An adaptive walking intervention to manage chronic pain in veterans with opioid use disorder engaged in opioid agonist treatment

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Subject Name: _____ Date:_____

Title of Study: Enhancing self-management skills for individuals with opioid use disorder

Principal Investigator: _____ Version Date: _07/01/2024_

RESEARCH SUMMARY

You are invited to take part in a research study because you are diagnosed with opioid use disorder and are receiving opioid agonist treatment (i.e., buprenorphine or methadone). This study is sponsored and funded by the Office of Research and Development Veteran's Health Administration and the VISN1 Mental Illness Education, Research and Clinical Center. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This initial summary is to give you key information to help you decide whether to participate. Detailed information follows this brief summary. Ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

Individuals with opioid use disorder receiving opioid agonist treatment often report physical and mental health challenges that result in a decreased quality of life. We are asking you to choose whether or not to volunteer for a research study that examines possible treatments to increase self-management strategies in individuals with opioid use disorder that are receiving opioid agonist treatment (i.e., buprenorphine or methadone). Your participation will include a screening visit, 4 outpatient treatment visits and a post treatment visit spread out over 6-10 weeks and 2 follow-up visits approximately 3 and 6-months post treatment. You will also be asked to complete surveys on a mobile device for a total of 8 weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may want to participate in this study because you could benefit from a brief 4 week group or individually administered treatment to increase self-management skills for conditions that commonly co-occur with opioid use disorder. For a complete description of benefits, refer to the Research Details.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may choose not to volunteer for the study because it involves a treatment with VA clinical staff with experience treating with opioid use disorder receiving opioid agonist treatment (i.e., buprenorphine or methadone). For a complete description of risks, refer to the Research Details.

The treatments being evaluated in this study are not intended to replace opioid agonist treatment, but rather to offer opportunities to learn self-management strategies to improve your quality of life. Your alternative is not to participate.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to evaluate group or individually administered treatments that can increase use of self-management strategies for individuals with opioid use disorder. Importantly, these treatments are designed to complement opioid agonist treatment (i.e., buprenorphine or methadone) clinical care. The knowledge from this study will provide information on whether a brief treatment combined with opioid agonist treatment can increase self-management strategies and quality of life in individuals with opioid use disorder.

HOW LONG WILL YOU BE IN THE STUDY?

This research study is expected to take approximately 4 years and we plan to recruit 60 completers. We are evaluating whether a brief 4 session treatment can improve conditions that commonly co-occur with opioid use disorder. Your participation will include a screening visit and pretreatment baseline (week 1), 4 outpatient treatment visits (week 2-5), and a post treatment visit (week 6) as well as 2 follow-up visits approximately 3 and 6-months post treatment (weeks 18 and 30). To examine possible changes in your physical and mental health associated with engaging in the group treatment, we will ask you to answer questions on a mobile device and enter your daily number of steps using a study provided pedometer. In total, your individual participation in the project will take approximately 30 weeks.

WHAT WILL HAPPEN IF YOU TAKE PART IN THE STUDY?

If you decide to participate in the research study, the following procedures will be followed:

Screening Session*:* A member of the research team will go over the informed consent form and administer a measures to confirm you are eligible to participate. We will ask you to complete study measures that include detailed questions about your medical problems, substance use history, psychosocial issues, and treatments you have received. A routine urine screening test will be performed to confirm participation in opioid agonist treatment and screen for drugs of abuse. The screening will last 1-2 hours.

After the screening visit, you will be randomized to one of two treatment groups. Assignment to a treatment group is like flip of a coin, with equal probability of being in either treatment group. We will schedule your pretreatment baseline mobile surveys 7 days prior to the start of the group-based treatment.

Mobile survey procedure: You will be asked to complete mobile surveys during pretreatment (week 1), 4 outpatient treatment visits (week 2-5), a post treatment visit (week 6), and 2 follow-

ups approximately 3 and 6-months post treatment (weeks 18 and 30). The mobile surveys will be identical throughout the study. You will be asked to respond to surveys 4 times per day or a total of 8 weeks as you go about your daily life. You will receive 3 texts during the day as well as one text for an end of day survey. We will also provide you with a pedometer and ask that you record your daily step count into end of day surveys. Surveys will be sent to a mobile phone number where we can send daily text messages with a link to complete the mobile survey. If you have a phone with a data plan and access to the internet, you may use your own phone to receive surveys. If you do not have a mobile phone, or have concerns about using your personal mobile phone to participate, we can loan you a smart phone to use while you are participating in the study. The phone number will be entered into a software program called Research Electronic Data Capture (REDCap) that is maintained on the Yale University secure server. The REDCap program will send a text message to the mobile device according to the programed schedule. Each message is a prompt to complete the mobile survey at that moment, or as soon as it is safe to do so. You should never attempt to read our texts or complete the survey when you are driving or in another situation where it is unsafe for you to be looking at your phone. You can complete each REDCap survey on a phone with Internet access, or on a computer with Internet access. Each survey will take you less than 3 minutes to complete, and will ask you about your current mood, environment, stress, opioid craving, sleep, and pain. This REDCap survey will not ask you for any identifying details (name, etc.). In the event there are issues with receiving text messages, we may use your email address to send surveys. Use of email address will follow the same process described above. If you use your personal phone, your number or email will not be linked to your survey responses in REDCap. Data you enter will be stored on the REDCap secure server at Yale, then transferred to VA for storage and analysis.

Outpatient Treatment Sessions*:* Treatment will occur in the Outpatient Addiction Recovery Services (Building 11A or 12A) and/or the Opioid Treatment Program (Building 36) at the VA Connecticut Healthcare System, West Haven Campus. Treatment will consist of 4 weekly group or individual sessions each lasting 30-45 minutes. These sessions will focus on discussing issues that are common in Veterans with opioid use disorder. You will be expected to continue to attend your regularly scheduled buprenorphine or methadone appointments while participating in the study. Treatment sessions will be facilitated by trained clinicians under the supervision of Dr. MacLean (Principal Investigator). Research clinicians will also assess for any adverse events related and unrelated to treatment. These events will be reviewed and referral to higher level of care will be provided as needed. Treatment participation will be documented in your Electronic Health Record. In order to ensure the treatment is being delivered properly, sessions will be audio recorded using a microphone that is plugged into a VA laptop. Except for your voice, the recording will be transcribed for analysis and any identifying information, such as your name, will not be transcribed.

Post-treatment Session: After completing treatment, you will meet with a research assistant to complete study measures and answer questions about treatment experience. This visit will last approximately 1 hour. Mobile surveys will continue for 1 week post-treatment. You will have the option of keeping your study provided pedometer.

Follow-up Sessions: You will be asked to return to the clinic for 3- and 6-month post-treatment follow up visits each lasting 1 hour to meet with a research assistant and complete study measures. Additionally, after each follow up session, you will asked to complete 1 week of mobile surveys and record your daily steps using a study provided pedometer. If the pedometer you were previously provided for treatment is lost or broken, a replacement will be issued.

For all study measures completed in the clinic or on mobile surveys, you are free to skip any questions that you prefer not to answer.

POSSIBLE MODIFICATIONS DUE TO COVID19 GUIDELINES

In light of COVID19 pandemic, the current study will strictly adhere to all current safety guidelines to protect research participants and staff. Should guidelines restrict face to face clinical visits and/or will not permit 6 feet of separation, treatment remotely on virtual platform (e.g., Veteran Video Connect or VVC). Research staff will contact participants and test logging into virtual platform prior to start of treatment.

WHAT IS EXPECTED OF YOU IF YOU TAKE PART IN THIS STUDY?

- Participate in four (4) treatment sessions focused on increasing self-management skills for issues that commonly co-occur with opioid use disorder.
- Do not attend any study visit or treatment session under the influence of alcohol or other substances.
- Complete mobile surveys and record daily step count over a total of 8 weeks: pretreatment baseline week, 4 weeks of outpatient group treatment, post-treatment week, a week at 3-month follow up and a week at 6-month follow up.
- We may perform periodic urine drug screenings and breathalyzers to ensure engagement in opioid agonist treatment.
- Report any new symptoms or other changes in your health that you experience.
- Keep your study appointments. If you miss an appointment, please contact research staff to reschedule as soon as you know you will miss the appointment.
- While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT YOU HAVE IF YOU TAKE PART IN THIS STUDY?

The risks of study participation include loss of confidentiality of information. Details of this risk are outlined below:

1) Confidentiality of information.
2) Your research records will be kept as confidential as possible. A unique code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.). Additionally, the study code number for study measures completed in the clinic will be different from the study code number of survey data in REDCap. The master list linking names to code numbers will be kept separately from the research data. At this time, all data will be kept in accordance with VHA guidelines. Treatment rules regarding confidentiality and privacy will be explained at the start of each treatment and all participants. In the event of group treatment, participants will be asked to adhere to requirements of not discussing any aspect of group discussion with individuals outside the group setting. Audio recordings of treatment sessions are immediately saved on a VA server and once the information has been transcribed, the original recording will be deleted. The name of the audio file will use a study code that does not include any identifying information. Only people approved to work on the study will have access to the audio recordings and deidentified transcriptions. Study Measures.
   Some people become uncomfortable with being asked questions about their drug use or medial history; if, for any reason, you wish not to answer specific questions, or you wish to terminate the session, you will be able to do so.

3) Mobile surveys
   Similar to the study measures, the REDCap program that sends text messages or an email to the mobile device you are using for the study will not collect identifying information. If someone other than you sees these messages on the mobile device you are using for the study, they may use the link to access the survey and see the kinds of questions you are being asked. They will NOT have access to your previous survey responses or any of your other study data, but they may learn that you are involved in a research study by seeing this link.

   Importantly, If you are using your personal mobile device, your phone number or email will be used to send you survey links.The researchers who manage the REDCap survey software could access your phone number or email and potentially identify you from that number. However, the REDCap survey items and responses will not include your name or other identifying information. A code number will be used to identify your surveys as belonging to you. The master list linking your name to the code number will be kept in a separate, secure location at the VA, so the software managers will not be able to determine which survey responses are yours. All Yale researchers are trained in privacy and data security.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include greater confidence addressing issues related to physical and/or mental health. Additionally, the information we get from this study might help others with your conditions.

HOW WILL YOUR PRIVATE INFORMATION BE PROTECTED?

Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible. A code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.). A separate, unique study code number will be used to identify your surveys via REDCap. The master list linking names to code numbers will be kept locked and separately from the research data. To protect the confidentiality computer records related to you or your family members, information that could be used to identify you individually will be stored only on a separate protected VA server. It will not be possible to identify you based on any data entered into study measures on REDCap.

All research information will be secured in locked files. Your identity will not be revealed in any reports or publications resulting from this study. Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as the Food and Drug Administration, (FDA), the Government Accounting ability Office (GAO), or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), as well as members of the Research Administrative staff of VA Connecticut.

Medical Record: Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all research subjects. Therefore, if you participate in this study, a medical record will be created if you do not already have one. Notes from your visits, procedures, and laboratory tests will be included in this record. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future.

Clinical Trial: A description of this clinical trial will be available on http://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.

Storage and Future Use of Data or Specimens:

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

WHAT ARE THE COSTS TO YOU IF YOU TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

IS THERE PAYMENT TO YOU IF YOU TAKE PART IN THIS STUDY?

- You will receive payment through the mail in the form of a check or direct-deposit from the VA. You may also elect to receive payment through vouchers that can be redeemed at the VACHS canteen services.
- Compensation is subject to withholding for outstanding Federal debts; for example, defaulted student loans, child support or back taxes. If you have any Federal debt there is a possibility that you may not receive any money after your participation.
- You will not be paid for attending outpatient group treatment sessions.
- Clinic visits: Payment will be $30 for the screening visit, $40 for the post-treatment visit, $55 for the 3-month follow up visit, and $65 for the 6-month follow up visit. Payment for completing all in-clinic assessments will be $190.
- Mobile surveys: You will receive $1.00 for every survey completed during the day (3/day for 8 total weeks) for a total of $168. You will receive $1.50 for every end of day survey you complete (1/day for 8 total weeks) for a total of $84. Payment for completion of mobile surveys will be a maximum of $252.
- Total payment for in-clinic assessments and mobile surveys is up to $442.
- If you withdraw from the study or are terminated from the study, you will only be paid for the visits you participated in prior to withdrawing.

Payment schedule

Visits	Amount paid	Total
Screening Visit	$30.00	$30.00
Post-treatment visit	$40.00	$40.00
3-month follow up visit	$55.00	$55.00

6-month follow up visit	$65.00	$65.00
Daily mobile surveys	$1.00 per survey (3x/day)	Total of 168 surveys = $168
End of day mobile survey	$1.50 per survey (1x/day)	Total of 56 surveys = $84
		Max payment = $442

WHAT WILL HAPPEN IF YOU ARE INJURED BECAUSE OF YOUR BEING IN THE STUDY?

If you are injured as a direct result of your participation in this research study, VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). Except in very limited circumstances, this medical treatment will be provided in a VA Medical facility. There are no plans to provide compensation for disability or other losses over the long term or if an injury becomes apparent after your participation in the study has ended. However, by agreeing to participate in this research study, you are not waiving or giving up any legal rights to seek compensation.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

AFTER HOURS: Psychiatric Emergency Room at the VA Connecticut Healthcare System and ask for the Substance Abuse Research Psychiatrist at after hours

Emergency and ongoing medical treatment will be provided as needed.

WHO ELSE MAY YOU CONTACT IF YOU HAVE QUESTIONS?

- If you have questions about your rights as a study subject, or you want to make sure this is a valid VA study, you may contact the Chairman of the Human Studies Subcommittee at
- If you have questions about the research and use of private information or biospecimens you may call the Principal Investigator
- In the event of a research-related injury to yourself, you may call the Human Studies Subcommittee Coordinator at.

If you have questions, complaints or concerns about the study or if you would like to obtain information or offer input you may call the Principal Investigator

DO YOU HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary.

Refusal to take part in the study will involve no penalty or loss of benefits or rights to which you are otherwise entitled.

You may withdraw from the study at any time without any penalty or loss of benefits.
If you choose to withdraw from the study, no additional follow-up visits will be requested.

If you withdraw from the study, the study cannot collect further information from you, but the data already collected prior to your withdrawal will still be retained and used for research study purposes.

RIGHT OF INVESTIGATOR TO TERMINATE YOUR PARTICIPATION

Your participation in this study may be terminated any time during the study without your consent if: 1) the study physician/medical monitor decides that continued study participation may cause physical or psychological harm to you; or 2) you become unable or unwilling to fulfill the scheduled visits and procedures.

If your participation is terminated, you will still be paid for the study protocol components you already participated in. We do not expect withdrawal from the study to have any adverse effects on your health or welfare. If you are withdrawn from the study, no additional follow-up visits will be requested.

WILL YOU BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be informed of any new findings developed during the course of the research that may affect your willingness to continue participation.

You will be informed of results of clinical relevance or concern if found during your screening session or study participation.

Subject Name: _____ Date:_____

Title of Study: Enhancing self-management skills for individuals with opioid use disorder

Principal Investigator: _____ Version Date: _07/01/2024_

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the research team has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study You also confirm that you have read this consent document, or it has been read to you. You will receive a copy of this consent document after you sign it.

I agree to participate in this research study as it has been explained in this document.		
_____ Subject's Name	_____ Subject's Signature	_____ Date

_____ Person Obtaining Consent	_____ Person Obtaining: Signature	_____ Date