Montessori Approaches in Person-Centered Care (MAP-VA): An Effectiveness-Implementation Trial in Community Living Centers

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WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is designed to see if changing the way activities are structured makes them more meaningful and enjoyable to Veterans like you. We will be partnering with staff at your Community Living Center (CLC) to learn new ways of interacting to build a greater sense of community and for Veterans to take a more active role in daily tasks and decisions. We will also see if these changes affect how Veterans are feeling (for example, mood, irritability, medicines needed to feel calm, pain, etc.). Some of this information is available in the records that VA collects already, and other information will be collected from the staff in the CLC.

You are being asked to volunteer for this study because you live in a Community Living Center (CLC). We will ask you questions about what your life is like here before and after we work with the staff. This study is conducted by [redacted] at the Tuscaloosa VA Medical Center with support from the VA Health Services Research and Development Service (HSR&D).

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

Your participation in this research is voluntary. You may choose not to participate in the study at all or leave the study, that is stop the survey, at any time without penalty.

If you decide to take part, this is what will happen:

- You would meet with a research team member to learn about the study, ask any questions you might have, and make sure you understand your rights as a volunteer.
- Next, you would be asked to answer questions about your feelings, your satisfaction with life at the CLC, and your opinions about the environment here. The questions take about 30 minutes to 1 hour.
- We will work with your CLC for about 18 months. We plan to do our Veteran survey 4 times (spread out over a 7-month period) and will ask if you are interested each time. When we do the surveys, we will find a time convenient for you and in a private space within this CLC or VA facility.
- By repeating the questions over many months, we will be able to see whether changes have affected your life at the CLC. If you only want to participate once, that is fine too. Your participation will only last about 7 months.
- You can let the research staff know if you change your mind about finishing the questions or if you would like to skip any questions that you prefer not to answer.

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

There are no direct benefits to answering surveys. However, you may enjoy having the opportunity to provide feedback on the environment and your care. You may also enjoy meeting with the research team and providing your opinions. This study could also lead to future benefits to CLC staff and veterans working or living in CLCs by helping improve care and opportunities for meaningful engagement.

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

There are minimal risks to participants. However, any research has possible risks and discomforts. This study does not involve any additional treatments or medications.
Your participation in this study may involve all, some, or none of the following:

- Answering questions may cause some discomfort or embarrassment.

- You may become tired while filling answering the survey questions. If this happens, you may finish the survey at another time.
- Though unlikely, it is possible that your answers could be seen by others outside of the study team. The risk is minimal because we will collect minimal private information and will only use identification numbers on the surveys – not your name.

HOW WILL MY INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you.

This information will be protected in the following ways:

- Asking our questions in a private and secure area.
- Keeping all study documents in a locked bag or on a password-protected computer located in a secure area.
- Your private information will be kept separately from your survey answers and other resident data. Only your unique participation identification number will appear in the study database. No one except the study team will have access to these records or know that your specific answers are linked to you.
- For this study, we expect that approximately 350 individual Veterans from eight VA CLCs will participate. None of your private information will be shared with other participating CLCs.
- Once identifiable information is removed, the information collected 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.
- The only time that confidentiality is broken is when it is necessary to protect your safety. For example, if information obtained in this study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a member of your clinical team.

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 Tuscaloosa VA Institutional Review Board (IRB), our local Research and Development Committee, our VA Co-Investigators, and other study monitors may look at or copy portions of records that identify you.

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.

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 can refuse to participate now or withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. Discontinuation will in no way affect the quality of care you receive now, or in the future, at this institution or your right to participate in other studies.

If you discharge or are no longer a resident at the CLC or are unable to complete surveys at a later time due to your health, the study team will not request your participation in future surveys for this study. The investigator or your doctor may also withdraw you without your consent, for medical or administrative reasons, in a study that has not ended. The research team may continue to use data collected prior to your withdrawal, but cannot collect further information, except from public records. If you decide to withdraw, please contact Dr. Michelle Hilgeman.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have any questions, comments or concerns about this study, you can contact the following people:

- Principal Investigator at [redacted] or [redacted]
- Project Manager at [redacted] or [redacted]
- 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 Tuscaloosa VA IRB Administrator at [redacted]

WILL I BE TOLD NEW OR CLINICALLY RELEVANT INFORMATION?

You and your treatment team will be informed of any important discoveries made during this study which may affect you, your condition, or your willingness to participate. Information obtained in this study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

HOW DO I AGREE TO PARTICIPATE IN THE RESEARCH STUDY?

By beginning the survey questions, you are voluntarily consenting to participate in this study. You are agreeing that the project team has explained the research study to you. That you have been told of the risks or discomforts and possible benefits of the study. And that you have been given the chance to ask questions and obtain answers.

You will receive a copy of this information sheet for your records.