Study Title: Movement and Music Intervention for Dementia

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Movement and Music Intervention for Dementia

Deb Kegelmeyer, Anne Kloos, Douglas Scharre

Dementia impacts 5%-7% of individuals >60 years old.[1] It impacts the individual's ability to perform work, care for him/herself and ultimately leads to physical disability. There is a high caregiver burden associated with dementia and many individuals end their lives in a long-term care facility. Overall caring for individuals with dementia is a psychological, physical and financial burden on their loved ones and society. Average total cost of care per person with dementia ($287 038) is greater than that of person's with cancer ($173 383).[2] Although Medicare expenditures were similar across groups, average out-of-pocket spending for patients with dementia ($61 522) was 81% higher than that for individuals without dementia ($34 068).[2]

Best care for individuals with dementia currently involves the use of cholinesterase inhibitors to slow cognitive decline. There is no curative therapy and most treatments are implemented to manage behavioral symptoms. There is evidence in both animal and human studies that exercise modifies metabolic, structural and functional dimensions of the brain, even in older adults.[3] Emerging evidence points to a protective effect of exercise on cognitive function in those with mild to moderate dementia but studies are limited in design and scope and while some show benefit others show no impact of exercise on cognition.[3, 4]

Neuroplasticity requires that the correct type and dosage of exercise be applied. Research to date has demonstrated that individuals with mild to moderate dementia retain the ability to undergo neuroplasticity but the type of exercise and dosage needed are not yet clear. Studies have shown that exercise in individuals with dementia can lead to improved balance[5], strength and aerobics[6, 7] and function[4-6]. Studies showing improved cognitive function included a combination of exercise and an activity that was cognitively challenging.[4, 5, 8] Cheng et al. (2014) demonstrated cognitive improvement through the use of a cognitively challenging game, Mahjong.[9] In their study the group who participated in Tai Chi 3 times a week for 12 weeks did not have a slower rate of global deterioration.[9] Two studies demonstrate that optimal benefit may be obtained through the use of an exercise intervention that includes cognitively challenging activities. Law et al. (2014) had individuals with mild cognitive impairment participate in functional task training or in cognitive training alone.[4] Both groups demonstrated improved cognitive function but only the functional task training group improved in functional status and everyday problem solving activities.[4] Lam et al. (2015) compared exercise, cognitive activity or both to demonstrate that the use of both exercise and cognitive training is superior to either one alone.[8]

It is recommended that exercise programs be structured, individualized, higher intensity, longer duration and multicomponent to bring about improvement in cognitive

function in those with dementia.[3] Due to the current reimbursement market in the insurance industry individualized programs are only feasible for a short duration unless the individual can pay out of pocket for the program. Compliance can be an issue with higher intensity, longer duration programs as demonstrated by the Lam et al. study in which 25% of the participants dropped out before the one year intervention ended.[8] This study included one hour of exercise 3 times a week for a year which was effective but a 25% drop out rate is concerning. The other studies demonstrating improvement in cognitive performance in individuals with dementia ranged from 6 – 48 sessions.[4, 5, 9] Exercise session length was typically 60 minutes.

Dance is increasingly becoming a popular form of exercise intervention for individuals with Parkinson disease (PD)[10-12] and dementia[13-16]. Dance is an aerobic exercise that challenges balance and involves functional transitions. In addition learning dance sequences is cognitively challenging. Dance is a structured, multicomponent exercise that can be higher intensity and thus fulfills the criteria laid out by Kirk-Sanchez et al. (2014) of qualities of an exercise program likely to bring about change in cognitive function.[3] In individuals with Parkinson disease and dementia it has been shown to improve motor function.[10-12, 14-16] In individuals with PD studies have shown improvement in cognitive function as measured by MoCA[11, 12], the Brooks spatial task[12], reverse corsi block test of working memory,[12], frontal assessment battery at bedside and mental rotation task[10]. The only study examining impact of dance on cognition in individuals with dementia showed slight improvement in mini-mental status exam scores.[16]

Music is an integral part of dancing and as such its impact on cognitive and behavioral function must be considered. Studies show that listening to music activates specific areas of the brain, most associated with emotional behaviors.[17] Areas activated are the insular and cingulate cortex, hypothalamus, hippocampus, amygdala and prefrontal cortex.[17] Listening to music has been shown to impact behavior and evoke reminiscing in individuals with dementia.[18] Given its potential impact on neural function we propose to include a control group who will listen to live music performances in a group setting. The control group is proposed to elucidate potential benefits of group socialization and music and differentiate these from the potential benefits of the dance training.

We hypothesize that a structured dance program involving novelty and learning of sequences will improve both motor and cognitive function in individuals with mild to moderate dementia greater than a control intervention of social music listening. Aims of this study are to investigate the impact of dance training on 1.) Functional movements such as sit to stand transfers and walking; 2.) Balance; and 3.) Cognitive function in individuals with mild to moderate dementia.

METHODS

Ninety individuals with a diagnosis of mild to moderate dementia will be recruited to take part in the study. Participants will be equally distributed into a dance training group or a control group who will listen to music in a group setting. Group placement will alternate unless the participant expresses a strong preference to be in a specific group.

Inclusion Criteria	**Exclusion Criteria**
Diagnosis of dementia (mild to moderate) MMSE equivalent score ≥ 10	Unable to walk 10 feet unassisted
Age > 60 years old	Presence of orthopedic disorder that impacts walking
Able to follow simple instructions	Presence of other neurologic diagnosis that impacts cognitive or motor function such as stroke, Parkinson disease or traumatic brain injury

Enrollment

Participants will be recruited from local neurology clinics, support groups and senior living communities. Potential participants will be told about the study and screened to determine if he/she meets inclusion/exclusion criteria using the screening form administered by a researcher. After screening the participant will be consented and then given the Mini Mental State Exam Equivalent (MMSE equivalent). Individuals with a score < 10 (severe dementia) will be disqualified and will not continue in the study.

Outcome Assessment:

Participants will be recruited and enrolled until there are 15 participants completed in each group. Baseline measures will be assessed by a trained assessor prior to start of the intervention (0-2 weeks), intermediate assessment at 6 weeks and post-intervention assessment 0-2 weeks after completing the intervention. Assessment will take 60 minutes and will be conducted either at a senior living community center, or at the MEND laboratory in Atwell Hall, Ohio State University.

<u>Primary Outcome Measures</u>

- Motor: Timed up and Go cognitive

The timed up and go cognitive assesses the ability to stand up, walk, turn and sit back down while doing a cognitive task. The individual is timed first while doing the task without a secondary cognitive task and then while doing the task and counting backwards from 100 in increments of 3. It is valid and reliable measure of mobility and dual task ability.[19]

Cognitive: MoCA

The Montreal cognitive assessment is a valid and reliable screening tool for dementia that assesses the major cognitive domains. [20] It is a paper test that takes 5 to 10 minutes to administer.

Secondary Outcome Measures

- Balance - miniBESTest
  The mini BESTest is a clinical balance assessment tool that aims to target and identify 6 different balance control systems that has been shown to be valid and reliable in the elderly[21]. It takes 10 – 15 minutes to administer and involves tests static and dynamic balance and includes the TUG cognitive.
- Activities and Function - Functional Rating Scale of Symptoms of Dementia (care partner fills out)
  A scale in which the caregiver rates the ability of the individual with dementia to perform daily care activities, memory and sleep.[22]
- Caregiver burden – Caregiver Burden Scale
  A survey tool that is a valid and reliable measure to assess perceived burden among people caring for others with disabilities.[23]

Intervention:

The dance class will be a 90 minute group class held 2 times per week for 12 weeks. Class will consist of seated warm up and stretching routines followed by seated dance that becomes progressively more challenging and leads into standing dance activities. Each participant will stand behind their chair so that the chair can be used to assist with balance. Dance activities initially comprise simple one step moves and progress to more complex sequences. Sequences will be carried over session to session to promote learning of longer sequences. The dance class will be taught by a trained dance instructor who has experience in teaching dance to individuals with neurodegenerative diseases.

The control group will meet one time per week for 90 minutes and will listen to live music performances. These performances are held in the community room of a local senior care living facility and include residents of the senior care community. Control participants will attend with their caregivers and will have opportunity to socialize with other study participants as well as members of the senior care community. Music style and type varies week to week and is chosen to be appropriate to individuals over 65 years of age.

Statistical Analysis:

We calculated the number needed based on previous studies and arrived at 15 per group. Given there is an expectation that some subjects will be found to not meet the

inclusion criteria when given the mini mental status exam equivalent after consenting and that some individuals may drop out we are asking for permission to enroll a maximum of 45 participants in each group. Once each group has 15 individuals actively participating we will stop enrollment

A one-way ANOVA will be performed for each outcome variable to estimate differences between groups. Where data is nonparametric the Kruskal-Wallis one-way ANOVA will be utilized to estimate differences between groups. Post-hoc Bonferroni comparisons with alpha set a priori at $p<0.05$ will be utilized to determine where there are significant differences.

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The Ohio State University Consent to Participate in Research

Study Title: **Movement and Music Intervention for Individuals with Dementia**

Principal Investigator: **Deb Kegelmeyer**

Sponsor: Mangurian Foundation

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

Dementia impacts 5%-7% of individuals >60 years old. It impacts the person's ability to perform work, care for him/herself and ultimately leads to physical disability. There is a high caregiver burden associated with dementia and many individuals require care in a long-term care facility. There is some emerging evidence that music based interventions may have a protective effect on the brain in those with dementia. There is also evidence that doing activities that engage the brain through music are beneficial. This study seeks to investigate the potential benefits of a music based intervention for individuals with dementia.

2. How many people will take part in this study?

90 individuals with a diagnosis of mild to moderate dementia will be recruited to participate in this study

3. What will happen if I take part in this study?

You will be asked to take a screening test that is a pen and paper test of your memory and thinking. If your score is greater than 10 you would be able to continue to participate in the study. If your score is less than 10 you would not be able to continue to participate in the study. If you meet the criteria to be in the study you will be assessed with pen and paper tests of your memory and thinking. You will have your walking, coordination, and mobility assessed. We will ask permission from you to interview a study partner or family member who knows you well. This person must be willing to come with you to the study visit to answer questions about your thinking and functioning abilities

After the initial assessment you will be assigned to one of two groups. Both groups will involve listening to music. You may also be asked to take part in an interactive program with the music that would include dance. You will attend class 1 to 2 times per week for 3 months. Each session will be 1.5 hours long. Classes will be held at a senior living facility.

You will undergo all of the assessment tests after 6 weeks and again at the end of the study, after the 3 month long music based intervention.

4. How long will I be in the study?

The study will last for 3 to 4 months. This includes 3 assessments and 3 months of the music based intervention. The music based intervention involves 1-2 sessions per week. Each session is 1.5 hours long.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

There is a risk that you could become tired or have muscle soreness after the class. You will be allowed to rest whenever you need to rest. Muscle soreness, if it develops, usually resolves within 24 hours. There is a risk that you could fall during the music intervention. There will be chairs and trained instructors to minimize this risk.

7. What benefits can I expect from being in the study?

The music intervention may provide you with entertainment and could be enjoyable. In addition, you will be able to socialize with other individuals who have dementia. You may obtain some physical conditioning from the music intervention.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

Unless you are a resident of the facility, you will have to travel to and from Parkside Village Senior Living (730 N Spring Rd, Westerville, OH 43082) 1-2 times a week for 3.5 months. There will be no cost for parking but you will incur costs for gasoline.

11. Will I be paid for taking part in this study?

There is no payment for taking part in this study.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact ***Deb Kegelmeyer 614-293-0214***.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. Douglas Scharre, MD at 1-614-293-4969**.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM**
	Date and time

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
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The Ohio State University Consent to Participate in Research

CAREGIVER CONSENT

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Principal Investigator: **Deb Kegelmeyer**

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2. How many people will take part in this study?

90 individuals with a diagnosis of mild to moderate dementia will be recruited to participate in this study. In addition a spouse or caregiver of each individual with dementia will provide information for the study.

3. What will happen if I take part in this study?

You will be asked to answer questions regarding how well the individual with dementia functions at home while performing every day tasks. This is a one page questionnaire. In addition you will be asked to fill out a caregiver burden survey to obtain information regarding your feelings about caring for an individual with dementia. You will be asked to do these assessments 3 times during the study, at the start of the study, 6 weeks into the study and at the end of the study.

4. How long will I be in the study?

The study will last for 3 to 4 months. This includes 3 assessments. Each assessment will take you 5 to 10 minutes.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

We have not identified any risks associated with filling out the questionnaires.

7. What benefits can I expect from being in the study?

There are no known benefits from filling out the questionnaires.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

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- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

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A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

You may have to drive to and from the dance, music, or assessment sessions at Parkside Village Senior Living (730 N Spring Rd, Westerville, OH 43082) 1-2 times a week for 3.5 months. There will be no cost for parking but you will incur costs for gasoline.

11. Will I be paid for taking part in this study?

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If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. Douglas Scharre, MD at 1-614-293-4969**.

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