The Utilization of Story Retell Strategies by People with Moderate Alzheimer's Dementia

An Honors Thesis (HONR 499)

by

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Abstract

Dementia is a group of symptoms related to memory loss and overall cognitive impairment (American Speech-Language-Hearing Association, 2016). Of all of the etiologies of dementia, Alzheimer's ranks as the most common, accounting for up to 70% of cases (American Speech-Language-Hearing Association, 2016). While efforts to understand and treat this disease continues to progress, professionals (e.g., speech-language pathologists) work to create appropriate and effective therapy strategies for clients and caregivers. In this study, I look to analyze the effectiveness of story retell strategies in moderate Alzheimer's dementia patients. Pictello, a story application, provides patients with visual and textual cues to help eliminate conversational breakdowns, enhancing the conversation experience for both the speaker and listener. This method is supported through evidence that written and picture cues have been shown to improve conversations of people with dementia, yet no studies have investigated its use on tablets for study retell (Bourgeois, 1990).

Acknowledgments

I would like to thank Dr. Julie Griffith for advising me through this project. Her help during this ambitious and difficult process was second to none. Without her help, this research would not have come to life in the way that I had envisioned from the beginning.

I would like to thank, Tim, Chele, Blair, Zach, Haley, and Bradley for their encouragement and support throughout the pursuit of this project. This is only the beginning of an incredible career and adventure.

Meta-analysis

To carry out this project, substantial background research needed to be conducted. Utilizing knowledge learned from previous coursework, I generated a small foundation for the project. I found textbooks and articles specifically analyzing the topics of my research, and used them to model a plan for clinical studies. With the help of my advisor, Dr. Griffith, I completed the appropriate documentation (IRB applications) and drafted other necessary forms (background essay, consent/assent forms, recruitment forms, and story retell checklist). While the paperwork has been completed, I await IRB approval to conduct the research in my career as a graduate student. This project is a display of my passions. I have not found myself to be so dedicated to anything else in my life quite like I am to this pursuit. It was a challenge; I never would have conceived a year ago that I would be capable of conducting my own research. I encountered numerous writing blocks and late nights studying trying to devise the most useful clinical applications for my future clients. Now, in this paper, it all has come together. All of my research and knowledge will move forward into practical application with my future clinical trials. This paper is meant to inform the reader of the importance of research in dementia within the field of speech-language pathology and of the direction in which we can begin that process together.
The Utilization of Story Retell Strategies by People with Moderate Alzheimer’s Dementia

The American Speech-Language Hearing Association (ASHA) indicates cognition as one of the domains of practice of speech-language pathologists (SLPs). This unique area of expertise offers a variety of complex subject matter. Dementia is one of the most common syndromes affecting cognition. Dementia results in an acquired global loss of brain function, which is slow and insidious in nature and gradually affects every major area (e.g., speech, language, cognition, pragmatics, swallowing) of concern of the SLP (Manasco, 2016). The ability of the SLP to construct vital treatment plans for this population requires a detailed understanding of the syndrome itself.

The Latin translation for the term “dementia” is “out of one’s mind” (Manasco, 2016). The symptoms of the syndrome support the translation, the primary symptom being memory loss. Other symptoms include persistent compromises in language, visuospatial skills, personality, and cognition (Manasco, 2016). With an estimated 24.3 million people living with dementia, the role of the SLP becomes increasingly vital (Manasco, 2016).

The role of the SLP in dementia is the assessment and treatment of cognitive and communication deficits in addition to the training and counseling of caregivers (Manasco, 2016). The relationship between cognition and communication cannot be easily dissected, as effective speech and language planning require adequate cognitive ability. Problems in communication, therefore, are likely to arise when cognitive abilities are impaired (Manasco, 2016). To be able to restore communication in these clients, the SLP must first address the cognitive deficits of memory, facial recall, vocabulary, word finding, which are all affected by dementia (Manasco, 2016). Dementia is the syndrome, but there are a variety of etiologies of dementia. By a 60-80 percent, the most common is Alzheimer’s disease (Alzheimer’s Association, 2016; Manasco,
Alzheimer’s disease is the sixth most common cause of death in the United States. There are no known treatments to stop or slow the progression of the disease. Alzheimer’s disease, in addition to cognitive symptoms, has physical markers that are located in the brain. Neurofibrillary tangles, amyloid plaques, and granulovacuolar degeneration are pathologic changes that were once only visible during a brain autopsy. Recent developments conducted at the University of Pittsburgh now offer a fairly noninvasive test for Alzheimer’s disease using a combination of radioactive compound and positron emission tomography that can detect and diagnose the disease in vivo (Manasco, 2016).

Some of the most valuable information sources for Alzheimer’s patients and families are available through the Alzheimer’s Association and the Alzheimer’s Foundation of America. The Alzheimer’s Foundation of America defines Alzheimer’s disease as “a progressive, degenerative disorder that attacks the brain’s nerve cells, or neurons, resulting in loss of memory, thinking, language skills, and behavioral changes” (Alzheimer’s Foundation of America, 2016). Alzheimer’s disease manifests through a variety of symptoms and stages. Moderate Alzheimer’s dementia, the subject of this research, is the middle, or second, stage of Alzheimer’s disease. Symptoms within the second stage include periods of disorientation, the worsening memory/attention skills, increased personality changes, the desire to wonder, further diminishing expressive language skills, bladder control deficits, sleep disturbances, and sundowner syndrome (Manasco, 2016). The second stage is remarkable because it is when a patient’s symptoms begin to affect that person’s quality of life and interactions with others (Manasco, 2016). During the moderate stage of Alzheimer’s the management of symptoms becomes increasingly more important to prolong the individual’s transition to the final stage of the disease.
Nearly all research in the area of Alzheimer’s and dementia treatment in the field of speech-language pathology stems from the studies of Michelle S. Bourgeois, Ph.D., CCC-SLP. Dr. Bourgeois’s most recent book publication is *Memory & Communication Aids for People with Dementia*, published in 2014. The purpose of the book is to describe the evolving memory strategies and aids being researched, as well as provide therapy guides for clinicians of individual’s with dementia. Research in the area of memory aids, conducted by Bourgeois and colleagues, is responsible for the first empirically validated memory aids for dementia patients. Her studies conclude that memory aid wallets and books increased the number of on-topic statements of fact during conversation and decreased the number of ambiguous, erroneous, and perseverative utterances said during the same conversations. She emphasizes the importance and relevancy of memory aids with dementia patients through personal encounters with professional caregivers, family, and client interactions (Bourgeois, 2013).

While Bourgeois’ book makes an overwhelming contribution to information on dementia and the clinical roles of the SLP with these clients, Bourgeois recognizes the need to explore and evaluate the use of memory aids and other written cues for the many unique expressions of memory impairment (Bourgeois, 2013). One of the areas that needs more research is the specific examination of memory aids and story retell strategies in dementia patients. Due to the overwhelming variety of dementias and severities, this study will examine the use of visual and textual supports as a memory aid to facilitate story retell with people with moderate Alzheimer’s dementia.

**Hypothesis**

It is hypothesized that the utilization of the picture and verbal prompt strategies will have a positive impact on story retell in Alzheimer's patients by reducing the effects of memory loss
and increasing the ability to provide sufficient details with minimal conversation breakdowns. This hypothesis is consistent with the findings of previous research conducted by Dr. Michelle Bourgeois. In her previous research, Dr. Bourgeois concludes that memory aids with written and picture cueing effectively improve communication of persons with dementia by reducing the effects of memory loss (Bourgeois, 1990).

Method

Inclusion/Exclusion Criteria

Participants of the study are limited to men and women at least 18 years of age with a physician’s diagnosis of moderate Alzheimer's dementia. There is no ceiling on a maximum age for participants. Vision and hearing capabilities need to satisfy requirements for completing the therapeutic tasks (i.e., identify pictures, words, and follow one-step commands). Prospective participants that cannot satisfy these demands will be excluded from the study to preserve fidelity. The number of participants is limited to 3-5 people.

Recruitment Procedures

The research team will contact local pathologists and discussing the purpose of the research project. The team will ask for referrals of potential participants who may be interested in the project. Once potential participants are identified, a member of the research team will contact or discuss with the participant and legal guardian (if necessary) the purpose of the project and initiate the consent process. If the legal guardian and/or client wish to proceed, the legal guardian, legal representative, or the client will sign the appropriate consent forms.

Assessment Procedures

The study will be broken down into multiple one-hour sessions. The first session is dedicated to participants completing an initial assessment with the primary investigator (PI).
This assessment includes a) visual and hearing screening (i.e., dB/VU meter to ensure appropriate conversation volume is use, b) a standardized cognitive assessment: the Mini Mental State Exam-2, c) a client and caregiver interview. The purpose of the interviews is to establish a personalized story and to gather pictures from the participants' life events.

**Treatment Procedures**

The following sessions will make up the treatment process. The first step of treatment is a controlled story training session with the PI. Participants will be asked to identify the “who,” “what,” “when,” “where,” “why,” and “how” of the story. They will participate in compensatory strategies, such as utilizing an iPad for visual reinforcement through pictures and text provided by the PI. The program will provide auditory reinforcement through simulated reading programming and verbal prompting. Participants will be asked to review the strategies with the PI and to attempt to retell the story. The participants will engage in a minimum of one and no more than three controlled story training sessions. In order to move on in the therapy protocol, participants must be able to state all necessary elements of a story retell with no more than ten cues.

The second step of the treatment process is a personalized story training session with the PI. The personalized training session will utilize a story from the pasts of the participants and personal pictures gathered during the assessment interviews. Participants will be asked to identify the “who,” “what,” “when,” “where,” “why,” and “how” of the story. They will participate in compensatory strategies, such as utilizing an iPad for visual reinforcement through pictures and text provided by the PI. The program will provide auditory reinforcement through simulated reading programming and verbal prompting. Participants will be asked to review the strategies with the PI and to attempt to retell the story. The participants will engage in a
minimum of one and no more than three personalized story training sessions. In order to move on in the therapy protocol, participants must be able to state all necessary elements of a story retell with no more than ten cues.

The third and final step of the treatment process is a personalized story-retell session with a novel listener who will be trained by the research team. The research listener will be trained and will be restricted to asking clarifying questions or provide comments to topics initiated by the participant. Following the interaction with the research participant, the research listener will undergo an interview with the PI to determine if all necessary elements were present in the participants’ story.

Analysis

The final personalized story retell session will be recorded in its entirety. The video will be transcribed verbatim, and the transcripts will be coded for the following dependent measures: description, prompting, and conversation breakdowns.

Discussion

Limitations

This study provides information pertinent to clinical practice of the SLP with moderate Alzheimer’s patients but is limited its exploratory nature. Without more testing and research, the strategies presented will not have a solid foundation of empirical evidence for evidence-based practice. Another limitation is that this investigation examines the effects of specific intervention strategies on moderate Alzheimer’s dementia patients, and it does not generalize to other levels of Alzheimer’s severity. By limiting the group to this specific stage of the disease, discrepancies in treatment procedure reliability, validity and flexibility are affected. Also, the results of the study reflect the specific treatment procedures utilized in the training sessions.
Deviation from the procedural protocol may cause discrepancies in results. Additionally, this study limits itself to eight days maximum with each client, which may not be enough time to provide evidence that the strategies in this research trial maintain over time. The population size of this study is significantly smaller than other clinical research studies. By limiting population size to 3-5 participants, generalization to a larger population is not proven. Further research needs to be conducted to further test the validity and reliability of this study for the overall population of moderate Alzheimer’s patients, rather than just the few participants of the study.

Research Implications

As this is an exploratory study, new research information will be added to the database of the role of the SLP with Alzheimer’s patients. Regardless of the level of effectiveness of the strategies utilized in this study, this new information will direct future research in the area of Alzheimer’s and story-retell. Furthermore, future research could examine the ability of participants and caregivers to troubleshoot systems used in this study.

Clinical Implications

Should the study conclude that these strategies are not effective, clinicians will have evidence that this process is not productive for future clients. If the study concludes that these strategies are effective, clinicians will have another treatment strategy to implement with moderate Alzheimer’s dementia clients. Foreseen advantages of this form of communication aid are the adaptability and simple interface of the technology, personalization, and the vast variety of applications that can work with the user for numerous daily communication functions (e.g., story telling, communicating wants and needs, etc...)

Quality of Life

In the article Supporting Narrative Retells for People With Aphasia Using Augmentative
and Alternative Communication: Photographs or Line Drawings? Text or No Text? evidence suggests that visual and linguistic supports improved story retell in participants with aphasia (Griffith, Dietz, & Weissling, 2014). Improved story retell was also found in the The Impact of Interface Design During an Initial High-Technology AAC Experience: A Collective Case Study of People with Aphasia, as the authors note that the time that participants in the study spent on off-topic commentary during story retells decreased with the use of augmentative and alternative communication (ACC) devices (Dietz, et al., 2014). Bourgeois mentions in her book that memory aids promote social interaction of nursing home residents between volunteers, other residents, and the nursing staff, providing benefits for all involved (Bourgeois, 2013).

Consistently, previous research provides evidence for improved quality of life (QoL) of patients through the use of memory aids in conversation, yet it is unclear if the results are generalizable to dementia patients.

**Conclusion**

There is a limited supply of research in the field of speech-language pathology on dementia. Since Alzheimer’s disease is the leading cause of dementia and reaching epidemic levels, it should be an area of immediate concern to SLPs. While there is some valuable research available to practicing clinicians, specific research on story-retell strategies for Alzheimer’s patients is lacking. This study understands the need for information for current and future researchers and clinicians. The results of this investigation will provide clinicians with more information and will help to guide future research.

The field of speech-language pathology is undoubtedly one in a constant state of change. The evolution of research, clinical practice, and education in the field proves to make dramatic gains in client successes. Providing more information on the field and distributing this
knowledge benefits not only professionals in the field, but also society as a whole. Opening the lines for better communication between all members of society is essential to the state of the future.
References


Manasco, M. (2016). Introduction to neurogenic communication disorders (2nd ed.). Burlington, Massachusetts: Jones & Bartlett Learning, LLC.
ALZHEIMER'S DEMENTIA

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Hello, I am seeking participants for a clinical study to investigate the effectiveness of story retell strategies in persons with moderate Alzheimer’s dementia. The study should take no more than three to seven sessions to complete.

To participate in the study, you must be at least 18 years of age and have sufficient hearing and visual abilities. Your participation in this study is completely voluntary. Your responses will be used solely for research purposes. All data will be collected anonymously and will be saved on a password-protected computers and servers.

If you're interested in participating, please contact the primary investigator of the study, Ashleigh Kramer, at 812-614-4347.

If you have any questions about this study or your ability to participate, please contact Julie Griffith by email: jgriffith2@bsu.edu. Your time and participation is greatly appreciated.

Thank you.

Ashleigh Kramer & Julie Griffith, Ph.D. CCC-SLP
HIPAA Privacy Authorization Form

**Authorization for Use or Disclosure of Protected Health Information**

(Required by the Health Insurance Portability and Accountability Act, 45 C.F.R. Parts 160 and 164)**

**1. Authorization**

I authorize ________________________________ (healthcare provider) to use and disclose the protected health information described below to ________________________________ (individual seeking the information).

**2. Effective Period**

This authorization for release of information covers the period of healthcare from:

a. □ [ ] to [ ].

**OR**

b. □ all past, present, and future periods.

**3. Extent of Authorization**

a. □ I authorize the release of my complete health record (including records relating to mental healthcare, communicable diseases, HIV or AIDS, and treatment of alcohol or drug abuse).

**OR**

b. □ I authorize the release of my complete health record with the exception of the following information:

□ Mental health records

□ Communicable diseases (including HIV and AIDS)

□ Alcohol/drug abuse treatment

□ Other (please specify): ________________________________
4. This medical information may be used by the person I authorize to receive this information for medical treatment or consultation, billing or claims payment, or other purposes as I may direct.

5. This authorization shall be in force and effect until ____________ (date or event), at which time this authorization expires.

6. I understand that I have the right to revoke this authorization, in writing, at any time. I understand that a revocation is not effective to the extent that any person or entity has already acted in reliance on my authorization or if my authorization was obtained as a condition of obtaining insurance coverage and the insurer has a legal right to contest a claim.

7. I understand that my treatment, payment, enrollment, or eligibility for benefits will not be conditioned on whether I sign this authorization.

8. I understand that information used or disclosed pursuant to this authorization may be disclosed by the recipient and may no longer be protected by federal or state law.

__________________________________________
Signature of patient or personal representative

__________________________________________
Printed name of patient or personal representative and his or her relationship to patient

__________________________________________
Date
Kramer: An Examination of Communication Rehabilitation in Moderate Alzheimer’s Dementia

Study Purpose and Rationale
The purpose of this study is to determine the effectiveness of story-retell strategies as a memory aid for Alzheimer’s patients. Specifically this investigation will examine the influence of pictures and verbal prompts on the ability of Alzheimer’s patients to provide story details without communicative breakdowns. We hypothesize that the utilization of the picture and verbal prompt strategies will have a positive impact on story-retell in Alzheimer’s patients by reducing the effects of memory loss.

Inclusion/Exclusion Criteria
Participants must be adult men and women with moderate Alzheimer’s dementia. Vision and hearing capabilities must satisfy requirements for completing the therapeutic tasks (i.e. identify pictures and words and follow one-step commands).

Participation Procedures and Duration

Assessment:
Participants complete an initial assessment, including a visual and hearing screening. Participants will complete two standardized assessments: the Mini Mental State Exam-2 and the Dementia Rating Scales-2. Client/family interviewing will be conducted to establish a personalized story and to gather pictures from the client’s life events.

Treatment

a. Selected participants will go through a controlled story training session with the primary investigator. Participants will be asked to identify the “who,” “what,” “when,” “where,” and “why” of the story. They will utilize an iPad for visual reinforcement through pictures provided by the primary investigator. The app will allow participants aid in retelling the story. Participants will be asked to review the therapy with the primary investigator and to attempt to retell the story to the primary investigator. This controlled story training will be a minimum of one session and no more than three sessions. In order to move on in the therapy protocol, participants must be able to state all necessary elements of a story retell with no more than moderate cues.

b. Participants will go through a personalized story training session with primary investigator. Participants will be asked to identify the “who,” “what,” “when,” “where,” and “why” of the story. They will utilize an iPad for visual reinforcement through pictures provided by the primary investigator. The app will allow participants aid in retelling the story. Participants will be asked to review the therapy with the primary investigator and to attempt to retell the story to the primary investigator. This personalized story training will be a minimum of one session and no more than three sessions. In order to move on in the therapy protocol, participants must be able to state all necessary elements of a story retell with no more than moderate cues.

c. Participants will retell the personalized story to a novel listener who will be trained by the research team. The research listener will be trained to be a conversational partner who will be restricted to asking clarifying questions or providing comments to topics initiated by the participant. Following the interaction with the research participant, the research listener will undergo an interview with the primary investigator to determine if all necessary elements were present in the participant’s story. The primary investigator will evaluate the number of conversational breakdowns and prompts, along with the effectiveness of the provided strategies.

Audio or Video Recordings (if applicable)
Video recordings will be included in this study. Each treatment session will be recorded to provide the primary investigator more time to review participant responses for a higher level of accuracy. These recordings will be stored on a private server in a locked room and will be deleted along with other participant information after a 3-5 year time period. Only members of the research team will have access to these recordings.

Disclosure of Alternative Procedures
There are no alternative procedures for this study.

Data Confidentiality or Anonymity
All data will be maintained as confidential (if collecting identifiable data, i.e., audio/video recordings and no identifying information such as names will appear in any publication or presentation of the data.)
Storage of Data and Data Retention Period
Information will be obtained from medical records, specifically date of birth for standardized assessment purposes. Name and phone number will be collected for contact purposes, such as making follow-up appointments. Video recordings will be made of all the treatment sessions. All identifiable information will be stored on HIPAA compliant servers in a locked office and will only be accessible to the research team.

Risks or Discomforts
There are no perceived risks for participating in this study.

Who to Contact Should You Experience Any Negative Effects from Participating in This Study
If you should experience any negative effects from participating in this study, please contact the primary investigator, Ashleigh Kramer, at 812-614-4347 or Neuropsychology of Indiana at 317-672-0541.

Benefits
Patients may have an increase in cognitive communication skills necessary for story retelling.

Voluntary Participation
"Your participation in this study is completely voluntary and you are free to withdraw your permission at anytime for any reason without penalty or prejudice from the investigator. Please feel free to ask any questions of the investigator before signing this form and at any time during the study."

IRB Contact Information
For one’s rights as a research subject, you may contact the following: For questions about your rights as a research subject, please contact the Director, Office of Research Integrity, Ball State University, Muncie, IN 47306, (765) 285-5070 or at irb@bsu.edu.

An Examination of Communication Rehabilitation in Moderate Alzheimer’s Dementia
*******

Consent
I, __________________________, agree to participate in this research project entitled, An Examination of Communication Rehabilitation in Moderate Alzheimer’s Dementia. I have had the study explained to me and my questions have been answered to my satisfaction. I have read the description of this project and give my consent to participate. I understand that I will receive a copy of this informed consent form to keep for future reference.

To the best of my knowledge, I meet the inclusion/exclusion criteria for participation (described on the previous page) in this study.

_________________________________________  ______________________________________
Participant’s Signature  Date

Researcher Contact Information

Principal Investigator:  Faculty Supervisor:
Ashleigh Kramer, Graduate Student  Dr. Julie Griffith
Speech-language Pathology  Speech-language Pathology
Ball State University  Ball State University
Muncie, IN 47306  Muncie, IN 47306
Telephone: (812) 614-4347  Telephone: (765) 285-8177
Email: akkramer@bsu.edu  Email: jgriffith2@bsu.edu
Kramer: *The Utilization of Story Retell Strategies by People with Moderate Alzheimer's Dementia*

**Assent Form**

My name is Ashleigh Kramer. I am trying to learn about moderate Alzheimer’s dementia. I want to investigate what story-retell strategies are most effective for everyday communication. If you would like, you can be in my study.

If you decide you want to be in my study, you will have your vision and hearing screened and take a cognitive test. You will also complete three to seven days of treatment, where you will tell stories using an iPad. On the last day of treatment, you will tell a story to someone new.

There are no perceived risks for participating in this study. By participating in this study, you may be a better story reteller.

Other people will not know if you are in my study. I will put things I learn about you together with things I learn about other Alzheimer patients. When I tell other people about my research, I will not use your name, so no one can tell I’m talking about you.

Your legal representative has to say it’s OK for you to be in the study. After they decide, you get to choose if you want to do it too. If you don’t want to be in the study, no one will be mad at you. If you want to be in the study now and change your mind later, that’s OK. You can stop at any time.

My telephone number is 812-614-4347. You can call me if you have questions about the study or if you decide you don’t want to be in the study any more.

I will give you a copy of this form in case you want to ask questions later.

**Agreement**

I have decided to be in the study even though I know that I don’t have to do it. Ashleigh Kramer has answered all my questions.

__________________________________________________________
Signature of Study Participant

__________________________________________________________
Signature of Researcher

__________________________________________________________
Date

__________________________________________________________
Date
## Mini-Mental State Examination (MMSE)

Patient's Name: ___________________________ Date: ____________

**Instructions:** Ask the questions in the order listed. Score one point for each correct response within each question or activity.

<table>
<thead>
<tr>
<th>Maximum Score</th>
<th>Patient's Score</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td></td>
<td>&quot;What is the year? Season? Date? Day of the week? Month?&quot;</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>&quot;Where are we now: State? County? Town/city? Hospital? Floor?&quot;</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient’s response is used for scoring. The examiner repeats them until patient learns all of them, if possible. Number of trials: ______</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>&quot;I would like you to count backward from 100 by sevens.&quot; (93, 86, 79, 72, 65, ...) Stop after five answers. Alternative: &quot;Spell WORLD backwards.&quot; (D-L-R-O-W)</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>&quot;Earlier I told you the names of three things. Can you tell me what those were?&quot;</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>&quot;Repeat the phrase: 'No ifs, ands, or buts.'&quot;</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>&quot;Take the paper in your right hand, fold it in half, and put it on the floor.&quot; (The examiner gives the patient a piece of blank paper.)</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>&quot;Please read this and do what it says.&quot; (Written instruction is &quot;Close your eyes.&quot;)</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>&quot;Make up and write a sentence about anything.&quot; (This sentence must contain a noun and a verb.)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;Please copy this picture.&quot; (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.)</td>
</tr>
</tbody>
</table>

**Total:** 30

(Adapted from Rovner & Folstein, 1987)
Instructions for administration and scoring of the MMSE

Orientation (10 points):
- Ask for the date. Then specifically ask for parts omitted (e.g., "Can you also tell me what season it is?"). One point for each correct answer.
- Ask in turn, "Can you tell me the name of this hospital (town, county, etc.)?" One point for each correct answer.

Registration (3 points):
- Say the names of three unrelated objects clearly and slowly, allowing approximately one second for each. After you have said all three, ask the patient to repeat them. The number of objects the patient names correctly upon the first repetition determines the score (0-3). If the patient does not repeat all three objects the first time, continue saying the names until the patient is able to repeat all three items, up to six trials. Record the number of trials it takes for the patient to learn the words. If the patient does not eventually learn all three, recall cannot be meaningfully tested.
- After completing this task, tell the patient, "Try to remember the words, as I will ask for them in a little while."

Attention and Calculation (5 points):
- Ask the patient to begin with 100 and count backward by sevens. Stop after five subtractions (93, 86, 79, 72, 65). Score the total number of correct answers.
- If the patient cannot or will not perform the subtraction task, ask the patient to spell the word "world" backwards. The score is the number of letters in correct order (e.g., dlorw=5, dlrow=3).

Recall (3 points):
- Ask the patient if he or she can recall the three words you previously asked him or her to remember. Score the total number of correct answers (0-3).

Language and Praxis (9 points):
- Naming: Show the patient a wrist watch and ask the patient what it is. Repeat with a pencil. Score one point for each correct naming (0-2).
- Repetition: Ask the patient to repeat the sentence after you ("No ifs, ands, or buts."). Allow only one trial. Score 0 or 1.
- 3-Stage Command: Give the patient a piece of blank paper and say, "Take this paper in your right hand, fold it in half, and put it on the floor." Score one point for each part of the command correctly executed.
- Reading: On a blank piece of paper print the sentence, "Close your eyes," in letters large enough for the patient to see clearly. Ask the patient to read the sentence and do what it says. Score one point only if the patient actually closes his or her eyes. This is not a test of memory, so you may prompt the patient to "do what it says" after the patient reads the sentence.
- Writing: Give the patient a blank piece of paper and ask him or her to write a sentence for you. Do not dictate a sentence; it should be written spontaneously. The sentence must contain a subject and a verb and make sense. Correct grammar and punctuation are not necessary.
- Copying: Show the patient the picture of two intersecting pentagons and ask the patient to copy the figure exactly as it is. All ten angles must be present and two must intersect to score one point. Ignore tremor and rotation.

(Folstein, Folstein & McHugh, 1975)
**Interpretation of the MMSE**

<table>
<thead>
<tr>
<th>Method</th>
<th>Score</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Cutoff</td>
<td>&lt;24</td>
<td>Abnormal</td>
</tr>
<tr>
<td>Range</td>
<td>&lt;21</td>
<td>Increased odds of dementia</td>
</tr>
<tr>
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<td>&gt;25</td>
<td>Decreased odds of dementia</td>
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<td>Education</td>
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<td>Abnormal for high school education</td>
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<td>&lt;24</td>
<td>Abnormal for college education</td>
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<td>Severity</td>
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<td>18-23</td>
<td>Mild cognitive impairment</td>
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<tr>
<td></td>
<td>0-17</td>
<td>Severe cognitive impairment</td>
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**Sources:**

The twins find dogs everywhere we go.
### THE UTILIZATION OF STORY RETELL STRATEGIES BY PEOPLE WITH MODERATE ALZHEIMER'S DEMENTIA

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<th>Yes/No</th>
<th>Description</th>
<th>Prompts</th>
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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Ashleigh Kramer (ID: 5336919)
- **Email:** akkramer@bsu.edu
- **Institution Affiliation:** Ball State University (ID: 1568)
- **Institution Unit:** Speech Pathology and Audiology
- **Phone:** 8126144347

- **Curriculum Group:** RCR FOR SOCIAL, BEHAVIORAL & EDUCATIONAL RESEARCHERS
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - RCR
- **Description:** This course is for investigators, staff and students with an interest or focus in Social and Behavioral research. This course contains text, embedded case studies AND quizzes.

- **Report ID:** 18506028
- **Completion Date:** 05/10/2016
- **Expiration Date:** N/A
- **Minimum Passing:** 80
- **Reported Score:** 100

### REQUIRED AND ELECTIVE MODULES ONLY

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<tr>
<td>Using Animal Subjects in Research (RCR-Basic) (ID: 13301)</td>
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<td>Research Involving Human Subjects (RCR-Basic) (ID: 13566)</td>
<td>05/10/16</td>
<td>5/5 (100%)</td>
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<tr>
<td>Ball State University (ID: 13475)</td>
<td>05/10/16</td>
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CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

Collaborative Institutional Training Initiative
at the University of Miami
COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COURSEWORK Transcript REPORT**

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- **Report Date:** 05/10/2016
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Collaborative Institutional Training Initiative at the University of Miami
COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

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- Phone: 8126144347

- Curriculum Group: Social & Behavioral Research - Basic/Refresher
- Course Learner Group: Same as Curriculum Group
- Stage: Stage 1 - Basic Course
- Description: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

- Report ID: 18506027
- Completion Date: 23-Aug-2016
- Expiration Date: 23-Aug-2019
- Minimum Passing: 80
- Reported Score*: 89

**REQUIRED AND ELECTIVE MODULES ONLY**

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<td>3/3 (100%)</td>
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<tr>
<td>Students in Research (ID: 1321)</td>
<td>09-Aug-2016</td>
<td>5/5 (100%)</td>
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<tr>
<td>History and Ethical Principles - SBE (ID: 490)</td>
<td>09-Aug-2016</td>
<td>5/5 (100%)</td>
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<tr>
<td>Defining Research with Human Subjects - SBE (ID: 491)</td>
<td>09-Aug-2016</td>
<td>4/5 (80%)</td>
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<td>The Federal Regulations - SBE (ID: 502)</td>
<td>09-Aug-2016</td>
<td>5/5 (100%)</td>
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<tr>
<td>Assessing Risk - SBE (ID: 503)</td>
<td>09-Aug-2016</td>
<td>4/5 (80%)</td>
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<td>Informed Consent - SBE (ID: 504)</td>
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<td>5/5 (100%)</td>
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<td>Research with Prisoners - SBE (ID: 506)</td>
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<td>Research with Children - SBE (ID: 507)</td>
<td>09-Aug-2016</td>
<td>4/5 (80%)</td>
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<td>Research in Public Elementary and Secondary Schools - SBE (ID: 508)</td>
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<td>4/5 (80%)</td>
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<tr>
<td>International Research - SBE (ID: 509)</td>
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<td>4/5 (80%)</td>
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<td>Internet-Based Research - SBE (ID: 510)</td>
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<td>Research and HIPAA Privacy Protections (ID: 14)</td>
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<td>Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)</td>
<td>23-Aug-2016</td>
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<td>Conflicts of Interest in Research Involving Human Subjects (ID: 498)</td>
<td>23-Aug-2016</td>
<td>4/5 (80%)</td>
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<td>Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)</td>
<td>23-Aug-2016</td>
<td>5/5 (100%)</td>
</tr>
<tr>
<td>Ball State University (ID: 13475)</td>
<td>10-May-2016</td>
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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT

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- **Phone:** 8126144347
- **Curriculum Group:** Social & Behavioral Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

- **Report ID:** 18506027
- **Report Date:** 31-Aug-2016
- **Current Score**: 91

### REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES

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<th>Module</th>
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<tr>
<td>Students in Research <em>(ID: 1321)</em></td>
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<td>Ball State University <em>(ID: 13475)</em></td>
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<td>09-Aug-2016</td>
<td>5/5 (100%)</td>
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<tr>
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<td>4/4 (100%)</td>
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<tr>
<td>Unanticipated Problems and Reporting Requirements in Social and Behavioral Research <em>(ID: 14928)</em></td>
<td>23-Aug-2016</td>
<td>5/5 (100%)</td>
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<td>Conflicts of Interest in Research Involving Human Subjects <em>(ID: 488)</em></td>
<td>23-Aug-2016</td>
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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2

COURSEWORK REQUIREMENTS*

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• Email: akramer@bsu.edu
• Institution Affiliation: Ball State University (ID: 1568)
• Institution Unit: Speech Pathology and Audiology
• Phone: 8126144347
• Curriculum Group: Basic Biosafety Training
• Course Learner Group: Training for Investigators, Staff and Students Handling Biohazards.
• Stage: Stage 1 - Biosafety/Biosecurity
• Description: Initial training targeted for researchers handling or who will handle biohazards in a research or clinical laboratory.

This training addresses an awareness in biohazards, risk assessment and key risk management principles, including work practices, personal protective equipment, engineering controls, and emergency response.

• Report ID: 18506029
• Completion Date: 23-Aug-2016
• Expiration Date: 23-Aug-2017
• Minimum Passing: 80
• Reported Score*: 92

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<td>Biosafety Course Overview (ID: 13314)</td>
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<td>7/8 (88%)</td>
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<tr>
<td>Laboratory-Acquired Infections (ID: 13454)</td>
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<tr>
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<td>Medical Surveillance (ID: 13456)</td>
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<td>Risk Management: Work Practices (ID: 13898)</td>
<td>23-Aug-2016</td>
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<td>Work Safely with Sharp Instruments (ID: 13899)</td>
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<td>2/2 (100%)</td>
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<td>Disinfection and Sterilization (ID: 13900)</td>
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<tr>
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Web: https://www.citiprogram.org
# COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

**COMPLETION REPORT - PART 1 OF 2**

**COURSEWORK REQUIREMENTS**

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- **Stage:** Stage 1 - RCR
- **Description:** This course is for investigators, staff and students with an interest or focus in Social and Behavioral research. This course contains text, embedded case studies AND quizzes.

<table>
<thead>
<tr>
<th><strong>Report ID:</strong></th>
<th>18506028</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Completion Date:</strong></td>
<td>10-May-2016</td>
</tr>
<tr>
<td><strong>Expiration Date:</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Minimum Passing:</strong></td>
<td>80</td>
</tr>
<tr>
<td><strong>Reported Score</strong>:</td>
<td>100</td>
</tr>
</tbody>
</table>

## REQUIRED AND ELECTIVE MODULES ONLY

<table>
<thead>
<tr>
<th>Module</th>
<th>Date Completed</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mentoring (RCR-Basic) (ID: 16602)</td>
<td>10-May-2016</td>
<td>5/5 (100%)</td>
</tr>
<tr>
<td>Using Animal Subjects in Research (RCR-Basic) (ID: 13301)</td>
<td>10-May-2016</td>
<td>5/5 (100%)</td>
</tr>
<tr>
<td>Research Involving Human Subjects (RCR-Basic) (ID: 13566)</td>
<td>10-May-2016</td>
<td>5/5 (100%)</td>
</tr>
<tr>
<td>Ball State University (ID: 13475)</td>
<td>10-May-2016</td>
<td>No Quiz</td>
</tr>
</tbody>
</table>

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: [https://www.citiprogram.org/verify/726465e1c-96a9-436d-9c62-a8a86b6b193f](https://www.citiprogram.org/verify/726465e1c-96a9-436d-9c62-a8a86b6b193f)

**CITI Program**

Email: support@citiprogram.org
Phone: 888-529-5929
Web: [https://www.citiprogram.org](https://www.citiprogram.org)
**NOTE:** Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

<table>
<thead>
<tr>
<th>Name: Ashleigh Kramer (ID: 5336919)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Email: <a href="mailto:akkramer@bsu.edu">akkramer@bsu.edu</a></td>
<td></td>
</tr>
<tr>
<td>Institution Affiliation: Ball State University (ID: 1568)</td>
<td></td>
</tr>
<tr>
<td>Institution Unit: Speech Pathology and Audiology</td>
<td></td>
</tr>
<tr>
<td>Phone: 8126144347</td>
<td></td>
</tr>
<tr>
<td>Curriculum Group: RCR FOR SOCIAL, BEHAVIORAL &amp; EDUCATIONAL RESEARCHERS</td>
<td></td>
</tr>
<tr>
<td>Course Learner Group: Same as Curriculum Group</td>
<td></td>
</tr>
<tr>
<td>Stage: Stage 1 - RCR</td>
<td></td>
</tr>
<tr>
<td>Description: This course is for investigators, staff and students with an interest or focus in Social and Behavioral research. This course contains text, embedded case studies AND quizzes.</td>
<td></td>
</tr>
<tr>
<td>Report ID: 18506028</td>
<td></td>
</tr>
<tr>
<td>Report Date: 31-Aug-2016</td>
<td></td>
</tr>
<tr>
<td>Current Score**: 100</td>
<td></td>
</tr>
</tbody>
</table>

**REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES**

<table>
<thead>
<tr>
<th>Module</th>
<th>MOST RECENT</th>
<th>SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using Animal Subjects in Research (RCR-Basic) (ID: 13301)</td>
<td>10-May-2016</td>
<td>5/5</td>
</tr>
<tr>
<td>Ball State University (ID: 13475)</td>
<td>10-May-2016</td>
<td>No Quiz</td>
</tr>
<tr>
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<td>10-May-2016</td>
<td>5/5</td>
</tr>
<tr>
<td>Mentoring (RCR-Basic) (ID: 16602)</td>
<td>10-May-2016</td>
<td>5/5</td>
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Verify at: [https://www.citiprogram.org/verifv726485e1d-98a9-436e-a62a-ae8a9b8b193f](https://www.citiprogram.org/verifv726485e1d-98a9-436e-a62a-ae8a9b8b193f)

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: [https://www.citiprogram.org](https://www.citiprogram.org)
# IRB Human Subjects Research Application and Protocol Form

## Principal Investigator Information

<table>
<thead>
<tr>
<th>Principal Investigator Name:</th>
<th>Ashleigh Kramer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Degree: BS</td>
<td>Department: Speech-language Pathology and Audiology</td>
</tr>
<tr>
<td>Email: <a href="mailto:ashleigh.kramer@gmail.com">ashleigh.kramer@gmail.com</a></td>
<td>Phone Number: +1 (812) 514-4347</td>
</tr>
<tr>
<td>Affiliation: Ball State Undergraduate Student</td>
<td>Type of Student Research: Honors Thesis</td>
</tr>
</tbody>
</table>

**Principal Investigator Research Experience:**

1. Have you ever been a Principal Investigator? **Yes**
2. How many years have you been conducting research in any capacity? **0** Years
3. Have any of your prior studies been suspended or terminated by BSU or a third party? **Yes**
4. Have you or any member of your research staff ever been sanctioned for unethical behavior in research activities? **Yes**

## Principal Investigator Agreement

I have read and understand the Ball State University's "Policy for the Protection of Human Subjects in Research," as stated in the Faculty and Professional Personnel Handbook, and I agree:

a. to accept responsibility for the scientific and ethical conduct of this research study,

b. to obtain IRB approval prior to revising and altering the research protocol, informed consent, or study documents, and

c. to immediately report any serious adverse events and/or unanticipated problems as a result of this study to the IRB within 24 hours.

## Faculty Advisor Information

If the Principal Investigator (PI) is a STUDENT with Ball State University, a BSU Faculty Member advising or supervising the student must be listed below:

<table>
<thead>
<tr>
<th>Faculty Advisor Name:</th>
<th>Julia Griffith</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Degree: PhD</td>
<td>Department: Speech-language Pathology and Audiology</td>
</tr>
<tr>
<td>Email: <a href="mailto:jgriffith2@bsu.edu">jgriffith2@bsu.edu</a></td>
<td>Phone Number: +1 (765) 285-8177</td>
</tr>
</tbody>
</table>

## Faculty Advisor Assurance Statement

As the Faculty Advisor for this study, I certify that I have reviewed and support this protocol and approve the merit of this research project and the competency of the investigator(s) to conduct the project. My involvement in this study is as follows (Check Box):

- I will be involved in this project. My name is listed and my responsibilities (described in the Key Personnel section) include supervision and oversight of this project.
KEY PERSONNEL

List all Key Personnel (including Faculty Advisor), other than the PI, who will have a role in the research project. Thesis and Dissertation Committee Members are not required unless they will work with you on your research project.

<table>
<thead>
<tr>
<th>Personnel Name</th>
<th>Department/Organization</th>
<th>Role on the Study</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Julia Griffith</td>
<td>SPAA</td>
<td>Faculty Advisor</td>
<td>Help with recruitment, assessment, and data analysis.</td>
</tr>
</tbody>
</table>

HUMAN SUBJECTS RESEARCH TRAINING

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

As of January 1, 2010, Ball State University policy requires that all Principal Investigators, Faculty Advisors, and all Key Personnel complete the CITI Training. To comply with the educational requirement, you and all key personnel (including faculty advisors) must have completed the online training modules on the protection of human subjects. For more information and link to CITI’s website, please go to the Office of Research Integrity website.

Have you and all key personnel completed the required online training modules?  
- Yes  
- No

NOTE: If this is your first BSU IRB submission, please include a PDF copy of your CITI Training Certificate, along with your Key Personnel.

Responsible Conduct of Research Training Modules (RCRT): If your project is federally funded by the National Science Foundation, you and all key personnel (including faculty advisor), must complete the Responsible Conduct of Research Training Modules on CITI, along with the Basic/Refresher Course or Biomedical Course.

OTHER TRAINING

Are there any specialized training(s) required for your project (i.e., certification for medical procedures, training in crisis response, etc.)?  
- Yes  
- No

RESEARCH PROJECT INFORMATION

Project Title: The Utilization of Storytelling Strategies by People with Moderate Alzheimer’s Dementia

*The project Title must match all documents and IRBnet.

SUBJECT INFORMATION

<table>
<thead>
<tr>
<th>Total Number of Participants (Estimate or Range)</th>
<th>Gender</th>
<th>Minimum Age</th>
<th>Maximum Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-15</td>
<td>Both</td>
<td>18</td>
<td>None</td>
</tr>
</tbody>
</table>

SUBJECT POPULATION

Check all that apply:
- Normal Adult Population (18 years or older)
- Students (18 years or older)
- Children (Minors/Students 0-17 years)*
- Pregnant Woman (Physical Experiments, Examinations, or Medical Research)*
- Prisoners*
- People with Diminished Capacities*

12/5/2015-v.9
Yea

PROTECTED POPULATION: This will require either Expedited or Full Board Review. Please explain the purpose of using this population:

The purpose of using this population is to provide insight to treatment options for persons diagnosed with Alzheimer's dementia.

SUBJECT RECRUITMENT

1. Will the research project be advertised on any electronic/paper media (Email, Social Media, etc)? ( ) Yes ( ) No

RECRUITMENT PROCEDURES

1. Describe in detail how you will recruit your participants for your study:

2. If any screening (questionnaire) will be done for recruitment, will the questionnaire data be used for the study if the participant is not qualified for the study?

SUBJECT INCLUSION/EXCLUSION CRITERIA

Inclusion Criteria: A set of conditions that must be met in order for subject(s) to participate in the study (including age of the participants)

Participants will be adult men and women with moderate Alzheimer's dementia.

Exclusion Criteria: A set of conditions that the subject(s) may not be allowed to participate in the study.

Vision and hearing capabilities must satisfy requirements for completing the therapeutic task (i.e. identify pictures and words and follow one-step commands).

POTENTIAL RISKS/DISCOMFORTS TO THE SUBJECT(S)

Will there be any anticipated or potential risks or discomforts to the subject(s) during the study? (Yes) ( ) No

( ) Yes ( ) No

DECEPTION/CONCEALMENT OF SUBJECT(S)

Deception Withoutholding information for the purpose of the study.

Will this project involve either Deception or Concealment? ( ) Yes ( ) No

SUBJECT AND STUDY BENEFITS

Will there be any benefits to the subject and/or to the study? ( ) Yes ( ) No
PROJECT SITE LOCATION
Provide the following information where you will conduct your study (location of data collection, interviews, etc.)

Check all that apply:

☐ Ball State University Campus (including Buns Laboratory School)

☒ Off-Site Locations or Schools

Locations/Schools: We are going to contact site locations upon IRB approval and a letter of support will be attained from all interested facilities.

☐ Internet (Be sure to read any policy regarding data ownership and protection)

☐ Online Survey Sites (Check all that apply)
  ☐ Qualtrics
  ☐ MTurk (Amazon)
  ☐ SurveyMonkey
  ☐ Other

☐ IU Ball Memorial Hospital (Contact Alfrada Bright-abright@iuhealth.org, BMH's IRB)

☐ International Countries

☐ U.S. Based Field Study

☐ Other

LETTER OF SUPPORT: Any research that is conducted at a non-BSU institutions or organizations is required to obtain a Letter of Support. The Letter of Support must be on the institution or organization’s letterhead and signed by a person of authority to grant access to the site for the study (i.e., Director, Manager, Principal, Superintendent, etc.). The Letter of Support must be uploaded on IRBNet as part of your package submission. An email message is NOT sufficient to meet this requirement.

In cases where sites, agencies, etc., have not been identified yet (original submission), please indicate this in the Application and make sure to upload the letter on your IRBNet project number once the letter is obtained. This is handled as a Modification process once the project has been approved.

COLLABORATIVE/MULTI-SITE RESEARCH PROJECTS
Will the proposed research project be conducted as a collaborative research (i.e., research that involves two or more institutions/organizations that hold Federally Assurances* and have duly authorized IRBs)?

*Federally Assurances: An institution committing to the Department of Health Human Services that will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46.

☐ Yes

☐ No

FUNDING

Have you applied for funding or have received funding for your project?

☐ Yes

☐ No

DATA COLLECTION, STORAGE, AND SECURITY

1. Will any information regarding the participant's identity (e.g., name, DOB, SSN, ID Number, address, phone, etc.) be collected on Informed Consent(s) or Study Documents?

☐ Yes

☐ No

Information will be obtained from medical records, specifically date of birth for standardized
If Yes, explain why and what security measures will be taken: **Assessment purposes. Name** and **phone number** will be collected for contact purposes, such as making follow-up appointments. All identifiable information will be stored on **HIPAA compliant servers** in a locked office.

If you are collecting identifiable information, will the information be stored with the participant’s responses?
- Yes [ ]
- No [x]

2. Are you planning on using the participant’s identifiable information on presentations or publications?
- Yes [ ]
- No [x]

3. Will you be using Audio or Video Recording for your project?
- Yes [ ]
- No [x]

   Will the recordings be used for presentations or publications?
- Yes [ ]
- No [x]

4. Where will the data (electronic/paper) be stored during and after the study is complete? (Check all that apply):
- [x] Locked Cabinet/Office
- [x] Password Protected Computer/Flash Drive/DVD/CD or other Storage Media
- [ ] Home
- [ ] Online Data Storage
- [ ] Other

5. How long will you keep the data (raw and final)? **Data will be kept for three to five years.**

   If your data (raw) is retained indefinitely, please provide an explanation for why and make sure that you have an explanation on the informed consent:

   [ ]

6. Who will have access to the raw and final data besides yourself? (Check all that apply):
- [x] Faculty Advisor
- [ ] Research Team (Co-PI, Research Assistant, Graduate Assistant, etc.)
- [ ] Off Campus Collaborator or Consultant
- [ ] Sponsor
- [ ] Federal Agency (NIH, FDA, NSF, etc.)
- [ ] Other

### DATA CONFIDENTIALITY/ANONYMITY

**Anonymous Data**: Defined by where the researcher(s) may not identify of the subject with his/her data at any time during the study. *(Online or Paper Surveys/Questionnaires, archival de-identified data, etc.)*

**Confidential Data**: Defined by when coding the identity of the subject and his or her data by using personal identifiers, there exists a means for identifying the subject. *(Interviews, audio or video recordings, using identifiable information, etc.)*

Indicate whether your data is Anonymous or Confidential and explain what provisions will be taken to maintain privacy and security:

**Confidential data will be collected. Upon collection, identification will be coded in a system to protect participant’s information. The raw confidential data will only be accessible to the research team and will be kept in HIPAA compliant storage.**
SPECIAL TYPES OF DATA

1. Family Educational Rights and Privacy Act (FERPA)
   A. Will educational records or information found in educational records, as defined by FERPA be used?
      ☐ Yes  ☑ No

2. Health Insurance Portability and Accountability Act (HIPAA)
   A. Will health, medical, or psychological records or information found in medical/health records, as defined under HIPAA be used?
      ☐ Yes  ☐ No
   If Yes, has the applicable institution's Privacy Officer performed a HIPAA assessment to determine if an exemption to the HIPAA signed release authorization for research requirement exists, or will you get signed authorization for research of information for research?
      ☐ Yes (Include a copy of the assessment or letter from the appropriate Privacy Officer)  ☑ No
      (Include a copy of the authorization form to be used.)

COMPENSATION

1. Are subjects being paid or receiving incentives for participating in this study?
   ☐ Yes  ☑ No

2. Are subjects being reimbursed for expenses (travel, gas, food, hotel, etc.)?
   ☐ Yes  ☑ No

3. Will students receive extra credit for a course if they participate in the study?
   ☐ Yes  ☑ No

4. Will students receive course or departmental research credit for their participation?
   ☐ Yes  ☑ No

5. Is there a completion bonus?
   ☐ Yes  ☑ No

6. Will there be compensation for research-related injury?
   ☐ Yes  ☑ No

7. If the participants withdraw from the study (during or after), will they receive their incentives/compensation or research credit?
   ☐ Yes  ☑ No  ☑ Partial/Pro-Rated
   If No, please explain why: There is no compensation or reward provided for participating in this study.

8. Other (Please Explain):

   If you are using BSU funds, you will need to contact the BSU Office of University Controller (765-285-8444) or visit their website for procedures and policies regarding tax information to be collected from participants.

SUBJECT FINANCIAL EXPENSES

Will subjects have any financial expenses to participate in the study (e.g., travel, gas, food, hotel etc.)?
   ☑ Yes  ☐ No

NOTE: If a subject has to travel to the location site to participate in the study via car, plane, train, bus, etc., they will incur financial expenses.

STUDY PROTOCOL

STUDY PURPOSE

State the objectives of the research and, when appropriate, any hypotheses you have developed for the research.

The purpose of this study is to determine the effectiveness of story-telling strategies as a memory aid for Alzheimer's patients. Specifically, this investigation will examine the influence of pictures and verbal prompts on the ability of Alzheimer's patients to provide story details without communication breakdowns. We hypothesize that the utilization of the picture and verbal prompt strategies will have a positive impact on story-telling in Alzheimer's patients by reducing the effects of memory loss.

RATIONALE

1/3/2015 v.9
**RESEARCH REFERENCES/CITATIONS**
List any references/citations that you researched based on your study purpose and rationale for your project. If there are no references or citations used for your project, please explain why.

See attached

---

**METHODS AND PROCEDURES**
Describe the study and design in detail and all procedures in which the subject will be asked to participate. If surveys and questionnaires are used for the study, how will they be distributed to the researcher? If the research involves more than one visit to the research location, specify the procedures to take place at each session, the amount of time for each session, the amount of time between sessions, and the total duration of the sessions. If multiple researchers will be involved in the project, identify who will conduct which procedure(s).

<table>
<thead>
<tr>
<th>Step 1:</th>
<th>Send an e-mail to nursing home personnel providing information about the study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2:</td>
<td>Interested participants or family members will contact research team, or, if referred by facility's speech pathologist, the research team will contact potential participants.</td>
</tr>
<tr>
<td>Step 3:</td>
<td>Informed consent or assent would be given.</td>
</tr>
<tr>
<td>Step 4:</td>
<td>Assessment</td>
</tr>
<tr>
<td>Day 1:</td>
<td>Participants complete an initial assessment, including a visual and hearing screening. The hearing screening will include a dBwU meter to ensure an appropriate conversational volume was used. Participants will complete two standardized assessments: the Mini Mental State Exam-2 and the Dementia Rating Scales-2. Client/family interviewing will be conducted to establish a personalized story and to gather pictures from the client's life events.</td>
</tr>
<tr>
<td>Step 5:</td>
<td>Treatment (all treatment sessions will be recorded for treatment fidelity)</td>
</tr>
<tr>
<td>a.</td>
<td>Selected participants will go through a controlled story training session with the PI. Participants will be asked to identify the &quot;who,&quot; &quot;what,&quot; &quot;where,&quot; &quot;when,&quot; &quot;why,&quot; and &quot;how&quot; of the story. They will participate in compensatory strategies, such as utilizing an iPad for visual reinforcement through pictures provided by the PI. The program will provide written models of the phrases, auditory reinforcement through simulated reading programming, and verbal prompting. Participants will be asked to review the strategies with the PI and to attempt to retell the story to the PI. This controlled story training will be a minimum of one session and no more than three sessions. In order to move on in the therapy protocol, participants must be able to state all necessary elements of a story retold with no more than ten cues.</td>
</tr>
<tr>
<td>b.</td>
<td>Participants will go through a personalized story training session with the PI. Participants will be asked to identify the &quot;who,&quot; &quot;what,&quot; &quot;where,&quot; &quot;when,&quot; &quot;why,&quot; and &quot;how&quot; of the story. They will participate in compensatory strategies, such as utilizing an iPad for visual reinforcement through pictures provided by the client/family. The program will provide written models of the phrases, auditory reinforcement through simulated reading programming, and verbal prompting. Participants will be asked to review the strategies with the PI and to attempt to retell the story to the PI. This personalized story training will be a minimum of one session and no more than three sessions. In order to move on in the therapy protocol, participants must be able to state all necessary elements of a story retold with no more than ten cues.</td>
</tr>
<tr>
<td>c.</td>
<td>Participants retell the personalized story to a novel listener who will be trained by the research team. The research listener will be trained to be a conversational partner who will be restricted to asking clarifying questions or providing comments to topics initiated by the participant. Following the interaction with the research participant, the research listener will conduct an interview with the PI to determine if all necessary elements were present in the participant's story. The PI will evaluate the number of conversational breakdowns and prompts, along with the effectiveness of the provided strategies.</td>
</tr>
</tbody>
</table>
INFORMED CONSENT

Please indicate what type(s) of Informed Consent (IC) will be used for this study? (Check all that apply)

☒ Adult (18 years or older)
☐ Parental Permission (Minors: 0-17 years old)
☐ Child Assent (Minors: 0-17 years old - This must be written in age-appropriate language)

Informed Consent Process/Signature Waiver

Are you applying for an alteration of the Informed Consent process or a waiver of the Informed Consent signature requirement? ☐ Yes ☐ No

PLEASE NOTE: If English is NOT the primary language of the participants, then the Informed Consent must be also be translated in the participant’s native language. Include the translated Informed Consent with your package and a statement as to how (or by whom) the Informed Consent was translated.

PROJECT DOCUMENTS

Check the box(es) of ALL the documents you submitted for your project on IRBNet:

☒ Application and Protocol Form
☒ Adult Informed Consent(s)
☐ Parental Permission Consent (for Minors)
☐ Child Assent (for Minors)
☒ Recruitment Letter(s)
☒ Survey/Questionnaire/Interview Questions
☒ Data Collection Forms
☒ HIPAA/FERA Documents
☐ Media Permission Form(s)
☐ Letters of Support
☐ Debriefing Letter(s)
☒ CITI Training Certificates
☐ Other (Explain):

IRBNET ELECTRONIC SIGNATURE:

The new package created for submission for your project must be electronically signed in IRBNet by you, the Principal Investigator (and Faculty Advisor, if you are a student). Your signature indicates your certification that the information provided in this document is accurate and current.