THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Main Consent Form

TITLE: Pilot Test of Contingency Management (CM) and Brief Motivational Interviewing + Substance Free Activity Session Interventions + Mindfulness-Based Adherence Promotion (BSM)

PRINCIPAL INVESTIGATOR: Karen Derfinko, Ph.D.
66 N. Pauline St.
Memphis, TN 38105

CO-INVESTIGATOR(S): Matt Harris, PhD
Karen Johnson, MD, MPH
James Murphy, Ph.D.
Fridtjof Thomas, Ph.D.
Marthinus Zeeman, MD
Ronald Lynn Cowan MD, Ph.D.

1. INTRODUCTION:

You are being given the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study.

The purpose of this study is to compare the effects of Contingency Management (CM) and Brief Motivational Intervention + Substance Free Activities Session + Mindfulness-Based Adherence Promotion (BSM) for medication adherence in patients who are initiating buprenorphine-naloxone treatment at University Clinical Health (UCH) Center for Addiction Science and The American Recovery Centers (ARC).

This is a pilot study. A pilot study is an initial study examining a new method or treatment. For this study, we are looking at ways to help patients starting buprenorphine-naloxone Medication-Assited Treatment.

Procedures:

This will be a randomized clinical trial to pilot these interventions (CM or BSM) across the first 4 weeks of burprenorphine-naloxone treatment, starting one week after today's initial intake visit.

You will be randomly assigned (like the flip of a coin) to receive CM or BSM. You have a 50/50 chance of receiving CM or BSM. The investigator will not be the person who decides which you receive. A computer program that gives random numbers will be used to decide which you receive. It is not known which treatment, if either, is better.

Both treatments are experimental. Group one, CM (Contingency Management), is a form of treatment where incentives are provided for certain behaviors. For this study, you would receive a gift card when your urine screen is positive for buprenorphine. Group 2, BSM (Brief Motivational Intervention + Substance Free Activities Session + Mindfulness-Based Adherence

Promotion), will have one-one-one sessions with a counselor to discuss their goals, how to reach these goals, and the importance of drug-free activies.

In this study, we will be collecting data from your medical record as you complete visits for your clinical care. We will also be asking you to complete some additional questionnaires about your prescription drugs, medication (buprenorphine-naloxone), delayed discounting, opioid cravings, engagement in substance free activities, clinical opioid withdrawal, and adverse events.

Your participation in this study will last about 4 months.

There are 5 visits, including today's visit. During COVID-19, we will plan to do the remainder of these visits over the phone.

The following procedures are being performed for research purposes only:

- Screen for eligibility
- Obtain informed consent
- Randomization procedures
- Copying information such as your medical history, prescription history, urine toxicology, results, diagnoses, from your medical record;
- 5 visits with study staff for treatment and/or assessment;
- Counseling sessions
- Audio recording of counseling sessions; and
- 6 questionnaires.

For a detailed explanation of the procedures, refer to the section of this consent form entitled, DETAILED PROCEDURES TO BE FOLLLOWED.

Risk:
There is a potential risk that the questionnaires and audio recording, during the intervention, may make you feel uncomfortable or cause troublesome feelings.

For a detailed list of the potential risks, refer to the section of this consent form entitled, RISKS ASSOCIATED WITH PARTICIPATION.

Benefits:
Your withdrawls or cravings may improve while you are in this study; however, this cannot be promised. Both interventions are experimental and still being evaluated for effectiveness in this population.

The results of this study may help people with opioid use disorder in the future stick to the medicated assisted treatment, and help minimize relapse.

Alternatives:
You cannot receive the **CM** or **BSM** treatment without participating in this study.

You will receive medical treatment for your opioid use disorder as normal with UCH and The ARC whether or not you participate in the study.

If you do not participate in this study, none of the procedures described in this consent form will be performed. However, you can attend group counseling at CAS and The ARC as normal, or seek an outside counselor.

Voluntary Participation:
Your participation in this research study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Deciding to not take part in this research study will not change your regular medical care in any way.

If you are a student of UTHSC, participating or not participating in this study will in no way influence your grade in any course. If you are a resident or fellow of UTHSC or UCH, participating or not participating in this study will in no way influence your academic standing. If you are an employee of UTHSC or UCH, participating or not participating in this study will not affect your employment status.

2. DETAILED PROCEDURES TO BE FOLLOWED:
Forty subjects will be participating in this study.

The study will take place at UCH Center for Addiction Science located at 6401 Poplar Ave. Suite 500 Memphis, TN 38119, and The ARC located at 2965 N. Germantown Pkwy Suite 128 Barlett, TN 38133.

Visit 0 (This will take an additional 30 min. at your routine doctor visit):
- Provide study details
- Screen for eligibility
- Obtain informed consent
- Randomization to study group
- Complete baseline questionnaires (i.e., eligibility questions, contact information, demographics such as gender and race, employment questions, public assistance questions, opioid diagnosis and opioid-related questions, other substance use questions, mental health questions, treatment history, and current treatment satisfaction.)

Visit 1-4 CM Group (In-person at regular office visit, or over the phone; 10 min.):
- Complete assessment questionnaires
- Study staff will collect information from your medical chart (i.e., prescription information, urine toxicology results, a medical diagnosis such as mental and substance use disorders.)
- Review urine screen

- Gift card draw

Visit 1-4 BSM Group (In-person at regular office visit, or over the phone; 40 min.):

- Complete assessment questionnaires
- Study staff will collect information from your medical chart (i.e., prescription information, urine toxicology results, a medical diagnosis such as mental and substance use disorders.)
- Review urine screen
- Receive counseling session
    - We will ask your permission to audiorecord the session for quality assurance.
    - During the session you will discuss personal reasons for change.
    - Identify opioid free activities that you can regularly do to get enjoyment out of life without opioids.
    - Learn skills to help you understand what the body is experiencing and how to cope with stress.

Visit 4 ONLY CM and BSM Group (After completion of office visit and assessment; either in-person or over the phone; 10 min.):

- Study staff will collect information from your medical chart (i.e., prescription information, urine toxicology results, a medical diagnosis such as mental and substance use disorders.)
- Treatment satisfaction questionnaire

We will complete a 30-day follow up medical chart review that does not require contact with the study staff or clinic.

Your participation in this research study may be stopped by the study doctor without your consent for any of the following reasons:

- If you do not show up for visits
- If you do not follow the study doctor's instructions

If you decide to stop taking part in this research study, you should tell your study doctor, and any information that you have already provided will be kept in a confidential manner.

3. RISKS ASSOCIATED WITH PARTICIPATION:

There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). There may also be further stigma due to the loss of confidentiality of this sensitive information. However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

The research may involve risks to you which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

Drug Screening:
You will undergo screening for illicit (street) drug(s) as part of your standard care treatment from UCH and The ARC. We will copy these results to your research file. If others find out you have tested positive for illegal drugs, it may cause mental stress, unfair treatment from other people, problems with getting insurance or finding a job, legal difficulties, or other unknown problems.

Questionnaires/Surveys:
Completion of some of the questionnaires may make you feel uncomfortable or cause troublesome feelings or emotions. You may refuse to answer any of the questions and you may take a break at any time during the study.

Audio Recording:
Having your voice recorded may make you feel uncomfortable. You may take a break during any time of the study. There is also a potential risk of loss of confidentiality that someone who listens to your audio recording might identify you.

4. CONFIDENTIALITY:

Research records
All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

All your electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

Your identifiable research records will be transmitted to UTHSC using an encrypted method (not regular email), where your information is replaced with a code and password only known to the entities below).

Your private information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

Medical Records
Information about your participation in this study or the results of procedures performed in this study will not be placed in your medical record.

Presentations/Publications
While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

Limits to Confidentiality
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, may be reported to a third party to protect the rights and welfare of those at potential risk.

Authorization to Use and Disclose Protected Health Information for Research Purposes
Under federal privacy regulations, you have the right to decide who can review and copy your identifiable health information (called "protected health information" or PHI). PHI collected in this study may include information such as:

- Past and present medical records
- Records about your study visits
- Records about phone calls made as part of this research
- Research records

By signing this consent form, you are giving your permission for the study doctor and the study staff to get your PHI from your doctor and/or facilities where you have received health care. They may also share your PHI with:

- The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
- Researchers at University of Memphis
- University Clinical Health
- The American Recovery Centers
- National Institutes of Health (NIH)

However, some of these organizations or institutions above do not have the same obligations to protect your PHI.

Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

Your PHI will be used until the study is completed.

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

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, 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 and documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except when: (1) there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases); (2) you have consented to the disclosure, including for your medical treatment; or (3) the materials are 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 National Center for Complementary and Integrative Health which is funding this project.

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.

5. COMPENSATION AND TREATMENT FOR INJURY:
You are not waiving any legal rights or releasing the University of Tennessee, University Clinical Health, The American Recovery Centers, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee, University Clinical Health, and The American Recovery Centers do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee, University Clinical Health, and The American Recovery Centers do not provide for treatment or reimbursement for such injuries.

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide acute medical treatment, and will provide you with a subsequent referral to appropriate health care facilities.

If you are injured or get sick as a result of being in this study, you and/or your insurance will be billed for the costs associated with this medical treatment.

No compensation will be available to you for any extra expenses that you may have as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc. No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

6. QUESTIONS:

Contact Dana Guerrero, Study Coordinator, at 901-448-3174 (office line) if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.

If you feel you have had a research-related injury, contact Dr. Marthinus Zeeman at 901-866-8630, 24-hours a day, 7-days a week. This number is for an answering service who will direct your call to the appropriate location.

You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at http://www.uthsc.edu/research/compliance/irb/ if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

7. PAYMENT FOR PARTICIPATION:

Your payment throughout the study will be in the form of either Walmart or Kroger gift cards, depending on your preference.

If you are assigned to the **CM group**, you will receive a $50 gift card for showing up for each scheduled appointment (S1-S4), and completing an assessment. You will also have the oppoturnity to draw from a fishbowl if it is determined that your urine screen is positive for buprenorphine. The fishbowl gift card amounts will range from $25 to $100. It is possible to earn $25-$400 with the fishbowl. If all 4 screens are buprenorphine-posive, you will receive a $100 bonus gift card. Total possible gift cards earned while in the study group are $50-$700.

If you are assigned to the **BSM group**, you will receive a $50 gift card for showing up for each scheduled appointment (S1-S4), completing the assessment, and completing the counseling session. Total possible gift cards earned while in the study group are $50-$200.

If you do not complete the study, you will be paid for the visits you have completed.

8. COSTS OF PARTICIPATION:

There are no costs to you for participating in this study.

9. FUTURE CONTACT:

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways:

- The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.

- A text message will be sent to the phone number(s) you provided to us requesting that you call us or text us back to reschedule.
- An email will be sent to the email address provided.
- A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.
- A message on Facebook will be sent if you have provided us with your Facebook page information.

Put your initials on one of the lines below:

_____We CAN attempt to find/contact you in the above ways.

_____We MAY NOT attempt to find/contact you in the above ways.

Sometimes we wish to keep your contact information, medical diagnosis, and other health information in order to contact you in the future and tell you about other studies in which you might be eligible to participate.

Put your initials on one of the lines below:

_____We CAN keep your contact information and health information to ask you about participating in future studies.

_____We MAY NOT keep your contact information and health information to ask you about participating in future studies

10. CONSENT OF SUBJECT:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

_____ _____ _____
Signature of Research Subject (18 years +) **Date** **Time**

_____
Printed Name of Adult Research Subject

_____ _____ _____
Signature of Person Obtaining Consent **Date** **Time**

_____
Printed Name of Person Obtaining Consent

In my judgment, the subject has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____ _____ _____
Signature of Investigator **Date** **Time**