Study Title: Augmenting early phase substance use treatment with therapeutic work activity to improve clinical outcomes: a new indication for an old intervention.

NCT number: NCT04969081

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Subject Name: _____ Date:_____

Title of Study: Augmenting early phase substance use treatment with therapeutic work activity to improve clinical outcomes: a new indication for an old intervention.

Principal Investigators: Joanna Fiszdon, Ph.D. & Morris Bell, Ph.D Version Date: 05/10/21

RESEARCH SUMMARY

You are invited to take part in a research study because you are in the early phase of recovery from substance use disorder. This study is sponsored by VA Rehabilitation Research and Development Service. 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?

By doing this study, we hope to learn whether VA work services help Veterans in the early phase of recovery from a substance use disorder to stay clean and sober, feel better about themselves, and improve their functioning. Your active participation in this research will last about 6 months.

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

You may want to volunteer for this study because it will help us learn more about how VA work services can help Veterans recover from substance use disorders. The study is safe, will not interfere with usual treatment services and may lead to knowledge that may help others. 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 participate in this study because you may find answering questions about yourself uncomfortable and/or because you can obtain VA work services without going through study procedures. For a complete description of risk and alternative treatments, refer to the Research Details.

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?

The primary purpose of this study is to learn whether VA work services help Veterans in the early phase of recovery from a substance use disorder to stay clean and sober, feel better about

themselves, and improve their functioning. VA work services have been available for a long time at VACHS, but there has been no systematic study to determine their benefits for people in early recovery from substance use disorders. VA provides a variety of work services to meet the needs of Veterans who plan to return to competitive employment and also for Veterans who may have no immediate plans to return to competitive employment but recognize the value of work activity for their mental health. By conducting this study, we hope to better understand the important role VA work services may play in recovery from substance use disorders for all Veterans, whether they plan to return to competitive employment or not.

HOW LONG WILL YOU BE IN THE STUDY?

This research study is expected to take approximately four years. Your individual active participation in the project will take approximately 6 months. This will include active involvement in VA work services for at least 3 months and a follow-up meeting about 6-months from the time you started the study. We hope to have approximately 140 Veterans complete the study.

WHAT WILL HAPPEN IF YOU TAKE PART IN THE STUDY?

If you agree to be in this study and sign this consent form, we will ask you whether you plan to seek competitive employment and want VA work services to help you or whether you have no immediate plans to return to competitive employment but are interested in working at the VA in a work program as part of your recovery. These VA work services are provided as a clinical service and are not research activities. We will help you connect with these services and will monitor your involvement in them.

Baseline Assessment: We will have an initial meeting with you to learn more about your medical and substance use history by asking you questions in a structured interview. We will ask you to provide a urine sample that we use as a toxicology screen and to do a breathalyzer test to detect alcohol use. These procedures provide us with an objective measure of current substance use. We will ask that you complete some questionnaires that ask about your day to day functioning and how you feel about yourself. You are free to skip any questions that you don't want to answer. A required component of the study is that you also provide us with contact information of someone who can help us get in touch with you in the event that we are unable to maintain contact directly. If we need to reach out to them, we will only identify ourselves as VACHS staff trying to reach you, and will not share with them anything about you participating in this specific study. As an optional component, we will also ask you to give one of the study questionnaires about your day to day functioning to someone who knows you well so that they can fill it out with regard to how they think you are doing. This could be a close friend, a relative, a residential counselor, or a housemate. This is not a requirement of the study, and you should only give the questionnaire to someone if you really want to. The questionnaire will not contain your name, but only your unique study number. We will provide a self-addressed stamped envelope, and that person can mail the completed form back to us. The interviews and

questionnaires will occur in a private office. It usually takes about 90 minutes to complete these procedures.

Randomization: After the initial meeting you will be randomly assigned to the Work Services condition or to the Services as Usual Condition in a ratio of 2 to 1, which means that you are twice as likely to be in the Work Services condition than in the Services As Usual condition. Randomization means that the assignment is done by chance (like a lottery). Please note that the randomization only refers to whether or not we help facilitate referrals to VA work services, and that the VA work services themselves are a clinical service, and not a study procedure.

Work Services**:**

- *If you are randomized to Work Services condition and told us that you plan to seek competitive employment*, we will facilitate a referral to the Therapeutic and Supported Employment Services at VACHS, also called Vocational Rehabilitation. They will determine what vocational services best meet your needs. This may include help with resume writing and finding job opportunities; it may include Compensated Work Therapy involving time-limited employment at VACHS; or it may include Supported Employment involving a job coach who helps you with job searching and supportive services once you have a job. These services are to help you obtain employment at minimum wage or above.
- *If you are randomized to Work Services and you told us that you have no immediate plans for competitive employment*, we will facilitate a referral for you to another program that offers part-time, time-limited paid work activity provided in accommodating VACHS work settings.

  Being referred to a VA work program does not obligate you to follow-through with the referral or participate in the work program.

Services as Usual: If you are randomized to the Services as Usual condition, we will not facilitate a referral for you to any work services. Your substance use treatment team will make recommendations and referrals for continuing your substance use treatment at VACHS, which may or may not include VA work services. If you are referred for Vocational Rehabilitation or Work Recovery services by your treatment team and are in the Services as Usual condition, you will be discontinued from this study.

Regardless of your condition assignment, you are free to seek employment without using VA work services, and there are no restrictions on your receiving other services or treatment for your substance use disorder. We only ask that you tell us about your work activity and relevant treatments when we meet with you.

Weekly meetings for 13 weeks: Whether you are in the Work Services condition or the Services as Usual condition, we will ask you to return each week for 13 weeks to our research offices currently located in Building 8 for a brief meeting. At this meeting you will be asked about your substance use over the preceding week, about any substance use related treatment or AA/

NA meetings you attended and about any VA work or employment you may have had outside the VA. We will also ask you to do a breathalyzer test to detect alcohol use and to provide a urine sample that we use as a toxicology screen These visits will usually take about 20 minutes each week.

Follow-up at 13 weeks: At 13 weeks, in addition to the usual weekly procedures, we will ask you to complete the same questionnaires you completed before you were randomized. We will also ask you to give the same questionnaire about your day to day functioning to someone who knows you well. That person can mail it back to us. This is not a requirement of the study and you should only give the questionnaire to someone if you really want to. This visit should take about 60 minutes.

Follow-up at 6 months: Approximately 6 months from the time you started the study, we will invite you back again for a follow-up meeting. At that meeting, we will ask you about your substance use, your substance use treatment, your AA/NA meeting attendance and about any VA work or employment you may have had outside the VA. We will ask you to do a breathalyzer test to detect alcohol use and to provide a urine sample that we use as a toxicology screen. We will ask that you complete the same questionnaires that ask about your day to day functioning and how you feel about yourself. We will also ask you to give the same questionnaire about your day to day functioning to someone who knows you well. That person can mail it back to us. This is not a requirement of the study and you should only give the questionnaire to someone if you really want to. This visit should take about 45 minutes.

Additional study procedures: For a timeframe of approximately 12 months from when you start in the study, we will monitor your VA medical record to obtain additional information about your clinical service use, including participation in VA work services and in VA medical and mental health services. This will not require any effort on your part. We will use this information to help us better understand the long-term impact of receiving VA work services on your overall functioning as well as on your VA treatment use/costs.

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

Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.

At each visit, tell us about your substance use and the treatment services you use. Provide urine samples and participate in the breathalyzer test. Complete your questionnaires.

Ask questions as you think of them.

If you want to participate in another research study, please let us know. 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.

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

Any procedure has possible risks and discomforts. There are no foreseeable risks except those involving a loss of privacy and confidentiality. There are no known physical risks to any of the interviews or questionnaires or to the collection of urine samples or breathalyzer tests.

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.

Some people become uncomfortable when asked questions about their psychiatric history, substance use, or their day to day functioning. If, for any reason, you wish not to answer specific questions or you wish to terminate a research session, you will be able to do so.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. The work services described above are available by clinical referral. However, the information we get from this study might help others because we may learn more about the importance of providing work services in the early phase of recovery from substance use disorders. If work services help people with their recovery goals, these services may become recommended for people in early recovery.

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

The work services described above are available by clinical referral. You do not have to take part in this study to access these services. Your treatment team will work with you to access VA services that they recommend for your continued recovery, and you may discuss work service options with your treatment team.

HOW WILL YOUR 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:

- Paper documents are locked in filing cabinets in locked offices.

- Information collected electronically will be done so on computers protected with passwords and stored on the secure VA network.
- Only authorized persons will have access to the information gathered in this study.
- Only a code number will identify your research records. The code number will not be based on any information that can identify you (for example, social security number, initials, birthdate, etc.)
- The master list linking names to code numbers will be kept separately from the research data.

There are times when we might have to show your records to other people. For example, our local Research and Development Committee, the Government Accountability Office (GAO), the Office for Human Research Protections (OHRP), Office of Research Oversight (ORO), or other study monitors who may look at or copy portions of records that identify you.

As part of the assessments, we will ask you questions about psychiatric symptoms. If, in the course of our study procedures, we have reason to be concerned for your safety or feel that you may be a threat to the safety of others, we will inform your VA clinician who may wish that you be evaluated in the Psychiatric Emergency Room at VA Connecticut Healthcare System. Your clinician or the psychiatrist on duty might decide to hospitalize you, even if you do not wish to be hospitalized. If we are unable to contact your clinician and have concerns about your safety, we may escort you to the psychiatric emergency room, where you will be evaluated, and a decision may be made to hospitalize you.

Storage and Future Use of Data or Specimens:
Your research data will be stored by the study Principal Investigators, Dr. Joanna Fiszdon and Dr. Morris Bell, at VACHS indefinitely, with access restricted to authorized research personnel. Identifiers might be removed from the identifiable private information that is collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Medical Record
We will include information about your study participation in your medical record. We will make a note in your VA electronic medical record after each of your visits with us. The note will include information about the urine toxicology and breathalyzer test and any other clinically relevant observations that we make. These notes may be read by others involved in your medical care. We believe that it is in your best interest to share this information, but such information may affect your VA treatment or your involvement in work services in a way that you may not like. For example, a positive urine toxicology screen may result in your work assignment being altered to ensure your safety. Such clinical decisions are separate from our research procedures.

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.

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?

Payment is included in this study to compensate you for your time and inconvenience. All participants will be paid for their participation as follows:

- Baseline assessment = $50
- 13 weekly substance use assessments = $10 each ($130 total)
- 3-month and 6-month follow-up assessment = $75 each ($150 total).

Maximum total payment is $330 over the course of 6 months.

Payment will be made according to current VA procedures. Participants may choose to have a check mailed to the address they provide or they may choose electronic fund transfer (EFT) if they provide required banking information. Study payments are subject to withholding for outstanding federal debts (i.e. defaulted student loans, interstate child support, back taxes, etc.) without notification. Due to limitations in the Financial Management System, payments made to participants through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount. Your social security number will be used for this purpose. An alternative payment option is via a voucher to be used at the VA Canteen store or cafeteria.

WHAT WILL HAPPEN IF YOU ARE INJURED BECAUSE OF YOUR 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 subject with study procedures. Emergency and ongoing medical treatment will be provided as needed.

There are no plans to provide compensation for disability or other losses occurring 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:
The VA Connecticut Research Coordinator at [redacted] OR

Dr. Joanna Fiszdon at [redacted] or
Dr. Morris Bell at [redacted]
and
AFTER HOURS:
Psychiatric Emergency Room at [redacted]

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 Stuies Subcommittee at 203-932-5711 x3350.
If you have questions, complaints or concerns about the study or if you would like to obtain information or offer input you may call Dr. Morris Bell at [redacted] or Dr. Joanna Fiszdon at [redacted]

DO YOU HAVE TO TAKE PART IN THE STUDY?

Participation is voluntary and refusal to take part in this study, or withdrawing from the study, will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue taking part in this study at any time without any penalty or loss of benefits. If you withdraw from the study you can still receive the same standard of care that you otherwise would have received. Data already collected prior to your withdrawal will still be used but no further information will be collected.

RIGHT OF INVESTIGATOR TO TERMINATE YOUR PARTICIPATION

Your participation in this study may be terminated or suspended if you are hospitalized, or if your clinician feels that your participation in this study is interfering with your care or is making your symptoms worse. If, in the opinion of the principal investigators, a participant is no longer appropriate for the study, his or her participation may be discontinued without regard to the participant's wishes.

WILL YOU BE TOLD NEW INFORMATION ABOUT THIS STUDY?

If any new findings are developed during the course of the research which may affect your willingness to continue in the research, you will be contacted and provided with the information.

RE-CONTACT

We may wish to re-contact you to invite you to participate in future research projects of this type.

Initial here: _____ I agree to be contacted for future research projects of this type.

Subject Name: _____ Date:_____

Title of Study: Augmenting early phase substance use treatment with therapeutic work activity to improve clinical outcomes: a new indication for an old intervention.

Principal Investigators: Joanna Fiszdon, Ph.D. & Morris Bell, Ph.D Version Date: 05/10/21

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*