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: JULY 3, 2021

GRAND VALLEY STATE UNIVERSITY
KIRKHOF COLLEGE OF NURSING

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 Registered August 16, 2018
Researcher: Sandra L. Spoelstra

As a Legal Authorized Representative (LAR) or Durable Power of Attorney (DPOA) that is activated for health care for a beneficiary in the Michigan Medicaid MI Choice Waiver program, you are being asked to give consent for the beneficiary to participate in a research study. The box below highlights key information about this study for you to consider when deciding whether or not to give consent for the beneficiary to participate. Carefully consider the information before you decide whether to give consent for the beneficiary to participate.

Key Information for You to Consider
Voluntary Consent. You are being asked to allow the beneficiary to take part in a research study. It is up to you whether you choose to give consent for the beneficiary to participate. There will be no penalty or loss of benefits to which the beneficiary is otherwise entitled if you do not give consent for the beneficiary to participate or continue to participate. **Purpose**. The purpose is to help caregivers provide care to beneficiaries in MI Choice in phase 3 of the study. **Duration**. It is expected that the participation may take up to 4-months, but may last up to 1 year. **Procedures and Activities.** A researcher will contact the beneficiary's caregiver to complete a survey asking about the caregiver and the beneficiary. Then, the caregiver will be given a toolkit to use when providing care. The caregiver will complete surveys asking their use and satisfaction with the toolkit and the beneficiary's health status. You will give consent for the beneficiary to take part in the study, for a researcher to contact the beneficiary's caregiver, and for access to the beneficiary's MI Choice usual assessment data. **Risks**. It is not expected that the beneficiary will be placed at any physical, financial, or legal risk or harm as a result of taking part in this study. **Benefits**. There are no direct benefits to the beneficiary, but we believe the knowledge gained from the study will assist caregivers to care for the beneficiaries. **Alternatives**. Participation is voluntary, and the only alternative is not to give consent for the participant to participate.

How will this study help me?
Information from this study may help researchers understand how caregivers assist beneficiaries to remain at home. The beneficiary may experience improvement in activities of daily living, instrumental activities of daily living, pain, falls, depression, hospital and ED visits. The beneficiary will not be placed at increased physical, financial, or legal risk as a result of taking part in the study. It may take some time and effort for to answer questions and accept extra home visits. The beneficiary will continue to receive care under the direction of their waiver clinicians, even if you do not give consent for the beneficiaries to take part in this study.

Who can participate?
We are inviting MI Choice Waiver beneficiaries with Alzheimer's Disease or dementia who did not Opt-out of the Main Trial as agreement to participate is still valid, are 18 years of age or older, speak and read English, and located in Michigan to participate.

We are asking the as LAR or DPOA that is activated for health care in the MI Choice Waiver you provide consent for the MI Choice Waiver beneficiary to participate.

What will you receive?
This study does not affect the beneficiary's services. Even if the LAR or DPOA chooses not to give consent to the researcher to view the beneficiary's health data, the beneficiary may have a Registered Nurse, Social Worker, and/or Occupational Therapist from MI Choice conduct a home visit to ask some questions about the beneficiary's condition and services. If needed, the beneficiary may receive the following:

- Care designed to the beneficiary's desire.
- Tips on how to live at home safely and how to make daily activities easier
- Medication review and management
- Up to 10 additional home visits with a Registered Nurse, a Social Worker, and/or an Occupational Therapist
- Additional phone calls

Each home visit will usually last 1-hour and each phone call will last about 10-minutes. This is in addition to the beneficiary's usual MI Choice services.

The beneficiary's caregiver will:

- Receive a toolkit to use when providing care to the beneficiary
- Complete phone surveys asking about their characteristics, self-efficacy, and relationship to the beneficiary (15 minutes); their use of the toolkit (5 minutes) monthly for 3 months; and their self-efficacy, satisfaction with the toolkit, and the beneficiary's health status (15 minutes).
- Upon completion of the study, you will receive up to $250 to compensate time spent on five surveys, prorated at $50 for each survey completed.

What information will be used for research?
Researchers will be collecting the data in surveys, notes, and the beneficiary's assessment data collected by their Supports Coordinator during usual care. This will include information about the caregiver's characteristics, their relationship to the participant, their self-efficacy, their use and satisfaction of the toolkit, and the beneficiary's health status. The beneficiary's assessment data will include information about their characteristics (age, gender, race), daily living activities, pain, depression, falls, and hospital or emergency department visits. We will have the beneficiary's name, phone number, and address but this information is ONLY known by the researcher and will be stored on a secure server. To prevent the beneficiary's identity being connected with other data, we will remove individual identifiers (name, phone and address) from the data. NO private information will be shared with anyone other than the researcher, and their results will be pooled among the other beneficiaries.

Are there risks?
Participating in this study will not change any risks associated with the beneficiary's usual MI Choice services because they will get the same services as non-participants. There is always risk when transferring private health information, but study staff 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 by study staff. A Certificate of Confidentiality has been obtained from the Department of Health and Human Services for this study. To help protect the beneficiary's 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. It is not expected that the beneficiary will be placed at any physical, financial, or legal risk as a result of taking part in this study.

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

What if I change my mind during the study?
You, on behalf of the beneficiary, are free to change your mind at any time and may withdraw the beneficiary from the study by calling Sandra Spoelstra at 616-331-5905. We will remove the data from our study.

If you have questions about the research study call:
Sandra Spoelstra, Grand Valley State University, at 616-331-5905

If you have any questions about your rights as a research care recipient:
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

What do I have to do?
If you, on behalf of the beneficiary, are willing to let us use the beneficiary's information to better understand how to use a toolkit for caregivers, please give consent for the beneficiary to be included in the study.

If you do not wish to have the beneficiary participate, do not sign this form.

DOCUMENTATION OF INFORMED CONSENT

By providing consent on behalf of the beneficiary, you certify that you reviewed, had a chance to ask questions about the study and the consent form, and received answers that fully satisfy those questions. You are voluntarily giving consent as evidence of your decision to allow the beneficiary to participate in this research study and you give authorization for release of the beneficiary's private health information relative to this research. You will receive a copy of this form.

_____
Printed Name of Beneficiary

_____ _____
Printed Name of Legally Authorized Representative or Durable Power of Attorney — Relationship to Beneficiary

_____ Date: _____
Signature of Legally Authorized Representative or Durable Power of Attorney

_____ Date: _____
Witness

This study was approved by the Grand Valley State University Human Research Review Committee (Protocol 20-213-H) on 2/19/2020.