UAB IRB
Approved
12-Nov-2025
until
09-Sep-2026

CONSENT FORM

Title of Research: A Bundled Intervention to End Opioid Overdoses by Increasing Treatment Uptake Post Emergency Department Discharge

UAB IRB Protocol#: IRB-3000013272

Principal Investigator: Li Li, MD, PhD

Co-Principal Investigator: Lauren Walter, MD; Aniket Malhotra, MD; Rongbing Xie, PhD

Sponsor: The National Institute of Drug Abuse and the Department of Psychiatry & Behavioral Neurobiology

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The main purpose of the study is to test if a bundled treatment, that includes a peer support specialist, buprenorphine prescription, and linkage to a community treatment program will be possible/feasible to be implemented and accepted by patients. Feasibility will be measured by rates of participant enrollment (i.e., able to enroll 18 participants in the first year and 12 participants in the second year with last enrollment in the 6th month of second year). Patient's acceptability will be measured using 2 surveys, including 1) patient satisfaction survey; and 2) Credibility and Expectancy Questionnaire (takes about 8-10 minutes to complete both surveys).
Duration & Visits	This is a 12-week study, which will consist of 3 visits and telehealth checkups. Your first visit will occur at the UAB Hospital (including Emergency department or inpatient settings) and the enrollment will last for about 1 hour. Your second visit will occur 1 month after your hospital visit, which will take about 20 minutes, and you will be asked if you are currently prescribed buprenorphine and to complete some surveys. Your third visit will occur 3 months after your hospital visit, which will take about 20 minutes, and you will be asked again if you are currently prescribed buprenorphine and to complete some surveys. Both the second and third visits will be either in the laboratory of Dr. Li or via secured telehealth. In addition to these 3 visits, you will be contacted using telehealth by a peer support specialist and a study physician as stated in the following procedures. During the study, your buprenorphine will be prescribed by one of the study physicians in this study, including Drs. Li/Walter/Malhotra.

	After the completion of the 3-month intervention, participants will be invited to participate in a 4th visit which is the 6-month post-study assessment. This 6-month post-study assessment will include the same surveys as the 1-month follow-up and additional questions focusing on these thematic blocks: duration of continuous abstinence, ongoing medication adherence, total use days of illicit opioids,, use of alcohol or other substances following the study completion, occurrence of overdose events after the study completion. Paid minutes and mobile phones solely for research purpose will be provided as needed to ensure participants' enrollment and track participants. We anticipate up to 20% of our participants will be offered no cost phones and/or minutes. We also request the participants to return the phones to study staff at the end of the 3rd visit (or the second follow-up visit at 3-months).
Overview of Procedures	Following hospital discharge, a peer support specialist will contact you daily in Week 1 post- discharge, twice in Week 2, and weekly thereafter for 12 weeks using UAB medicine secured TEAM telehealth or encrypted phones. Each contact will be 15-20 mins. Physicians will also contact you monthly and as needed about buprenorphine prescription and your adherence to buprenorphine and addiction treatment, lasting 20-30mins/each time, using telehealth (i.e., UAB medicine secured TEAM or encrypted phones). During the 12-week study period, buprenorphine adherence and linkage to a community addiction treatment program at 1-month and 3-month after enrollment will be determined. Buprenorphine adherence is determined by a composite measure of any or all of the following: participant self-report, the state Prescription Drug Monitoring Programs (PDMP), or electronic medical records (EMR) documentation of an active prescription. Linkage rate is also determined by a composite measure of any or all of the following: participant self-report, EMR documentation of attendance at an addiction treatment program, or reports from addiction programs. We will also collect data of repeat overdose and ED revisits from our participants although this is not the primary outcome measure. Given the potential for the 3-month intervention period to be insufficient for observing repeat overdose and ED revisits, we will extend the monitoring of repeat overdoses and ED revisits through EMR documentation quarterly throughout the R61 study period.
Risks	The most common potential risk includes a breach of confidentiality. You may experience some anxiety when peer support specialists contact you and physicians assess your progress and response to buprenorphine. However, both peer support specialists and physicians are experienced providers to help you if you are in psychological distress. You will be given extra time to collect your thoughts and

	emotions during the study visits. The PI will also be available, if needed, to develop an appropriate clinical plan on how to address emotional distress including anxiety, including relaxation skills. Use of buprenorphine medication is associated with side effects such as: 1) constipation; 2) headache; 3) nausea and vomiting; 4) dizziness; 5) drowsiness and fatigue; 6) sweating; 7) tooth decay; and 8) insomnia. Buprenorphine withdrawal symptoms if the person stops or reduces buprenorphine dosages include: 1) anxiety or depressed mood; 2) nausea, vomiting, or diarrhea; 3) insomnia; 4) craving; 5) muscle aches/body aches; 6) fever and chills; and 7) headache and concentration difficulties. Buprenorphine is an opioid, but it is a partial agonist which is very different from other opioids. Due to its feature as a partial agonist, it protects people from overdose. However, it may cause overdose if people take more than prescribed and/or combine it with other sedatives, including alcohol. So please take it as prescribed.
Benefits	You may or may not benefit from participating in this study. Your participation may provide valuable information to the medical community about the treatment of OUD and non-fatal overdose.
Alternatives	The only alternative is that you do not have to participate in this study.

Purpose of the Research

We are doing a research study to find out if a bundled treatment, that includes a peer support specialist, buprenorphine prescription, and linkage to a community treatment program, will be feasible to be implemented and accepted by patients (main purpose). We will focus on patients with opioid use disorder and non-fatal opioid overdose after they are discharged from the emergency department (ED) or inpatient at UAB hospital. Opioid use disorder is one type of addiction that is the same as previous terms of opioid abuse and opioid dependence, but it replaced these old terms since May, 2013 by the American Psychiatric Association. Peer support specialists play a critical role in increasing treatment uptake and retention in opioid use disorders (OUD). However, the use of peer support specialists is not widely adopted in post-emergency department and inpatient care for patients with OUD and non-fatal opioid overdoses. Studies show that telehealth is an effective method to provide care for patients taking medications for opioid use disorders (MOUDs). The goal of the current protocol is to test a bundled intervention of telehealth, peer support specialists, buprenorphine, and linkage to community-based addiction treatment programs that targets post-ED and inpatient care in patients with nonfatal opioid overdoses. We plan to enroll and complete 30 participants in this two-year study. Feasibility will be measured by rates of participant enrollment (i.e., able to enroll 18 participants in the first year and 12 participants in the second year with last enrollment in the 6th month of second year). Patient's acceptability will be measured using 2 surveys, including 1) patient satisfaction survey; and 2) Credibility and Expectancy Questionnaire (takes about 8-10 minutes to complete both surveys).

In the meantime, we plan to collect data on buprenorphine adherence rate, linkage rate to community partners after participants complete the study, and repeat overdose/ED revisits although they are not primary outcome measures. Buprenorphine adherence rate is determined by a composite measure of any or all of the following: participant self-report, the state Prescription Drug Monitoring Programs (PDMP), or electronic medical records (EMR) documentation of an active prescription. Linkage rate is also determined by a composite measure of any or all of the following: participant self-report, EMR documentation of attendance at an addiction treatment program, or reports from addiction programs. Data of repeat overdose and ED revisits will be collected from EMR at UAB hospital. Adherence rate is not the primary outcome in the study, but we will monitor treatment retention rate and expect approximately 70% participants complete follow-up assessments at 1 month and 3 months. So "improvement" will be considered as increased retention rate compared with historical data (i.e., <50%). We also plan to collect data on participants' craving and overdose risks, their childhood trauma experiences, and mental health status throughout the study.

Explanation of Procedures

Study Visit 1: UAB hospital (i.e., emergency room or inpatient setting)

The study visit begins with the consent process. During the consent process, the purpose of the study, its risks and benefits, your rights as a research participant, and what will be required of you will be discussed. You will be given time to ask questions and have your questions answered by the researchers, including the trained research assistant and study physicians. You will be consented using an iPad or written informed consent at your preference. You will be provided a paper copy if desired. After providing the informed consent, you will undergo a screening, which involves a clinical interview by one of our study physicians to determine if you have a diagnosis of opioid use disorder. To determine eligibility, we will also administer a clinical interview regarding your opioid use history.

If eligible, you will complete the remaining study procedures at this visit.

Next, we will collect information about your medication history. Female participants will have a urine pregnancy test (if of child-bearing potential); women who are pregnant cannot participate in the study because they are anticipated to need a higher level of care than we can provide. As part of the study, we will collect your demographics through UAB electronic medical records, including age, gender, race/ethnicity, health insurance status, marital status, education level, and employment status. We will also collect your telephone number, Social Media Handles (Facebook Messenger, Instagram, or Whatsapp), and email address for study purposes. To minimize the loss of follow-up, we will collect 1-2 phone numbers from your friends/family if you are willing to provide. We will not call them unless we have difficulty contacting you. The study plans to provide participants with no-cost phones and minutes for research purpose up to 20% of participants. Participants are required to return the phones to study team at the end of 3-month intervention/follow-up assessment. Study visit 1 will last approximately one hour.

Study visits after UAB hospital discharge

Telehealth, i.e., UAB medicine secured TEAM or encrypted phones, will be used for participants to be seen by physicians and peer support specialists. A peer support specialist will contact you daily in Week 1 post-ED discharge, twice in Week 2, and weekly thereafter for 12 weeks using telehealth. To secure the quality of peer service to you, peer will audio record

30-40% of peer sessions. Our qualitative statistician will listen to recordings to assure the fidelity of peer service. Recordings will be saved securely at UAB platform (i.e., Box) and only study team has access to it and will be destroyed within 6 months after they are analyzed by our qualitative statistician. Peer will record 1-2 sessions in the first week and 1 session in the second week, then every other week until the study is completed (12 weeks total). If scripts will be produced from recordings, they will be saved in Box as well and destroyed within 6 months too. If participants withdraw their consent before the study is completed, their recordings will be destroyed right after the team is notified. Peers and physicians will educate you on addiction, address any of your concerns about buprenorphine and addiction treatment and remind you to take buprenorphine as prescribed. A study physician will assess you monthly and prescribe you buprenorphine using telehealth during the study. Peers will also encourage and assist you to engage in community-based treatment programs for continuity of care after this intervention is completed.

During the 12-week study period, you will be asked about your buprenorphine adherence status and linkage to community addiction treatment program status at 1-month (visit 2) and 3-months (visit 3) after your enrollment. A follow-up visit will occur 6 months after the 3-months intervention period (visit 4), which will include additional questions focusing on these thematic blocks: duration of continuous abstinence, ongoing medication adherence, total use days of illicit opioids since intervention, use of alcohol or other substances, occurrence of overdose events after completing the study. At the enrollment and each follow-up visit, you will also be asked to complete 7 or 8 survey questions which take approximately 15 mins to complete. They are 1) patient satisfaction survey; 2) Credibility and Expectancy Questionnaire; 3) Opioid Overdose Risk Behavior Scale; 4) Childhood trauma questionnaire (at enrollment and 3-month follow-up only); 5) Patient health questionnaire-9 and general anxiety disorder -7; 6) craving scale, 7) the Pittsburgh sleep quality index, and 8) the Barratt Impulsiveness Scale. The 6-month follow-up. Visits 2,3, and 4 will be in the laboratory of Dr. Li located in Sparks center building 1029 at UAB or using telehealth (i.e., UAB medicine secured TEAM or encrypted phones). Each visit takes about 30-45 minutes to complete, and you will be compensated with $50 at 1-month follow up visit, $100 at 3-month follow-up visit, and $30 at 6-month post-study follow-up visit for your time and efforts.

Benefits

You may or may not benefit from participating in this study. Your participation may provide valuable information to the medical community about the treatment of OUD and non-fatal overdose.

Risks and Discomforts

You may experience some anxiety when you are contacted by the peer support specialist and study physicians. However, both peer support specialists and physicians are experienced providers to help you with regards to any psychological distress that you may experience. Also, you will be given extra time to collect your thoughts and emotions. The researcher will be available, if needed, to develop an appropriate clinical plan to address your emotional distress, including relaxation skills.

Buprenorphine is a tolerable medication. At the beginning, you might experience mild headache and nausea, but usually these symptoms will disappear within 1-2 weeks, and you may not have to seek medical care. Other common side effects could include: constipation,

dizziness, vomiting, drowsiness and fatigue, sweating, dry mouth, tooth decay, muscle aches and cramps, insomnia or problems sleeping, fever, changes in your vision, tremors, palpitations in your chest, problems with paying attention. Other serious side effects of this medication include: respiratory distress and becoming dependent/addicted. However, we will start with low dosage and dosage may be increased gradually as tolerated. Dosage range will be 4-24mg, oral, daily.

Buprenorphine withdrawal symptoms if the person stops or reduces buprenorphine dosages may include: 1) anxiety or depressed mood; 2) nausea, vomiting, or diarrhea; 3) insomnia; 4) craving; 5) muscle aches/body aches; 6) fever and chills; and 7) headache and concentration difficulties. **So please do not discontinue it abruptly without consulting the study physicians.**

Buprenorphine is an opioid, but it is a partial agonist which is very different from other opioids. Due to its feature as a partial agonist, it actually protects people from overdose. However, it may contribute to overdose if people take more than prescribed and/or combine it with other sedatives, including alcohol. **So please take it as prescribed.**

Although every provision will be made to ensure confidentiality, there is always the chance that your privacy may be breached. Confidentiality may also be breached in cases where it is legally necessary to do so (e.g., report of known or suspected overdose attempts or even suicidal attempts).

All information gathered in this study will be used for the above stated research purpose; however, there are federal and state laws that require us to publicly share information gathered following study completion. All personally identifiable information will be removed before files are shared with other researchers or results are made public. This research will be shared in order to comply with NIH data sharing requirements to make federally funded research reproducible and reliable. There is no risk of breach of confidentiality with sharing data stripped of all its identifiers.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?

All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the

information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

Your consent form will be placed in your medical record at UAB Health System or Children's of Alabama. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient), results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient), a medical record will be created for you to maintain results of research tests or procedures.

All information within your medical record can be viewed by individuals authorized to access the record.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who may use and give out this information?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, *University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Healt*h, as necessary for their operations; the UAB IRB and its staff

Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

This research will be covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the *[insert Sponsor]* which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Alternatives

Your alternative is to not participate in the study.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

If you have health insurance, your insurance will be charged to pay for the buprenorphine medication. You may be charged for co-payment for buprenorphine medication as usual. To our knowledge, there is no co-payment for public health insurance, including Medicaid and Medicare. If you do not have health insurance to pay buprenorphine medication, it will be paid by the study-related grant. Otherwise, there will be no cost to you from participation in the research. The services of peer support specialists and study physicians will be provided to you at no cost.

Additional post-study Follow-Up and Re-Consent

An additional follow-up 6-months post the completion of the 12-week intervention will be conducted on completed participants who are willing to. Participants who have already completed the intervention will need to be reconsented through either hardcopy or an E-Consent form to participate in this 6-months post-study assessment. Participants who complete the 6-month post study assessments will be compensated $30 for their effort.

Payment for Participation in Research

You will receive a $30 prepaid debit card upon completion of visit 1 and a $50 debit card upon completion of 1-month follow-up assessment (visit 2), and a $100 debit card upon completion of 3-month follow-up assessment (visit 3), and a $30 debit card upon completion of 6-month post-study follow-up (visit 4) (total $210).

Payment for Research-Related Injuries

The National Institute of Drug Abuse and UAB have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Optional

Permission to Contact for Future Studies

In the future, members of the research team or other investigators may have research opportunities that may be of interest to you. As part of this study, we would like you to allow us to share basic contact information (i.e., name, phone number, mailing address, MRN) with these investigators so that they may contact you regarding future research. You do not have to agree to be contacted by future researchers or participate in their studies to be part of this study. You may request at any time that your approval for contact be removed from records. If you decide you want your approval removed, you may contact the Principal Investigator.

Initial your choice below:

_____ I agree to be contacted regarding participation in future research studies. This includes permitting the study team to contact me and refer me to appropriate studies and share my contact information.

_____ I do not agree to be contacted for future research.

Questions

If you have any questions, concerns, or complaints about the research or research-related injury including available treatments, you may contact Dr. Li. She can be reached at 205-934-6269 or after hours by paging her at 205-934-3411.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or

toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you agree to participate in this study. You will receive a signed copy of this consent form.

_____

Signature of Participant Date

_____

Signature of Investigator or Person Obtaining Consent Date