

Enhancing Older Adult's Everyday Memory Function
Study Protocol
NCT #: NCT04088136
12/07/2022

RCT PROTOCOL

Project Overview

The Everyday Memory and Metacognitive Intervention (EMMI) is assessed in comparison to an Active Control group (MSC). Participants are randomly assigned to either the EMMI group or MSC group. All participants, regardless of being assigned to the EMMI group versus MSC group, follow the same procedure (outlined below). The only difference between the two groups is the type of memory training the participants receive, which corresponds to the type of shaping calls they receive and the evening surveys they complete.

The intervention was administered in small groups of 3-6 persons all from the same intervention arm (MSC or EMMI). There were four group learning experiences (GLEs), 2 per week for 2 weeks. Individuals viewed PowerPoint presentations given by the interventionist and assistants. These sessions lasted 3 hours and emphasized interaction and group discussion of key points, as well opportunities for participants to share with each other ideas or insights they gained through working on in-class exercises. Participants also completed assigned homework tasks practicing trained skills between each session. Homework was discussed in the next GLE, but was also reviewed in one-on-one shaping calls, in which a member of the team contacted each participant to discuss how they were working with and using the trained techniques, with specific reference to homework exercises.

A key measurement method for the study was using smartphone apps on burner Samsung Galaxy phones that were locked down so as to enable use of the phone only for the research study. Individuals reported on everyday memory experiences via event-based memory problem reporting and an end-of-day diary that recorded reports of memory failures that had occurred that day. The training program for participants required extensive technical support in how to use these burner phones for ecological momentary assessment (EMA).

7-Week Schedule for Each Group of Participants

Task	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7
Screening	X						
Informed Consent	X						
Random Assignment	X						
Intake Interview	X						
Pre-Test Sessions		X					
Phone Shipment/Delivery			X				
GLE with Shaping Calls			X	X			
EMA with Shaping Calls					X		
EMA without Shaping Calls						X	
Prospective Memory Call-in Task						X	X
Post-Test Sessions							X
Debrief							X

Waiver of Informed Consent + Telephone Screening for Study Eligibility

1. WAIVER: Before screening, research team member will obtain telephone consent.
2. SCREENING: After telephone consent is obtained, administer the Telephone Interview for Cognitive Status (TICS). A TICS score of 31 or above is required to participate in the study.
3. Email the participant the consent form via DocuSign.

Intake Interview

1. INTERVIEW: After we receive the informed consent form in DocuSign, participants will be scheduled for their 1-hour intake interview, held on Zoom. All notes collected during the interviews will be entered into a Qualtrics form.

Pre-Test

1. Pre-Test Session #1 (Online):
 - a. Demographic Questionnaire
 - b. Technology Questionnaires
 - c. COVID-19 Questionnaire
 - d. Leisure Activity Scale
 - e. Letter Sets Test
 - f. Personal Beliefs about Memory
 - g. Global Beliefs about Memory
 - h. Word List Free Recall
2. Pre-Test Session #2 (Online):
 - a. Shipley Vocabulary
 - b. Perceived Stress Scale
 - c. Satisfaction with Life Scale
 - d. Memory Functioning Questionnaire
 - e. Memory Compensation Questionnaire
 - f. Personality Questionnaire
 - g. Pattern Comparison
 - h. Verbal Paired Associates

Group Learning Experience + Shaping Calls #1, #2, #3

1. The “Group Learning Experience” (GLE) includes the memory classes. These classes involve a small group of participants (3-6 people) who meet with the trainer to learn the memory strategies.
2. The EMMI and MSC GLEs include four classes (either Mondays/Thursdays or Tuesdays/Fridays) across the span of two weeks. Shaping calls will occur during both weeks of the GLE, plus the week following the conclusion of the GLE.
3. EMMI GLE:
 - o GLE Day 1
 - i. Topics:
 1. Beliefs About Memory
 2. Intentional Encoding
 3. Spaced Retrieval
 - ii. In-Class Activities: N/A

- iii. Homework:
 1. HW #1: Belief Restructuring
 2. HW #2: New Name Learning
 - o GLE Day 2
 - i. Topics:
 1. Goal setting and how to do it
 2. External Aids
 3. Stop Think Plan Act
 - ii. In-Class Activities:
 1. Spaced Retrieval
 2. Routines and Habits
 - iii. Homework:
 1. HW #3: Daily Goal Setting
 2. HW #4: External Aids
 3. HW #5: Stop/Think/Plan/Act
 - o GLE Day 3
 - i. Topics:
 1. Implementation Intentions
 2. Medications
 3. Habits and Routines
 - ii. In-Class Activities:
 1. Implementation Intentions
 - iii. Homework:
 1. HW #6: Medication Intentions
 2. HW #7: Routines and Habits
 - iv. Provide Prospective Memory Call-in Task Instructions
 - o GLE Day 4
 - i. Topics:
 1. Smartphone Training
 2. Review next steps in study
 - ii. In-Class Activities: N/A
 - iii. Homework: Submit practice Memory Blip Survey
- 4. MSC GLE:
 - o GLE Day 1
 - i. Topics:
 1. Beliefs About Memory
 2. Intentional Encoding
 3. Organizational Strategies
 - ii. In-Class Activities:
 1. Categorizable Free Recall Task Version #1
 - iii. Homework:
 1. HW #1: Belief Restructuring
 2. HW #2: Categorizable Free Recall Task Version #2
 - o GLE Day 2
 - i. Topics:
 1. Organizational Encoding
 2. Associative Encoding/Mediation strategies
 - ii. In-Class Activities: N/A
 - iii. Homework:

1. HW #3: Serial Free Recall
 2. HW #4: Paired Associates
 - o GLE Day 3
 - i. Topics:
 1. Associative Encoding
 2. Self-Testing
 - ii. In-Class Activities:
 1. Create paired associates flashcards
 - iii. Homework:
 1. HW #5: Self-Testing
 - iv. Provide Prospective Memory Call-in Task Instructions
 - o GLE Day 4
 - i. Topics:
 1. Distinctiveness
 2. Smartphone Training
 3. Review next steps in study
 - ii. In-Class Activities:
 1. Paired Associates Homework #5 (same word pairs studied during GLE Day 3):
 - iii. Homework: Submit practice Memory Blip Survey
5. SHAPING CALLS DURING GLE WEEKS 1 and 2:
- o WEEK 1: Two shaping calls are held during GLE Week 1 (one call the day after each GLE). During these calls, check-in on homework and ask the participant if they have any questions.
 - o WEEK 2: One shaping call during GLE Week 2 (one call after GLE Day 3). During the call, check-in on homework and questions.
6. PROSPECTIVE MEMORY (PM) CALL-IN TASK:
- o During GLE Day 3 (for both groups), participants are instructed to call the lab two times in Week 6 and two times in Week 7. This task is an assessment of prospective memory. PM Calls should not be scheduled during the participant's Post-Test sessions in Week 7.

16-Day Measurement Period + Shaping Calls #4, #5, #6

1. The day after GLE Day 4, participants will begin the 16-day measurement period. Every day for 16 consecutive days, participants will complete the Morning Survey, Evening Survey (i.e., nightly diary), and blip reports in the Memory Blip Survey (event-based ecological momentary assessment app).
2. MEASUREMENT PERIOD WEEK 1: Participants will receive three additional shaping calls from the lab after the conclusion of the GLE. The sixth call is a check-in to let the participants know the research team will not call them again, but that they can call us if questions/problems come up. Before holding shaping calls #4, #5, and #6, the research team member should review the memory blips submitted by each participant.
3. MEASUREMENT PERIOD WEEK 2: Participants will not receive shaping calls during the second measurement period week.

Prospective Memory Call-in Task

1. Participants are asked to complete four Prospective Memory (PM) calls during Weeks 6 and 7. PM calls are typically scheduled on Monday/Wednesday and Tuesday/Friday in Weeks 6 and 7, respectively. No PM calls are scheduled over the weekends. Typically, calls are scheduled between 9:00am – 6:00pm.

- Participants will be given instructions for this task during GLE Day 3. Participants may reschedule any PM calls that conflict with their schedule on or before GLE Day 4.
2. PM contacts will either be made via phone call, text, or email.

Post-Test

1. Post-Test Session #1 (Online):
 - a. COVID-19 Questionnaire
 - b. Personal Beliefs about Memory
 - c. Global Beliefs about Memory
 - d. Simulated Everyday Memory: Prescription Refill
 - e. Simulated Everyday Memory: Banking
 - f. Verbal Paired Associates
2. Post-Test Session #2 (Online):
 - a. Story Recall
 - b. Perceived Stress Scale
 - c. Satisfaction with Life Scale
 - d. Memory Functioning Questionnaire
 - e. Memory Compensation Questionnaire
 - f. Word List Free Recall

Debrief & Participant Compensation

1. After the participant completes Post-Test Session #2, call the participant and read the debriefing statement.
2. Payment issued by check.

Re-Design to Accommodate COVID-19

The original study proposal envisaged group learning sessions to take place on the campus of Georgia Tech, as was done with our original intervention study (Pearman et al., 2020). The pandemic forced us to convert to completely remote assessment, which also required providing technical support to participants in using web-based platforms. All questionnaires, surveys, and cognitive tests were administered via Qualtrics forms, except the proprietary iFunction programs used to simulate everyday complex IADLs. Programs had to be modified to account for computing power and bandwidth issues for some participants, identified in pilot data. Some (but relatively little) data were lost through lost internet connections, program crashes, etc.