Effects of Improvisational Dance on Cognition and Daily Function Among People With Parkinson's Disease

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A Introduction

A1 Study Abstract

Parkinson's disease is a neurodegenerative disease that results in various deficits, including cognitive impairments, for which there is a lack of interventions. Improvisational dance (ID) is spontaneously generated movement, similar to how one moves in everyday life. ID requires the integration of cognitive capacities to execute movements, and thus may strengthen cognitive processes involved in daily life function. ID has been shown to improve motor function in people with PD. The purpose of this study is to understand the effects of ID on cognition and daily function for people with PD. Specifically, it will test the effect of IMPROVment®, a method of ID designed for people with PD, on cognition and daily function. We will conduct a quasi-randomized wait-list controlled trial. Participants will be recruited and screened for eligibility through the St. Louis Chapter American Parkinson's Disease Association. Inclusion criteria includes: 50 years or older, PD diagnosis (mild to moderate), follows simple verbal cues, walks at least 3 meters independently , no contraindications in physical activity, mild cognitive impairment (determined by MOCA score), and no diagnosis of other severe comorbidities. The target sample size is 15-20 participants. Once enrolled, participants will undergo baseline testing (T1). Then participants will be randomly assigned to one of two groups: ID or waitlist control (WC). Participants in the ID group will begin a 12-week intervention where the group will meet once a week for a 1-hour IMPROVment® class. Participants in the WC group will continue with their regular routine for 12 weeks. After 12 weeks, all participants will complete Time 2 testing (T2; primary endpoint). Then WC participants will participate in the same IMPROVment® class for the following 12 weeks followed by Time 3 testing (T3; exploratory endpoint). For primary analysis, assessment scores will be compared across time point (T1, T2) and group (ID, WC) using mixed model ANOVA. Our results will provide further information on the effects of the IMPROVment® method for people with PD.

A2 Primary Hypothesis

The *central hypothesis* is that engagement in an improvisational dance (ID) class will benefit cognition and daily function among people with PD.

A3 Purpose of the Study Protocol

The purpose of this study protocol is to detail the various aspects of this study.

B Background

B1 Prior Literature and Studies

IMPROVment® was initially created for people with PD and has been used in several research studies since its conception[4, 7, 14]. This method was developed by Christina Tsoules Soriano, a dance researcher, and is a standardized intervention used with a wide range of older adults. The proposed study will follow the protocol developed by its creators. IMPROVment® has been shown to have positive impacts on motor function in people with PD, but cognition and daily function have not yet been assessed. Because

IMPROVment® was developed specifically for people with PD and is centered around community engagement, physical and mental fitness, and freedom to create movement, it has high potential to improve the performance and participation of people with PD. Further, because it challenges cogntion in ways that resemble the cognitive challenges of daily life, we hypothesize that it will be particularly beneficial for cognitive aspects of daily function. Furthering the evidence base for this method and demonstrating if it can be implemented by outside groups will increase its availability to the population of people with PD at large.

B2 Rationale for this Study

People with Parkinson's disease (PD) experience cognitive deficits.

Up to 50% of the 10 million people with PD experience cognitive deficits, specifically in visuospatial function, memory, and executive function[1, 8-11]. Visuospatial function is the ability to identify and integrate the context of the surrounding visual space. People with PD experience increased difficulty in mobility due to decreased depth perception, inhibiting them from completing everyday activities safely and effectively[8]. Along with visuospatial deficits, people with PD experience memory issues, such as deficits in working memory, long-term memory, and procedural memory, which can inhibit them from completing familiar tasks, and learning new tasks[8]. The area in which cognitive deficits are often most prevalent in people with PD is executive function. Executive function consists of higher-order cognitive processes including, decision making, inhibition of unnecessary behaviors, and self-monitoring. Specifically, people with PD experience issues in multitasking, planning and organizing, and problem solving[8, 11].

PD-related cognitive deficits negatively impact daily function.

The progression of PD and associated level of impairment is highly individualized. People with PD experience impairments in areas of motor, affect, and cognition, all of which impact one's daily function. Daily function includes one's *performance* of daily activities as well as their general involvement in daily activities and life situations (termed *participation)*. Since PD is categorized as a movement disorder, research and clinical care often emphasize its motor deficits. Recent literature, however, suggests that cognitive deficits, and specifically executive dysfunction, present the most problems in everyday life for people with PD[2, 12]. Executive function largely contributes to how one carries out his/her daily functions. Dysfunction in this area of cognition can be detrimental to an individual with PD's engagement in everyday life. Research shows that executive dysfunction contributes to reduced social engagement, leisure participation, and issues with instrumental activities of daily living (iADL's), such as medication management and meal preparation[2, 3, 12]. Due to its negative effects on daily function, effective interventions to address cognition in PD are imperative.

Dance is an emerging intervention for people with PD.

Dance is emerging as a potential therapy for people with PD. Dance is thought to be particularly effective because of "its entertaining nature and facilitation of participants' involvement"[16]. This notion is supported by evidence showing that participants have more consistent attendance and motivation for dance compared to more traditional exercise programs[17]. Evidence supports the use of several styles of dance as therapy, including, but not limited to, tango, ballet, and modern[5, 6, 13, 16, 17]. The various styles of dance emphasize different types of movement tempos, dynamics, and postures, as well as cognitive processes. In this way, dance may address a wide range of daily functions

since activity performance and participation require a variety of movements and cognitive processes.

In line with the traditional focus on motor function in PD, much of the literature and evidence on dance as an intervention for PD emphasize physical deficits[5]. For example, dance has been associated with significant improvements in gait and balance for people with PD[5, 13]. However, dance is not only a motor task but also requires the integration of cognitive processes to learn, plan, and execute movements. Cognition has been included as a secondary outcome in several studies of dance, and improvements in processing speeds in motor planning and judgement and cognitive task switching have been observed[5, 13]. Researchers in the field have called for studies to focus explicitly on the cognitive effects of dance for people with PD because of the growing amount of evidence suggesting non-motor improvements with dance[6, 14, 15].

Improvisational Dance (ID) may be particularly effective for addressing cognition and daily function in people with PD.

People live their lives based on unplanned, natural movement. For people with PD, this lack of structure can present problems with everyday activities, such as functional mobility and iADL tasks. ID is spontaneous movement that is thought of and executed on the spot. Movement in ID challenges motor planning, decision making, and flexible thinking that "builds on the idea that daily living requires flexible, adaptive responses to real-life challenges"[14]. This direct application of ID to real life may render ID a particularly beneficial form of dance for people with PD. This idea is supported by Joan Toglia's Dynamic Interactional Model, which looks at cognition in terms of the interaction between the person, activity, and the environment[20]. In practice, this frame of reference is used to build cognitive strategies that apply to varying situations. In ID classes, participants may benefit from the strategies given in class and apply them to real-life situations. Further, the free movement of ID requires the participant to use higher order cognitive processes and by challenging these processes, we may strengthen them.

Another benefit to ID classes is that there is no right or wrong, and no set movements. These features allow free expression through movement and broad accessibility to the population of people with PD in which there is a wide range of functional capacity. Participants involved in more structured dance classes have reported feeling overwhelmed by the strict nature of the class, so they may prefer the self-determination of ID[14].

Community-based programs promote activity engagement among people with PD.

Aside from dance itself, ID classes provide a fun, social form of activity engagement for participants. Research shows that people with PD that engage in PD-specific community-based programs are more likely to participate in everyday activities and roles[21, 22]. Not only does participation in community-based programs increase activity participation, research suggests that community engagement increases participation in activities that people with PD ceased at the onset of their diagnosis[22].

C Study Objectives

C1 Primary Aim

Investigate the effects of IMPROVment® on cognition for people with PD.
To test this aim, participants' cognition will be assessed using the NIH Toolbox Cognitive Battery (NIH (CB)), the Alternate Uses Task (AUT), and the Weekly Calendar Planning

Activity (WCPA). Cognitive test scores will be compared across time points (T1, T2) and between groups (ID, WC) using a mixed model repeated measures ANOVA. We hypothesize that IMPROVment® will have positive effects on the cognitive abilities of people with PD.

C2 Secondary Aim

Investigate the effects of IMPROVment® on daily functions for people with PD. Participants will also complete two questionnaires to assess daily function: Older Americans Resources and Services Scale- Extended Version (OARS-Ex) and PROMIS Satisfaction with Participation in Discretionary Social Activites (SPDSA). These scores will be compared similar to the above aim. We hypothesize that IMPROVment® will have positive effects on daily function in people with PD.

C3 Rationale for the Selection of Outcome Measures

The following table details the outcome measures involved in this study. Members of the research team have been trained in the following measures.

Assessment	Description
NIH (CB)	A comprehensive, performance-based test comprised of motor, emotion, sensation, and cognition assessments. For the purpose of this study, we will be using the cognitive battery to assess processes involved in learning and comprehension (i.e. thinking, remembering, problem-solving, judging). The battery consists of tasks involving the use of executive function, memory, attention, and language.
AUT	A verbal test of divergent thinking where the participant is given the name of an object and must name as many uses of that object as possible in a 3-minute time period. This assessment measures verbal fluency, originality, flexibility, and elaboration.
WCPA	A performance-based measure that assesses an individual's level of executive function. The task involves entering a list of errands into a calendar while following rules, keeping track of time, and managing conflicts.
OARS-Ex	A self-report questionnaire-based assessment that assesses perceived *performance* in ADL and iADL tasks by reporting the level of difficulty that they experience while completing the specific activity. Areas assessed include ADL tasks (walking, eating, dressing, grooming, getting in and out of bed, bathing, and toileting) and IADL tasks (using a telephone, traveling, shopping, preparing meals, housework, managing medication, and handling money)[18].
SPDSA	A self-report questionnaire that assesses satisfaction with leisure activities and relationships with friends.

D Investigational Agent

NA

E Study Design

E1 Overview or Design Summary

This is quasi-randomized wait-list controlled trial. Once enrolled, participants will undergo T1 assessments consisting of the primary outcome measures for each aim (described above and attached) and other relevant factors (e.g. demographics, clinical characteristics, motor function). Participants will be randomly assigned (coin flip) to one of two groups: ID or WC group. Although our aim is to randomize participants to the different groups, if someone has a strong preference or inability to participate in one group or the other due to scheduling issues, we will try to accommodate his/her preferences. Each group will have 7-10 participants, a typical size for ID classes. This ensures enough participants to create a cohesive group, but also to provide an appropriate level of safety. The ID group will participate in a 12-week intervention where the group will meet once a week for a 1-hour IMPROVment® class. Participants in the WC group will continue with their regular routine for 12 weeks. After 12 weeks, all participants will complete T2 testing. Then WC participants will participate in the same IMPROVment® method for the following 12 weeks followed by T3 testing.

E2 Subject Selection and Withdrawal

2.a Inclusion Criteria

Inclusion criteria for this study include over 50 years old, PD diagnosis with Hoehn and Yahr stage 1-3 (mild to moderate), independently walks at least 3 meters and ability to comprehend and follow simple verbal cues.

2.a Exclusion Criteria

Exclusion criteria of this study include, a Montreal Cognitive Assessment score less than or equal to 21 (indicating cognitive impairment that may interfere with class participation), diagnosis of other severe comorbidities, and contraindications to physical activity. In addition, participants must attend at least ten of the twelve classes for their data to be included in analysis (they will still be allowed to participate in the classes).

2.b Ethical Considerations

Participants will be given the choice to be involved in the study and may withdraw at any time without penalty.

2.c Subject Recruitment Plans and Consent Process

Participants will be recruited and screened for eligibility through the St. Louis Chapter American Parkinson's Disease Assocation (APDA). Approximately 15-20 participants diagnosed with PD will be recruited for this study. Consent will be obtained from each participant by select members of the research team. Each participant will be walked through the informed consent document in detail and allowed to ask questions with no cohersion. Participants will be re-assented to additional research processes after 9.24.2019 upon IRB reapproval.

2.d Randomization Method and Blinding

After consent is given and T1 testing is completed, participants will be randomly assigned (coin flip) to either participate immediately (i.e., starting the next week) in 12-weeks of IMPROVment (ID group) or to continue with regular routine for 12 weeks before starting IMPROVment (WC group). Once we reach 10 participants in a group, remaining participants will be assigned to the other group. In addition, if the participant would like to be a part of this study, but can only participate in one group or the other, we will try to accommodate his/her needs.

2.e Risks and Benefits

Risks:
Participantion in this study could result in the following risks. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.
One risk of participating in this study is that confidential information about participants may be accidentally disclosed. We will use our best efforts to keep the information about participants secure.
Another risk of participating in this study is an increased risk for falls. Although we do not expect the participants to fall during the intervention, precautionary measures are in place to decrease this risk (i.e. certified therapist present at all times, OT students monitoring the participants, movement modifications sitting in a chair).

Benefits:
Participants will not directly benefit from being in this study. Participants may indirectly benefit from participating in this study with the increased social participation and entertaining nature of the study program.
However, we hope that, in the future, other people might benefit from this study because it will help to provide information on how people with PD can best learn and remember in their daily lives.

2.f When and How to Withdraw Subjects

Participants may withdraw from this study at any time. To withdraw, participants will tell a member of the study team that he/she is no longer interested in participating in the study. He/she may withdraw completely from the dance classes or continue to dance and just withdraw from testing.

2.g Data Collection and Follow-up for Withdrawn Subjects

Data already collected on participants who withdraw from the study will be securely stored in a RedCap database. With the participants' consent, they may be used for comparison to those who remain in the study or for description of those who withdraw. If a participant would like to withdraw their data, they will be equipped with the procedure to follow on the Human Research Protocol Office website.

E3 Study Drug

NA

F Study Procedures

F1 Screening for Eligibility

Participants will be screened for eligibility using the "Inclusion/Exclusion Criteria Referral Form: IMPROVment® Class Participation" (Appendix 1)

F2 Schedule of Measurements

T1 testing will include the collection of demographics information, National Institute of Health Toolbox Cognitive Battery, the Weekly Calendar Planning Activity, Alternate Uses Task, and the Unified Parkinson's Disease Rating Scale Section 3 Motor exam. Participants will also be asked to complete the Older Americans Resources and Services scale, Satisfaction with Participation in Discretionary Social Activities scale, the Parkinson Anxiety Scale, the Sleep Disturbance Scale, the Parkinson's Disease Fatigue Scale and the Depression Scale questionnaires. These questionnaires can be completed prior to the first day of intervention via RedCap survey mode or on paper if preferred. In addition, participants will be asked to complete a brief mood questionnaire at the beginning and end of each class. The participant will mark how they are feeling on 4 scales (see Appendix 4).
After the first 12 week period of intervention, both groups will be invited back to complete those same assessments (T2). After the second 12 week period, only the WC group will T3 testing with the same assessments.

F3 Class Structure

Classes will take place at the APDA in their group fitness room. Participants will use chairs and music during the class. Class will be instructed by an occupational therapy (OT) student that has trained as a dancer for 20 years and is certified to administer the IMPROVment® method after attending an in-person training by its original creators and continues to receive feedback to better the administration of IMPROVment®[7]. Class will begin and end with participants sitting in a circle formation to eliminate any feelings of hierarchy among the participants by creating a unified group. The classes consist of three parts: seated exercise, standing barre work, and across the floor movement (refer to Table 1). Movement cues are given by the instructor to the participants and progress through the themes of isolation, shape, time, flow, space/direction, and effort (refer to Table 2). Classes will be structured by using a set class protocol created by the IMPROVment team to ensure consistency in the method delivery. Music that is popular with the age demographic will be played throughout the entire class. Trained OT students in the Cognitive and Occupational Performance Lab (PI: Erin R. Foster) and the APDA's certified physical therapist (Tricia Creel, DPT) will attend all classes to ensure participant safety.

Please see Appendix 2 for a detailed list of exercises that comprise class structure.

F4 Safety and Adverse Events

4.a Safety and Compliance Monitoring

Trained occupational therapy graduate students in the Cognitive and Occupational Performance Laboratory (PI: Erin R. Foster) and the APDA's certified physical therapist (Tricia Creel, DPT) will attend all classes to ensure participant safety. We do not anticipate any serious adverse events; however, class participation may increase the risk for falls and minor resulting injuries (e.g., bruises, scrapes). We expect this occurrence to be low if at all present, as the participants have relatively low fall risk and precautionary measures are in place to prevent falls (i.e. certified PT and OT students present at all times to monitoring participants' safety, safety modifications [e.g. sitting in a chair]).

4.b Medical Monitoring

NA

4.c Definitions of Adverse Events

NA

4.d Classification of Events

NA

4.e Data Collection Procedures for Adverse Events

See Adverse Event Reporting Form in Appendix 3. Data on the number and type of adverse events will be collected and reported when study results are disseminated.

4.f Reporting Procedures

See Adverse Event Reporting Form in Appendix 3.

4.g Adverse Event Reporting Period

Adverse events will be reported to the PI immediately (within one day), and the participant will be encouraged to report them to his/her primary care physician or neurologist within the week.

4.h Post-study Adverse Event

NA

G Statistical Plan

G1 Sample Size Determination and Power

Each group will have 7-10 participants, a typical size for ID classes. This ensures enough participants to create a cohesive group, but also to provide an appropriate level of safety. Since this is a pilot study, power analyses were not conducted. Rather, data from this study can be used to power future studies. Although attrition is not anticipated, we aim to recruit 10 participants per group to ensure there are at least 7 participants in the class.

G2 Interim Monitoring and Early Stopping

NA

G3 Analysis Plan

Aim 1: Investigate the effects of IMPROVment® on cognition for people with PD. Cognition will be assessed at pre (T1) and post (T2) using the NIH (CB), AUT, and WCPA. Scores obtained in these assessments will be compared across time point and group using mixed model ANOVA.

Aim 2: Investigate the effects of IMPROVment® on daily functions for people with PD. Daily function will be measured at pre (T1) and posttest (T2) using the OARS-EX and SPDSA. Scores will be compared across time point and group using mixed model ANOVA.

G4 Statistical Methods

See above. Analysis will be conducted with IBM SPSS software.

G5 Missing Outcome Data

Participants with missing data will be excluded from analyses involving those data. Since this is a small pilot study, we intend to maximixe the use of data we can collect.

G6 Unblinding Procedures

NA (this is not a blinded study)

H Data Handling and Record Keeping

H1 Confidentiality and Security

Confidentiality will be maintained in accordance with applicable state and federal laws. Subject data will be coded numerically to protect individual identity. No identifiers will be used in presentation or publications. All data will be stored in locked cabinets or on computers within a private, secure network protected by a PIX firewall with remote access only permitted through virtual private network connections, as per HIPAA guidelines. Patients will be informed of all risks prior to participation. Subjects will be told that they may discontinue participation at any time, that they have the alternative not to participate in the study, and that this will not impact their medical care. All key personnel involved in the design or conduct of research involving the human subjects will receive

the required education on the protection of human research participants and HIPAA guidelines prior to funding of this project. Consent will be obtained in a private setting in the room where the experiment will take place. Data will be stored in REDCap on the secure WUSM server.

A photographer will attend class to capture images of the intervention. All participants have signed a photo release forms for the APDA and will sign a photo release form for Washington University (Appendix 5).

H2 Training

Members of the research team will be trained in the assessments and/or how to assist during the dance classes prior to the start of the study. Testers will watch training videos, practice administering the tests, and perform a checkout assessment that is reviewed by an expert.

H3 Case Report Forms and Source Documents

NA

H4 Records Retention

Data collected under this protocol will be kept for a minimum of 7 years after the study is complete.

H5 Performance Monitoring

NA

I Study Monitoring, Auditing, and Inspecting

NA

J Study Administration

J1 Organization and Participating Centers

This study will take place in the following locations: Washington University in St. Louis School and Medicine and the American Parkinson's Disease Association St. Louis Chapter.

J2 Funding Source and Conflicts of Interest

J3 ***Lee Silverman Voice Treatment (LSVT) Global is funding this research study. This means that Washington University is receiving payments from LSVT 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 LSVT for conducting this study.*** ***Committees***

NA

J4 Subject Stipends or Payments

Subjects will be given a checkfor participating in this study.

J5 Study Timetable

Recruitment will occur once the IRB is approved through approximately August 2019, and the study will begin in Semptember 2019. This will ensure ample time for participants to consider participating in the study. Participation in this study is completely voluntary and that will be verbally told to each participant and on the written consent.

Prior to the start of the study, research team members will be trained and checked out on each assessment and the use of RedCap.

Baseline testing will occur in late August 2019, allowing the intervention to begin in September 2019 and run for the following 12 weeks until November 2019. Post testing will occur in that following week. Due to the holiday season and school schedules, the control participants will begin the second wave of intervention in January 2020 until March of 2020.

K Publication Plan

The research team plans to publish findings from this study at its completion.

L Attachments

L1 Tables

Table 1. ***IMPROVment® Class Components***

Class Components	**Description**
Seated Exercise	Class begins with all participants seated in a chair. Movement cues are given to move different parts of the body in different qualities (i.e. sharp and soft). This part of class serves as a warm up for the body prior to engaging in bigger movements.
Standing Barre Work	Movement progresses from a seated position to standing while still holding onto the chair for extra support. Barre work begins to

	test balance abilities and increase level of movement executed (i.e. balancing on one leg).
Across the Floor	This is the section of class in which ID is incorporated most in several movement activities. These ID tasks are done both individually, in partners, and as a large group. Participants are not limited to staying close to their chairs and move around throughout the space using ID movement (i.e. moving in sync with another person in the room).

Table 2. *IMPROVment® Class Themes*

Class Themes	**Description**
Isolation	Movement of a specific body part or parts.
Shape	How the body moves as a whole, as a combination of body parts, or as individual body parts. Shape can also be impacted by other objects in the environment (i.e. chairs, walls, other participants).
Time	The relationship between the body's movement and music. Time can also be impacted by the movement of other participants.
Flow	The transition between movement, specifically the continuity of movement.
Space/direction	The connection of movement to the physical environment. This is how movement is carried through space in both a stationary, seated position and locomotion throughout the classroom.
Effort	The movement quality (i.e. light, heavy, free, structured).

L2 Appendices

Appendix 1: Inclusion/Exclusion Criteria Referral Form

Inclusion/Exclusion Criteria Referral Form: IMPROVment® Class Participation

PATIENT NAME: _____ DATE: _____
PATIENT DOB: _____
PARENTS NAMES: _____
ADDRESS: _____
PHONE: _____

Inclusion Criteria

_____Yes _____No - Age: 50+
_____Yes _____No - Parkinson's Disease Diagnosis
_____Yes _____No - Hoehn Yahr Score between 1 and 3
_____Yes _____No - Cognitive status: able to follow simple commands like
_____Yes _____No - Walks at least 3 meters independently

Exclusion Criteria

_____Yes _____No - History of adverse effects related to physical activity
_____Yes _____No - Severe comorbidities

Appendix 2: Class Structure

Warm up: (25 minutes)

- Finding group breath
- Alternating squeezes, raining, and patting up and down entire body with hands
- Head dance moving up and down/side to side
- Make different faces
- Swimming with arms (forward & backward circles)
- Circular and angular movements with UE (alternating between these)
    - Elbows
    - Wrists
    - Fingers
    - Combination
- Catching lightening bugs
    - Reaches outward→ starting to challenge seated balance
- Mime box around you
    - Reaching high, low, twisting through spine
- Activity
    - Make a meal, do your morning routine, favorite leisure activity
- Heel toe the feet out and in to each other
- Leg dance- bending and lengthening through the knees
    - Adding knee lifts into chest
- Circular and angular movements with UE (alternating between these)
    - Knees
    - Ankles
    - Combination
- Moving one arm and one leg
    - Variations of combinations of this
- Stretches
    - Legs
        - Figure 4 stretch
        - Leg out in front and flex ankle (option to stretch forward)
        - Seated lunge

Standing Barre Work (10 mins)

- Releves and plies
- Painting with toe on floor
- Lifting toe off the floor
- Chair duet

Center Work (20 mins)

- Group sculpture
- Mirroring
- Find a shape and match someone else's
- Mold person into shape and then match the shape
- Group flocking
- Pass the energy

Cool Down (5 mins)

- Repeat stretches
- Group breaths

Appendix 3: Adverse Event Reporting Form

Adverse Event Reporting Form

ID for PD	
Visit Date: _____	
Subject ID:_____	Study Staff: _____

Date of the event: _____ Date resolved: _____ Date staff informed: _____

Is this a **serious** adverse event? **Yes** **No**

If yes, circle type of event:

a. Death

b. Hospitalization

c. Life threatening illness or accident

d. A permanent disability or incapacity

e. Abnormal laboratory or diagnostic test result requiring immediate medical attention

f. Other serious illness that might have resulted in an SAE without aggressive medical intervention

Description of event: _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Did the participant receive treatment for AE/SAE? **Yes** **No**

If yes, where: _____

If hospitalized: Date of admission: _____ Date of discharge: _____

List below all therapy/medications taken by the patient related to this adverse event. (Attach additional pages if necessary)

MEDICATION	DOSE/ ROUTE/ FREQUENCY	START DATE	STOP DATE	INDICATION

Any medical history related to the event? **Yes** **No**
If yes, explain_____

ACTION TAKEN (circle all that apply):

a. None
b. Medical Intervention
c. Hospitalization
d. Intervention discontinued
e. Other _____

OUTCOME (circle appropriate response):

a. Recovered without treatment
b. Recovered with treatment
c. Still present, no treatment
d. Still present, being treated
e. Residual effect(s) present, no treatment
f. Residual effect(s), present, being treated
g. Subject died

Need to follow-up? Yes NO _____

Grade the **severity** of the adverse event:		Grade the **association** of the adverse event with the intervention:	
Mild	☐	**Not related (NR)**	☐
Moderate	☐	**Possibly related (P)**	☐
Severe	☐	**Definitely related (D)**	☐
Life-threatening or **disabling**	☐		
Fatal	☐		

Principal Investigator's Signature: _____ Date: _____

Appendix 4: VAS Mood Scales

VAS Scales for PD Symptoms and Comfort

Record ID Date Before After

1. **happy/sad**
   Please rate the way you feel at this moment
   from 'very sad' to 'very happy'

very sad very happy

(Place a mark on the scale above)

2. **calm/nervous**
   Please rate the way you feel at this moment
   from 'very calm' to 'very nervous'

very calm very nervous

(Place a mark on the scale above)

3. **lively/sluggish**
   Please rate the way you feel at this moment
   from 'very lively' to 'very sluggish'

very lively very sluggish

(Place a mark on the scale above)

4. **overall well being**
   Please rate the way you feel at this moment
   from feeling 'very poorly' to 'very well'

very poorly very well

(Place a mark on the scale above)

Appendix 5: Washington University Photo/Image Release Form

PHOTO/IMAGE RELEASE FORM

I hereby grant the Washington University ("University"), Washington University School of Medicine and its agents permission to use photographic portraits, pictures, digital images or videotapes of me, or in which I may be included in whole or part, or reproductions thereof in color or otherwise for any lawful purpose whatsoever, including but not limited to use in any University publication or on the University websites, without payment or any other consideration.

I hereby waive any right that I may have to inspect and/or approve the finished product or the copy that may be used in connection therewith, wherein my likeness appears, or the use to which it may be applied.

On behalf of myself, my heirs, representatives, executors, and assigns, I hereby release, discharge, and agree to indemnify and hold harmless the University and its agents from all claims, demands, and causes of action that I have or may have by reason of this authorization, including any liability by virtue of any blurring, distortion, alteration, optical illusion, or use in composite form, whether intentional or otherwise, that may occur or be produced in the taking of said photos or videotapes, or in processing tending towards the completion of the finished product.

THIS IS A RELEASE OF LEGAL RIGHTS.
READ IT CAREFULLY AND BE CERTAIN YOU UNDERSTAND IT BEFORE SIGNING

_____ _____
(Signature) (Date)

_____
(Printed Name)

☐ I am 18 years old or older.

If the person signing is under age 18, there must be consent by a parent or guardian, as follows:

I hereby certify that I am the parent or guardian of _____, named above, and do hereby give my consent without reservation to the foregoing on behalf of the person named above.

_____ _____
(Parent/Guardian's Signature) (Date)

_____
(Parent/Guardian's Printed Name)

Rev. 5/1/2014

L3 Informed consent documents

Washington University in St. Louis

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

INFORMED CONSENT DOCUMENT – Parkinson's Disease Participants

Project Title: Effects of Improvisational Dance on Cognition and Daily Function Among People with Parkinson's Disease

Principal Investigator: Erin Voegtli, OTD, OTR/L

Research Team Contact: Tasha Doty
(314) 362-7160

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 at the St. Louis American Parkinson's Disease Association (APDA).

The purpose of this research study is to determine if improvisational dance (ID) has benefits related to cognition and daily function in everyday life for people with Parkinson's Disease (PD).

WHAT WILL HAPPEN DURING THIS STUDY?

The following describes what will occur throughout the course of the study.

1. Pre-course assessments: Before the program, you will be asked to complete four assessments that evaluate cognition and participation and performance in daily life. The assessments will be completed on paper and/or on a device at the American Parkinson's Disease Association and will be completed before the 12-week course. These assessments will take 60-90 minutes.
2. Intervention: You will be randomly assigned to either participate in 12-weeks of the improvised dance course or into the waitlist control group in which your routine will remain the same for 12-weeks. If you would like to be a part of this study, but require

timing accommodations, you can request to be placed into the intervention group or the waitlist control group.

3. Post-Course Assessments: After the 12-week course has been completed, you will be asked to complete the same assessments you did during the pre-course session.
4. Waitlist Control Intervention: If placed in the waitlist control group, you will participate in 12-weeks of the improvised dance course.
5. Post-Course Assessments: After the 12-week course has been completed, you will be asked to complete the same assessments you did during the pre-course session.

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 ID works for people with PD. 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

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or commercial sponsors of research. We may also share your data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

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 _____

My data may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes _____ No

Initials _____ Initials _____

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 20 people with PD 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 include five pre-study assessments (60-90 minutes) and post-study assessments (60-90 minutes). This is a total of about 2-3 hours.

You will be enrolled in this study for a total of 14 weeks. If you are randomly assigned to the ID group, your study participation would involve attending the pre-study and post-study assessments and weekly ID classes that meet for 1-hour for 12 consecutive weeks.

If you are enrolled in the waitlist control group, your participation will require pre-study and post-study testing in the two weeks surrounding first wave of ID classes as well as weekly ID classes that meet for 1-hour for 12 consecutive weeks, followed by post-testing.

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.

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. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

Another risk of participating in this study is an increased risk for falls. Although we do not expect the participants to fall during the intervention, precautionary measures are in place to decrease this risk (i.e. certified therapist present at all times, OT students monitoring the participants, movement modifications sitting in a chair).

WHAT ARE THE BENEFITS OF THIS STUDY?

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You will not directly benefit from being in this study. You may indirectly benefit from participating in this study with the increased social participation and entertaining nature of the study program.

However, we hope that, in the future, other people might benefit from this study because it will help to provide information on how people with PD can best learn and remember in their daily lives.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this study.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payments from other agencies, organizations, or companies to conduct this research 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
- University representatives to complete University responsibilities
- 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.

To help protect your confidentiality, we will keep paper records locked in a filing cabinet in a locked office. Electronic data will be stored in a web-based, secure, centralized database created by the Washington University Division of Biostatistics. The database can only be accessed through two password-protected portals and contains no identifying information. For the duration of the study, we will keep your name and phone number in a password protected master list on our secure WUSM server in case we need to contact you during the study. This information will be destroyed once the study is over.

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. Sharing this information will allow 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.

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 (Health Insurance Portability and Accountability Act). To take part in this research, you must five 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 the 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 and 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

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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.

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.

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.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Maggie Fleita at 773-330-1703 or e-mail m.fleita@wustl.edu. If you feel that you have been harmed in any way by your participation in this study, please contact Tasha Doty at 314-362-7160 or Erin Foster at 314-286-1638.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 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.

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

_____ _____

(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)

L4 Questionnaires and Written Assessments

Quesitonnaire 1: Older Americans Resources and Services Scale- Extended Version (OARS-Ex)

Now I'd like to ask you about some of the activities of daily living, things that we all need to do as part of our daily lives. I would like to know if you can do these activities without any help at all, or if you need some help to do them, or if you can't do them at all.

1. Can use the telephone...
   1 no difficulty (including looking up numbers and dialing)
   2 slower or with greater difficulty
   3 need some help (can answer the phone or dial operator in an emergency, but need a special phone or help in getting the number or dialing)
   4 need moderate help
   5 or are you completely unable to use the phone

2. Can get to places out of walking distance...
   1 without help (can travel on buses, taxis, or drive your own car)
   2 slower or with greater difficulty
   3 with some help (need someone to help you or go with you when traveling)
   4 need moderate help
   5 or are you unable to travel unless emergency arrangements are made for a specialized vehicle like an ambulance?

3. Can go shopping for groceries or clothes (assuming has transportation)...
   1 without help (taking care of all shopping needs yourself, assuming you had transportation)
   2 slower or with greater difficulty
   3 with some help (need someone to go with you on all shopping trips)
   4 need moderate help
   5 or are you completely unable to do any shopping?

4. Can prepare your own meals...
   1 without help (plan and cook full meals yourself)
   2 slower or with greater difficulty
   3 with some help (can prepare some things but unable to cook full meals yourself)
   4 need moderate help
   5 or are you completely unable to prepare any meals?

5. Can do your own housework...
   1 without help (can scrub floors, etc.)
   2 slower or with greater difficulty
   3 with some help (can do light housework but needs help with heavy work)
   4 need moderate help
   5 or are you completely unable to do any housework?

6. Can take your own medicine...
   1 without help (in the right doses at the right time)
   2 slower or with greater difficulty
   3 with some help (able to take medicine if someone prepares it for you and/or reminds you to take it)
   4 need moderate help
   5 or are you completely unable to take your own medications?

7. Can handle your own money…
   1 without help (write checks, pay bills, etc.)
   2 slower or with greater difficulty
   3 with some help (manage day to day buying but need help with managing checkbook and paying bills)
   4 need moderate help
   5 or are you completely unable to handle your own money?

8. Can you eat ...
   1 without help (able to feed yourself completely)
   2 slower or with greater difficulty
   3 with some help (need help with cutting, etc.)
   4 need moderate help
   5 or are you completely unable to feed yourself?

9. Can you dress and undress yourself ...?
   1 without help (able to pick out clothes, dress and undress yourself)
   2 slower or with greater difficulty
   3 with some help
   4 need moderate help
   5 or are you completely unable to dress and undress yourself?

10. Can you take care of your own appearance, for example combing your hair and (for men) shaving ...
   1 without help
   2 slower or with greater difficulty
   3 with some help
   4 need moderate help
   5 or are you completely unable to maintain your appearance yourself?

11. Can you walk ...
   1 without help (except from a cane)
   2 slower or with greater difficulty
   3 with some help from a person or with the use of a walker, or crutches, etc.
   4 need moderate help
   5 or are you completely unable to walk?

12. Can you get in and out of bed ...?
   1 without any help or aids
   2 slower or with greater difficulty
   3 with some help (either from a person or with the aid of some device)
   4 need moderate help
   5 or are you totally dependent on someone else to lift you?

13. Can you take a bath or shower ...?
   1 without help
   2 slower or with greater difficulty
   3 with some help (need help getting in and out of the tub, or need special attachments on the tub)
   4 need moderate help
   5 or are you completely unable to bathe yourself?

14. Do you ever have trouble getting to the bathroom on time?
   N/A I have a catheter or colostomy
   1 never
   2 occasionally
   3 sometimes
   4 often
   5 always

Written Assessment 1: Unified Parkinson's Disease Rating Scale (UPDRS) - III. MOTOR EXAMINATION

Unified Parkinson's Disease Rating Scale (UPDRS) - III. MOTOR EXAMINATION

☐	**18. Speech** 0 = Normal 1 = Slight loss of expression, diction and/or volume. 2 = Monotone, slurred but understandable; moderately impaired 3 = Marked impairment, difficult to understand 4 = Unintelligible
☐	**19. Facial expression** 0 = Normal 1 = Minimal hypomania, could be normal "Poker Face" 2 = Slight but definitely abnormal diminution of facial expression 3 = Moderate hypomania; lips parted some of the time 4 = Masked or fixed faces with severe or complete loss of facial expression; lips parted ¼ inch or more
Face RUE LUE RLE LLE	**20. Tremor at rest** 0 = Absent 1 = slight and infrequently present 2 = Mild in amplitude and persistent. Or moderate in amplitude, but only intermittently present 3 = Moderate in amplitude and present most of the time 4 = Marked amplitude and present most of the time
Right Left	**21. Action or postural tremor** 0 = Absent 1 = Slight; present with action 2 = Moderate in amplitude, present with action 3 = Moderate in amplitude with posture holding as well as action 4 = Marked in amplitude, interferes with feeding
Neck RUE LUE RLE LLE	**22. Rigidity** (Judged on passive movement of major joints with subject relaxed in sitting position. Cog wheeling to be ignored). 0 = Absent 1 = Slight or detectable only when activated by mirror or other movements 2 = Mild to moderate 3 = Marked, but full range of motion easily achieved 4 = Severe, range of motion achieved with difficulty

Right Left	**23. Finger taps** (Subject taps thumb with index finger in rapid succession with widest amplitude possible, each hand separately.) 0 = Normal 1 = Mild slowing and/or reduction in amplitude 2 = Moderately impaired. Definite and early fatiguing - may have occasional arrest in movement. 3 = Severely impaired. Frequent hesitation in initiating movements or arrest in ongoing movement 4 = Can barely perform the task
Right Left	**24. Hand Movements** (Subject opens and closes hand in rapid succession with widest amplitude possible, each hand separately.) 0 = Normal 1 = Mild slowing and/or reduction in amplitude 2 = Moderately impaired. Definite and early fatiguing - may have occasional arrests in movement 3 = Severely impaired. Frequent hesitation in initiating movements or arrests on on-going movements. 4 = Can barely perform the task
Right Left	**25. Rapid alternating movements of hands** (Pronation - supination movements of hands, vertically or horizontally, with as large an amplitude as possible, both hands simultaneously.) 0 = Normal 1 = Mild slowing and/or reduction in amplitude 2 = Moderately impaired. Definite and early fatiguing - may have occasional arrests in movement 3 = Severely impaired. Frequent hesitation in initiating movements or arrests on ongoing movements 4 = Can barely perform the task
Right Left	**26. Leg ability** (Subject taps heel or ground in a rapid succession, picking up entire leg. Amplitude should be about 3 inches.) 0 = Normal 1 = Mild slowing and/or reduction in amplitude 2 = Moderately impaired. Definite and early fatiguing - may have occasional arrests in movement 3 = Severely impaired. Frequent hesitation in initiating movements or arrests on on-going movements 4 = Can barely perform the task

☐	**27. Arising from chair** (Subject attempts to arise from straight-back wood or metal chair with arms folded across chest.) 0 = Normal. 1 = Slow, or may need more than one attempt. 2 = Pushes self up from arms of seat. 3 = Tends to fall back and may have to try more than one time, but can get up without help. 4 = Unable to arise without help.
☐	**28. Posture** 0 = Normal. 1 = Not quite erect, slightly stooped posture; could be normal for older person. 2 = Moderately stooped posture, definitely abnormal; can be slightly leaning to one side. 3 = Severely stooped posture with kyphosis; can be moderately leaning to one side. 4 = Marked flexion with extreme abnormality of posture.
☐	**29. Postural stability** (Response to sudden posterior displacement produced by pull on shoulders while subject erect with eyes open and feet slightly apart. Subject is prepared.) 0 = Normal 1 = Retropulsion, but recovers unaided. 2 = Absence of postural response, would fall if not caught by examiner. 3 = Very unstable, tends to lose balance spontaneously. 4 = Unable to stand without assistance.
☐	**30. Gait** 0 = Normal 1 = Walks slowly, may shuffle with short steps, but no festination or propulsion. 2 = Walks with difficulty, but requires little or no assistance; may have some festination, short steps, or propulsion. 3 = Severe disturbance of gait, requiring assistance. 4 = Cannot walk at all, even with assistance.

Unified Parkinson's Disease Rating Scale (UPDRS) - III. MOTOR EXAMINATION

☐	**31. Body, bradykinesia and hypokinesia** (Combining slowness, hesitancy, decreased arm swing, small amplitude and poverty of movement in general.) 0 = Normal 1 = Minimal slowness, giving movement a deliberate character; could be normal for some persons. Possibly reduced amplitude. 2 = Mild degree of slowness and poverty of movement which is definitely abnormal. Alternatively, some reduced amplitude. 3 = Moderate slowness, poverty or small amplitude of movement. 4 = Marked slowness, poverty or small amplitude of movement.

Written Assessment 2: Alternate Uses Tast

Alternate Uses Task

"In this task, you will be given the names of four common objects, on at a time. You will have 3 minutes to think of as many uses as possible for each object, especially thinking about creative uses. There are many common and obvious uses for each object that you can list. You are encouraged to also think of as many creative ideas for using these objects as you can. Creative ideas are ideas that strike people as clever, unusual, interesting, uncommon, humorous, innovative, or different. While being creative, the uses also need to be realistic. For example, if the object was a tire, you would not say it could be a ring, because that is not actually possible. While it could be a ring for a giant, this is also not possible as giants are imaginary. The uses also need to be specific – avoid general or vague answers. So for the tie, you should not say "to play with," but you could instead say "to use as a swing." Try to let your thoughts flow freely to say as many creative uses for each object as you can. Don't worry if you think your answer sounds silly or think it might be wrong. Just try to keep naming as many uses as you can think of. Do you have any questions?"

•Place the page with the object name in front of the participant. Allow 3 minutes to verbally state as many uses as possible. Record responses on the response sheet. If no new response is made for 15 seconds, gently prompt the participant, saying *"how else could you use this object?"* if another 15 seconds pass with no new response, prompt *"remember, don't worry if it sounds silly."* After the third 15 second pause, ask the participant if they would like to discontinue to task. Record the total amount of time allowed for the trial and proceed to the next object. Be sure to record the total time allowed for each object.

Newspaper

1.	10.
2.	11.
3.	12.
4.	13.
5.	14.
6.	15.
7.	16.
8.	17.
9.	18.

Total time for Newspaper: _____

Brick

1.	10.
2.	11.
3.	12.
4.	13.
5.	14.
6.	15.
7.	16.
8.	17.
9.	18.

Total time for Brick: _____

Rope

1.	10.
2.	11.
3.	12.
4.	13.
5.	14.
6.	15.
7.	16.
8.	17.
9.	18.

Total time for Rope: _____

Bed Sheet

1.	10.
2.	11.
3.	12.
4.	13.
5.	14.
6.	15.
7.	16.
8.	17.
9.	18.

Total time for Bed Sheet: _____

M References

1. Tanner, C. M. & Aston, D. A. (2000). Epidemiology of Parkinson's disease and akinetic syndromes. Current Opinion in Neurology, 13, 427-430. doi: 10.1016/S0733-8619(05)70259-0
2. Foster, E.R. & Hershey, T. (2011). Everyday Executive Function Is Associated with Activity Participation in Parkinson Disease Without Dementia. *OTJR: Occupation, Participation and Health,* 31(1), 16-22. doi: 10.3928/15394492-20101108-04
3. Foster, E.R. (2014). Instrumental Activities of Daily Living Performance Among People with Parkinson's Disease Without Dementia. *The American Journal of Occupational Therapy,* 68, 353-362. doi:10.5014/ajot.2014.010330
4. Batson, G., Migliarese, S. J., Soriano, C., H. Burdette, J., & Laurienti, P. J. (2014). Effects of Improvisational Dance on Balance in Parkinson's Disease: A Two-Phase fMRI Case Study. *Physical & Occupational Therapy In Geriatrics, 32*(3), 188-197. doi:10.3109/02703181.2014.927946
5. Hashimoto, H., Takabatake, S., Miyaguchi, H., Nakanishi, H., & Naitou, Y. (2015). Effects of dance on motor functions, cognitive functions, and mental symptoms of Parkinson's

disease: a quasi-randomized pilot trial. *Complement Ther Med, 23*(2), 210-219. doi:10.1016/j.ctim.2015.01.010
6. McNeely, M. E., Duncan, R. P., & Earhart, G. M. (2015). Impacts of dance on non-motor symptoms, participation, and quality of life in Parkinson disease and healthy older adults. *Maturitas, 82*(4), 336-341. doi:10.1016/j.maturitas.2015.08.002
7. Soriano, C. T., & Batson, G. (2011). Dance-making for adults with Parkinson disease: one teacher's process of constructing a modern dance class. *Research in Dance Education*, 12(3), 323-337. doi: 10.1080/14647893.2011.614334
8. Dubois, B. & Pillon, B. J. (1996). Cogntive Deficits in Parkinson's Disease. *Journal of Neurology,* 244(2), 2-8. doi: 10.1007/PL00007725
9. Goldman, J., & Litvan, I. (2011). Mild Cognitive Impairment in Parkinson's Disease. Minerva Medica, 102(6), 441–459.
10. Uc, E.Y., Rizzo, M., Anderson, S.W., Qian S., Rodnitzky, R.L., Dawson, J.D. (2005). Visual dysfunction in Parkinson disease without dementia. *Neurology,* 65, 1907-1913. doi: 10.1212/01.wnl.0000191565.11065.11
11. Janvin, C., Aarsland, D., Larsen, J.P., & Hugdahl, K. (2003). Neuropsychological profile of patients with Parkinson's disease without dementia. *Dementia and Geriatric Cognitive Disorders,* 15, 126-131. doi: 10.1159/000068483
12. Roheger, M., Kalbe, E., Liepolt-Scarfone, I., (2018). Progression of Cognitive Decline in Parkinson's Disease. *Journal of Parkinson's Disease,* 8(2), 183-193. doi:10.3233/JPD-181306
13. Ventura, M. I., Barnes, D. E., Ross, J. M., Lanni, K. E., Sigvardt, K. A., & Disbrow, E. A. (2016). A pilot study to evaluate multi-dimensional effects of dance for people with Parkinson's disease. Contemporary Clinical Trials, 51, 50-55. doi:10.1016/j.cct.2016.10.001
14. Batson, G., Hugenschmidt, C. E., & Soriano, C. T. (2016). Verbal auditory cueing of improvisational dance: A proposed method for training agency in Parkinson's disease. Frontiers in Neurology, 7(FEB). doi:10.3389/fneur.2016.00015
15. Marchant, D., Sylvester, J. L., & Earhart, G. M. (2010). Effects of a short duration, high dose contact improvisation dance workshop on Parkinson disease: A pilot study. Complementary Therapies in Medicine, 18(5), 184-190. doi:10.1016/j.ctim.2010.07.004
16. de Natale, E. R., Paulus, K. S., Aiello, E., Sanna, B., Manca, A., Sotgiu, G., . . . Deriu, F. (2017). Dance therapy improves motor and cognitive functions in patients with Parkinson's disease. NeuroRehabilitation, 40(1), 141-144. doi:10.3233/nre-161399
17. Westheimer, O., McRae, C., Henchcliffe, C., Fesharaki, A., Glazman, S., Ene, H., & Bodis-Wollner, I. (2015). Dance for PD: a preliminary investigation of effects on motor function and quality of life among persons with Parkinson's disease (PD). Journal of Neural Transmission, 122(9), 1263-1270. doi:10.1007/s00702-015-1380-x
18. Shulman, L., Pretzer-Aboff, I., Anderson, K., Stevenson, R., Vaughan, C., Gruber-Baldini, A., Reich, S., & Weiner, W. (2006). Subjective reports versus objective measurement of activities of daily living in Parkinson's disease. *Movement Disorders*, 21(6), 794-799.
19. Franchignoni, F., Ferriero, G., Giordano, A., Guglielmi, V., & Picco, D. (2007). Rasch psychometric validation of the Impact on Participation and Autonomy questionnaire in people with Parkinson's disease. *European Journal of Physical and Rehabilitation Medicine, 43*(4), 451-461.
20. Toglia, J.P. (2005). A dynamic interactional model to cognitive rehabilitation. In N. Katz (ed.) Cognition and Occupation in Rehabilitation: Cognitive Models for Intervention in Occupational Therapy, (pp 29-72). Bethesda, MD: AOTA.
21. Sabari, J.S., Ortiz, D., Pallatto, K., Yagerman, J., Glazman, S., & Bodis-Wollner, I. (2014). Activity engagement and health quality of life in people with Parkinson's Disease. *Disability and Rehabilitation,* 37(16), 1411-1415. Doi: 10.3109/09638288.2014.972588

22. Foster, E. R., Golden, L., Duncan, R. P., & Earhart, G. M. (2013). Community-based Argentine tango dance program is associated with increased activity participation among individuals with Parkinson's disease. *Archives of Physical Medicine and Rehabilitation*, 94(2), 240-249. doi:10.1016/j.apmr.2012.07.028
23. Coubard, O., Duretz, S., Lefebvre, V., Lapalus, P., & Ferrufino, L. (2011). Practice of contemporary dance improves cognitive flexibility in aging. *Frontiers in Aging Neuroscience, 3*(13). doi:10.3389/fnagi.2011.00013