Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: A Tailored Medication Management Intervention for Older Adults

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Research Team Contact: Rebecca Bollinger, OTD, OTR/L
Phone Numbers: 314-273-4117 / 314-273-4119

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are an older adult who takes multiple medications on a daily basis and stated you sometimes have difficulty taking them correctly.

The purpose of this research study is to determine if an intervention designed to improve ability to manage medication in the home is feasible and acceptable to older adults living in the community.

WHAT WILL HAPPEN DURING THIS STUDY?

If you decide to participate, you will complete a series of visits in the home or via a HIPAA secure telehealth platform. For visits completed remotely, you will be loaned a mobile device to complete the visit remotely. You will also receive training in how to use the technology, if necessary.
During the first visit, an occupational therapist (OT) will ask you questions about your

health, background information and your medications. You may choose to skip any questions you do not want to answer. You will also demonstrate your medication management routine for the occupational therapist. This visit should last about one hour.

After that visit is completed, you will be randomly assigned to one of two groups, either the tailored medication management intervention (TIMM) group or the attention control group. What happens in each group is different. The PI will use a method like a coin toss to decide which group you are in. You will have an equal chance of being assigned to either group.

- If you are in the **TIMM group:**
  - You will receive 1-2 additional 75 minute visits, completed either in the home or remotely, during which you and OT will problem solve any difficulties you are having with medication management. The OT will help you figure out ways to make your medication management routine easier and help you complete it accurately and independently. If you need equipment to help you take your medication more easily (e.g. pill sorter, medication alarm clock), that will be provided to you at no cost.
  - Additionally, your medication regimen will be reviewed by a pharmacist to make sure all the medication you take is appropriate for older adults and for your health conditions. The pharmacist will relay any suggestions to your doctor and your doctor will decide if any changes to your medication regimen is necessary. If your doctor decides to make any changes to your regimen, the pharmacist will review any suggested changes with you over the phone or remotely). No changes will be made without your approval.

- If you are in the **attention control group:**
  - You will receive 2 additional 75 minute social visits (either in home or remotely) from a trained research assistant. No medication management intervention is provided to this group.

For both groups, immediately upon the completion of the initial treatment/control visits, you will receive a follow-up visit, completed either in the home or remotely, from a trained rater who will ask you questions similar to the questions asked at the first visit. They will include questions about your health and medication management routine. This visit will take about one hour. This visit will be repeated at your final study visit six months later.

If we have difficulty reaching you during your participation in the study, we will first

attempt to reach out to your alternate contact. Next, we will mail a letter asking you to call us upon receiving the letter.

Will you save my research data to use in future research studies?

As part of this study, we are obtaining data from you. We would like to use this data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding how a tailored intervention can improve medication management for older adults. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you for use of your data. By allowing us to use your data you give up any property rights you may have in the data.

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My data may be stored and used for future research as described above.

_____ Yes _____ No
Initials Initials

- Identifiers may be removed from your private information including data and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

Audio/Video Recording or Photographs

One aspect of this study involves taking pictures of your home environment, specifically where you set up and take your medication. If we complete the visit(s) remotely, we will take screen shots or video during the telehealth visits. Pictures or videos to help the OTs identify difficulties you are having taking medication. Photographs will be stored electronically on a password protected server. Only the principal investigator and study

team members will have access to the photographs. Photographs will be kept as part of the electronic study record.

I give you permission to take photographs of my medication management routine during this study.

_____ Yes _____ No
Initials Initials

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 40 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for six months. You will complete 4-5 total visits for the study. Visits will range from 60-75 minutes. The initial visits with an occupational therapist (treatment) or research assistant (control) will be scheduled about 1 week apart at a time that is convenient to you. Your last two visits will be about five months apart, with your overall participation lasting six months.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Likely: In-home evaluations and assessments of barriers may cause you to feel fatigue or aggravation.

Less likely: Some questions may touch on emotionally-sensitive issues that could cause you anxiety, embarrassment, or other forms of emotional stress.

Testing and assessments will be stopped if you develop fatigue, agitation, or emotional distress. You can take a break or you can finish the questions at another time.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you

secure, and we think the risk of accidental disclosure is very small. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

We hope that, in the future, other people might benefit from this study because our findings will help us determine if our intervention is feasible and acceptable to older adults. With this information, we will be able to conduct a larger trial to determine if this intervention is effective in improving medication adherence in older adults.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The American Occupational Therapy Foundation (AOTF) is funding this research study. This means that the Washington University is receiving payments from AOTF to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from AOTF for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- Your primary care physician if a medical condition that needs urgent attention is discovered

- The American Occupational Therapy Foundation
- University representatives to complete University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will assign your study data a study identification number and all data collected will be labeled with that number. All data will be kept under double-lock protection. All hard copy forms that contain personal identifiers (e.g., name, address, phone numbers) will be stored in a separate locked file drawer under double-lock protection. To guard against unauthorized data access, all shared-use computer systems at Washington University School of Medicine are protected with passwords, which are changed at 4-month intervals. Only individuals with a particular "need to know" status are given access, and system privileges are carefully restricted. All personal computers to be used in the Administrative Unit are located within a secure area, and the system is locked when not in use.

We will disclose to the proper authorities information shared with us or activities we observe concerning abuse, neglect or harm to others or yourself.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975. Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

Can we contact you by email and text?
We would like to contact you by email and text for the purposes listed below. Some of these messages may contain health information that identifies you.

- Examples of reasons we might email you include to schedule appointments, send links to telehealth platform/appointments, provide examples of modifications, email an updated medication list.

Only the research team will have access to your email and text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email or text:

- There is always a risk that the message could be intercepted or sent to the wrong email address or phone number. To avoid this, we will send a test message to ensure we have the correct email address or phone number.
- When using any computer, you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address or phone number that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ Yes _____ No
Initials Initials

Do you agree to allow us to send your health information via text?

_____ Yes _____ No
Initials Initials

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study.
If you decide to leave the study early, we will ask you to call us and inform us that you no longer wish to participate.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because the PI decides it might be in your best interest to follow-up outside the study. The PI will share any new information that could change how you feel about continuing in the study.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Rebecca Bollinger, 314-273-4119. If you feel that you have been harmed in any way by your participation in this study, please contact principal investigator Emily Somerville, OTD, OTR/L, 314-273-4117.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on

the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)