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

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Consent Form for Participation in a Research Study
University of Massachusetts Amherst

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Study Title:	**Towards the Development of a Mobile-Health Technology Designed to Encourage the Use of Serious Game-based Interventions in Patients with MCI outside the Clinic**

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1. WHAT IS THIS FORM?

This form is called a Consent Form. It will give you information about the study so you can make an informed decision about joining this research. We encourage you to take some time to think this over and ask questions now and at any other time. If you decide to join, you will be asked to sign this form and you will be given a copy for your records.

2. WHAT ARE SOME OF THE IMPORTANT ASPECTS OF THIS RESEARCH STUDY THAT I SHOULD BE AWARE OF?

Joining this research is voluntary, and we are asking for your consent before your joining this study. This research is to study the following three points.

1) Does the routine play of Neuro-World cognitive training games improve cognitive function among adults with mild cognitive impairment?
2) Can we understand your cognitive function based on your performance in Neuro-World game play?
3) What mobile program can we develop to encourage users to continue to play Neuro-World cognitive training games?

If you agree to join this study, you will be asked to either 1) routinely play Neuro-World cognitive training games and join online co-design sessions to share your experience and thoughts on ways to improve your adherence to playing Neuro-World or 2) go about your typical routine daily activities. Your interaction with the researchers (e.g., clinical assessments, weekly follow-ups, online co-design sessions, other correspondences) will be video/audio-recorded for research purposes. It is possible that confidentiality is breached. However, the researchers will do their best to protect your privacy/confidentiality following the steps explained in Section 9. You may experience fatigue while playing Neuro-World games.

3. WHY ARE WE DOING THIS RESEARCH STUDY?

The goal of this research study is 1) to study the effectiveness of routinely playing Neuro-World cognitive training games in improving your cognitive function, 2) to estimate cognitive function based on your performance in Neuro-World, and 3) to understand how mobile program should be developed to help you continue to play Neuro-World games routinely.

4. WHO CAN PARTICIPATE IN THIS RESEARCH STUDY?

You can join the study if

1) your cognitive function is greater than or equal to 17 and smaller than 26 on the Montreal Cognitive Assessment that the researcher administers
2) you are 55 years old and above
3) you can use a tablet computer independently
4) you have access to a computer for online video communication (e.g., Zoom).

You CANNOT participate in this study if

1) if you have diagnosis of neurologic or psychiatric disorder other than mild cognitive impairment
2) if you have a history of diagnosed traumatic brain injury
3) if you have uncorrected hearing or vision impairment
4) if you have any significant upper-limb motor impairment that could affect the use of a tablet computer
5) if you have diagnosis of dementia with Lewy bodies, progressive supranuclear palsy, multiple system atrophy, or vascular parkinsonism
6) if you have diagnosis of dementia
7) if you are and will be participating in any other therapist-supervised cognitive training.

If you need help navigating technology (such as using Zoom or using 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, your helper should

1) be 18 years or older
2) know your condition to perform the study tasks
3) can be contacted by the researchers when needed.

Your helper SHOULD NOT

1) be hired to provide care for you
2) have impairments that can affect their ability to perform their study tasks.

5. WHERE WILL THIS RESEARCH STUDY TAKE PLACE AND HOW MANY PEOPLE WILL PARTICIPATE?

You will do all the tasks in your home. Any meeting with the researchers will be done online using video communication programs, such as Zoom. We expect to include a total of 50 adults with mild cognitive impairment and their helpers in this study.

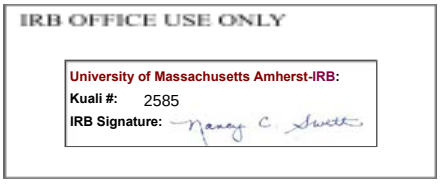
6. WHAT WILL I BE ASKED TO DO AND HOW MUCH TIME WILL IT TAKE?

If you agree to join this study, you will be asked to do the following.

During the clinical trial (related to the first research question):

At the beginning of the study, 12 weeks, and 24 weeks after the beginning of study, we will do cognitive assessments for you using clinically validated tools, such as

1) Mini-Mental State Examination (MMSE)
2) Montreal Cognitive Assessment (MoCA)
3) Digit Forward/Backward Span (DFS/DBS)



4) Geriatric Depression Scale (GDS)
5) Short Form 36 (SF-36)
6) Alzheimer's Disease Cooperative Study/ADL scale adapted for MCI (ADCS/ADL/MCI).

At the completion of the Neuro-World cognitive training, we will do usability assessment for playing Neuro-World on the tablet computer using the questionnaire, such as

1) System Usability Scale (SUS)
2) NASA Task Load Index (NASA-TLX)

It may take approximately 2 hours to complete all the assessments.

If you are assigned to **Group A**, **1)** for the first 12 weeks, we will ask you to play Neuro-World games 30 minutes per day, twice a week. The total duration that you will play Neuro-World will be 12 hours. During the 12-week period, the researchers will contact you and ask if you adhered to the prescribed Neuro-World cognitive training. Each phone call will last approximately 5 minutes, which will amount to 2 hours in total. Three times a week, you will receive an email to report the time of additional cognitive and physical activities that you have been engaged in the past two days. Each response will take less than 1 minute, which will amount to about 0.6 hours in total. **2)** After completing the 12 weeks of the Neuro-World cognitive training, the researchers will contact you and ask if there exist any significant changes in the level of your daily activities. Each phone call will last approximately 5 minutes, which will amount to 2 hours in total. Three times a week, you will receive an email to report the time of additional cognitive and physical activities that you have been engaged in the past two days. Each response will take less than 1 minute, which will amount to about 0.6 hours in total.

If you are assigned to **Group B**, **1)** for the first 12 weeks, the researchers will contact you and ask if there exist any significant changes in the level of your daily activities for the first 12 weeks. Each phone call will last approximately 5 minutes, which will amount to 2 hours in total. Three times a week, you will receive an email to report the time of additional cognitive and physical activities that you have been engaged in the past two days. Each response will take less than 1 minute, which will amount to about 0.6 hours in total. **2)** After the 12 weeks, the researchers will ask you to play Neuro-World games 30 minutes per day, twice a week. The total duration that you will play Neuro-World will be 12 hours. During the 12-week period, the researchers will contact you and ask if you adhered to the prescribed Neuro-World cognitive training. Each phone call will last approximately 5 minutes, which will amount to 2 hours in total. Three times a week, you will receive an email to report the time of additional cognitive and physical activities that you have been engaged in the past two days. Each response will take less than 1 minute, which will amount to about 0.6 hours in total.

During the online sessions (related to the third research question):
We will ask you to join one online 1:1 interviews to share with the researchers your opinions and thoughts of ways to help you continue to use Neuro-World. The online interview will last up to 2 hours.

Total number of hours:
You will spend about **25.2 hours** in total.

Potential for additional contact:
In case we need more information or further help after the above-explained research activities are done, we may contact you again.

7. WILL BEING IN THIS RESEARCH STUDY HELP ME IN ANY WAY?

You may not benefit directly from joining this study. However, your cognitive function may improve from a routine play of Neuro-World cognitive training games. Also, the research results may help the researchers design better cognitive training games and mobile programs, which may help improve at-home cognitive training in the future and benefit adults with mild cognitive impairment in general.

8. WHAT ARE MY RISKS OF BEING IN THIS RESEARCH STUDY?

It is possible that you experience hand/wrist and/or cognitive fatigue while playing Neuro-World cognitive training games. In addition, it is possible that confidentiality is breached. To minimize such a risk, we will take the steps explained in Section 9 below.

9. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

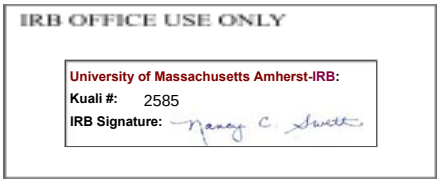
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Your privacy and confidentiality are important to us. As part of study, we will collect the following information.

1) your demographic information, such as your age and gender
2) the assessment scores, such as MMSE and MoCA, that are explained in Section 6
3) the performance of your game play, such as the game stages you reached, time to solve each game stage
4) the video/audio recording of your interactions with the researchers (e.g., clinical assessments, weekly follow-ups, online co-design sessions, other correspondences)
5) your contact point, such as phone number.

The following steps will be used to protect the confidentiality of your study records. We will use algorithms to automatically detect faces and blur them in the recorded videos so that faces cannot be recognized. Materials and data will be kept for seven years in secure places in the laboratories and the cloud services that are supported by the University of Massachusetts Amherst and the Rutgers University. Paper materials, such as signed informed consents, will be kept in a locked cabinet within the laboratories. Only authorized researchers will access the above-mentioned data for research-related purposes using the encrypted and password-protected computers. The representatives of the IRB (Institutional Review Boards) and OHRP (Office for Human Research Protections) may review the collected data. At the conclusion of this study, the researchers may present and/or publish their findings. When reported in any publications or presentations, research results will be presented in a way that you cannot be identified.

10. WILL MY INFORMATION (BIOSPECIMENS OR PRIVATE INFORMATION) BE USED FOR RESEARCH IN THE FUTURE?



The information that can identify you will be removed, and only the resulting de-identified information or biospecimens may be used for future research without additional informed consent from you.

11. WILL I BE GIVEN ANY MONEY OR OTHER COMPENSATION FOR BEING IN THIS RESEARCH STUDY?

You will be compensated based on the number of sessions you finish in the clinical trial of this study. More specifically, you will be paid $6.5 for each Neuro-World game play and $36 for each suite of cognitive assessments and one online interview. Hence, if you finish all 24 sessions, 3 suites of assessments, and 1 online interview session, you will be paid $300 in total. You will not be paid for screening assessments.

Since you are being compensated for joining this study, your personal information may be released to the accounting officials at University of Massachusetts, Amherst. If payment to you is $600 or more in any one calendar year, the University of Massachusetts, Amherst is required to report this information to the IRS as taxable income. This information will be kept confidential and will only be used to process payment.

12. WHO CAN I TALK TO IF I HAVE QUESTIONS?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the AHHA lab (413-545-8875; umass.ahha.lab@gmail.com).

If you have any questions concerning your rights as a research subject, you may contact the University of Massachusetts Amherst Human Research Protection Office (HRPO) at (413) 545-3428 or humansubjects@ora.umass.edu.

13. WHAT HAPPENS IF I SAY YES, BUT I CHANGE MY MIND LATER?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.

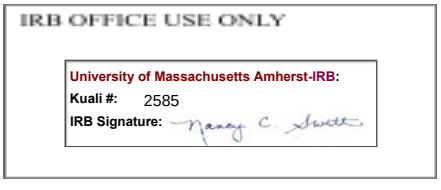
If you join this research study and want to drop out, you should tell us. We will make sure that you stop the study safely. It is possible that we may ask you to drop out of the study before you finish it. If this happens, we will tell you why.

14. WHAT IF I AM INJURED?

The University of Massachusetts does not have a program for compensating subjects for injury or complications related to human subjects research. If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researchers can be contacted using 413-545-8875 or umass.ahha.lab@gmail.com.

15. SUBJECT STATEMENT OF VOLUNTARY CONSENT

When signing this form, I am agreeing to voluntarily enter this study. I have had a chance to read this consent form, and it was explained to me in a language which I use. I have had the opportunity to ask



questions and have received satisfactory answers. I have been informed that I can withdraw at any time. A copy of this signed Informed Consent Form has been given to me.

_____	_____	_____
Participant Signature:	Print Name:	Date:

I agree to be video/audio-recorded during interactions with the researchers □ _____
Print Name:

I do not agree to be video/audio-recorded during interactions with the researchers □ _____
Print Name:

By signing below I indicate that the participant has read and, to the best of my knowledge, understands the details contained in this document and has been given a copy.

_____	_____	_____
Signature of Person Obtaining Consent	Print Name:	Date:

IRB OFFICE USE ONLY

University of Massachusetts Amherst-IRB:
Kuali #: 2585
IRB Signature: Nancy C. Hewett