Study Title: A Randomized Controlled Trial of MISSION-CJ for Justice-Involved Homeless Veterans with Co-Occurring Substance use and Mental Health Disorders

NCT ID #: NCT04523337

ICF Document Date: 7/13/2023

Participant Name: _____ Date:_____

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Principal Investigator: Dr. David Smelson VA Facility: Bedford VAMC

Principal Investigator for Multisite Study: Drs. David Smelson and Daniel Blonigen

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PI/SC Approval Date: 06/14/23

LSI Approval Date: N/A

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KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the Department of Veteran's Affairs Human Services Research & Development. 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 includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

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

By doing this study, we hope to learn whether a community linkage and behavioral health treatment program (Maintaining Independence and Sobriety through Systems Integration, Outreach, and Networking- Criminal Justice, or "MISSION-CJ") reduces criminal recidivism, improves behavioral health, and increases VA and non-VA community linkages. Your participation in this research will last about 15-months.

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

Although we do not guarantee or promise that you will receive any benefits from this study, the information we get from this study might help us treat future patients. *For a complete description of benefits, refer to the Detailed Information section of this consent.*

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

It is possible that a few of the questions asked of you (e.g., alcohol and drug use; criminal history) may cause you some discomfort. However, such questions should not cause you any more discomfort than the questions that are typically asked of other Veterans in mental health treatment. These questions are not anticipated to cause you any harm. *For a complete description of risks, refer to the Detailed Consent.*

DO YOU HAVE TO TAKE PART IN THE STUDY?

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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. If you agree to participate, you may withdraw from the study at any time, and you may refuse to answer any specific questions.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. David Smelson at the Bedford VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is:

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

This research study is looking at a new program (Maintaining Independence and Sobriety through Systems Integration, Outreach and Networking – Criminal Justice, or "MISSION-CJ") to reduce recidivism and achieve recovery. The purpose of this study is to evaluate MISSION-CJ as a way to reduce recidivism and improve overall health outcomes by having Veterans attend a series of group sessions, activities, and offering assertive community outreach. These sessions and activities will focus on topics such as relationships with others, substance use, linkages to other needed VA and non-VA services, and reintegrating into the community. With this research we hope to find out if the intervention is effective for Veterans by comparing a group of Veterans who receive MISSION-CJ programming with a group of Veterans who receive MISSION Peer Support (enhanced usual care offering Veterans peer support groups and community linkage support). The way we will learn about differences between the 2 groups is by doing survey assessments with participants as well as interviews. If the research is successful, our study team will work towards distributing MISSION-CJ training materials to other VA sites and treatment programs.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 15-months. Your individual participation will take 15-months. Specifically, you will be asked to participate in an intervention for 6-months and then after that 6-months we will contact you to complete a final follow-up assessment with you 9-months later (total of 15-months).

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you choose to participate, the research study staff will ask you to meet with a member of the research team in-person, over the phone, or by video conference (e.g., VA Video Connect). You will be asked to answer a series of questions and fill out some surveys about your background including your substance use, criminal history, and health. You may withdraw from the study at any time, and you may refuse to answer any specific questions. Your name will also not be on any questionnaire or survey to ensure confidentiality. We will ask for your social security number to access your VA medical records only to obtain information on your medical history including the type and amount of health care services you receive from the VA. None of the information collected by the research study team will be shared outside the VA. This will only be accessed by approved members of the study's research team. This session will take about 90 minutes.

After you complete this session, you will be assigned by a computer to one of the 2 groups; you will have approximately a 50% chance of being in the group that receives MISSION-CJ, and approximately a 50% chance of being in the group that receives MISSION Peer Support (Enhanced Usual Care) sessions. Neither you nor the study staff can decide which group you will be assigned to – this is called randomization (like flipping a coin). Regardless to which group you are assigned you will continue receiving VA treatment and services as usual.

We plan to recruit a total of 150 unique Veterans for the study from three VA MH RRTPs (Bedford VAMC, Palo Alto VAHS, and Central Arkansas VHS) and other similar residential programs affiliated with both sites. Of the 150, 50 will be recruited from the Bedford VA MH RRTP and similar residential programs affiliated with Bedford VA.

MISSION-CJ

If you are randomized to MISSION-CJ, you will be told your first appointment with your Case Manager and Peer Specialist who will be providing MISSION-CJ programming. You will be offered MISSION-CJ programming for a total of 6-months. Over the course of the study, of the 50 Veterans a total of 25 Veterans from the Bedford VA will be randomized to participate in MISSION-CJ.

1. During months 1-3, you will receive about 2 hours of services per week (1 hour, twice a week) from your Case Manager and Peer Specialist. These sessions will include activities aimed at improving your physical and behavioral health, reduce recidivism risk, and provide you with linkages to VA and non-VA care.
2. During month 4, you will continue to be offered MISSION-CJ programming once a week.

3. During month 5, you will be offered programming from your Case Manager and Peer Specialist team biweekly.
4. During month 6, you will meet with your Case Manager and Peer Specialist team once during this last month. This meeting will focus on making sure the necessary community supports have been established so that you can transition from MISSION-CJ.

To help you engage in the programming being offered, Case Manager and Peer Specialist teams will (a) remind you at the end of each group about the treatment schedule and emphasize the importance of full participation; (b) contact you if you miss a session to determine the reasons for the absence and encourage participation in future sessions; and (d) encourage participation via assertive community outreach in MISSION-CJ if you are irregularly discharged from the MH RRTP or leave the residential program you are enrolled in.

MISSION Peer Support (Enhanced Usual Care)

If you are randomized to MISSION Peer Support, you will be told your first group session which will be led by a Peer Specialist. You will be offered MISSION-Peer Support for a total of 6-months. Over the course of the study, of the 50 Veterans a total of 25 Veterans from the Bedford VA MH RRTP and similar residential programs will be randomized to participate in MISSION Peer Support.

1. During months 1-3, you will receive about 2 hours of services per week (1 hour, twice a week) from your Case Manager and Peer Specialist. These sessions will focus on behavioral health, recovery, and community integration.
2. During months 4-6, you will continue to be offered MISSION-Peer Support from the same Peer Specialist for 1-hour once a week. These sessions will focus on community linkages to VA and non-VA services.

Although you will not receive direct support from a Case Manager, the Peer Specialist delivering services will meet with a Case Manager Consultant for support and feedback. These meetings will not use any names or personal health information.

Follow Up Interviews

Regardless of which group you are assigned to (MISSION-CJ, or MISSION Peer Support) you will be contacted for at 6- and 15-month follow-up interviews which may take place at the VA or over the phone, whichever is more convenient for you. These interviews will take about 1 hour each, and a member of the research team will ask you a series questions and to fill out some surveys about substance use, and health. Again, you may withdraw from the study at any time and you may refuse to answer any specific questions. In the event you are in a jail or prison at those times, we will still attempt to contact you in these settings to conduct the 6- and 15-month interviews. Because you may have moved or could be hard to contact after leaving the treatment program, we ask that participants in the study provide us with some additional ways to find you. We ask that you give us the names, addresses and phone numbers of 3

people who would know your whereabouts, and can be reached to give us this information. We also ask that if you have a probation officer, that you give us their name and contact information. Regardless of where you are, if we cannot speak to you directly, we will not tell anyone else what the study is about. Research team members will only ask for you, and if necessary, say that the call is about a "health survey", but nothing more about the subject matter of the study.

MISSION-CJ Phone Interview

Only if you are randomized to MISSION-CJ in this study, you may also be asked to complete an extra phone interview to share your thoughts on your participation in the MISSION-CJ program and ways to improve the program. Up to 36 Veterans will be included in this portion of the study. Additionally, if you do not complete the entirety of the MISSION-CJ program you may still be contacted for a phone interview to share your thoughts on your participation. We will ask that this final interview be audio-recorded in order to transcribe and code the interview. Your identity will not be made known. The information from this interview will be transcribed into a written version that can be studied by the researchers. The transcription will be performed by a professional VA medical transcription agency specifically chosen for this study. You may refuse to participate in this interview portion of the study and still take part in the rest of the study.

Your safety and the safety of others in the treatment program will be monitored by the project staff throughout your time in this study. If at any time the research study members you pose a danger to yourself or others, the researchers will need to break confidentiality, which includes making a report to the proper authorities and/or providing additional help to you as dictated by VA regulations and state law.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

If you are randomly chosen to be a part of the MISSION-CJ group, you will be offered 2-3 hours of MISSION-CJ programming weekly, delivered by a Case Manager and a Peer Specialist treatment team assigned to you. You will be asked to attend MISSION-CJ sessions approximately twice per week for the first 3 months in addition to your usual treatment. Sessions will last 1 hour each. These sessions will include activities aimed at improving your physical and behavioral health, reduce recidivism risk, and provide you with linkages to VA and non-VA care Then, you will be offered for another 3 months (6 months total) – approximately once a week for one month, bi-weekly for one month, and one time in the final month of MISSION-CJ programming.

If you are in the group that receives MISSION-Peer Support (Enhanced Usual Care), you will be asked to attend MISSION Peer Support groups. Sessions will be delivered approximately twice per week for the first 3 months. Then, you will continue to be offered about 1 hour of weekly linkages to VA and non-VA programs for an additional 3 months.

Also, if you are assigned to the group that does not receive MISSION-CJ, we ask that you not seek out MISSION-CJ treatment elsewhere during the study period of 1 year and 3 months (15-months). Both groups will be asked to do another interview by a research study staff at 6 and 15 months after the first interview. These interviews will also last about 1 hour. You have the right to refuse to answer any question that makes you uncomfortable during any of these sessions.

If you are assigned to MISSION-CJ in this study, you may also be asked to complete an extra phone interview to share your thoughts on your participation in the MISSION-CJ program and ways to improve the program. We will ask that this final interview be audio-recorded in order to transcribe and code the interview. Your identity will not be made known on this recording. You have the right to not answer any questions you do not wish to answer. During the interview, you have the right to withdraw at any point in time. However, if a de-identified audio recording was already obtained at the time of withdrawal from the study, the audio recording and interview transcription will still be a part of the evaluation of this study. The information from this interview will be transcribed into a written version that can be studied by the researchers. The transcription will be performed by a professional VA medical transcription agency specifically chosen for this study.

As a research participant, you will be expected to:

- Keep your study appointments. If you plan to miss an appointment, please contact the research staff to reschedule as soon as you know you will miss the appointment.
- Complete your interviews as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.

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

Any procedure has possible risks. The procedures in this study may cause all, some, or none of the risks listed. Rare, unknown, or unexpected risks also may occur. Nonetheless, precautions will be taken to further reduce any risks to you in this study. Specifically, you are encouraged to have any questions answered and concerns addressed to your satisfaction prior to being asked to provide consent.

It is possible that a few of the questions asked of you (e.g., alcohol and drug use; criminal history) may cause you some discomfort. However, such questions should not cause you any more discomfort than the questions that are typically asked of other Veterans in mental health treatment. These questions are not anticipated to cause you any harm.

If you agree to participate, you may withdraw from the study at any time, and you may refuse to any answer any specific questions. All information will be confidential and used only for the purposes of the research study. You may contact the site PI or a research assistant with any questions at any time. We will tell you if we learn of new information that could change your mind about taking part or continuing in this research study.

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 cannot and do not guarantee or promise that you will receive any benefits from this study. However, the information we get from this study might help us treat future patients.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

The alternative to participating in this study is not to participate. Your decision whether or not to participate in this study will not affect your standard medical care.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- Records will be kept locked in filing cabinets, on computers protected with passwords, only study staff will have access to this information.
- Information about study participants may be discussed at meetings with the other sites, but you will not be identified by name.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you by name or any other information.

As noted above, we will ask for your social security number to access your VA computer records to obtain information on your medical history including the type and amount of health care you receive from the VA. If you choose to not share your Social Security Number you will not be able to participate in this study; however, this decision will not affect your medical care or eligibility for services. The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, or our local Research and Development Committee may look at or copy portions of records that identify you.

In attempting to contact you, the research assistant will explain to any other person whom they reach that s/he is trying to locate you regarding a health survey. We will not include your name on any interview forms. Instead, these documents will be given ID numbers that are not linked to you. The list that contains names, contact information, and ID numbers will be kept on computer files that can only be seen by project staff, and all data with personal information will be stored in locked file drawers.

This informed consent will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others as dictated by VA regulations and state law. This form does not prevent you or a member of your family from releasing data about yourself or your involvement in this study, if you so choose.

CERTIFICATE OF CONFIDENTIALITY:

The Principal Investigator (David Smelson, Psy.D.) has applied for a Certificate of Confidentiality from the National Institute of Health (NIH), which will help protect the privacy of research participants. The Certificate protects against the involuntary release of information about participants collected during the course of covered studies. The researchers involved in the studies cannot be forced to disclose your identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. The Certificate does not mean that NIH approves or disapproves of the project. It only adds special protection for research information that identifies you. However, the participant or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the participant

or his/her guardian requests the release of information in writing, the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review Dr. Smelson's records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: suspected child or elderly abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

We will include information about your study participation in your medical record.

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.

WHAT ARE THE COSTS TO ME IF I 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.

Payment Offered for Participation:
Regardless of your assignment to the MISSION-CJ intervention or Enhanced Usual Care, you will be asked to complete an interview when you enter your treatment program (in-person, by phone, or by video conference (e.g., VA Video Connect)) and two follow-up interviews (in-person, by phone, by video conference (e.g., VA Video Connect, or by mail) 6- and 15-months later. Telephone, video conference (e.g., VA Video Connect), and mail interviews will be permitted for follow-up interviews to maximize retention. You will be reimbursed $25 after completion of the first interview. For the 6- and 15-month follow-up assessments, you will be reimbursed $50 and $75 respectively. If you are selected to take part in the phone interview to answer questions about MISSION-CJ, after finishing the sessions, you will be reimbursed $25 after completion of that interview. There are 2 ways that you can be paid: one is being paid by a gift card or the second by VA canteen vouchers. The research assistant will pay you immediately after completion of each interview.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures.

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:

Emergency and ongoing medical treatment will be provided as needed. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in the study is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

If you decide to withdraw after starting the study, data that has already been collected prior to your withdrawal will be continued to be used for research purposes and be kept according to the research study data retention policy. However, no further information will be collected about you.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The investigators may also withdraw you from the study and the study intervention may be stopped without your consent for one or more of the following reasons:

- No longer meet criteria for DSM-5 diagnosis
- Express homicidal ideation.
- Failure to follow the instructions of the investigators and/or study staff.
- The investigators decide that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

Any withdrawal from the study on the part of investigators will not affect the standard care that you are already receiving in the residential program or any other VA health care to which you are entitled.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

- **Questions, Concerns, or Complaints:** If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Principal Investigator (David Smelson, Psy.D.). You should also contact him at any time if you feel you have been hurt by being a part of this study.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

The data that you provide for this study will be retained after the study is completed and may be used to re-contact you about participating in future VA research projects. This data will be stored in locked filing cabinets at the Bedford VAMC and on servers that are firewalled and password-protected. Once the study is completed, only research staff on the current project will have access to your data. Approximately 3-5 years after your participation in the current

study is completed, if additional research funding is obtained, we may re-contact you via phone and ask you to participate in another phone interview to learn more about your health and well-being at that time. All those who participate in the current study will be eligible to participate in this future study.

Would you like to be contact for future VA research studies?

☐ YES

☐ NO

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____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, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date

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