Cognitive Stimulation Therapy for Residents With Dementia in Skilled Nursing Facilities: A Randomized Controlled Trial

May 2, 2025

Participants with a Power of Attorney ICF

CONSENT TO PARTICIPATE IN RESEARCH

Study Title: Cognitive Stimulation Therapy: Cognitive Functioning and Occupational Engagement in Mild-to-Moderate Dementia within Skilled Nursing Facilities

Name of Student Researcher(s): Michael Agee, OTS; Abigail Halsey, OTS, MA; Jenna Range, OTS; Zoe Webb, OTS

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Funding Organization: Northern Kentucky University

Key Information

Study Purpose: This study led by occupational therapy students will use Cognitive Stimulation Therapy (CST) at the participant's facility. The goal is to find out if CST increases individuals with dementia's memory, thinking skills, ability to perform daily activities, and socialization.

Major Requirements of the Study: To participate in this student-led project, each individual is required to be diagnosed with mild to moderate dementia. Participants should also be aged 18 and older and speak and understand English well.

Significant Risks: The activities in this study are considered safe and low-risk for injury.

Potential Benefits: Benefits to participants may include: increased social engagement, increased cognitive abilities (communication, memory, etc.), and/or increased performance in daily tasks.

Duration of Participation: 2 sessions per week (45-60 minutes per session) for 7 weeks for a total of 14 sessions.

Introduction

The person you represent is invited to take part in a research study conducted by Michael Agee, Abigail Halsey, Jenna Range, Zoe Webb, and Dr. Terrance Anderson from the Doctor of Occupational Therapy Program at Northern Kentucky University. Before deciding if the person you represent should join the study, please read this form and ask questions if you do not understand something.

Why are we doing this research?

In this research study, we want to learn more CST and its effects on individuals with mild-to-moderate dementia. We are looking at how CST affects an individual's participation in their daily activities, social engagement, and cognitive functioning. There is limited research on occupational therapists (OTs) administering CST in the aging population with dementia in nursing homes in the United States, so we are looking to expand research here in the United States. We want to improve care, cognition, independence, and quality of life for this population.

We are asking the person you represent and other people ages 18 years and older with a diagnosis of mild-to-moderate dementia to be in the research. To participate, the person you represent needs to live in a nursing home, participate in recreational activities, understand and speak English well, have good vision, hearing, and speech, and tolerate at least one hour of therapy.

Who should be in the research?

Individuals who are 18 years or older with diagnosed mild-to-moderate dementia can join the study. They must live in a nursing home, engage in at least 45 minutes of recreational or social activities each week, and score in the mid-range on the Alzheimer's Disease Assessment Scale–Cognitive Subscale (ADAS-Cog). Additionally, they should speak English well and have good vision, hearing, and speech to participate in group activities. Participants and their POA must also provide informed consent by signing this form to be included in the study.

Who should not be in the research?

The person you represent cannot join this study if they: are 17 years of age or younger; are not receiving maintenance or recreational services; have communication barriers; do not speak English as a first or second language, do not have a dementia diagnosis; have a severe case of dementia, receive hospice care; score in the high range on the ADAS-Cog; had CST treatment before; have a history of traumatic brain injury or learning disability; and are participating in other research that may influence outcomes that are being tested. The criteria above are to ensure the right participants are in the study and to keep the results accurate.

What will you do in the research?

If the person you represent decides to take part in this study and you approve, here is what will happen: they will participate in a 7-week long group CST program, which will be performed within their facility by trained occupational therapy students under the supervision of an occupational therapist. The person you represent may be placed into the control group and, as a result, will not receive CST during the study period. Each week, the trained students will choose activities that evidence has shown to improve cognition or delay memory loss.

Before the program starts, researchers will test the participant's cognition (thinking skills and memory), noting any areas that may need improvement. In each session, the participant will participate in group activities for approximately 45 to 60 minutes. The sessions will consist of a 10 minute introduction followed by 25 minutes of activities and a 10 minute summary. After 7 weeks, researchers will check the participant's cognition and note any changes from the first test. Researchers want to see if CST impacts the level of cognition. Based on the study, we will find out if CST helps people with dementia reduce cognitive impairment and/or slow down the effects of dementia.

How long will you be in this research?

Participation will take approximately 2 sessions per week (45-60 minutes per session), for 7 weeks, for a total of 14 sessions.

What Other Choices are There?

Joining this study is up to you and the person you represent. At any point during the seven weeks, the participant can change their mind and quit the study group without punishment. The participant can say no to participating in treatment sessions for any reason. During any session, the participant can change their mind, leave the session, and/or quit the study altogether. We want your loved one to join in during the sessions and will try to make activities fun, but they are allowed to skip any group activities.

They can also skip any questions that they do not wish to answer. Whatever you and the person you

represent decide will not punish you or result in loss of benefits or services to which the client deserves.

What are the bad things that can happen from this research?

Based on past research, there have been no documented harmful side effects from participating in CST. This means that there is a low risk of harm from joining this study. If something bad were to happen, then we will follow HIPPA Law and the facility's protocol. We will also report the incident or injury to the faculty advisor.

There is a small chance that the participant's personal information could be accidentally shared; however, the researchers are taking steps to protect their data.

What are the good things that can happen from this research?

Cognitive Stimulation Therapy may improve cognition and memory, quality of life, mental health, social interactions, and overall daily functioning. By joining this study, the person you represent may receive this treatment, which may reduce symptoms of dementia and depression, delay cognitive decline, and improve their quality of life. CST is a proven holistic treatment that does not require medicine. CST can be used if a patient wants a natural way to manage their condition. CST can be used in addition to medicine to help prevent or delay various symptoms.

This research may further the understanding of dementia and identify a treatment approach that is effective for dementia.

How will information about you be kept private?

Confidentiality cannot be guaranteed: Because of the kind of data, we cannot promise that the participant's data will stay private. It may be possible that others will know what they have reported. We will make every effort to ensure that participants' information remains private, but we cannot guarantee total confidentiality. Their name and identity will not be in any reports for publication. However, it may be possible for someone to recognize their story/situation/response. We will ask all group members to keep the information they hear in this group private, but we cannot guarantee that everyone will do so.

We will take the following measures to protect their information: files with names will be encrypted and moved to a secure system, and their name will be changed to a code. Only the students of the research team and faculty advisor will have access to their information through a password-protected flash drive. Their name will not be included on data collection sheets, only the ID. Documents containing their name will be stored in the faculty advisor's office and on a flash drive that is password-protected, protecting their privacy. After the completion of the study, data will be kept for six years. Paper documents will be shredded and devices where data is stored will be erased afterwards.

We would like your permission to keep the participant's data for future research studies related to this one. If you agree, then their data will be stored in the faculty advisor's office on a password-protected flash drive.

Will the person you represent be paid to be in this research study?

The participant will not be paid for participating in this study.

Will we share the research results with you?

The information we learn in this study could be important for the health and well-being of the person you represent. You and the participant will get a paper copy of the finalized research. You may need to talk to professionals to understand the results.

What happens if you are injured from being in this research?
The activities we will do at the facility are safe and low-risk for harm. If your loved one or someone else gets injured, then the protocol of the facility will be followed.

Mandated Reporting
We are mandated reporters. This means that if we learn or suspect that a participant is being abused or neglected, we are required to report this to the authorities.

Who do you call if you have questions or problems?
If you have questions about this research, please contact the primary communication coordinator, Michael Agee, OTS, at: ageem2@nku.edu . You may also contact the faculty member supervising this work: Terrance Anderson, OTD, MS, OTR/L, at andersont13@nku.edu.

If you have any questions regarding your rights as a research participant, please contact the Chair of NKU's IRB, Andrea Lambert South, Ph.D., 859-572-6615 or irbchair@nku.edu.

Signatures
Signing this document means that you understand the information given to you in this form and that you voluntarily agree to participate in the research described above.

Participant

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent Date

Legally Authorized Representative (LAR)

_____ _____
Signature of Legally Authorized Representative (LAR), Date

_____
Description of the LAR's authority must be provided

Study Staff

_____ _____
Signature of Individual Obtaining Consent Date

Please sign both consent forms, keeping one for yourself