

OFFICIAL TITLE OF STUDY:

Statewide Implementation of CAPABLE-
Community Aging in Place, Advancing Better
Living for Elders in the Michigan Medicaid
Home and Community Based Waiver Program

NCT NUMBER: NCT03634033

Registered August 16, 2018

DOCUMENT DATE: FEBRUARY 6, 2019



Research Study

Title: Statewide Implementation of CAPABLE (Community Aging-in-Place, Advancing Better Living for Elders) in the Michigan Medicaid Home and Community Based Waiver Program (NIA1R15AG058193-01A1S1; NCT03634033)

Researcher: Sandra L. Spoelstra

You are being asked to participate in a research study. The box below highlights key information about this research study for you to consider when making a decision whether or not to participate. Carefully consider this information and the additional information on this form. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

Voluntary Consent. You are being asked to volunteer for this research study. It is up to you whether you choose to participate or not. If you choose NOT to participate, there are instructions below on how to opt out of the research. Opting out will NOT affect your MI Choice services.

Purpose. This is a collaborative research effort between the Grand Valley State University College of Nursing, the State of Michigan Department of Health and Human Services, and the National Institutes of Aging to find out if different supervisory procedures add to how well CAPABLE works to help participants stay at home and in the community.

Duration. It is expected that your participation will last one year.

Procedures and Activities. You will be receiving services from a Registered Nurse, Social Worker, and/or Occupational Therapist, and we will be recording the outcomes of services by collecting information regarding your daily activities, falls, pain, depression, emergency department visits, and hospitalizations.

Risks. There is always risk when transferring private health information, but the researcher and Project Manager will be obtaining the information from the secure server of the electronic health record and keeping the data on a secure server with access only to the researcher and Project Manager.

Benefits. There are no direct benefits to you, but your information will help us better understand how to help participants stay in their homes longer.

Alternatives. Participation is voluntary and if you choose to opt out, your services will not be affected.

How will this study help me?

Information from this study may help researchers understand how to help participants stay in their home longer.

Who can participate?

We are inviting about 15,000 MI Choice participants that:

- Are 21 years of age or older and have chosen NOT to opt out of this study.

What will you receive?

This study does not affect your services. It only seeks to use your health information. You will receive the following MI Choice services, even if you choose not to give the researcher your health data: A Registered Nurse, Social Worker, and/or Occupational Therapist from MI Choice will conduct a home visit to ask some questions about your condition and services. If needed, you will receive the following:

- Care designed to your desire
- Tips on how to live in your home safely and how to make daily activities easier
- A medication review

- Up to 10 additional home visits with a Registered Nurse, a Social Worker, and/or an Occupational Therapist
- Additional phone calls

Each home visit usually lasts 1-hour and phone calls last about 10-minutes. This is all in addition to your usual MI Choice services.

What information will be used for research?

We will be collecting your health data stored within your electronic health record. This will include information about daily activities, falls, pain, depression, emergency department visits, and hospitalizations. We will have your name in order to follow your progress, but this information is known **ONLY** to the researcher and Project Manager and will be stored on a secure server. To prevent your identity to be connected with your data, we will remove specified individual identifiers (e.g. phone numbers, social security numbers, etc.) from the data. **NO** private information will be shared with anyone other than the researcher and Project Manager, and your results will be pooled among the other participants. The Researcher and Project Manager will have access to the electronic health record.

Are there risks?

Participating in this study will not change any risks associated with your usual MI Choice services because you will get the same services as non-participants. There is always risk when transferring private health information, but the researcher and Project Manager will be drawing the information from the secure server of the electronic health record, and then keeping the data on their own secure server with access only to the researcher and Project Manager. A Certificate of Confidentiality has been obtained from the Department of Health and Human Services for this study. To help protect your privacy, this certificate prevents researchers from being required (subpoenaed) to disclose identifying sensitive information collected for this study for use in court in most cases. There will be no additional financial costs. Information is collected during home visits, over the phone, and via review of your health record.

- If you have questions, issues, or concerns about your health, call your doctor.
- If you have questions about the research study call: Sandra Spoelstra, Grand Valley State University, at 616-331-5905

What do I have to do?

If you are willing to let us use your information to better understand how well the program is working, you do not have to do anything, as you will be included in the study.

If you wish to **NOT** have your information used, you can opt out of the study. Please know that you will still receive all of the services. Your decision to participate or not will not affect your current or future MI Choice services. You will continue to receive the same services from MI Choice. We simply will remove your information from our research database.

To opt out and **NOT** have your information used, please contact the researcher via phone:

- Sandra Spoelstra at Grand Valley State University at 616-331-5905.

What if I change my mind during the study?

You are free to change your mind at any time and you may withdraw from the study if you like by calling Sandra Spoelstra at 616-331-5905. We will remove your data from our study.

If you have any questions about your rights as a research participant, please contact the Office of Research Compliance & Integrity at Grand Valley State University, 1 Campus Dr., Allendale, MI Phone 616-331-3197. E-mail: rci@gvsu.edu

This research protocol has been approved by the Institutional Review Board at Grand Valley State University. Study No. 19-061-H Expiration: November 21, 2020.

V2 2-6-2019