Study Title: Adapting the Shed-MEDS Deprescribing Intervention to Dementia Care in Assisted Living
Version Date: 04/24/24
PI: Jennifer Kim, DNP, GNP-BC, GS-C

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

Researchers at Vanderbilt University Medical Center (VUMC) are conducting a pilot study with assisted living facility residents who have dementia. This study includes the use of a deprescribing intervention that was used with hospitalized older adults in the Shed-MEDS clinical trial, recently conducted at VUMC. The results of the Shed-MEDS clinical trial showed the ability to reduce an older adult's total number of medications and potentially inappropriate medications through the use of a patient-centered deprescribing intervention. Results also showed the importance of a clinician talking with a surrogate decision maker when making decisions about deprescribing medications. The purpose of this pilot study is to see if the deprescribing intervention used in the Shed-MEDS clinical trial is beneficial for older adults who live in an assisted living facility (ALF) and to examine its feasibility.

We know that many medicines commonly prescribed to older adults may have side effects that cause you to feel dizzy, unsteady, or confused. However, we do not know if stopping or reducing medicines will improve your health or any of these symptoms. We also do not know for the majority of prescribed medications, the risk of symptom or condition return when a medicine is stopped or reduced. "Deprescribing" is the planned and supervised act of stopping or reducing the dosage of a medication that is either harmful or unnecessary. Although older adults living in assisted living facilities often take many medications, including unnecessary medications, little is known about the influence of deprescribing in this population.

Study Title: Adapting the Shed-MEDS Deprescribing Intervention to Dementia Care in Assisted Living
Version Date: 04/24/24
PI: Jennifer Kim, DNP, GNP-BC, GS-C

The implementation period of this study is approximately 3 months (90 days). Your participation includes short interviews (less than 30 minutes) at enrollment and the end of 90 days that may be conducted in person or on the telephone.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you reside in an assisted living facility and are currently taking 5 or more medications (or 1 potentially inappropriate medication) to treat your health conditions. The purpose of this study is to reduce the number of medicines you take, if appropriate, and determine how this affects your health.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide if you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information. All references to medical record access are referring to the assisted living facility's medical records which have been shared with VUMC through a medical record release.

Following consent, the implementation period of the study will last approximately 3 months (90 days). At the beginning of enrollment, we will collect the following information: demographics (age, gender, race/ethnicity, education), medical history, current medications, and legally authorized representative (surrogate) name and contact information.

Next, a trained research assistant or research nurse practitioner (NP) will interview either in person in a private room at the assisted living facility or on the telephone. You will be asked questions about your beliefs and attitudes towards medications as well as your perception of your quality of life. A basic cognitive assessment (Brief Interview for Mental Status- BIMS) will also be completed. This is the same assessment that is regularly done by the assisted living facility staff.

Study Title: Adapting the Shed-MEDS Deprescribing Intervention to Dementia Care in Assisted Living
Version Date: 04/24/24
PI: Jennifer Kim, DNP, GNP-BC, GS-C

After reviewing your list of medications and discussing with the assisted living facility's medical team, the research NP will then talk with you via phone or a private in-person visit at the facility about your medicines and try to identify potentially inappropriate medicines that you are willing to stop or reduce the dosage of. We will not make any changes to a resident's medicines, but will communicate recommendations to the medical team at the assisted living facility (nurse practitioner and/or medical doctor). Any changes to medication orders will be written by the assisted living facility medical team, not the research NP. The facility's protocol for alerting a surrogate to a medication change will be followed.

A trained research assistant or research NP will contact you again via phone in approximately 3 months (90 days). You will be asked the same questions that you were asked when you were enrolled in the study.

Throughout the 3-month period of the study, the research NP (or trained research assistant) will be monitoring your status as it is related to medications that have been deprescribed. The research NP will also review your medication list at 30 days (1 month), 60 days (2 months), and at 90 days (3 months). Safety information about falls, emergency room visits, hospitalizations, and total number of recorded episodes of behavioral and psychological symptoms of dementia (BPSD) will also be recorded.

All collected data will be used by the research team to evaluate the feasibility and effectiveness of the deprescribing intervention within an assisted living facility.

Side effects and risks that you can expect if you take part in this study:
The most common side effects a resident may experience are symptoms that result from stopping a medicine or reducing the dose of a medicine, including the return of the symptoms or condition for which the medicine was originally prescribed. Side effects may differ for different types of medicines, and the dose may be lowered over days or weeks to lessen the likelihood of side effects. Here is a summary of the possible side effects based on the type of medicine that is stopped or reduced and how frequently that side effect is expected to occur:

Medication Class	Potential Side Effect of Stopping the Medication	Expected Frequency of Side Effects
1. Blood Pressure Lowering Medications	• Increase in blood pressure • Chest pain, shortness of breath	• Common (>10%) • Rare (<1%)

Study Title: Adapting the Shed-MEDS Deprescribing Intervention to Dementia Care in Assisted Living
Version Date: 04/24/24
PI: Jennifer Kim, DNP, GNP-BC, GS-C

2. Diuretic Medications	• Leg swelling, weight gain, shortness of breath	• Common (>10%)
3. Sedative / Hypnotic Medications	• Insomnia, tremor, anxiety, • Seizures	• Common (>10%) • Rare (<1%)
4. Antidepressants	• Nausea, diarrhea, abdominal pain, sweating, headache, dizziness, cold and flu-like symptoms, anxiety, irritability, trouble sleeping • Mood changes, agitation, distress, restlessness, rarely suicidal ideation	• Uncommon (1-10%) • Rare (<1%)
5. Medications for Constipation (Laxatives)	• Constipation	• Uncommon (1-10%)
6. Opioids	• Moderate to Severe Pain (Pain level >= 6) that patient is unable to tolerate • Signs of withdrawal (restlessness, runny nose, goose flesh, sweating, muscle cramps, insomnia, nausea, diarrhea, pain, secretion of tears, increased heart rate, dilation of the pupils, breathlessness, decrease or impairment in daily function	• Common (>10%) • Rare (<1%)

Study Title: Adapting the Shed-MEDS Deprescribing Intervention to Dementia Care in Assisted Living
Version Date: 04/24/24
PI: Jennifer Kim, DNP, GNP-BC, GS-C

7. Urinary Incontinence Medications	• Return of incontinence symptoms	• Common (>10%)
8. Vitamins and Supplements	• None	• None
9. Gastrointestinal Reflux Disease / Dyspepsia Medications	• Return of dyspepsia, upper gastrointestinal symptoms	• Common (>10%)
10. Aspirin	• Chest pain, stroke	• Rare (<1%)

Your symptoms will be monitored by the nursing staff at the assisted living facility. A medicine can be added back or increased back to its original dose at any time if you experience discomfort or other symptoms. If our research team identifies a medicine you are taking that is potentially unsafe or that may cause problems, we will notify the medical team at the assisted living facility.

The research study team will not make recommendations to stop or reduce medicines related to a transplant procedure, antiretroviral therapy for HIV, or chemotherapy treatment.

Risks that are not known:
Because this deprescribing intervention has not been used in an assisted living facility, there may be risks that we do not know about at this time.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: The ability to determine the best way to stop or reduce medicines for older adults with dementia living in an assisted living facility. This study may also help us understand how reducing medications might improve how well a resident takes a medicine and the cost of their medicines, including the use of health services (e.g., emergency room, hospital visits). Your loved one may or may not benefit from participating in this study.

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator with input from the National Institutes of Health & Aging that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt University Medical Center** to treat the injury.

Study Title: Adapting the Shed-MEDS Deprescribing Intervention to Dementia Care in Assisted Living
Version Date: 04/24/24
PI: Jennifer Kim, DNP, GNP-BC, GS-C

There are no plans for Vanderbilt or the National Institutes of Health & Aging to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt University Medical Center or the National Institutes of Health & Aging to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Jennifer Kim, DNP at 615-936-0739. You may also contact Sandra Simmons, VUMC co-investigator, at 615-343-6729. If you cannot reach Jennifer Kim or Sandra Simmons via phone, please page the study doctor (615-831-4010).

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
Your doctor may take you out of this study if they believe that stopping or reducing any of your medicines may lead to greater health risk than benefit for you. This may be because your doctor believes that all of your prescribed medicines are helping your symptoms and/or medical conditions. We will make every attempt to discuss our recommendations for stopping or reducing your medicines with each of your doctors, in addition to you, before any changes are made to your medicines by your medical provider.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you can tell anyone on our research team at any time. Deciding to not be part of the study will not change your regular medical care at the assisted living facility in any way.

Confidentiality:
Research subjects' identities will be kept confidential at all times. Subject identifiers will never be revealed in publication, presentation, or other scientific purpose. All de-identified data will be maintained in locked file cabinets and locked offices at the Vanderbilt University Medical Center (VUMC) Center for Quality Aging and only accessible by the research team. All study subjects will be assigned a unique study identification number for use in computer database and analytic work. Linkage of patient study IDs to patient identifiers will be maintained by the PI and Project Coordinator only, with

Study Title: Adapting the Shed-MEDS Deprescribing Intervention to Dementia Care in Assisted Living
Version Date: 04/24/24
PI: Jennifer Kim, DNP, GNP-BC, GS-C

username/password protected access. All electronic data is kept in password-protected computer files on secured VUMC servers that is username and password protected. Study tables for data gathering will have two layers of password protection. De-identified data will be shared between VUMC and Vanderbilt University (VU) via the REDCap electronic database.

This study has support from the National Institutes of Health (NIH). Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help. The National Institutes of Health & Aging and/or the Vanderbilt research team may share your information, without identifiers, with others or use it for other research projects not listed in this form. The National Institutes of Health & Aging, and the research team will comply with all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
All efforts, within reason, will be made to keep your research health information (RHI) private. Some of the RHI will include medical information shared with VUMC from the assisted living facility. All research data will be locked file cabinets and locked offices at the Vanderbilt University Medical Center (VUMC) Center for Quality Aging and only accessible by the research team. All electronic data is kept in password-protected computer files on secured VUMC servers that is username and password protected. Study tables for data gathering will have two layers of password protection. De-identified data will be shared between VUMC and Vanderbilt University (VU) via the REDCap electronic database.

Study Results:
As part of the study, Dr. Jennifer Kim and the research team may share the results of your study and/or non-study linked information related to your medicines and your responses to our interview questionnaires, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, the National Institutes of Health & Aging, and the assisted living

Study Title: Adapting the Shed-MEDS Deprescribing Intervention to Dementia Care in Assisted Living
Version Date: 04/24/24
PI: Jennifer Kim, DNP, GNP-BC, GS-C

facility staff. Federal privacy rules may not apply to these groups; they have their own rules to assure that all efforts, within reason, will be made to keep your RHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____

STATEMENT BY SURROGATE AGREEING TO PATIENT'S PARTICIPATION

I, _____ [name of decision-maker/surrogate],

Study Title: Adapting the Shed-MEDS Deprescribing Intervention to Dementia Care in Assisted Living
Version Date: 04/24/24
PI: Jennifer Kim, DNP, GNP-BC, GS-C

am the _____ [state relationship to participant]

of _____ [state participant's name]. I have read the informed consent document or it has been explained to me. I have had the opportunity to ask any questions and all of my questions have been answered. I have been informed that an investigational treatment may be administered to _____ [participant's name]. I believe receiving such treatment would be in the interests of [participant's name] and is consistent with what he/she would have decided had he/she been able to do so.

Your decision to allow your family member/friend to participate in this research study is voluntary. You may choose not to allow his/her participation and he/she will receive alternative treatments without affecting his/her healthcare/services or other rights. You are also free to withdraw him/her from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to allow continued participation in this research study, you will be notified so that you can make an informed decision whether or not to continue your family member/friend's participation in this study.

Your family member/friend will periodically be re-evaluated for the capacity to give consent. If he/she is found to be capable, continued participation in this study would only occur with his/her consent.

_____ _____/_____/_____
Signature of Health Care Decision-Maker/Surrogate Date

_____ _____/_____/_____
Signature of Witness Date

_____ _____/_____/_____
Name and Signature of person obtaining consent Date