FOR IRB USE ONLY
$STAMP_IRB
$STAMP_IRB_ID
$STAMP_APPRV_DT
$STAMP_EXP_DT

Study title: Functionally-tailored Oral Care Intervention for Community-dwelling Older Adults With Dementia and Their Caregivers

Identifiers: NCT04238520

Document date: 02-17-2023

INFORMED CONSENT DOCUMENT

Project Title: **Functionally-tailored Oral Care Intervention for Community-dwelling Older Adults with Dementia and Their Caregivers (Patient) - feasibility**

Principal Investigator: **Xian Jin Xie**

Research Team Contact: **Eileen Olderog-Hermiston, RDH, BS**
319-335-7182
eileen-olderog-hermiston@uiowa.edu

If you are the legally authorized representative of a person who is being invited to be in this study, the word "you" in this document refers to the person you represent. You will be asked to read and sign this document to give permission for the person you represent to participate in this research study.

This consent form describes the research study to help you decide if you want to participate. This form 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 as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- 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 are inviting you to participate in this research study because you have been diagnosed with mild cognitive impairment or dementia.

The purpose of this research study is to evaluate the feasibility of the individualized oral care intervention for people with dementia.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 210 people will take part in this portion of the study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, our research team member will visit your residence. Our research team member will visit your residence to collect data. You will be randomly assigned to either the intervention or control group. You are more likely to be assigned to the intervention group (3 to 1

possibility).

If you are assigned to the intervention group. Our research team will visit you weekly for 4 weeks for a hand-on oral intervention education session. At the end of the 4th week, we will need to collect the data again. You will have an option to schedule a separate visit for this data collection.

If you are assigned to the control group, our research team will deliver a non-tailored intervention session at the end of the first visit or visit you once after the first visit and again 4 weeks afterwards for data collection.

We will collect the data again at 3 months after the 4-week visit to re-evaluate the program for both groups. These visits will last approximately 60-90 minutes.

Some of the visits can be completed at College of Dentistry if you choose to.

WHAT WILL HAPPEN DURING THIS STUDY?

If agree to participate in this study these following assessments will be done to determine your continued eligibility

1) Standardized Mini-Mental State Examination for participants who is documented with cognitive impairment

If you did not meet the criteria, you will not be able to continue to participate in this study. However, your contact information will be kept for future research opportunity, if you agree to that part of the research later in this document. You can opt out from any contact from our research team member in the future.

If you are eligible to continue, you will be assigned to receive one of the two study treatments, either the functionally-tailored oral care intervention or a standard oral hygiene education that is currently delivered in the dementia dental care.

You will be asked about your daily activities, your mood status, and questions about oral health. We also will ask you to complete tasks, such as open or close your mouth, writing a sentence or remember words.

We will ask you about how your perceived your oral health status, your memory, your mood and your behaviors, and if you are able to do some daily tasks.

If in the intervention, oral care skills and related techniques developed earlier by the research team (e.g., reminding strategy, quality improvement and behavior management) will be demonstrated/delivered, followed by hand-on practice to your caregiver. The training is divided into 4 modules, each module will take 45 minutes. After the skill training session, you and a caregiver will review and discuss skills learned in the preceding session(s). A work plan will be developed at the end of each session and reviewed in the next session to make needed adjustment. Your caregiver will document his or her oral care activities using daily oral care logs. You may be asked to provide a feedback of the training session.

Trainers will also be asked to keep a log of what they cover in each session and to evaluate the implementation of the intervention across several key areas. These include whether the session addressed the educational needs and challenges encountered you and your caregiver and engagement during sessions; and the extent to which they perceive that you and your caregiver understood the information and materials presented. Any dental visits that occur during the study period, as well as oral hygiene educations received from their dentists, will be recorded (to adjust for the influence of community dental providers during data analysis). Assessments will take place at baseline, the conclusion of the intervention (i.e., 4-weeks) and 3 months after the conclusion of the intervention. The research team will call you and check to see if you have any questions or problems with oral hygiene care. The research team will provide any suggestions and answer any problems or concerns you may have, reinforce the importance of the intervention, and remind you to fill out the oral care log. The feasibility assessment and daily oral care log will be evaluated again at 3 months follow-up.

If you are in the control group, you will receive a standard oral hygiene education that is currently delivered for patients with dementia in a dental clinic. However, you will have an option to participate in our intervention program after the end of the trial. If you choose so, we will collect data from you similar to what described above for the intervention group. You will receive extra compensation if you choose to receive the intervention.

Health information that will be collected from both groups
All oral health assessments' scores will be obtained as part of the study, as well as other cognitive, functional, and mood assessment scores. Your past cognitive impairment diagnosis will be used to confirm your eligibility for the study. Your health history and medication list will be used to analyze the result. Your details about any other dental visit during study period will be collected.

Data Storage for Future Use
As part of this study, we are obtaining data from you. We would like to study your **data** in the future, after this study is over.

The tests we might want to use to study your data may not even exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding individuals with cognitive impairment, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your data, but decide in the future that you would like to have it removed from future research, you should contact Eileen Olderog-Hermiston, 801 Newton Rd. Iowa City, Iowa 52246, Tel. 319-335-7182, email: eileen-olderog-hermiston@uiowa.edu **.** However, if some research with your data has already been completed, the information from that research may still be used.

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

My data may be used for future research.

_____ Yes _____ No

Audio Recording/Video Recording/Photographs

One aspect of this study involves making audio recordings or video recordings/photographs of you. The purpose of the recording is for our research team to review the oral intervention contents and assess oral care technique to help facilitate the training that you may need. The research team will have access to this audiotape. It will be destroyed after the study is closed.

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

I agree to have the research team record video of me during the assessments.

_____ Yes _____ No

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.

Assessments and intervention can cause some uncomfortable feelings, fatigue, frustration or embarrassment.

There is a risk of loss of confidentiality of data. Measures in place to protect confidentiality are indicated in the 'What About Confidentiality' section later in this document.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from participation in the study. However, you will receive a free oral examination and your caregiver will receive a specific tailored oral health care training only to you. We hope that, in the future, other people might benefit from this study because this study will make us understand a better way to provide oral hygiene care training for caregivers of people with dementia. It may benefit both caregivers and people with dementia because caregivers will learn to perform an appropriated oral hygiene care technique that will be specifics to people in their care. People with dementia, therefore, may have better oral health.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you continue to receive a standard oral hygiene education from your dentist.

FOR IRB USE ONLY
$STAMP_IRB
$STAMP_IRB_ID
$STAMP_APPRV_DT
$STAMP_EXP_DT

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

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

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will receive a total amount of $75. You will receive $25 check per each completed appointment at 1st, 4-week and 3-month visit. You may also need to provide your address if a check will be mailed to you. You will receive extra $50 compensation if you are in the control group and choose to receive the intervention ($25 at 4th week of the intervention and at the end of 3-month follow-up). If you choose to complete part of the study at College of Dentistry, they will receive parking compensation for the amount of time spending with us.

WHO IS FUNDING THIS STUDY?

The U.S. Department of Health & Human Services, National Institutes of Health is funding this research study. This means that the University of Iowa is receiving payments from the U.S. Department of Health & Human Services, National Institutes of Health 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 the U.S. Department of Health & Human Services, National Institutes of Health for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that 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.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- The University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will store paper data in a locked cabinet, and all digital files will be encrypted and password-protected. The information about you will be recorded using an ID code to protect your confidentiality. The link between the ID and your information will only be accessible to the

Principal Investigator. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards, and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to **Eileen Olderog-Hermiston, College of Dentistry, The University of Iowa, 801 Newton Rd. Iowa City, Iowa 52246 or email: eileen-olderog-hermiston@uiowa.edu.** However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

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. 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.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because in our judgment it would not be safe for you or the research team members to continue.

FOR IRB USE ONLY
$STAMP_IRB
$STAMP_IRB_ID
$STAMP_APPRV_DT
$STAMP_EXP_DT

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Eileen Olderog-Hermiston, 801 Newton Rd. Iowa City, Iowa 52246, Tel. 319-335-7182, email: eileen-olderog-hermiston@uiowa.edu . If you experience a research-related injury, please contact: Eileen Olderog-Hermiston, 801 Newton Rd. Iowa City, Iowa 52246, Tel. 319-335-7182, email: eileen-olderog-hermiston@uiowa.edu.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

WILL YOU KEEP MY NAME ON FILE TO GIVE TO OTHERS?

We will keep information about you in a special kind of computer listing called a registry. A registry keeps information about you on file so that *other* researchers, not involved in this particular study, may contact you in the future about whether you are interested in being in *different* research studies. The registry will contain information such as your name, address, age, and selected medical information such as diagnosis and treatment. We will keep the information in this registry secure on a password protected computer. You may request that your personal information be removed from this file at any time by contacting:

Eileen Olderog-Hermiston
Mailing Address: University of Iowa College of Dentistry
801 Newton Rd, Iowa City, IA 52240
Phone: 319-335-7188
E-mail: eileen-olderog-hermiston@uiowa.edu

_____Yes_____No I give you permission to put my name and personal information in a registry so that other researchers can contact me in the future about different research studies.

This Informed Consent Document 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 signing this Informed Consent Document. Y our 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 copy of this form.

Subject's Name (printed): _____

FOR IRB USE ONLY
$STAMP_IRB
$STAMP_IRB_ID
$STAMP_APPRV_DT
$STAMP_EXP_DT

Do not sign this form if today's date is on or after $STAMP_EXP_DT.

_____ _____
(Signature of Subject) (Date)

Parent/Guardian or Legally Authorized Representative's Name and Relationship to Subject:

_____ _____
(Name - printed) (Relationship to Subject - printed)

Do not sign this form if today's date is on or after $STAMP_EXP_DT.

_____ _____
(Signature of Parent/Guardian or Legally Authorized Representative) (Date)

Legally Authorized Representative:
In studies conducted in the state of Iowa, the first person on the list below who is reasonably available and competent must sign as the legally authorized representative even if another person on the list is more conveniently available.

1. The designated proxy (such as a Durable Power of Attorney for Health Care)
2. Court-appointed guardian
3. Spouse (does not include "Common-law" spouse)
4. Adult child
5. Parent
6. Adult sibling

<u>Statement of Person Who Obtained Consent</u>

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

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

FOR IRB USE ONLY
$STAMP_IRB
$STAMP_IRB_ID
$STAMP_APPRV_DT
$STAMP_EXP_DT