Title: A pilot study on mindfulness for pain and mental health outcomes

Clinicaltrial.gov number: NCT05286112

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Consent Script

You are being invited to take part in this research because you have chronic pain and had recent thoughts about death or about harming yourself. This is a VA research study that hopes to learn more about how to address chronic pain and thoughts of harming yourself. Our team has developed a non-medication intervention to help Veterans manage their pain and improve their mental health. This study will help us evaluate how well this treatment works.

What is involved in the study? Approximately 76 Veterans are expected to participate in this trial between the VA Finger Lakes Healthcare System and the Syracuse VAMC. Using a procedure like the flip of a coin, you will have a one in two chance of receiving the intervention to address pain and suicide risk, and a one in two chance of receiving education about living a healthy lifestyle. If you are randomized to the pain and suicide risk intervention, the sessions will cover structured material and exercises that involve strategies to manage pain and mental health issues. If you are randomized to the education condition, the meetings will discuss healthy living habits such as diet, exercise, sleep hygiene among other factors that may promote living a healthy lifestyle. Both treatments consist of 10 weekly sessions that last approximately 45-60 minutes each.

If you decide to participate, you will be asked to complete some questionnaires about your pain and mental health that will take approximately 60-90 minutes to complete. These will occur by telehealth or in-person when interested and/or available and will occur (1) prior to starting treatment (potentially today if you are available), (2) no more than one month after completing treatment, (3) approximately 3 months after treatment, and (4) approximately 6 months after treatment. We will also collect information on your current medical and mental health problems, and treatment use from your electronic medical record.

Your interviews and your intervention sessions may be video and/or audio-recorded and if so, the recordings will be copied to a computer file on a secure VA computer server and then erased from the audio recorder as applicable. The recordings will be used to assure that the research staff is conducting the research study according to the study's protocol. The files will be deleted at the earliest opportunity consistent with applicable VA requirements. You are free to refuse to participate in this portion of the study and can still take part in the rest of the study.

Confidentiality. All the information collected will be treated as confidential. Electronic information will be kept on secure password-protected VA computers on servers behind the VA firewall. Any paper records will be kept in locked filing cabinets, within locked offices at the Center of Excellence for Suicide Prevention, which is a secure facility at the Canandaigua VA Medical Center or the Syracuse VA Medical Center. None of your identifying information will be connected to your responses. Your identifying information will not be connected

to your responses, the information collected during this study, even if identifiers are removed, will not be used or distributed for future studies.

Importantly, none of this information will have any bearing on the healthcare that you receive. You proceed with your normal healthcare regardless of whether you choose to participate. At any time during this study, you can choose to withdraw from the study without prejudice or penalty. You can also choose not to answer any question at any time without any bearing on the healthcare that you receive from the VA. Again, these research activities do not replace your care as usual. Therefore, if you are already engaged in treatment for pain or mental health, you will be encouraged to continue that treatment as appropriate and addressing ongoing concerns can be addressed with your regular treatment provider. If, however, you have any concerns about the ongoing study or your one time contact with our interventionist, you should feel free to bring that up with study staff or the primary investigator, Dr. Ashrafioun.

The Investigator may terminate participation to the study for protection from excessive risk or lack of benefit or to maintain integrity of the data. Should this occur, an explanation will be provided and treatment options will be provided, as appropriate.

What are the risks of participation? Participation in this project is completely voluntary and you may withdraw at any time. Participation may involve risks that are unforeseeable. There is the possibility, though unlikely, that responding to questions on the survey may produce distress. Examples of distress include anxiety symptoms (e.g., shortness of breath, fear) or feeling down. If you experience distress during the interview, please discuss this with your interviewer. You may decide to stop the interview. We have no intention of sharing any of this information with your medical providers. However, if we are concerned about your safety, we will discuss it with you first and as a last resort reach out to emergency services if necessary. If you report any new medical concerns, we would encourage you to let your medical provider know of these concerns, but not contact them ourselves. Any significant new findings or clinically relevant results developed during the course of the research that may relate to your willingness to participate will be communicated to you in a timely manner.

Are there benefits to participating in the study? If you decide to take part in the study, there may or may not be direct medical benefits to you in terms of your mental health or medical conditions. However, you will be receiving treatment for your pain and mental health. We hope the information learned from the study will benefit other Veterans in the future as well. By conducting research studies such as this one, we can identify if this treatment can improve pain, mood, and the health of Veteran who may be at risk for suicide.

You will receive compensation for your time for participating in the study. This compensation will be in the form of direct deposits, debit cards, or checks mailed to you by the VA following each completed session. The

amount is as follows: Baseline assessment: $40; Post-treatment assessment: $40; 3-month follow-up assessment: $40 and 6-month follow-up assessment:$40

The total compensation for completing all components of the study is $160. Participants who do not complete the entire study for any reason will receive compensation for the components that were completed per the above pro-rated amounts and per the schedule of payments.

There is no cost to you for your participation.

All participants will have a Certificate of Confidentiality. What does this mean? A Certificate of Confidentiality has been received from the Department of Health and Human Services. The Certificate prevents Investigators and other project staff from being forced, even by court order subpoena, to reveal that you are in the project or to release any research data by which you may be identified. The Certificate does not prevent the Investigators and other project staff from releasing such information, but it would only be released according to both the strict confidentiality procedures of the VA and the rules of ethical research practice under the following circumstances: reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. At the final study appointment, we may ask if you're interested in other related studies. Whether or not you are interested, we will not retain your information for future contact unless you ask us directly to contact you at another time about these other opportunities. When applicable, this information will be kept behind a secure VA firewall and will only be accessible to approved study staff.

If you have questions about this study or to report a research-related injury, you can contact: Dr. Lisham Ashrafioun at (585) 430-2026. If you have general questions about giving your consent or your rights as a participant in this study or you would like to speak with an individual who is unaffiliated to this specific research study to discuss problems, concerns, and questions; obtain information or offer input you may call the Chairman of the Syracuse IRB or the Human Research Protection Program Administrator, at (315) 425-4400 X53607 or the Syracuse VA Patient Advocate at (315) 425-4345. You can also contact your local Patient Advocate: Amy Enderle at (585) 463-2653 in Rochester, Kerry Hall at (585) 393-7612 in Canandaigua, or Colleen Lancette at (315) 425-4345 in Syracuse.

Do you have any questions? Would you like to participate in the study today?

If the individual agrees to participate in the study, proceed with the Comprehension of Verbal Informed Consent below

Comprehension of Verbal Informed Consent

Participant Name: _____

Date: _____

"Now that we have reviewed the details about the study, I'm going to ask you a few questions to make sure you fully understand the research study. This is standard procedure for research studies completed over the phone."

1. **What is the purpose of this research study?**
2. **How long will the phone interviews take?**
3. **Will the information you share during this study be kept confidential?**
4. **Can you decide to stop answering the questions at any time?**

I would like to now confirm, are you willing to participate in this study?

□ Yes: Document oral consent below and continue.

□ No: Thank them for their time.

_____

Name of Subject [print]

Person Obtaining Consent
I have read this form to the subject. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. The subject has provided oral consent to participate in this study.

_____

Name [signature] **Title** [print] **Date**