A Tailored, Peer-delivered Intervention to Reduce Recurring Opioid Overdoses

NCT02922959

Consent approval date: 8/8/2018

UNIVERSITY OF CINCINNATI - Medical
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
Participant Consent

Study Title: A Tailored, Peer-delivered Intervention to Reduce Recurring Opioid Overdoses

UC IRB Study #:

Sponsor Name: The National Institute on Drug Abuse (NIDA)

Investigator Information:

Theresa Winhusen, PhD	513-310-0442
Principal Investigator Name	Telephone Number 24 hr Emergency Contact

Subject Name: _____ Date of Birth: _____/_____/____

INTRODUCTION:

A biomedical or health-related research study is performed to answer specific questions about a disease.

Before you agree to participate in this research study, it is important that you be told the purpose, procedures, benefits, risks, discomforts, and precautions of the research. You should also be told what alternative procedures are available to you if you do not participate in the research study. The informed consent document is a written summary of this information. Be sure to ask questions while you read this consent document and ask questions if there is anything that you do not understand.

Your participation in this research study is entirely voluntary.

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

The researcher and sponsor of this study do not promise that you will receive any benefits from this study.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research study is to compare two approaches to reducing the risk of future opioid overdoses in individuals experiencing a non-fatal opioid overdose. The first approach entails providing the individual with a NARCAN® kit, which can be used to help reverse an opioid overdose, and written information about overdose and substance use disorder treatment. The second approach expands upon the first approach by also providing a telephone, peer-based intervention to the individual.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you are at least 18 years old and you report having been treated for an opioid overdose in the last 6 months.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for approximately 12 months. It will take about 2.5 years before all volunteers have finished and the study is complete.

The researcher may decide to take you off this research study at any time. Reasons for withdrawal may include study funding being stopped or your failing to follow important instructions given by the investigator.

You may withdraw from the study at any time. If you decide to stop participating in the study, we encourage you to talk to the research team first. Another reason to tell the researcher that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful to you.

You may be contacted in the future by representatives of the University of Cincinnati who are interested in asking you survey questions about your participation in this research study. If you choose to participate in the survey, your responses will be used for quality assurance purposes only.

WHO IS CONDUCTING THE RESEARCH STUDY?

The person in charge of this research study is Theresa Winhusen, PhD of the University of Cincinnati (UC) Department of Psychiatry and Behavioral Neuroscience – Addiction Sciences Division. There may be other people on the research team helping at different times during the study.

Medical monitoring for the study is provided by Michael Lyons, MD.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 80 people will take part in this study at UC Addiction Sciences Division.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

1. SCREENING/BASELINE

If you decide to volunteer and sign this consent form, you will start screening procedures that help us to see whether or not this study is suitable for you. Screening procedures will take approximately 1 hour and 15 minutes to complete. The things that will happen during screening are done only for this research study and are not part of any other routine healthcare you may receive. For screening, you will be asked to:

- Answer questions about your alcohol and drug use, about things that can increase the risk of overdose, knowledge about overdose risk, and your knowledge, interest in, and barriers to getting treatment;
- Answer basic questions about your gender, race, and ethnicity;
- Provide contact information for people who can help us locate you in the future and sign a release of information for them
- Provide a urine sample to screen for drug use.

If after completing the screening process you are found to be eligible, this means that you can take part in the study if you choose to do so. If you are found to be ineligible, this means that you cannot take part in the study. Either way, you will receive $50 for your time and effort for completing the entire screening process.

2. RANDOMIZATION

If you are eligible and agree to take part in the study, you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group completely by chance. It is like flipping a coin.

If you are randomized to the control condition, you will receive contact information about local Medication Assisted Treatment (MAT) programs, educational information about Opioid Overdose (OOD) and about MAT, and a NARCAN® Nasal Spray kit; all of which will be provided during the enrollment visit.

If you are randomized to the experimental condition, you will receive contact information about local MAT programs, educational information about OOD and about MAT, and a NARCAN® Nasal Spray kit; all of which will be provided during the enrollment visit. You will receive a set of three personalized reports, and you will be scheduled to receive the Tailored Telephone Intervention delivered by Peers to Prevent Recurring Opioid Overdoses (TTIP-PRO) intervention within about 2 weeks following your enrollment into the study.

3. TTIP-PRO

If you are randomized to the experimental condition, you will receive the TTIP-PRO intervention which consists of two parts: 1) a 30-minute telephone intervention delivered by a trained Peer Interventionist; and 2) a set of three personalized reports, including a report on your personal risk factors for experiencing another OOD. The call will be recorded and stored long enough for an expert trainer to review the call for quality assurance purposes, after which the file will be deleted.

4. FOLLOW UP

You will complete a follow-up phone call in week 3 with research staff and in-person follow-up visits with research staff at 3, 6-, and 12-months following enrollment, regardless of how you are randomized.

Follow-up Phone Call

The week 3 phone call will last approximately 25 minutes. You will be asked to complete an interview to assess your knowledge about overdose risk, your interest in treatment, barriers to getting treatment, how you have been feeling since your enrolled in the study, and your feedback on the intervention you received following randomization.

In-Person Visits

You will be asked to come for follow-up visits 3, 6, and 12 months following your enrollment into the study. At each of these visits you will be asked to:

- complete questionnaires and interviews about how you have been feeling since the last study contact, your recent alcohol and drug use, whether or not you have had any additional overdoses, whether or not you have enrolled in MAT for opioid use disorder, and whether the NARCAN® Nasal Spray kit you received was used to help reverse an overdose;
- provide releases of information for medical records to confirm enrollment in MAT;
- provide a urine sample to screen for drug use.

At the month 3 and month 6 follow-up visits, you will also be asked to confirm/update information for people who can help us locate you in the future.

At the month 12 follow-up visit, you will also be asked to complete a questionnaire about your personal overdose risk.

Each follow-up visit will last approximately 40 minutes.

If you are currently or become a prisoner (including being in jail or prison, being on probation or parole, or being under house arrest or electronic monitoring), we would still like to find out how you are doing. Therefore, if necessary, we will make an effort to collect follow-up data from you over the phone or in person. Please note that your continued participation, in this event, will have no effect on your criminal case, or release or parole from jail or prison, or probation case.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

Breach of confidentiality: As with any study, there is a potential risk of loss of confidentiality. To maintain confidentiality, all study records and data will be secured, and information collected by the study will not be shared with your healthcare provider(s). Additionally, as described below, a Certificate of Confidentiality has been obtained for the study.

Emotional Discomfort: You may also experience some emotional discomfort from answering sensitive and/or personal questions. You may experience embarrassment in answering questions about your knowledge of MAT and opioid overdose. You can choose to not answer questions that you find to be too uncomfortable, or you may choose to withdraw from the study if you find participation too stressful.

Improper administration of the intervention by the Peer Interventionist: The Peer Interventionists will be provided with your first name and your phone number in a secure manner. As such, there is a chance of improper administration of the intervention. In order to prevent this, we will train and grade the Peer Interventionist candidates before allowing them to perform the intervention(s).

Side Effects of NARCAN® Nasal Spray:

NARCAN® Nasal Spray is an FDA-approved medication indicated for the emergency treatment of known or suspected opioid overdose. The primary side effect of NARCAN® is sudden opioid withdrawal symptoms. In someone who has been using opioids regularly, opioid withdrawal symptoms can happen suddenly after receiving NARCAN® Nasal Spray and may include the following:

Body aches	Diarrhea	Increased heart rate
Fever	Runny nose	Sneezing
Goose bumps	Sweating	Yawning
Nausea or vomiting	Nervousness	Restlessness or Irritability
Shivering or trembling	Stomach cramping	Weakness
Increased blood pressure		

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

If you agree to take part in this research study, there may not be a direct medical benefit to you. We hope the information learned from this research study will benefit other opioid overdose patients in the future. You may directly benefit from study participation in that you will receive information about risks for overdose, the signs of overdose, how to respond to an overdose, and factors that can reduce the risk of an overdose. You may also benefit from receiving a NARCAN® Nasal Spray kit.

WHAT OTHER CHOICES FOR CARE ARE THERE?

You may choose not to participate in this study. Choosing not to participate will not result in any penalty or loss of benefits to you.

WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other

proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, if the investigator learns about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, they will report that to the proper authorities. If keeping information private would immediately put you or someone else in danger, the researchers would release information to protect you or another person.

AVAILABILITY OF INFORMATION

You will receive a copy of this signed and dated consent form.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

You will not be charged for assessments related to this study. However, you and/or your third party payer (insurance, Medicaid, etc.) will still be responsible for costs related to substance use treatment and other healthcare costs not directly associated with this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

If you receive payments for being a part of this research study, you may be asked to complete an Internal Revenue Service (IRS) form. The amount you receive may count as income and may affect your income taxes. Your social security number will be required to complete the IRS form.

You will be paid up to $220 for your time and travel costs related to taking part in this study. Payments will be made to you with a prepaid debit card. The payment will be loaded onto your card within one business day of the completion of your visit. A schedule of the payments is below:

Visit	Amount
Enrollment/Randomization	$50
Week 3 Follow-up Call	$20
3-Month Follow-up Visit	$50
6-Month Follow-up Visit	$50
12-Month Follow-up Visit	$50
TOTAL	$220

Details of the system are explained on an additional information sheet.

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

In the event that you become ill or injured from participating in this research study, emergency medical care will be provided to you. The National Institute on Drug Abuse OR the University of Cincinnati will decide on a case by case basis whether to reimburse you for your out of pocket health care expenses.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

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

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

Nothing in this consent form waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Every effort will be made to maintain the confidentiality of your medical and research records related to this study. Agents of the University of Cincinnati, and the sponsoring company, the National Institute on Drug Abuse (NIDA), the monitor, the auditor, the Institutional Review Board (IRB), and other regulatory authority(ies) will be granted direct access to your original medical and research records for verification of research study procedures or study data without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing this consent form, you or your legally authorized representative are authorizing such access. The data from the study may be published; however, you will not be identified by name. Your identity will remain confidential unless disclosure is required by law.

Authorization to Use and Disclose Health Information

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you. You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you.

If you sign this informed consent form, you are giving permission for the use and disclosure of your health information for purposes of this research study. You do not have to give this permission. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form. However, if you do not sign this form, you will not be able to participate in the study.

Who Will Use and Disclose My Health Information? The study doctor and research staff (the study team) may use your health information to conduct, review, and determine the results of the study. The study team may also use your information to prepare reports or publications about the study. However, your name will not appear in any report or publication without your permission.

What Health Information will be Used and Disclosed? The study team will record your medical history, the treatment you receive, and the results of examinations and tests done during the study on study forms. Representatives from the groups identified below may need to look at your medical records to make sure that the information on the study forms is correct or that the study was conducted properly. Your medical records may include other health information about you and may include documents that directly identify you. Reviews like that will take place at the study center or where the medical records are stored and can take place after the study is over.

Who Will Receive My Health Information? Your study information or medical records (as described above) or both may be shared with the following people or groups:

- The study sponsor or its representatives, including companies it hires to provide study-related services
- UC Institutional Review Board and any other committees responsible for overseeing the research
- Staff of the UC Human Research Protection Program
- Federal and State agencies, such as the Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), and other US and non-US government bodies that oversee or review research

Will My Information be Protected by the Privacy Rule After it is Disclosed to Others? UC and UC Health are required by the Privacy Rule to protect your health information. After your information is shared with others, such as the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study. The goal of any such research would be to learn more about drugs, devices or diseases or to help design better studies in the future. When using your information in these ways, the sponsor may share it with regulatory authorities, other researchers, its business partners, or companies it hires to provide research-related services.

What Happens if I Leave the Study Early? If you stop participating in the study early for any reason, the study team will tell the sponsor why. If the study team asks you to come to any more study visits and you agree, the study team will send the sponsor information from those visits as well. All information collected about you may continue to be used and disclosed.

Will My Authorization Ever Expire? This Authorization does not have an expiration date.

The study team may need to correct or provide missing information about you even after your study participation is over and a review of your medical records may also take place after the study is over.

May I Take Back My Authorization? You have the right to take back (revoke) your Authorization at any time by writing to the person in charge of this research study whose information is listed on the front of this form. If you revoke your Authorization, the study team will not collect any new health information about you. However, they can continue to use and disclose any already-collected information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your Authorization, you can no longer continue to participate in the study.

May I Look At My Study Information? You have a right to see and make copies of your medical records. However, to ensure the validity of the study, you will need to wait to see your study records until the study is completed.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

If you have questions, concerns, complaints and/or suggestions about this research study or to report a research-related injury, please contact the researcher Theresa Winhusen, PhD at 513-310-0442 or a member of her staff.

Please call the University of Cincinnati Institutional Review Board at 513-558-5259 (Monday – Friday 8 am to 5 pm) if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, complaints and/or suggestions about the research.
- Cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

Comprehension Quiz

1. My participation in this study is entirely voluntary.	T	F
2. I may be randomly assigned to be contacted by a Peer Interventionist.	T	F
3. My participation in this study will last for approximately 12 months.	T	F
4. If randomized, I will be given a NARCAN® nasal spray kit.	T	F
5. This procedure is guaranteed to stop me from overdosing again.	T	F

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: A Tailored, Peer-delivered Intervention to Reduce Recurring Opioid Overdoses

UC IRB Study #:

Sponsor Name: National Institute on Drug Abuse (NIDA)

Investigator Information:

Theresa Winhusen, PhD	513-310-0442
Principal Investigator Name	Telephone Number 24 hr Emergency Contact

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. If I do not participate or if I discontinue my participation, I will not lose any benefits or any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this signed and dated form for my records and future reference. I have been given the information about the use and disclosure of my health information for this research study.

I give my consent to participate.

I authorize the release of information concerning treatment relating to drug abuse to the parties listed in the authorization section of this consent for the purposes described above.

Participant	Date

PERSON OBTAINING CONSENT
I have read this form to the participant and/or the participant has read this form. An explanation of the research was given and questions from the participant were solicited and answered to the participant's satisfaction. In my judgment, the participant has demonstrated comprehension of the information.

Signature and Title of Person Obtaining Consent and Identification of Role in the Study	Date

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

____I **want** the researcher to inform my primary care physician/specialist of my participation in this study.
___ I **do not want** the researcher to inform my primary care physician/specialist of my participation in this study.
___I do not have a primary care physician/specialist.
___The researcher is my primary care physician/specialist.

_____

Participant Date