

Official Study Title:

Towards the development of a mobile-health technology designed to encourage the use of serious game-based interventions in patients with mild cognitive impairment outside the clinic

NCT Number:

NCT04920123

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Study Protocol

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STUDY PROTOCOL

Study Procedures:

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7. [Tutorial for the intervention group](#)
8. [Checking compliance every week \(twice per week\)](#)
9. [Assessment after 12 weeks](#)
10. Returning tablet PC
11. Focus group (Online workshop)
12. Assessment after 24 weeks

Role Assignment

	UMass RA	Rutgers RA
Recruitment	O	O
Screening	O	O
Informed consent obtainment	O	O
Random assignment into two groups	O	X
Assessment at baseline	O (general instructions before assessment)	O (actual assessment)
Shipping tablet PC	O	X
Tutorial for the intervention group	O	X
Checking compliance every week	O	X
Assessment after 12 weeks	O (general instructions before assessment)	O (actual assessment)
Returning table PC	O	X
Focus group (Online workshop)	O	X
Assessment after 24 weeks	O (general instructions before assessment)	O (actual assessment)

1. Recruitment:

- **50** participants with Mild Cognitive Impairment (MCI) will be recruited as follows.

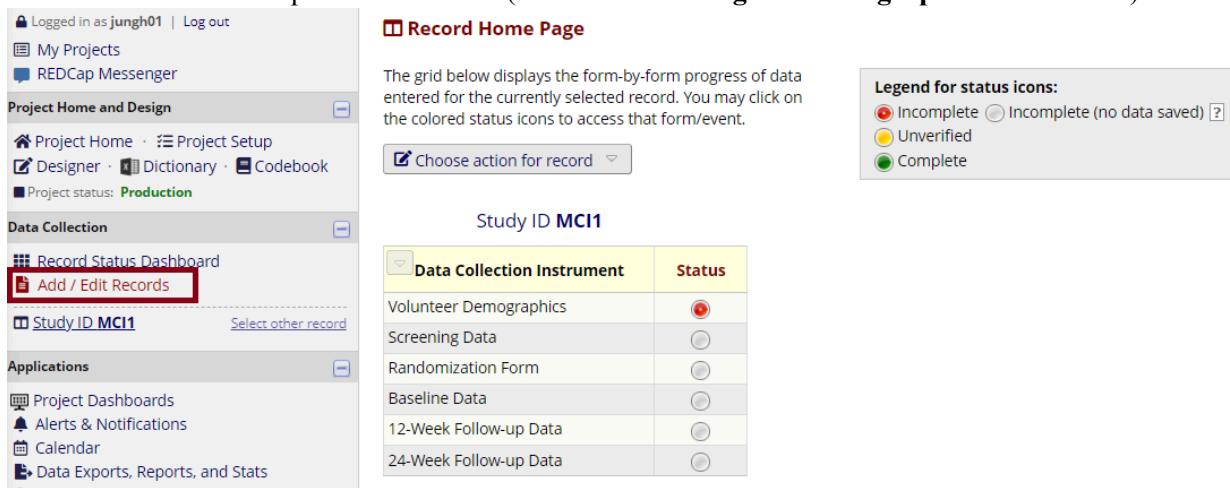
- Currently planned means:
 - Emailing recruitment flyers to residents in local senior centers in Amherst, MA and Union, NJ
 - Emailing recruitment flyers to support groups and conferences
 - Posting recruitment flyers on the Internet (e.g., ClinicalTrials.gov, National Alliance on Mental Illness; nami.org, Alzheimer's Association; alz.org, UMass newsletter)
 - Posting an abbreviated recruiting message + screen shots of flyers on the social media (e.g., Facebook, Twitter)
 - Recruiting message: *"If you believe you have mild cognitive impairment, and are interested in cognitive training using mobile games, please contact AHHA Lab (413-545-8875, umass.ahha.lab@gmail.com.)"*
 - Visit senior villages
- Optional means:
 - Using paid third-party services that perform the recruiting process
 - Advertising on local newspapers

- The flyer can be found in [**Appendix 1**](#). (unified phone number / email address)

- Available recruitment methods (website, social media group) are listed in the spreadsheet **(Patient Recruitment/Contact Information.xlsx)**

2. Screening (Both UMass & Rutgers RA can perform)

- When a volunteer contacts us through AHHA lab's email or phone number, their **name**, **phone number**, and **email** will be collected using email reply (email) or pre-recorded voicemail instruction (phone).
 - UMass and Rutgers RAs will check the email and the voicemail box regularly (1 time a week by each RA). The following is an example.
 - Rutgers RA: Mon
 - UMass RA1: Wed
 - UMass RA2: Fri
 - RAs will **add a new record** in the RedCap and enter the volunteer's **name** in the **Name Data instrument**, and **phone number** and **email** in the **MCI Participant Demographics instrument** of the RedCap and remove processed voicemail messages.
 - The convention for naming the study ID for a person with MCI will be, for example, **MCI21 (password for Neuro-World administration is woorisoft!@)**
 - The prefix **MCI** followed by an incrementing **number** with 0 padding for a single-digit number (e.g., **MCI02** will be assigned after **MCI01**; **MCI22** will be assigned after **MCI21**).
 - The study ID will be used for a MCI participant. In other words, an active caregiver will not be given a separate study ID.
 - If a caregiver participates in the study, RAs will enter the caregiver's **name** in the **Name Data instrument**, and **phone number** and **email** in the **Caregiver Demographics instrument** of the RedCap and remove processed voicemail messages.
 - The caregiver for the person with MCI will be given a separate study ID, for example **CARE21**.
 - The prefix CARE followed by an incrementing number that matches that of the person with MCI. (record in the **Caregiver Demographics instrument**)



Logged in as jungho01 | Log out

My Projects

REDCap Messenger

Project Home and Design

- Project Home
- Project Setup
- Designer
- Dictionary
- Codebook

Project status: **Production**

Data Collection

- Record Status Dashboard
- Add / Edit Records**
- Study ID **MCI1**
- Select other record

Applications

- Project Dashboards
- Alerts & Notifications
- Calendar
- Data Exports, Reports, and Stats

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Choose action for record

Study ID MCI1

Data Collection Instrument	Status
Volunteer Demographics	Incomplete
Screening Data	Incomplete (no data saved)
Randomization Form	Incomplete (no data saved)
Baseline Data	Incomplete (no data saved)
12-Week Follow-up Data	Incomplete (no data saved)
24-Week Follow-up Data	Incomplete (no data saved)

Legend for status icons:

- Incomplete (Red)
- Incomplete (no data saved) (Grey)
- Unverified (Yellow)
- Complete (Green)

- Any of the 3 RAs will call the volunteer, if the corresponding **Screening Data instrument** is not completed (i.e., not green), using the phone number in the **MCI Participant Demographics instrument**.
 - If the **volunteer** have approximately 30 minutes at the time of zoom call,
 - Each volunteer is asked for their demographic information, including gender, age, etc., which will be entered in the **MCI Participant Demographics instrument**.
 - If a caregiver participates in the study, each caregiver is asked for their demographic information, including gender, age, etc., which will be entered in the **Caregiver Demographics instrument**.

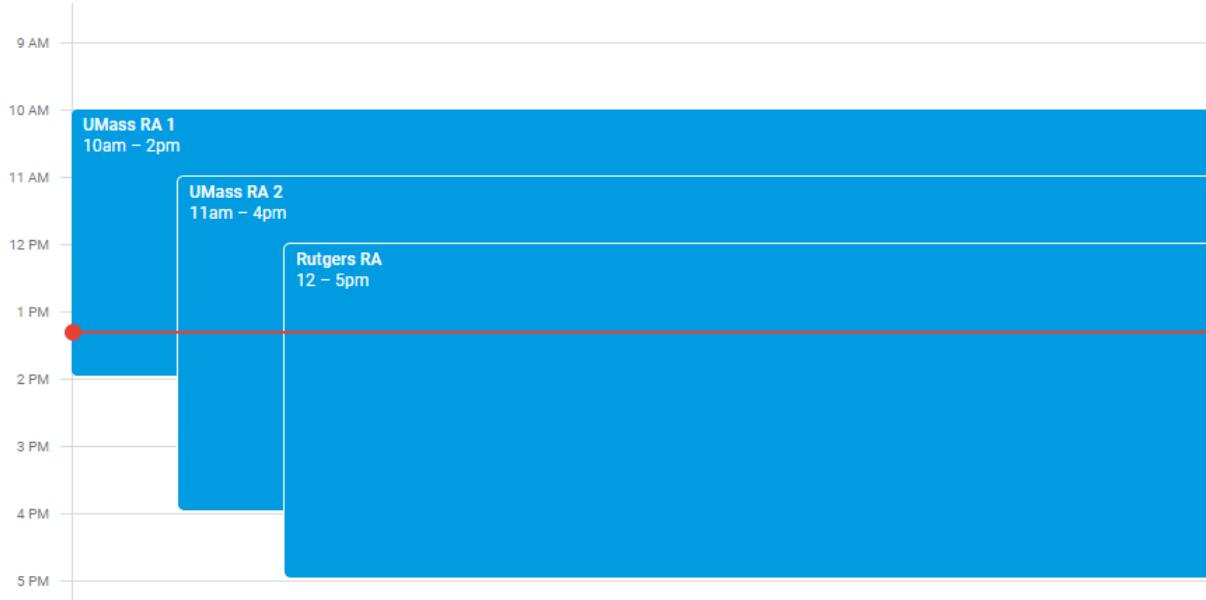
- Each volunteer is asked **inclusion and exclusion questions** (See [Appendix 2](#) for the inclusion & exclusion questions), answers of which will be entered in **the Screening Data instrument**.
- The volunteer's caregiver will be asked **inclusion and exclusion questions, the answers of which will be entered in the Screening Data instrument**. The fields are popped up when selecting 'Yes' to the questions 'Is a caregiver available to participate in this study'?
 - The volunteer, scoring MoCA 17 <= (score) < 26, will be included in our study.
- If both the volunteer and the active caregiver are eligible to join the study,
 - The RA will ask the **volunteer** and his/her active **caregiver** for their contact information, including their name, email address, and phone number if not collected yet, which will be entered in **the MCI Participant/Caregiver Demographics instrument**.
 - The RA will inform the volunteer and the active caregiver that the informed consent documents will be sent to them via email, and ask them to read, sign, and return the signed informed consent form.
 - The RA will change **the Form Status (Complete) field of the Screening Data** to Complete (i.e., green color). Green color indicates that the volunteer and the active caregiver are eligible for our study.
- If either the volunteer or the active caregiver or none of them is/are eligible to join the study,
 - All the contact information (name, email, phone number) will be removed from **the MCI Participant/Caregiver Demographics instrument**.
 - The demographic information and the answers to the inclusion/exclusion question will be stored.
 - The RA will change **the Form Status (Complete) field of the Screening Data** to Incomplete (i.e., red color). Red color indicates that the volunteer and the active caregiver are not eligible for our study.
- If the **volunteer** or his/her have active **caregiver** do not have time at the moment,
 - The RA will schedule an appointment for a phone screening and enter the date and notes in **the Contact Attempt field of the Screening Data instrument**.
 - The RA leaves **the Form Status field of the Screening Data instrument** to Incomplete.
- If the volunteer cannot be reached,
 - The RA will leave a message.
 - Message: "*Hello. This is – from the UMass Amherst research team. I am contacting you about your interest in participating in our research about mild cognitive impairment. I'd like to discuss your eligibility to participate in our research. I would be grateful if you could call back us when you are available. My number is ----. Thank you.*"
 - The RA will enter the attempted date, time, and responses in **the Contact Attempt 1/2/3 for MCI Participant or Caregiver** in the **Screening Data instrument**.
 - If the RA completes the screening, enter the completed date, time, and their name in the **Screening Data instrument**.
 - If all the Contact Attempt 1/2/3 are entered, the RA will change **the Form Status (Complete) field of the Screened Result instrument** to Incomplete (i.e., red color).

- For those who are eligible to participate in the study (called *participants* hereafter), see the [3. Informed consent obtainment](#) and [5. Assessment at baseline](#) within the phone call.

3. Informed consent obtainment (Both UMass can perform)

- (When the RA, volunteer, and the active caregiver remain on the phone after the screening process) An RA will email informed consent forms either to 1) the volunteer and the active caregiver to their email addresses separately or 2) the active caregiver depending on the participants' preference.

- UMass and Rutgers RAs will email at the end of the **2. Screening** when both the volunteer and the active caregiver are determined eligible for our study.
- Use DocuSign @ [DocuSign Login - Enter email to start sign in](#).
- If both the volunteer and the active caregiver have time,
 - The RA will give the volunteer and the active caregiver to read the informed consent form.
 - The RA will answer questions should the volunteer and the active caregiver have any.
 - When the volunteer and the active caregiver sign (using **DocuSign**) and return the signed informed consent form,
 - The RA will enter the date the forms are received.
 - The RA will change **the Form Status field of the Informed Consent instrument** to Complete.
 - The signed informed consent will be stored in the UMass-supported cloud (i.e., OneDrive).
 - The RA will schedule an assessment with the volunteer and the active caregiver for the baseline assessment when one UMass RA, the Rutgers RA, the volunteer, and the active caregiver are available for 2 hours in a row (AHHA lab account, umass.ahha.lab@gmail.com).
 - The RA will mark the scheduled assessment on the Google calendar.



- If the volunteer or the active caregiver do not have time,
 - The RA will schedule an appointment when any of the RAs are available based on the Google calendar (AHHA lab account, umass.ahha.lab@gmail.com).
 - The RA will inform other RAs of the scheduled appointment in the Slack channel.

- (When an RA is making a separate call) An RA, who is available at the scheduled appointment time, will call the volunteer, assuming that the active caregiver accompanies the volunteer.

- The RA will give the volunteer and the active caregiver time to read the informed consent form.

- The RA will answer questions should the volunteer or the active caregiver have any.
- When the volunteer and the active caregiver sign and return the signed informed consent form,
 - The RA will enter the date the forms are received.
 - The RA will change **the Form Status field of the Informed Consent instrument** to Complete.
 - The signed informed consent will be stored in the UMass-supported cloud (i.e., OneDrive).
 - The RA will schedule an assessment with the volunteer (optionally, and the active caregiver) for the baseline assessment when one UMass RA, the Rutgers RA, the volunteer, and the active caregiver are available for 2 hours in a row (AHHA lab account, umass.ahha.lab@gmail.com).
 - The RA will mark the scheduled assessment on the Google calendar.

4. Random assignment into two groups (Only UMass RA can perform)

- When the UMass RA finds a study ID with the completed **Informed Consent instrument** (i.e., green color), the RA refers to **random_group_assign.xlsx** (in the Google folder **Pre-determined randomization, which is only available to the UMass RAs**) and assigns the study ID to either Group A or B.

- **Group A**
 - First period: Neuro-World game intervention (12 weeks)
 - Second period: phone interaction + usual care (12 weeks)
- **Group B**
 - First period: phone interaction + usual care (12 weeks)
 - Second period: Neuro-World game intervention (12 weeks)

- **The Randomization instrument** will be hidden from the Rutgers personnel throughout the study.

<p>Highest level privileges:</p> <p>Project Design and Setup <input checked="" type="checkbox"/></p> <p>User Rights <input checked="" type="checkbox"/></p> <p>Data Access Groups <input checked="" type="checkbox"/></p> <p>Privileges for data exports (including PDFs and API exports), reports, and stats:</p> <p>Data Exports</p> <p>* De-identified means that all free-form text fields will be removed, as well as any date/time fields and Identifier fields.</p> <p>No Access <input type="radio"/></p> <p>De-Identified* <input checked="" type="radio"/></p> <p>Remove all tagged Identifier fields <input type="radio"/></p> <p>Full Data Set <input type="radio"/></p> <p>Add/Edit/Organize Reports <input checked="" type="checkbox"/></p> <p>Also allows user to view ALL</p>	<p><i>This privilege has no effect on data imports or data exports.</i></p> <table border="1"><thead><tr><th></th><th>No Access (Hidden)</th><th>Read Only</th><th>View & Edit</th></tr></thead><tbody><tr><td>Volunteer Demographics</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input checked="" type="radio"/></td></tr><tr><td>Screening Data</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input checked="" type="radio"/></td></tr><tr><td>Screened Result</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input checked="" type="radio"/></td></tr><tr><td>Informed Consent</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input checked="" type="radio"/></td></tr><tr><td>Randomization Form</td><td><input checked="" type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr><tr><td>Baseline Data</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input checked="" type="radio"/></td></tr><tr><td>12-Week Follow-up Data</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input checked="" type="radio"/></td></tr><tr><td>24-Week Follow-up Data</td><td><input type="radio"/></td><td><input type="radio"/></td><td><input checked="" type="radio"/></td></tr></tbody></table>		No Access (Hidden)	Read Only	View & Edit	Volunteer Demographics	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Screening Data	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Screened Result	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Informed Consent	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Randomization Form	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Baseline Data	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	12-Week Follow-up Data	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	24-Week Follow-up Data	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
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5. Assessment at baseline (Only Rutgers RA can perform assessment; UMass RAs will organize the overall meeting)

- A UMass RA will remind the participant of the scheduled assessment.
 - Give a call to the participant, remind them 1 day before the scheduled assessment in the following order.
 - Phone call
 - If not answering, text and email.
 - Give a call to the participant, remind them 2 hours before the scheduled assessment.
 - Phone call
 - If not answering, text and email.
- A UMass RA will organize the zoom meeting.
 - The UMass RA will initiate a zoom meeting.
 - A UMass RA will email a zoom link to the participant's email and the Rutgers RA approximately 10 minutes before the scheduled time.
 - The Rutgers RA will join the meeting.
 - Introduce RAs
 - Message: "*Hello, [Participant name]. I am [Umass RA name], and a researcher from UMass Amherst. Today, we will administer cognitive assessments and some surveys to you and your helper. They will take about 2 hours to complete. All the assessments will be administered by [Rutgers RA]. Can you introduce yourself briefly, [Rutgers RA]? Before starting assessments, I will break a room for [Rutgers RA] to give some important instructions for today's session.*
 - The UMass RA will break out a meeting room for the Rutgers RA, and the Rutgers RA will wait in the room.
 - The volunteer will join the meeting at the scheduled time.
 - The UMass RA will explain about the assessment.
 - Message:
 - Group A: "*OK. I will give the overall process of our study first. Our study participants are divided randomly into Group A/B. You are selected as Group A. It means that for the first 12 weeks, you play a cognitive game with the provided tablet PC. We will also follow up on your game playing experience and your cognitive and physical activity by call and email survey. They will be very brief and take about 1 min. After 12 weeks, you need to return a table PC, and do the second assessment, and don't need to do anything particular for the next 12 weeks. We will just check your cognitive and physical activity. For this assessment, an important note is that [Rutgers RA] should not know about which group you are in. Please know that [Rutgers RA] is only here for the assessment purpose. To assess your cognitive function without any bias, [Rutgers RA] should not know which group you are in, you already received a table PC, and start to play a game soon. So, if you have any concerns or questions related to our overall study procedure, game play or tablet PC, please feel free to talk to me or ask me. {optional} For today's assessment, [Helper Name] will be asked survey questions related to [participant name]'s daily activity first before starting cognitive assessment. I will break a zoom room for [participant name] during the survey, and let [participant name] join again after completing the survey. [participant name], do you feel comfortable with using zoom? After completing the survey, [helper name] please stay in the house but not in the room during the assessments.} The entire assessment will be video-recorded for future reference. Now the [Rutgers RA] will join and start the assessment. I will stay muted until the assessment is over, but if you have a question, please feel free to ask me.*

- Group B: “OK. I will give the overall process of our study first. Our study participants are divided randomly into Group A/B. You are selected as Group B. It means that For the first 12 weeks, you don’t need to do anything for this study but we will just check you about your cognitive and physical activity such as puzzles, board games or hiking like that. After 12 weeks, you will receive a table PC and play a cognitive training game. For this assessment, an important note is that Aurora should not know about which group you are in. *Please know that [name3] is only here for the assessment purpose. To assess your cognitive function without any bias, [Rutgers RA] should not know that you are starting 12 weeks with no game play and you will receive a table PC 12 weeks later. So, if you have any concerns or questions related to our overall study procedure, game play or tablet PC, please feel free to talk to me or ask me. {(optional) For today's assessment, [Helper Name] will be asked survey questions related to [participant name]'s daily activity first before starting cognitive assessment. I will break a zoom room for [participant name] during the survey, and let [participant name] join again after completing the survey. [participant name], do you feel comfortable with using zoom? After completing the survey, [helper name] please stay in the house but not in the room during the assessments.} The entire assessment will be video-recorded for future reference. Now the [Rutgers RA] will join and start the assessment. I will stay muted until the assessment is over; but if you have a question, please feel free ask to me.”*”
-
- The UMass RA will bring the Rutgers RA back to the main meeting room and start **recording the assessment**.
- Five different **Assessment Form (1-5) instruments** have a different randomized order of tests. RAs select an assessment form using **Assessment/Assessment Form Assignment.xlsx** in Google drive. Then, the questions and fields of the selected **Assessment Form instrument** will appear.
- The Rutgers RA will administer all the assessments and enter all answers to **the corresponding Assessment Form instrument**. The Rutgers RA will score the participant as he/she administers the assessments.
 - **(Videoconference version)** Montreal Cognitive Assessment (**MoCA**): Chapman, J. E., Cadilhac, D. A., Gardner, B., Ponsford, J., Bhalla, R., & Stolwyk, R. J. (2019). Comparing face-to-face and videoconference completion of the Montreal Cognitive Assessment (MoCA) in community-based survivors of stroke. *Journal of telemedicine and telecare*, 1357633X19890788.
 - **(Videoconference version)** Mini-Mental State Examination (**MMSE**): Timpano, F., Pirrotta, F., Bonanno, L., Marino, S., Marra, A., Bramanti, P., & Lanzafame, P. (2013). Videoconference-based mini mental state examination: a validation study. *Telemedicine and e-Health*, 19(12), 931-937.
 - **(Original)** Digit Forward Span (**DFS** from WAIS-IV): Powell, D. H., & Hiatt, M. D. (1996). Auditory and visual recall of forward and backward digit spans. *Perceptual and Motor Skills*, 82(3_suppl), 1099-1103.
 - **(Original)** Digit Backward Span (**DBS** from WAIS-IV): Powell, D. H., & Hiatt, M. D. (1996). Auditory and visual recall of forward and backward digit spans. *Perceptual and Motor Skills*, 82(3_suppl), 1099-1103.
 - **(Original)** Geriatric Depression Scale (**GDS**)
 - **(Original)** Short Form 36 (**SF-36**)
 - **(Original)** Alzheimer’s Disease Cooperative Study/ADL scale adapted for MCI participants (**ADCS/MCI/ADL24**)
- When the Rutgers RA completes the assessments, he/she will message the UMass RA in the smart phone texting group.
- The UMass RA will unmute.

- The Rutgers RA will leave.
- The UMass RA enters the address in **the Address to ship the tablet computer field of the MCI Participant Demographics instrument.**
- The UMass RA will inform the participant about the assignment result and explain the schedule.
 - Group A
 - Message: *“Do you have any questions so far? If not, I would like to explain what will happen next. We will ask you to play Neuro-World for 30 minutes a day, 2 days a week for 12 weeks. (accurate exactly two days, separate day) We already installed the cognitive training program, Neuro-World, in the table computer we sent. Also, we will call you twice a week to follow up your training. The call will take 1-2 minutes to briefly follow up on your training and thoughts related to the training. Before you start the training with the Neuro-World game, We will need to schedule a training session where we will go over all the games together and help you learn how to play all those games. It will take about one hour to go over all the games. When would be available to you this week or next week? ”*
 - Group B: *“Do you have any questions so far? If not, I will start to check your physical and cognitive activity about next week. I will send surveys to you very simple questions three times a week and call you twice a week. The phone call will take about 2 minutes. 12 weeks from now, we will ask you to play the cognitive training game, Neuro-World. Until then, we will follow up with you twice a week.”*

- All participants will be assessed using the following tests.

- We will use the original assessment if it is a questionnaire that can easily be done online.
- We will use the modified version for the videoconference-based administration (as opposed to telephone-based), if the original assessment is difficult to be done online. (According to Becky Ready) Some assessment tools, such as MoCA and MMSE, also test the visuospatial function of participants. The participants' performance on visuospatial-related questions is important information as well, which makes the videoconference-based version superior to the telephone-based version.

- The convention for naming the video-recorded interactions. **P1_A1_20210623.mp4** (participant number, event type and number, date)

- Assessments (before, after, follow-up) [A1, A2, A3]
- Weekly check-ups [C1, C2, ...]
- participants' initiated questions [Q1, Q2, ...]
- Online workshops [W]

- The computer that the researchers initially record audios/videos need to be encrypted (e.g., Windows 10 BitLocker Drive Encryption) and password-protected.

6. Shipping tablet PC (UMass RA will perform)

- A UMass RA will ship a tablet computer, a return label, and a hardcopy instruction for returning the tablet computer to the participant's address.

- The UMass RA will generate the shipping label using the UMass paying account (**F2E075**) and the participant's address stored in **the Address to ship the tablet computer field of the MCI Participant Demographics instrument**.
 - <https://www.easyship.com/blog/prepaid-return-labels>
 - <https://www.ups.com/us/en/campusship-support/return-services.page>
- The UMass RA will generate the returning label.
- The UMass RA will perform a factory reset on a tablet computer to be shipped.
- The UMass RA will perform all the updates.
- The UMass RA will install Neuro-World.
- The UMass RA will enter the study ID in Neuro-World.
- The UMass RA will double-check to make sure Neuro-World works as expected.
- The UMass RA will print out the instructions.
- The UMass RA will wrap the tablet + plastic case in a bubble wrap, put it in the air-inflated laptop package, and put it in the box.
- The UMass RA will put the printed instructions and the returning label in the box.
- The UMass RA will seal the box using scotch tape.
- The UMass RA will put a shipping label on the box and place it in the on-campus UPS pick-up location.
- The UMass RA will text and email both the participant and the caregiver about the estimated delivery date.
- The UMass RA will enter the shipped date, and the tracking number in **the Shipped Date field** (both **Shipping to the subject from the UMass**, **Returning to the UMass from the subject**) of **the Tablet Ship & Return instrument**.

- A UMass RA will track the delivery of the tablet computer.

- The UMass RA, on his/her assigned date, will check if any of the tablet computers are estimated to have arrived.
- The UMass RA tracks the delivery using the tracking number.
- If the package is reported to be delivered,
 - The UMass RA will call the participant (the caregiver if the participant cannot be reached) and confirm the delivery.
 - If the participant (or the caregiver) confirms the receipt of the tablet computer,
 - The UMass RA will schedule a tutorial session when the participant, the caregiver, and one UMass RA are available based on the Google calendar.
(AHHA lab account, umass.ahha.lab@gmail.com)
 - The UMass RA will notify the responsible UMass RA for the tutorial (the UMass RA, who schedules the tutorial session, may not be the one who is available for the tutorial session).
 - If the participant (or the caregiver) did not receive the package,
 - The UMass RA will contact UPS and file a claim for the missing tablet computer.
 - The UMass RA will ship another tablet computer to the participant.

- Purchase items through Deb (bergeron@cs.umass.edu).

7. Tutorial for the intervention group (UMass RA will perform)

- A UMass RA will remind the participant and the caregiver of the scheduled tutorial.
 - Give a call to the participant and the caregiver, remind them 1 day before the scheduled tutorial in the following order.
 - Phone call
 - If not answering, text and email.
 - Give a call to the participant and the caregiver, remind them 2 hours before the scheduled tutorial.
 - Phone call
 - If not answering, text and email.
- The UMass RA will organize the zoom meeting.
 - The UMass RA will initiate a zoom meeting.
 - A UMass RA will email a zoom link to the participant's email approximately 10 minutes before the scheduled time.
 - When the participant join, the UMass RA will start **video-recording** and start the tutorial session.
 - Important points:
 - How to use the tablet computer. (Prepare a video presentation with **Share sound & Optimize for video clip** toggled)
 - Open a cover
 - How to turn on
 - How to unlock
 - How to lock
 - How to wake (from the sleeping mode)
 - How to charge
 - How to change the volume
 - How to set up a wifi connection
 - How to use Neuro-World.
 - How to run
 - It takes a few seconds
 - Layout of the buttons (menus) on the initial screen
 - Tutorial on game mechanics
 - Encourage participants to go through the tutorial at the presence of connecting researchers
 - Answer any questions that the participants ask.
 - Daily training
 - Six games will be presented to the participant in a random order every time
 - A timer will keep track of the time that the participant plays each game
 - When 5 minutes are up, the participant will be moved to the next game
 - When the participant plays all 6 games, the daily training will be done
 - How to exit
 - The UMass RA will inform the participant and the caregiver about the self-administration and the weekly follow-up.
 - The UMass RA informs that
 - The participant can start self-administration of Neuro-World on the subsequent Monday.

- (Optional) The caregiver can help the participant to operate the tablet computer or start the daily training.
- (Optional) The caregiver cannot help the participant play the games.
- The researcher (i.e., a UMass RA) will contact the participant or the caregiver separately to ask about any potential issues.
- Should they have any questions, the participant or the caregiver can contact the UMass RA anytime through a phone call or an email to schedule a meeting. → Zoom link will be sent at a scheduled time. Video-record interactions.

- The UMass RA will store the video-recording in the MS OneDrive

- The UMass RA will initially store the Zoom video-recording in the encrypted & password-protected local computer.
- The UMass RA will upload the file to the HIPAA-compliant cloud storage supported by UMass Amherst (MS OneDrive)
- The UMass RA will remove the file from the local computer.

8. Checking compliance every week (UMass RA will perform)

- UMass RAs will follow up with the participant twice a week for 24 weeks by phone call.
- If the caregiver participates in the study, UMass RAs will follow up with the caregiver once a week for 24 weeks by phone call.

- The phone follow-up will be audio-recorded.
- For the participant,
 - During the experiment period
 - When the participant successfully adheres to Neuro-World training, a casual follow-up.
 - Message: "*How is Neuro-World training going?* Are there any significant changes in your daily activities? Could you explain in more detail? Thank you."
 - When the participant missed Neuro-World training this week, try to understand what hinders the participant's low adherence.
 - Message: "I noticed that you have not played Neuro-World this week. Is everything ok? Do you need any help?"
 - At the last follow-up call, ask the participant to return the tablet computer & arrange the 1:1 interview.
 - Message: "So, this week is your last Neuro-World training. Would you be able to return the tablet computer? Please wrap the tablet computer using bubble wrap. Put the wrapped tablet computer and the charger in the air-inflated package. Put the package in the paper box. Put the returning label on the box."
 - The RA will schedule the earliest available time for the participant and both UMass RAs.
(AHHA lab account, umass.ahha.lab@gmail.com)
 - For more details about the interview, refer to **11. Interview**.
 - During the control period
 - Message: (for MCI participant) "Are there any significant changes in your daily activities? Could you explain in more detail? Thank you."
 - Message: (for helper, optional) "Are there any significant changes in [NAME]'s daily activities? Could you explain in more detail? Thank you."
 - The RA enters the date that he/she made a call to the participant and whether he/she was successful connecting with the participant **in the Follow-up field of the Weekly Follow-up instrument**.
- For the caregiver (optional),
 - During the experiment period
 - When the participant successfully adheres to Neuro-World training, try to understand the third-person perspective of the participant's adherence to Neuro-World training.
 - Message: "*Can you tell me about how the participant plays Neuro-World training? Does he enjoy playing it? Does he focus when plays Neuro-World?*"
 - When the participant missed Neuro-World training this week, try to ask if the caregiver can encourage the participant to play Neuro-World.
 - Message: "Can you tell me about how the participant plays Neuro-World training? Does he enjoy playing it? Does he focus when plays Neuro-World? I noticed that the participant has not played Neuro-World

this week. Would you be able to encourage the participant to play Neuro-World x times this week?"

- At the last follow-up call, ask the participant to return the tablet computer.
 - Message: "So, this week is the participant's last Neuro-World training. Would you be able to help him/her to return the tablet computer? Please wrap the tablet computer using bubble wrap. Put the wrapped tablet computer and the charger in the air-inflated package. Put the package in the paper box. Put the returning label on the box."
 - The RA will schedule the earliest available time for the caregiver and both UMass RAs.
(AHHA lab account, umass.ahha.lab@gmail.com)
 - For more details about the interview, refer to **11. Interview**.
- The RA enters the date that he/she made a call to the participant and whether he/she was successful connecting with the participant **in the Follow-up field of the Weekly Follow-up instrument**.

- UMass RAs will follow up with the participant three times a week for 24 weeks by REDCap survey.
- If the caregiver participates in the study, UMass RAs will follow up with the caregiver once a week for 24 weeks by REDCap survey.

- For the participant,
 - In the past two days, did you do any COGNITIVE activities such as Sudoku, board games, word games, or any other activities you do to help your memory and mental capacity?
 - If yes, how long?
 - In the past two days, did you do any PHYSICAL activities or exercise such as going for a walk, biking, swimming, exercise videos/classes or anything else you can think of?
 - If yes, how long?
- For the caregiver (optional),
 - During this week, did you meet the participant?
 - In the past two days, did you see the participant do any COGNITIVE activities such as Sudoku, board games, word games, or any other activities you do to help your memory and mental capacity?
 - If yes, how long?
 - In the past two days, did you see the participant do any PHYSICAL activities or exercise such as going for a walk, biking, swimming, exercise videos/classes or anything else you can think of?
 - If yes, how long?

9. Assessment after 12 weeks (Only Rutgers RA can perform assessment; UMass RAs will organize the overall meeting)

- After 12 weeks, all participants will be assessed with the following tests **online (via zoom)**.

Detailed steps will be the same as the baseline assessment.

RAs will generate a new form for recording 12 weeks follow-up assessment from the corresponding Assessment Form instrument.

10. Returning tablet PC (UMass RAs will perform)

- A UMass RA will track the returning delivery of the tablet computer.
 - The UMass RA should have instructed the participant or the caregiver to return the tablet computer. If not,
 - Call the participant or the caregiver to provide the instructions. (Refer to **8. Checking compliance every week**)
 - The UMass RA, who is on the designed days, will check the tracking number based on **the Tracking number field (Returning to the UMass from the subject) of the Tablet Ship & Return instrument**. The following is an example.
 - UMass RA1: Wed
 - UMass RA2: Fri
 - If the returning package has been picked up by the UPS,
 - Enter the date in **the Shipped date field of the Tablet Ship & Return instrument**.
 - If the returning package is shown delivered,
 - The RA will retrieve the tablet computer.
 - The RA will check if both the tablet computer and the charger are included in the box.
 - If the returning package is shown delivered but the package is not delivered,
 - The RA will contact the UPS and file a claim.

11. Interview (UMass RAs will perform)

- A UMass RA will remind the participant and the caregiver of the scheduled interview.
 - Give a call to the participant and the caregiver, remind them 1 day before the scheduled interview in the following order.
 - Phone call
 - If not answering, text and email.
 - Give a call to the participant and the caregiver, remind them 2 hours before the scheduled interview.
 - Phone call
 - If not answering, text and email.
- Both UMass RAs and PIs (if applicable) will attend the interview.
 - One UMass RA will initiate a zoom meeting.
 - The UMass RA will email a zoom link to the participant (or the caregiver), another UMass RA, and PIs approximately 10 minutes before the scheduled time.
- List of potential questions for the participant.
 - What information and how do participants want to receive to better comprehend their cognitive performance and their compliance behaviors (frequency and duration)?
 - Can you tell us which Neuro-World games you did well?
 - How well did you do those games?
 - Can you tell us which Neuro-World games you did poorly?
 - How poorly did you do those games?
 - Is there anything else you want to know about your performance while you were playing those games?
 - Did you enjoy playing Neuro-World games?
 - What did you enjoy about playing Neuro-World games?
 - What did you not enjoy about playing Neuro-World games?
 - Can you tell us if knowing your performance in Neuro-World games helped you play Neuro-World routinely?
 - What other information would help you adhere to playing Neuro-World routinely?
 - What is the optimal design of the feedback mechanism (content, medium, and timing) to remind participants to self-administer the training?
 - What made it easy to access the information about your performance in playing Neuro-World games?
 - What made it difficult to access the information about your performance in playing Neuro-World games?
 - How can we present the information so that you can access it more easily?
 - What made it easy to understand the information about your performance?
 - What made it difficult to understand the information about your performance?
 - How can we present the information so that you can understand more easily?
 - How many times or often did you access the information about your performance?
 - How often would you be willing to access the information if it were presented in a way you preferred?
 - Are there any interaction barriers, such as video/audio instructions that may not be sufficiently informative, for participants to use the system, which have not been observed in our preliminary studies?
 - What made it easy to play Neuro-World?

- What made it difficult to play Neuro-World?
- Did you find the Tutorial easy to understand?
- Did you find the instructions in the games easy to understand?
- Was it easy to navigate the menu?
- How do you think we can improve the menu?

- Any comments?
 - Is there anything else you want to share with us?

- List of potential questions for the caregiver.

- How often did you have to remind the participant? Was this a burden for you?
- How much assistance did you have to provide help to participants?
- Did the participant avoid, complain, or otherwise protest when it was time to play Neuro-World?
- What advice do you have for us as we move forward with this research on Neuro-World training for persons diagnosed with MCI?

12. Assessment after 24 weeks (Only Rutgers RA can perform assessment; UMass RAs will organize the overall meeting)

- After 24 weeks, all participants will be assessed with the following tests **online (via zoom)**.

Detailed steps will be the same as the baseline assessment.

RAs will generate a new form for recording 24 weeks follow-up assessment from the corresponding **Assessment Form instrument**.

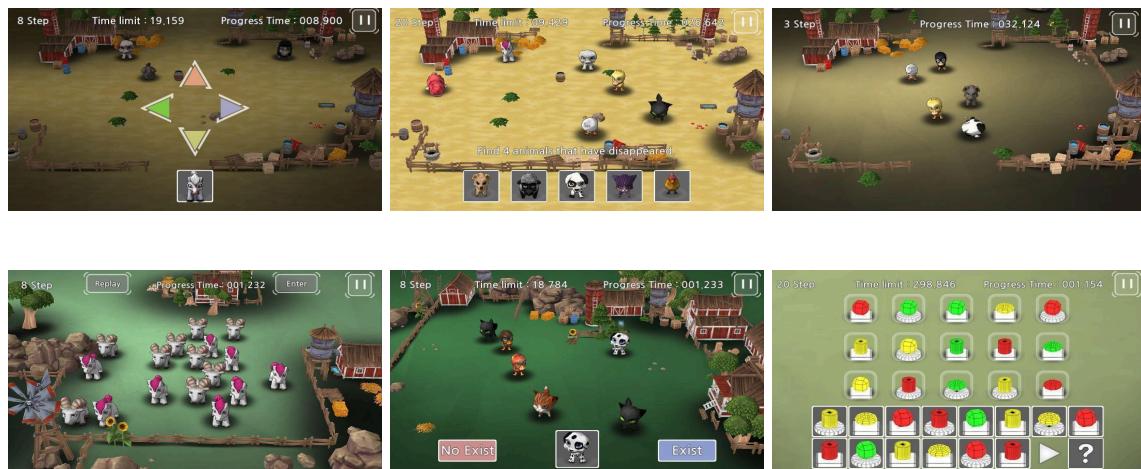
Towards the Development of a Mobile-Health Technology Based on Serious Game-based Interventions in Adults with MCI outside the clinic

Purpose

The purpose of this study is to learn: 1) if Neuro-World (mobile cognitive training games) can improve the cognitive function of adults with mild cognitive impairment (MCI), 2) if we can understand the cognitive function of adults with MCI based on their performance in Neuro-World, and 3) if we can learn practical challenges that adults with MCI face while playing Neuro-World.

Neuro-World

A tablet computer with pre-installed Neuro-world cognitive training games will be provided during the study.



Eligibility

Adults with MCI are eligible for the study if you 1) have mild cognitive impairment (we will assess your impairment level for you), 2) are 55 years old or older, 3) can use a tablet independently, and 4) have access to a computer for online video communication (e.g., Zoom).

Adults with MCI CANNOT participate in this study if you have 1) another neurologic or psychiatric disorder, 2) history of traumatic brain injury, 3) uncorrected hearing or vision

impairment, 4) any significant impairment in your arms that could affect tablet use, 5) diagnosis of dementia with Lewy bodies, progressive supranuclear palsy, multiple system atrophy, or vascular parkinsonism, 6) diagnosis of dementia, and 7) participation of any other therapist-supervised cognitive training.

If you need help navigating technology (such as using Zoom or mobile apps), you can choose to have a friend or family member help you throughout this study. If you choose this option, they will be enrolled in the study with you. In that case, helpers need to 1) be 18 years or older, 2) understand your condition, and 3) can be contacted by the study team regularly. The person is not eligible if he/she 1) has been specifically hired to provide care for you and 2) has any impairments that prevent them from helping you.

Task

1. We will ask adults with MCI to do one of the following for the study (not both).

Group A: 1) We will ask you to play Neuro-World cognitive training games 30 minutes per day, twice a week for 12 weeks in your home setting. During this period, we will give you phone calls and ask if you adhere to the cognitive training and ask you to report the time of any additional cognitive and physical activities three times a week. 2) Upon completing 24 sessions, we will ask you to join online sessions (e.g., Zoom) to share your experience of using Neuro-World 3) Then, we will give you phone calls and ask if you have any significant changes in the level of daily activities for another 12 weeks and ask you to report the time of any additional cognitive and physical activities three times a week. This study lasts about six months, and you will spend about 27.2 hours in total.

Group B: 1) We will give you phone calls and ask if you have any significant changes in the level of daily activities for 12 weeks and ask you to report the time of any additional cognitive and physical activities three times a week. 2) After the 12 weeks, we will ask you to play Neuro-World cognitive training games 30 minutes per day, twice a week for 12 weeks in your home setting. During this period, they will give you phone calls and ask if you adhere to the cognitive training and ask you to report the time of any additional cognitive and physical activities three times a week. 3) Upon completing 24 sessions, we will ask you to join online sessions (e.g., Zoom) to share your experience of using Neuro-World. This study lasts about six months, and you will spend about 27.2 hours in total.

2. If helpers participate in the study, we will ask helpers to do the following for the study.

1) We will ask you to check on adults with MCI you are helping if they do not adhere to cognitive training. **2)** We will ask you to assist adults with MCI in using a tablet computer and online communication technology as necessary. **3)** During the entire study, we will ask you to report the time of any cognitive and physical activities adults with MCI engage in once per week. **4)** During the 12-week period that adults with MCI use Neuro-World, we will contact you and ask for your perspective on their adherence to Neuro-World cognitive training. **5)** During the 12-week control period, we will contact you and ask if there are any significant changes in the activities of adults with MCI. **6)** Upon the completion of 12-week Neuro-World play, we will ask you to participate in a 1:1 interview to hear your experience and opinions as a helper. This study lasts about six months, and you will spend 4.4 hours in total for an interview and follow-up calls. You may need to spend an additional 27.2 hours in total. However, you will be asked for help only when it is necessary.

Compensation:

Adults with MCI will receive \$2 after each Neuro-World play and \$34 for each suite of cognitive assessments, which amount to a total of \$150. If helpers participate in the study, helpers will receive \$1 for each week of support and \$13 for each 1:1 interview, which amounts to a total of \$50.

If you are interested in participating or want to know more, please contact the AHHA Lab (413-545-8875, umass.ahha.lab@gmail.com).

For Adults with MCI

Thank you for speaking with us today. Before you officially enroll in this research study, I will be asking you to complete a screening questionnaire. It should take you no more than 30 minutes to complete. If you are determined ineligible to participate, your completed questionnaire will be destroyed. If you are determined eligible to participate, the completed questionnaire will become part of the study materials, and we will protect your information as confidential and safeguard it from unauthorized disclosure. Only research personnel will have access to the information contained in your screening questionnaire. If the screening questionnaire indicates that you are eligible to participate, we will proceed to obtaining your written informed consent for participation in the study. Do you have any questions?

The contacted researcher will ask the following questions regarding the inclusion criteria (2 minutes).

1. Are you 55 years old or older?
2. Can you turn on/off a smartphone or a tablet computer? Can you start an application and use it on your smartphone or a tablet computer? It is ok to receive help from your caregiver on operating your smartphone or tablet computer.
3. Do you have access to a computer for online video communication (e.g., Zoom, Microsoft Team, Google Hangouts)?

The contacted researcher will ask the following questions regarding the exclusion criteria (5 minutes).

1. Do you have diagnosed neurologic or psychiatric disorders other than mild cognitive impairment?
2. Do you have a history of diagnosed traumatic brain injury?
3. Do you have hearing or vision impairment that can hinder you from playing games?
4. Do you have any significant impairment in your arm that could affect the use of a tablet computer?
5. Do you have diagnosed dementia with Lewy bodies, progressive supranuclear palsy, multiple system atrophy, or vascular parkinsonism?
6. Do you have diagnosed dementia?
7. Are you receiving any therapist-supervised cognitive training?

For Caregivers (optional)

The contacted researcher will ask the following questions regarding the inclusion/exclusion criteria (2 minutes).

Inclusion criteria

1. Are you 18 years old or older?
2. Do you know about your care receiver's health conditions?
3. Will you be willing to be contacted by the researchers on a regular basis in case your care receiver needs external help?

Exclusion criteria

4. Are you hired to provide care for your care receiver?
5. Do you have any cognitive, behavioral, or motor impairments that can affect assisting your care receiver in the study?

ATTENTION

When you open the box, CHECK if the following items are in the box.

1. One air-filled container
2. One tablet (in the air-filled container)
3. One tablet cover (a tablet is in the cover)
4. One charger (in the air-filled container)
5. One UPS return label

Please KEEP EVERYTHING you received that includes the following.

1. One outer box
2. One air-filled container
3. One tablet
4. One tablet cover
5. One charger
6. One UPS return label

Please DO NOT START cognitive training games until the researchers contact you.

When the study is complete, the researchers will contact and ask you to return all the items. At the time, you will need to do the following.

1. Place the tablet (with its cover) in the air-filled container.
2. Place the charger in the air-filled container.
3. Place the air-filled container (with the tablet, the charger inside) in the outer box.
4. Seal the outer box.
5. Put the UPS return label on the outer box.
6. Place the box outside your front door.

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