your phone bill) as described in Group A.

You will choose a twice weekly testing schedule: Mondays and Thursdays, Mondays and Fridays, or Tuesdays and Fridays. You can change your schedule if you ask at least a week in advance. In weeks 1-3, you will leave a sample on each testing day. In weeks 4-24, your testing schedule will become variable. You will be asked to come to the clinic and leave samples on 0, 1 or both of your 2 testing days each week. As described in Group A, you should plan to leave samples on both of your testing days each week. Research staff will call or text you (your choice) on the morning of your testing days. Some days you may not need to come in. You will receive $2 per requested sample submitted regardless of results, plus a $20 bonus if you submit all requested samples in a four week period. In the case of an excused absence, you can come in the next day to avoid forfeiting the $20 bonus.

You will get one draw from the same bowl as Group B for your first sample that is negative for cocaine, amphetamine and methamphetamine. For each negative sample in a row, your draws will increase by 1 draw. After 7 negative samples in a row, your draws will increase by 2 draws for each negative sample in a row, until you reach a maximum of 25 draws. In sum, you will be asked to give 6 samples in weeks 1-3. In weeks 4-24, you will be asked to give between 15 and 35 samples. You can earn up to about 231 draws if you give all samples and they all test negative.

If you do not give a sample when asked or your sample is positive, you earn no draws that day. You will get 1 draw for your next negative sample. Draws will then increase by 1 draw for each negative sample in a row, until you get to 5 draws. After that, your draws will go back to the highest number you were at before the reset.

If you do not give a negative sample on a day you are asked, you will need to leave samples for at least your next two testing days. After a week of leaving negative samples, you will be asked to leave samples on 0, 1, or 2 of your testing days. If ever you miss two samples in a row, your cell service will be turned off (or you will not receive the $25/month). To get your service back, you must come to the clinic and give a sample. Your service will then be turned back on, even if you give a positive sample.

What Types of Risk Are Involved If I Choose To Participate?

(a) You may be disappointed if you are not assigned to the treatment group that you wanted. If you are unhappy with your group, you may end participation in this study.

(b) You may experience discomfort from providing breath and urine samples or answering questions about alcohol and drug use, medical problems and histories, HIV risk behaviors, psychosocial problems. To decrease any discomfort of providing breath and urine samples, we will use sample collection methods that are brief. Your results will remain confidential. If you are uncomfortable with any part of the interview, you may skip the question or take a break. We have used many of these procedures before without problems.

(c) You may have problems if we stop your cell phone service for missing two samples in a row. If you do not provide a sample when asked, research staff will phone or text you that same day. They will remind you that you need to leave a sample on your next testing day to keep your service. If your cell phone service is stopped, research staff will contact you to tell you that your service will be re-started if you give a sample.

(d) The information you give may become available to people who are not involved in this research or in treatment. Every effort will be made to protect your confidentiality. The next section describes steps taken to protect your personal information.

How Will My Personal Information Be Protected?

Confidentiality: Every effort will be made to protect the confidentiality of the information we gather from you. We cannot guarantee 100% confidentiality. The following steps will be taken to protect the confidentiality of your records in agreement with state and federal laws. A study number, not your name, will code your study information. Study numbers will be derived from a letter code identifying the study and site, followed by a 3 digit number that is a sequential indicator of the number of patients that have been enrolled in the study. Your study information and will be kept in a locked file cabinet. A master key, which links your name and study number, will be kept in a separate and secure location. Your study information will not be shared with clinic staff. At the end of this study, the researchers may publish their findings. Information will be presented in summary format. You will not be identified in any presentations or publications.

If you decide to take part in this research study, you will be asked to give us information about your substance use. We have obtained a Certificate of Confidentiality (CoC) issued by the National Institutes of Health (NIH). 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 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. If you become incarcerated and share your information with anyone, then the CoC will not be able to protect your privacy.

Also, because this research is sponsored by NIH, staff from that and other Department of Health and Human Services (DHHS) agencies may review records that identify you only for audit or program evaluation. They can't report anything that would harm the research

subjects. This Certificate, however, does not imply that the Secretary, DHHS, approves or disapproves of the project.

What Are The Benefits Of Participating In This Study?

(a) You may receive treatment that may help you stop abusing drugs and alcohol.
(b) You will receive careful evaluation of your medical and psychiatric status, alcohol and drug use.
(c) You may also help us learn how to better treat people with substance use disorders.

Will I Be Compensated For Participating In This Study?

(a) You will receive $35 in gift cards for today's interview.
(b) You will receive up to $50 for completing each of the interviews about 1, 3, 6, 9, 12, 15 and 18 months from today, for a total up to $350.
(c) You may win up to $5 for completing tasks at today's interview and the interviews about 3, 6 and 18 months from now. You will receive $25 in gift cards for completing computer tasks at around the times of today's interview, and the interviews 3 and 6 months from now, for a total of $75.
(d) You will receive $2 per requested sample submitted. Plus you will receive a $20 bonus if you submit all requested samples in a four week period.
(e) You will receive $25 for returning the study cell phone in working order.
(f) If you choose to use your own cell phone, you will also receive $25 in gift cards for each month that you do not miss submitting samples, for a total of up to $150. You will receive this payment at your 3 and 6 month interviews.

What If I Decide To Stop Participating In The Study?

If you decide to stop taking part in the study, your relationship with the clinic or the UConn Health will not be affected. If you decide to withdraw, please call the research team at 860-679-4556. Or, send a written notice to Dr. Sheila Alessi, 263 Farmington Avenue, Farmington, CT 06030-3944.

Can Someone Else Make Me Stop Participating In This Study?

The investigators may end your study participation. They would do so only if they feel it is in your best interest or if you are not following clinic rules. If this happens, it will not affect present or future care at this clinic or UConn Health/John Dempsey Hospital.

What If I Have Questions?

The Principal Investigator, Dr. Alessi, is willing to answer any questions you have about the study. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints or concerns about the research, you should call Dr. Alessi at 860-679-4556. For questions about your rights as a research subject you may contact a coordinator at the Institutional Review Board at 860-679-1019 or 860-679-4851. You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or ask general questions or obtain information about participation in clinical research studies. Please do not call the IRB number for medical issues or to schedule or cancel an appointment.

Consent To Participation:

By signing this form you acknowledge that 1) you have read, or have had read to you, this consent document, 2) have talked with research staff about this study and have been given the opportunity to ask questions and have them satisfactorily answered, 3) and voluntarily consent to participate in this project as described in this form.

By signing this form the individual obtaining consent is confirming that the above information has been explained to the participant and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Participant Feedback Form, will be provided to the participant.

_____	_____	_____
Participant's Printed Name	Participant's Signature	Date
_____	_____	_____
Name of Investigator or Person Obtaining Consent	Signature of Investigator or Person Obtaining Consent	Date