PROTOCOL TITLE:

The Adherence Promotion with Person-centered Technology (APPT) Project – NCT05016856

PRINCIPAL INVESTIGATORS:

Name: Zhe He

Department: School of Information

Telephone Number: (850) 644-5775

Email Address: zhe@fsu.edu

Name: Shayok Chakraborty

Department: Computer Science

Telephone Number: (850) 644-4029

Email Address: shayok@cs.fsu.edu

VERSION NUMBER/DATE:

Version 5.0 (12/11/2023)

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	6/08/21	A subset of participants (10) randomly chosen will also be asked to wear either a fitness tracker or smartwatch during the study. These devices may at some point be used to help people remember to engage in cognitive training at home. We want to understand peoples' attitudes toward these devices and barriers to using these devices. If participants are asked to wear one of these devices during the study, we will interview them at the end of the study to better understand their experiences, specifically challenges to long-term use.	Yes
2	09/05/22	1) The duration of the study was shortened from 6 months to 4 months.	Yes

		2) Additional, related measures were added to the assessment battery. 3) Compensation was increased to $400. 4) New Newspaper advertisement 5) Provided a new list of motivational messages that will be administered.	
3	10/11/22	1) Added email communication for IRB approval explaining to potential participants who have contacted us as a result of previous ads that we are now ready to begin enrollment. 2) Updated protocol and consent form to make clear procedures are currently remote (Zoom/Qualtrics surveys) 3) Pilot testing has been used to adjust estimates of sessions and timings over which measures will be administered. 4) To facilitate a contactless process – all payments will now be made in Amazon Gift Certificates distributed electronically to participants.	
4	08/16/2023	We are adding an additional, very brief measure of cognitive ability (COGTEL) to assess memory, reasoning, and verbal fluency. This measure is similar to, but shorter than, other approved measures. This additional measure will give us a more reliable assessment of cognition.	
5	12/11/2023	PI change – Drs. Zhe He and Shayok Chakraborty	Y

Table of Contents

1.0 Study Summary 4
2.0 Objectives* 5
3.0 Background* 5
4.0 Study Endpoints* 11
5.0 Study Intervention/Investigational Agent 11
6.0 Procedures Involved* 12
7.0 Data and Specimen Banking* 17
8.0 Sharing of Results with Subjects* 18
9.0 Study Timelines* 18
10.0 Inclusion and Exclusion Criteria* 18
11.0 Vulnerable Populations* 19
12.0 Local Number of Subjects 19
13.0 Recruitment Methods 19
14.0 Withdrawal of Subjects* 19

15.0 Risks to Subjects* 20
16.0 Potential Benefits to Subjects* 20
17.0 Data Management* and Confidentiality 20
18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects* 21
19.0 Provisions to Protect the Privacy Interests of Subjects 21
20.0 Compensation for Research-Related Injury 21
21.0 Economic Burden to Subjects 21
22.0 Consent Process 21
23.0 Process to Document Consent in Writing 22
24.0 Setting 22
25.0 Resources Available 22
26.0 Multi-Site Research* 22

1.0 Study Summary

Study Title	The Adherence Promotion with Person-centered Technology (APPT) Project – STUDY 1
Study Design	Random assignment
Primary Objective	Investigate adherence supports for technology-based cognitive training
Secondary Objective(s)	Understand individual difference factors related to adherence. Understand barriers to adherence to long-term use of wearable devices such as smartwatches.
Research Intervention(s)/ Investigational Agent(s)	Two different types of reminders will be examined if participants fail to complete their assigned cognitive training. These will be messages delivered via smartphone text messages.
IND/IDE #	NA
Study Population	Cognitively intact older adults aged 65 and above
Sample Size	190 participants
Study Duration for individual participants	4 months
Study Specific Abbreviations/ Definitions	AI - Artificial Intelligence (AI) APPT - Adherence Promotion with Person-centered Technology PCMC - Person-Centered Multimedia Computing

2.0 Objectives*

2.1 Describe the purpose, specific aims, or objectives.

Briefly, the goals of this project are to understand how to encourage and support adherence to cognitive training protocols (mental exercises delivered via a tablet) over an extended period of time (4 months), and uncover individual difference factors that can predict poor adherence in the future. Even effective cognitive interventions may fail if individuals do not adhere to them for an extended period of time. This project will compare a generic reminder system to an adaptive and personalized one. Both will feature reminders that will be delivered via smartphone text messages to participants' phones. The ultimate goal, as effective technology-based interventions to improve cognition become available, is to help support their benefit for older adults by maximizing long-term adherence.

2.2 State the hypotheses to be tested.

Hypothesis 1: Participants who receive adaptive and personalized reminders, delivered during times most suitable to encourage adherence based on their previous history of training engagement and response to reminders, and providing encouragement to form plans to improve adherence, and the option to postpone reminders to more convenient times, will adhere to more training sessions over the period of four months.

Hypothesis 2: Individual difference predictors, including measures of personality, technology proficiency, cognition, and attitudes toward cognitive training will predict and help identify participants who are more likely to engage in non-adherent behaviors in the future.

3.0 Background*

3.1 Describe the relevant prior experience and gaps in current knowledge.

Cognitive intervention adherence has crucial implications for the successful treatment of cognitive decline. Beneficial interventions will not have a major impact unless older adults engage with them. For a variety of interventions (e.g., pharmacological, nutrition, exercise), individuals who engage with treatment less frequently receive fewer benefits. The same is true of cognitive interventions. This was seen in the ACTIVE (Advanced Cognitive Training for Independent and Vital Elderly) randomized controlled trial; participants who adhered less to reasoning training demonstrated smaller training benefits (Willis and Caskie, 2013). For memory training, cognitive benefits have also been found to be lower for less adherent individuals (Bagwell & West, 2008). Anticipated adherence problems are consistent with the high attrition and low adherence rates of many home-based, technology-mediated cognitive training studies. Owen et al. (2010) conducted a six-week online study in which participants were asked to practice cognitive tasks designed to improve reasoning, memory, planning, visuospatial skills, and attention three times a week. Of 52,617 participants who were initially

enrolled, only 11,430 completed both pre- and post-assessments and at least two complete training sessions during the six-week period. Hardy et al., (2015) also conducted a large, online, randomized controlled trial that evaluated a longer cognitive training protocol (10 weeks). Just a little over half of all participants completed the study. In a recent 6-month online study of cognitive training, out of 2,557 older adults who were randomly assigned to receive reasoning training, only 863 remained at the 6-month follow-up session (Corbett et al., 2015). Boot et al., (2013) used a training program that was twelve weeks in length. Hand-held digital games were assigned to target perceptual and cognitive abilities. For the intervention of interest, participants only played, on average, 22 of the 60 hours of assigned training. Although a number of technology-based cognitive interventions have demonstrated promising effectiveness with respect to improving perceptual and cognitive abilities (e.g., Green & Bavelier, 2008; Kueider, Parisi, Gross, & Rebok, 2012; Powers, Brooks, Aldrich, Palladino, & Alfieri, 2013; Smith et al., 2009), the effectiveness of these interventions is likely to be minimal unless older adults are willing and able to engage in them.

In 2014, a Cochrane review was published on the efficacy of interventions for enhancing adherence (Nieuwlatt et al., 2014). Limited evidence for efficacy was found among the highest quality studies. Study quality was judged by the criteria put forth by the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2011). Only five high quality studies reported improvements in both adherence and clinical outcomes, and no common intervention properties appeared to link these studies. The report arrived at the pessimistic assessment: "Even the most effective interventions did not lead to large improvements in adherence or clinical outcomes." While this review focused on extremely heterogeneous interventions that could include healthcare provider involvement, counseling, and family and peer support, a follow up review on technology-mediated interventions for enhancing adherence was conducted (Mistry et al., 2015). This systematic review focused on interventions aimed at boosting adherence that included one or more technologies as the main component (e.g., reminders delivered through a medical device or information and communication technology). A total of 38 studies were identified, with only 50% of these studies reporting a significant improvement in adherence. Of the nine studies that involved interventions that relied primarily on electronic reminders, only three resulted in significant adherence improvements. Further, of the nine studies using electronic reminders, only two were judged as high quality (low risk of bias). With respect to technology-mediated interventions, this study concluded limited evidence for effectiveness, and that technology "will need to improve if clinically important effects are to be realized."

Unlike the interventions reviewed by these two reports, recently, Artificial Intelligence (AI) technology has been exploited to assess and reduce the risk of non-adherence in patients with chronic conditions. Common AI-based intervention schemes include face recognition and computer vision (Bain et al.,

2018), chatbots (Fadhil, 2018), and text messaging (Sarabi, Sadoughi, Orak, & Bahaadinbeigy, 2016). However, to the best of our knowledge, none of the AI platforms for adherence adapt to the lifestyle of every individual user. Each user is unique and technology should be tailored to meet their respective needs and expectations. The concept of person-centered multimedia computing (PCMC) was recently introduced, which caters to the needs and preferences of individual users toward the design and development of computing solutions (Panchanathan, McDaniel, Balasubramanian, 2012), rather than a one-size-fits-all design. One of the hallmarks of PCMC is co-adaptation (Panchanathan & McDaniel, 2014; Panchanathan, McDaniel, & Balasubramanian, 2013), the bidirectional interaction in which both the user and the system learn and adapt together over time through continual use. Through co-adaptation, individualized designs may be achieved while maintaining applicability to a broad range of users. Panchanathan et al. (2016) demonstrated that a person-centered AI technology, that adapts to the daily routine of a user and the context (whether at home or at work, for instance) delivers much better performance over a system that is context-ignorant and non-adaptive.

The innovation of the proposed research relates to the leveraging of the principles of PCMC and the promotion of the development of adaptive systems to reduce the risk of non-adherence. Take, for example, the case of promoting adherence to a cognitive training protocol. Initially, a particular user's daily activities and training preferences can be collected in advance of training and hard-coded into the system. If adherence lags, a text message reminder might be sent in advance of a preferred training time to encourage the participant to engage in training, and alert them that an ideal training time is approaching. After time, the system can then use data from actual training engagement (e.g., typical training times), the success of previous reminder attempts, and participant's text message responses to short questions related to reasons for adherence lapses, together with AI technology, to be more cognizant of the user's schedule. Our work is partly motivated by previous research in exploiting GPS data to learn users' activities, movement patterns, and locations using probabilistic machine learning frameworks. Over time, the system adapts to the behavior and lifestyle of users, inhibiting the system from generating adherence reminders at inappropriate times (e.g., while the user is likely engaged in another activity). However, in our case, using participants' own training history is a simpler, more flexible, less obtrusive, and more practical solution than obtaining and using GPS data to make these decisions. Such an adaptive technology has the potential to generate better interventions and increase adherence among older adults, and the proposed project will open up new vistas of research at the confluence of AI and person-centered adherence support.

Our decision to develop an adaptive and tailored system also draws heavily on the tailoring literature. Tailoring is an effective health communication strategy that recognizes the complexity of health decision making and behavior change.

Research has found that messages created based on an assessment and understanding of individual differences are more engaging and persuasive than generic or one-size-fits-all health messages. Moreover, meta-analyses provide empirical evidence of the benefits of tailored versus non-tailored interventions across a wide variety of health outcomes including smoking cessation, physical activity, diet and nutrition, and binge drinking (e.g., Lustria et al., 2013). Advances in computing have contributed significantly to the sophistication of tailored messaging and delivery. Computer-tailored interventions (CTIs) are behavior change interventions that use powerful expert systems to automate the collection of personal information and enable theory-based tailoring on a wide variety of psychosocial factors. These systems use complex algorithms to power the development of individualized messages or recommended actions from a content database -- approaching a level of tailoring that, in the past, could only be achieved through interactions with experts or trained health care providers (Lustria et al., 2009). These types of systems, however, require individual assessments that can be onerous to participants and requires significantly more development time given the multiple iterations of tailored messages that need to be developed. Our research has shown that this level of sophistication may not be necessary to enhance the persuasiveness of such systems. Instead, the challenge is how to raise the perceived personal relevance of the health message (or in our case, the reminder prompts; Lustria et al., 2016). We believe that basing tailoring on personal data collected ubiquitously in the background, may be a crucial step in finding a more cost-effective and efficacious approach for tailoring, which in turn has been found to be an effective method for promoting behavior change (and in our case, in increasing adherence).

References:

Bagwell, D. K., & West, R. L. (2008). Assessing compliance: Active versus inactive trainees in a memory intervention. *Clinical Interventions in Aging, 3*(2), 371-382.

Bain, E. E., Shafner, L., Walling, D. P., Othman, A. A., Chuang-Stein, C., Hinkle, J., & Hanina, A. (2017). Use of a novel artificial intelligence platform on mobile devices to assess dosing compliance in a phase 2 clinical trial in subjects with schizophrenia. *JMIR mHealth and uHealth*, *5*(2).

Boot, W. R., Champion, M., Blakely, D. P., Wright, T., Souders, D. J., & Charness, N. (2013). Video games as a means to reduce age-related cognitive decline: Attitudes, compliance, and effectiveness. *Frontiers in Psychology, 4* doi://dx.doi.org/10.3389/fpsyg.2013.00031

Corbett, A., Owen, A., Hampshire, A., Grahn, J., Stenton, R., Dajani, S., . . . Ballard, C. (2015). The effect of an online cognitive training package in healthy older adults: An online randomized controlled trial. Journal of the American Medical Directors Association, 16(11), 990-997. doi:10.1016/j.jamda.2015.06.014

Fadhil, A. (2018). A Conversational Interface to Improve Medication Adherence: Towards AI Support in Patient's Treatment. *arXiv preprint arXiv:1803.09844*.

Green, C. S., & Bavelier, D. (2008). Exercising your brain: A review of human brain plasticity and training-induced learning. *Psychology and Aging, 23*(4), 692-701.

Higgins J.P.T., Green S. (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from http://handbook.cochrane.org.

Kueider, A. M., Parisi, J. M., Gross, A. L., & Rebok, G. W. (2012). Computerized cognitive training with older adults: a systematic review. *PLoS One, 7*(7), e40588.

Lustria, M. L. A., Cortese, J., Gerend, M. A., Schmitt, K., Kung, Y. M., & McLaughlin, C. (2016). A model of tailoring effects: A randomized controlled trial examining the mechanisms of tailoring in a web-based std screening intervention. *Health Psychology, 35*(11), 1214-1224. doi:10.1037/hea0000399

Lustria, M. L. A., Cortese, J., Noar, S. M., & Glueckauf, R. L. (2009). Computer-tailored health interventions delivered over the web: Review and analysis of key components. *Patient Education and Counseling, 74*(2), 156-173. doi:10.1016/j.pec.2008.08.023

Lustria, M. L. A., Noar, S. M., Cortese, J., van Stee, S., Glueckauf, R. L., & Lee, J. (2013). A meta-analysis of web-delivered tailored health behavior change interventions. *Journal of Health Communication, 18*(9), 1039-1069. doi:10.1080/10810730.2013.768727

Nieuwlaat, R., Wilczynski, N., Navarro, T., Hobson, N., Jeffery, R., Keepanasseril, A., ... & Sivaramalingam, B. (2014). Interventions for enhancing medication adherence. *The Cochrane Library*.

Mistry, N., Keepanasseril, A., Wilczynski, N. L., Nieuwlaat, R., Ravall, M., Haynes, R. B., & Patient Adherence Review Team. (2015). Technology-mediated interventions for enhancing medication adherence. *Journal of the American Medical Informatics Association*, *22*(e1), e177-e193.

Owen, A. M., Hampshire, A., Grahn, J. A., Stenton, R., Dajani, S., Burns, A. S., . . . Ballard, C. G. (2010). Putting brain training to the test. *Nature, 465*(7299), 775-778. doi://dx.doi.org.proxy.lib.fsu.edu/10.1038/nature09042

Panchanathan, S., Chakraborty, S., & McDaniel, T. (2016). Social interaction assistant: a person-centered approach to enrich social interactions for individuals with visual impairments. *IEEE Journal of Selected Topics in Signal Processing*, *10*(5), 942-951.

Panchanathan, S., & McDaniel, T. (2015). Person-centered accessible technologies and computing solutions through interdisciplinary and integrated perspectives from disability research. *Universal Access in the Information Society*, *14*(3), 415-426.

Panchanathan, S., McDaniel, T., & Balasubramanian, V. (2012, November). Person-centered accessible technologies: Improved usability and adaptation through inspirations from disability research. In *Proceedings of the 2012 ACM workshop on User experience in e-learning and augmented technologies in education* (pp. 1-6). ACM.

Panchanathan, S., McDaniel, T., & Balasubramanian, V. N. (2013, July). An interdisciplinary approach to the design, development and deployment of person-centered accessible technologies. In *Recent Trends in Information Technology (ICRTIT), 2013 International Conference on* (pp. 750-757). IEEE.

Powers, K. L., Brooks, P. J., Aldrich, N. J., Palladino, M. A., & Alfieri, L. (2013). Effects of video-game play on information processing: A meta-analytic investigation. *Psychonomic Bulletin and Review,* DOI 10.3758/s13423-013-0418-z.

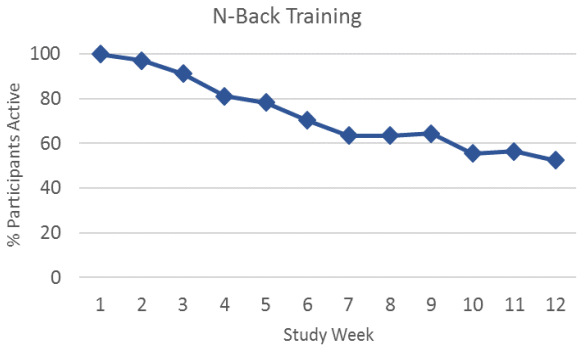
Sarabi, R. E., Sadoughi, F., Orak, R. J., & Bahaadinbeigy, K. (2016). The effectiveness of mobile phone text messaging in improving medication adherence for patients with chronic diseases: a systematic review. *Iranian Red Crescent Medical Journal*, *18*(5).

Smith, G. E., Housen, P., Yaffe, K., Ruff, R., Kennison, R. F., Mahncke, H. W., & Zelinski, E. M. (2009). A cognitive training program based on principles of brain plasticity: Results from the Improvement in Memory with Plasticity-based Adaptive Cognitive Training (IMPACT) study. *Journal of the American Geriatrics Society, 57*(4), 594-603.

Willis, S. L., & Caskie, G. I. (2013). Reasoning training in the ACTIVE study: how much is needed and who benefits? *Journal of Aging and Health*, *25* (8 suppl), 43S-64S.

3.2 Describe any relevant preliminary data.

A recent study, conducted by the NIA supported Center for Research and Education on Aging and Technology Enhancement (CREATE), with Boot at PI, has provided valuable pilot data for the proposed project. In this study, 120 older adults (age 64+) were assigned to engage in cognitive training (the Mind Frontiers software package, developed by Aptima, Inc.) at home on a 10-inch tablet. For three months, participants were asked to keep a schedule of completing 5 sessions of cognitive training per week, on different days, with each session lasting approximately 45 minutes (no reminders were involved). Training was composed of a variety of tasks, including gamified N-back working memory and inductive reasoning training. The software unobtrusively monitored adherence and wirelessly transmitted data to a central server (similar to the methods proposed later). The figure depicts the percentage of participants who engaged in N-back training over three months (left). Importantly, long-term adherence was a significant challenge. Although most participants engaged with the intervention during the first three weeks, by the 12th week only about half (53%) of participants engaged in training. Other training activities demonstrated a similar pattern of adherence decline. This result has important implications, not just for the ability of cognitive interventions to deliver an effective dose within the population, but for the ability of intervention studies to evaluate the impact of treatments to which study participants do not adhere. Instead of measuring adherence by whether any training occurred each week, when adherence is defined by whether participants completed the required number of sessions in a week, fewer than 40% of all participants received the prescribed training dose during the last week.



These data, along with previous studies that have used this software in our lab, indicate that the task is ideal to study this issue, and that the protocol poses minimal risk

s.

3.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

As described in the aforementioned Cochrane review, previous studies did not assess the effects of technology-based adherence supports that were adaptive and personalized. This represents the major scientific contribution of the proposed study. Scientific and scholarly work on adaptive, tailored, and custom interventions (e.g., Fadhil, 2017; Lustria et al., 2013; Panchanathan, Chakraborty, & McCaniel, 2016a) suggest this new approach has promise.

4.0 Study Endpoints*

4.1 Describe the primary and secondary study endpoints.

The study endpoint will occur 4 months after participants have received their tablet to engage in cognitive training.

5.0 Study Intervention/Investigational Agent

1.1 Description: Cognitive training will be delivered via a 10-inch computer tablet provided to participants. Cognitive training will be in the form of the Mind Frontiers game. Mind Frontiers presents seven different gamified neuropsychological tasks that are aimed at exercising working memory, processing speed, executive control, and spatial reasoning. Participants will be randomized into one of two conditions across two phases. Study participants will be asked each week to train for five sessions of 45-minutes each on five separate days. This poses a significantly greater adherence challenge (as indicated by pilot data, see above). In the reminder only condition, participants will receive an SMS message when it has been determined that they have not adhered to the prescribed intervention protocol for the week (e.g., when three days have accumulated in a week without training activity). This prompt will occur the morning after non-adherence for the week has been determined, and will encourage participants to engage in training each day for the rest of the week to minimize non-adherence. In the smart adherence support condition, this message will be timed based on preference and history information. Further, there will be additional support for participants who appear to have ceased training, be experiencing an adherence holiday, or exhibiting inconsistent gameplay. In these cases, preemptive prompts at the beginning of training weeks will provide encouraging support to resume training, with the timing of these prompts being determined by history, preferences, and responses to previous prompts. In the smart adherence support condition participants will also have the opportunity to "snooze" reminders for certain periods of time in the event of illness or travel.

At the start of the study, when participants are given their tablets, a subset of participants (10) randomly chosen will also be asked to wear either a fitness tracker or smartwatch during the study. These are commercially available devices such as a Fitbit or a or a

Samsung Galaxy Watch Active 2 (40mm). They will not be asked to use these devices to perform any specific tasks, but instead we intend to interview participants about their experiences wearing the devices. In the future, such devices might be useful in supporting adherence to home-based interventions by providing reminders when adherence has failed. Participants will be provided with standard manuals that come with the smartwatch.

5.1 Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

- *NA*

5.2 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- *NA*

6.0 Procedures Involved*

6.1 Describe and explain the study design.

Participants will be randomized to either the standard or smart adherence reminder condition. Participants will be asked to engage in regular 45-minute training sessions, 5 days per week for four months. Each session will require participants to play each of the games in the Mind Frontiers software suite. If the end of the week approaches and participants are not on schedule to complete their five sessions (e.g., they have not engaged in training for three days), a reminder prompt will be presented. This will push participants toward minimizing the number of missed session per week. As described previously, the smart adherence support system will provide preemptive prompts at the start of the week during apparent study discontinuation/adherence holidays. Individual difference variables will be collected pre-intervention, and measures of attitudes and perceptions of the reminder system will be collected post-intervention – see Table 1.

Table 1. Individual Difference Measure Predictors

Measure	Dimension	Motivation	Source
Demographics Questionnaire	basic demographics	CREATE model of Tech Adoption	Center for Research and Education on Aging and Technology Enhancement
Shipley Vocabulary	cognition: crystalized ability	CREATE model of Tech Adoption	Zachary & Shipley (1986)
WAISS-III Information	cognition: crystalized ability	CREATE model of Tech Adoption	Wechsler (1997)

Letter Sets	cognition: fluid ability	CREATE model of Tech Adoption	Ekstrom, French, Harman, & Dermen (1976)
Trails B (minus Trails A)	cognition: fluid ability	CREATE model of Tech Adoption	Reitan (1955)
Perceived Deficits Questionnaire	cognition: subjective cognition	Senior Technology Adoption Model	Sullivan et al. (1990)
36-Item Short Form Survey	general health	Senior Technology Adoption Model	Ware & Sherbourne (1992)
Cognitive Training Belief Scale	perceived usefulness of brain training	Pilot Data/Senior Technology Adoption Model	Rabipour & Davidson (2015)
Big Five Inventory	personality	Pilot Data, Personality and adherence literature	Donnellan, Oswald, Baird, & Lucas, (2006)
The General Self-Efficacy Scale (GSE)	self-efficacy	CREATE model of Tech Adoption	Schwarzer & Jerusalem (1995)
Mobile Device Proficiency Questionnaire	technology proficiency	CREATE model of Tech Adoption	Roque & Boot (2018)
Technology Readiness Index 2.0	technology attitudes	CREATE model of Tech Adoption	Parasuraman & Colby (2015)
Dementia Worry Scale	concerns regarding cognition	Health Belief Model	Kinzer et al. (2016)
Perceived Susceptibility to Cognitive Decline	concerns regarding cognition	Health Belief Model	Tiro, Vernon, Hyslop & Myers (2005)
Expectations Regarding Aging Survey	perceptions of aging	Health Belief Model	Sarkisian, Hays, Berry, & Mangione (2001)
Awareness of Age-Related Change 50-Item Questionnaire	perceptions of aging	Health Belief Model	Brothers, Gabrian, Wahl, & Diehl (2018)
Lifestyle Profile	habit formation	NA	Walker, Sechrist, & Pender (1995)
Martin and Park Environmental Demands (MPED) Questionnaire	busyness	NA	Martin & Park (2003)
ASK-20	habit formation	NA	GlaxoSmithKline (2013)
The Big Five Inventory–2 (BFI-2)	personality	NA	Soto & John (2017)
Self-Efficacy of Cognitive Training	self-efficacy (domain specific)	Health Belief Model	NA
NASA-TLX	training workload	Health Belief Model	NASA

Digit Symbol Substitution	cognition	CREATE model of Tech Adoption	Wechsler (1981)
Montreal Cognitive Assessment (MOCA)	Cognition	CREATE model of Tech Adoption	Z. Nasreddine (2004)

We will also use the remote cognitive assessment tool COGTEL (*Kliegel, M., Martin, M., & Jäger, T. (2007). Development and validation of the Cognitive Telephone Screening Instrument (COGTEL) for the assessment of cognitive function across adulthood. Journal of Psychology: Interdisciplinary and Applied, 141(2), 147–170.)*

This brief, online assessment of cognition will provide a more reliable assessment of cognition in additon to already admnistered measures.

All participants will receive a tutorial and remote instruction on how to engage in Mind Frontiers training software, based on training developed in our lab for similar projects.

The primary measure of interest is intervention adherence – how many sessions of training are completed over the 4-month intervention window.

Participants (10) randomly chosen to wear either a fitness tracker or smartwatch during the study will be interviewed at the end of the study regarding their experiences. Questions will include: 1) Were there specific barriers that made it difficult to continue to wear the device over the course of the study? 2) Were there particular strategies you used to remember to wear the device? Were there things that encouraged you to keep using it? 3) What are your likes and dislikes about the device? 4) Did you find the device useful? What did you use it for?

No data will be collected from these devices.

References:

Donnellan, M. B., Oswald, F. L., Baird, B. M., & Lucas, R. E. (2006). The mini-IPIP scales: tiny-yet-effective measures of the Big Five factors of personality. *Psychological Assessment*, *18*(2), 192-203.

Ekstrom, R. B., Dermen, D., & Harman, H. H. (1976). *Manual for kit of factor-referenced cognitive tests* (Vol. 102). Princeton, NJ: Educational Testing Service.

Rabipour, S., & Davidson, P. S. R. (2015). Do you believe in brain training? A questionnaire about expectations of computerised cognitive training. *Behavioural Brain Research, 295*, 64–70.

Reitan, R. M. (1955). The relation of the trail making test to organic brain damage. *Journal of consulting psychology*, *19*(5), 393-394.

Roque, N. A., & Boot, W. R. (2018). A new tool for assessing mobile device proficiency in older adults: the mobile device proficiency questionnaire. *Journal of Applied Gerontology*, *37*(2), 131-156.

Parasuraman, A., & Colby, C. L. (2015). An updated and streamlined technology readiness index: TRI 2.0. *Journal of Service Research*, *18*(1), 59-74.

Sullivan. (1990). Perceived deficits questionnaire (PDQ).

Schwarzer, R., & Jerusalem, M. (1995). Generalized Self-Efficacy scale. In J. Weinman, S. Wright, & M. Johnston, Measures in health psychology: A user's portfolio. Causal and control beliefs (pp. 35-37). Windsor, UK: NFER-NELSON.

Ware Jr, J. E., & Sherbourne, C. D. (1992). The MOS 36-item short-form health survey (SF-36): I. Conceptual framework and item selection. *Medical Care*, 473-483.

Wechsler, D. (1997). Wechsler adult intelligence scale-III.

Zachary, R. A., & Shipley, W. C. (1986). *Shipley institute of living scale: Revised manual*. WPS, Western Psychological Services.

6.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

Training and assessment tasks involve computer games and measures of cognition anticipated to involve minimal risk. Individual difference variables will be collected pre-intervention (across three days, 2-3 hour sessions), and measures of attitudes and perceptions of the reminder system will be collected post-intervention (1 day). Surveys do not ask sensitive questions, and participants will be free to not partake in any measure they find aversive and they will be allowed to skip questions they do not wish to answer.

The cognitive training will take the form of simple games, for example, see below for a "safe cracking" game that involves detecting patterns:



An inductive reasoning training task within the tablet-based Mind Frontiers software, similar to the inductive reasoning training within the ACTIVE trial. In this example, cognitive training is presented as a safe-cracking mini-game.

Risk of wearable devices are anticipated to be very minimal, no different from wearing a watch. Participants will be told that they can abandon use of the wearable device at any time under no penalty – they can still continue in the study and they will still receive financial compensation. They will be told to contact the experimenter and discontinue use of the wearable in the event of any adverse event (e.g., skin rash).

6.3 Describe:

- *Procedures performed to lessen the probability or magnitude of risks.*
    - No significant risks are anticipated for the proposed study. Pre-screening procedures will help identify those who may not be cognitively healthy and able to provide consent. The potential risks and discomforts will be discussed during the written informed consent process. The process will include information as to what to do and who contact if any discomfort occurs. The option to withdraw without penalty at any time will be emphasized. If a participant experiences discomfort or distress the researcher will stop the experiment immediately. When he or she feels able, the participant will be reminded of the option to discontinue participation,

contact the psychology clinic for advice at no charge, or continue the experiment.

- *All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.*
    - *NA*
- *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*
    - *See Table 1 and attachments*

6.4 What data will be collected during the study and how that data will be obtained.

- Paper records (survey and cognitive data) will be kept in locked files in a secure storage area at the William Johnson Building WJB 2022 (eHealth Lab) with names separate from identification numbers. All computer files (electronic surveys and adherence data) will be kept on password protected computers located in secure offices at the eHealth Lab. Data records will be identified only by a study ID number. They will not contain any personal information, such as name, social security number, address, or phone number. Identifying information used to contact participants will be kept separate in a separate password protected spreadsheet.

6.5 If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.

- *NA*

6.6 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

- *NA*

7.0 Data and Specimen Banking*

7.1 If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

- *NA*

7.2 List the data to be stored or associated with each specimen.

- *NA*

7.3 Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

- *NA*

8.0 Sharing of Results with Subjects*

8.1 If a participant requests their results, these results will be provided to the individual. However, the individual will be informed that the results that they receive are in no way diagnostic of any health condition and be advised that if they have concerns about his/her cognition that they should consult their physician.

9.0 Study Timelines*

9.1 Individual participants will participate for 4 months. All participants will have completed participation within 4.5 years of the study start, and all data analysis will be completed within 5 years.

10.0 Inclusion and Exclusion Criteria*

10.1 Describe how individuals will be screened for eligibility.

- Phone screening will take place to determine eligibility. Phone questions will determine basic eligibility with respect to age, hearing, and vision. Cognitive status will be checked remotely using the MMSE (*https://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/GetPdf.cgi?id=phd001525.1*).

10.2 Describe the criteria that define who will be included or excluded in your final study sample.

- Participants will include non-cognitively impaired older adults (age 65+) recruited from Tallahassee and Leon County. In total, 190 participants will be randomly assigned to one of two conditions that will involve smartphone reminder prompts to engage in cognitive assessment/training. The primary aim of this study is to uncover methods to boost adherence to these protocols so that cognitive decline can be detected and addressed early. Participants must have normal or corrected to normal visual acuity, and must pass a dementia screening. Participants will be required to have 20/60 vision with or without correction (Snellen Acuity Test). Participants who demonstrate signs of dementia will be excluded (a score of 26 or less on the Mini Mental State Examination - MMSE, using the Mungus Correction). Additionally, participants with self-reported Parkinson's, Alzheimer's disease, or any

other neurodegenerative disease will be excluded from participation, as well as participants with a terminal illness. Exclusion criteria will also include being blind or deaf (since individuals would be unable to engage in cognitive assessment), or severe motor impairment (severe tremors or debilitating arthritis in the hands). Only participants who plan to be in the area for the next four months will be included in the study to ensure that they can return for follow-up testing.

10.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)

- Only cognitively intact older adults (ages 65+) will be included in the sample.

11.0 Vulnerable Populations*

11.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

- NA

12.0 Local Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally.

- Participants will include non-cognitively impaired older adults (age 65+) recruited from Tallahassee and Leon County. In total, 190 participants will be randomly assigned to one of two conditions that will involve smartphone reminder prompts to engage in cognitive assessment/training.

12.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

- This study focuses on adherence, even if participants drop out of the study, useful information is gained (adherence drops to 0). The number of participants who are screened and enter is anticipated to the total sample (190).

13.0 Recruitment Methods

Several recruitment strategies will be implemented. First, at Florida State University, the Institute for Successful Longevity has developed a participant registry containing the contact information of close to 3,000 older adults who have indicated willingness to participate in research studies. This has proven an extremely useful recruitment tool for

other studies. Participants will also be recruited through advertisements in newspapers, radio and television advertisements, placement of flyers in community organizations and senior centers, mailing lists, voter registration lists, attendance at senior functions in community agencies and churches, and through contacts with community partners. We have found that this broad approach can help ensure the recruitment of a diverse sample. In terms of retention over the four-month study period, a check-in call will occur within the first week of the intervention, and midway through the intervention (three months) to encourage retention. However, more frequent contact will be avoided as to not influence intervention adherence, the primary outcome of the proposed study. Participants will be compensated financially to promote retention – $200 dollars for their time during in-remote assessment sessions and home-based training, with an additional $200 bonus awarded at the end of the study.

To facilitate remote sending of payments, all payment will be in the form of Amazon Gift Certificates.

As in previous adherence studies conducted in our lab, for participants indicating a desire to quit the study, we will offer the opportunity to remain in the study while engaging in a level of home training that better fits with their preference and schedule. This allows the participant to be retained as a poor adherer, instead of losing the participant as a "drop."

14.0 Withdrawal of Subjects*

Participants will be told that they can withdraw at any time and not be penalized. They will also be told that, if they no longer wish to engage in the intervention, they can cease gameplay or play to a lesser extent if they wish, and still be compensated if they indicate an inclination to withdraw. We do not anticipate any reason for experimenters to initiate a withdrawal, the only withdrawals will likely occur due to participants indicating an unwillingness to continue or a health or life change (e.g., moving out of the area) that would require discontinuation.

15.0 Risks to Subjects*

The primary risk is frustration if participants do not perform as well as they would like to perform, and fatigue due to the testing session. Participants will receive SMS text messages when they do not complete training/assessment assignments on time. These messages may represent a mild annoyance.

16.0 Potential Benefits to Subjects*

NA

17.0 Data Management* and Confidentiality

Participant confidentiality will be protected in that each individual participant can be connected to his or her data with a numerical key only known by the PI, lab coordinator, and post-doctoral researcher. This key is contained within a password protected file. All paper files, including consent forms, paper-and-pencil tests, and demographic information collected will be locked in file cabinets at all times. Consent forms will be stored separate from other participant data. These file cabinets are located in room WJB 2022, Dr. He's lab space. File cabinets can only be accessed by Dr. He and project staff and graduate students. Computer files containing performance data will be stored on

password protected computers within the lab, and these files will have no identifying information other than a numerical key. Lab access is restricted with a swipe card system (linked to faculty, staff, and student ID cards) to investigators, their graduate students, study staff, and approved undergraduate assistants.

Home-based cognitive assessment and training data will be encrypted and sent to a secure, password-protected server and database. This database will not include information related to participant identity. Only investigators and project staff/students will have access to this database.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

This research does not involve more than Minimal Risk to subjects.

19.0 Provisions to Protect the Privacy Interests of Subjects

Participant confidentiality will be protected in that each individual participant can be connected to his or her data with a numerical key only known by the PI, lab coordinator, and post-doctoral researcher. This key is contained within a password protected file. All paper files, including consent forms, paper-and-pencil tests, and demographic information collected will be locked in file cabinets at all times. Consent forms will be stored separate from other participant data. These file cabinets are located in the eHealth Lab directed by Dr. Zhe He. File cabinets can only be accessed by Dr. Zhe and project staff and graduate student. Computer files containing performance data will be stored on password protected computers within the lab, and these files will have no identifying information other than a numerical key. Lab access is restricted with a swipe card system (linked to faculty, staff, and student ID cards) to investigators, their graduate students, study staff, and approved undergraduate assistants.

Home-based cognitive assessment and training data will be encrypted and sent to a secure, password-protected server and database. This database will not include information related to participant identity. Only investigators and project staff/students will have access to this database.

20.0 Compensation for Research-Related Injury

NA

21.0 Economic Burden to Subjects

Because the study involves text messages, some minor data charges may occur. This is offset through participant compensation.

22.0 Consent Process

22.1 Consent will be obtained in the lab during the first visit using SOP: Informed Consent Process for Research (HRP-090). The MMSE will be used in advance of this measure to ensure participants can provide consent. Participants will be informed of their rights as participants. They will be completely informed as to the nature of the experiment and will be reminded of the right to withdraw from participation with no penalty. This will be emphasized verbally as well as within the

consent form. Participants are encouraged to contact the researchers immediately in the unlikely event of physical, emotional, or psychological discomfort. Participants will be given a phone number (the PIs office number) to contact with any questions or concerns, and another number (the PIs cell phone) to report any immediate instances of discomfort or adverse events. In the unlikely case of a serious emergency, participants will be directed to first contact emergency services. Participants will also be given information about how to reach the IRB if they have any questions or concerns regarding their rights as a participant.

23.0 Process to Document Consent in Writing

23.1 We will be using the "SOP: Written Documentation of Consent (HRP-091)."

24.0 Setting

- All data collection involving individual differences measures of attitudes, cognition, and technology experience will remotely over Zoom or Qualtrics Survey. Adherence data will be collected as participants engage in gameplay within their own home.

25.0 Resources Available

25.1 The eHealth Lab directed by Dr. Zhe He, consisting of a fully furnished suite with 3 separate rooms and a common room will be used for the onboarding session of this project. The lab is located in William Johnson Building WJB 2022. Each room can be used to simultaneously collect data from participants. Each room has a table, a chair, and computer/monitor for computer-based data collection. analtical analysis and experiment development software is available throughout the eHealth lab (NVIVO, SPSS, R, Python, Microsoft Office). The lab contains five large locking file cabinets for the secure storage of participant records, consent forms, and participant payment.

Experience with larger studies and similar populations in Tallahassee justify the feasibility of recruitment. A recent 1-yearlong study included over 200 older adults.

All graduate students, post-Docs, and experimenters will undergo thorough protocol training until the PIs are satisfied with their performance and their knowledge of how to deal with potential, but unlikely, adverse events.

26.0 Multi-Site Research*

N/A. This study does not involve multiple sites.