

Development and Validation of Virtual Reality Cognitive Training for Older Adults with Mild Cognitive Impairment: Protocol for a Mixed-Methods Program Evaluation Study

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Introduction: As research on cognitive training methods for older adults with mild cognitive impairment (MCI) progresses, fully immersive virtual reality cognitive training (fi-VRCT) has shown promise in enhancing cognitive function. However, its effectiveness in improving instrumental activities of daily living (IADL) and fostering independence is still unclear. This study aims to address these uncertainties by developing and validating a fi-VRCT program focused on IADL, with the goal of enhancing both cognitive function and IADL performance in older adults with MCI.

Methods and Analysis: This mixed methods program evaluation study consists of three phases: feasibility, intervention, and extension. In the feasibility phase, we will implement fi-VRCT in real-world community settings and invite 20 older adults with MCI to participate in a single training session. Participants will provide feedback through questionnaires and individual interviews. The intervention phase will involve a double-blind, cluster-randomized controlled trial with 52 older adults with MCI, who will be randomly assigned to either the fi-VRCT or control groups. Both groups will complete 16 sessions over eight weeks, with cognitive and functional performance assessed at various intervals. During the extension phase, feedback will be gathered from 26 participants who underwent fi-VRCT through focus group interviews and ongoing questionnaires. Quantitative and qualitative findings will be synthesized to refine the fi-VRCT program and elucidate training outcomes. Ultimately, fi-VRCT has the potential to enhance cognitive and functional abilities in older adults with MCI in community settings.

Ethics and Dissemination: Ethical approval has been obtained from the Research Ethics Committee at National Taiwan Normal University (202312EM009). The research findings will be disseminated through reputable, peer-reviewed journals and professional international conferences to engage and inform academic and clinical audiences.

Trial Registration: NCT06392412.

Keywords: cognitive training, instrumental activity of daily living, mild cognitive impairment, mixed-methods, older adults, virtual reality

Background

Mild cognitive impairment (MCI) is a prevalent cognitive impairment affecting older individuals.^{1,2} It is characterized by more pronounced cognitive difficulties in older adults compared to their peers of the same age, particularly in memory

and reasoning abilities.³ These cognitive changes disrupt their engagement in daily activities and are noticeable to family and friends.^{4,5} Recent research suggests a correlation between elevated levels of depression and reduced financial capacity in individuals with MCI when depression is present simultaneously.^{6,7} Mild cognitive impairment is widely viewed as a preclinical stage of early dementia, indicating a higher likelihood of progression to dementia.³ However, studies indicate that older adults with MCI may have the potential to return to healthy cognitive function or delay the onset of dementia.^{8–10} Longitudinal research shows that older adults with better cognitive performance^{8,9} or those who actively participate in task-oriented activities¹⁰ are more likely to transition from MCI to healthy cognition. These findings highlight the potential for improving cognitive performance in older individuals with MCI, suggesting that cognitive training could be one effective strategy to help restore their cognitive function.

Cognitive training (CT) is a non-pharmacologic approach that involves structured and controlled exercises to improve specific cognitive functions. It is frequently used to enhance cognitive abilities in older adults, focusing on reversing cognitive decline, promoting cognitive stability, and maintaining independence.^{11,12} Research has demonstrated that CT can improve overall cognitive performance, processing speed, memory, working memory, and executive function in older adults with MCI.^{13–16} Additionally, studies suggest that integrating robot programming with a tangible and manipulative system could be beneficial in CT for individuals with MCI.¹⁷ However, it remains uncertain whether improvements in certain cognitive regions translate into enhanced performance in instrumental activities of daily living (IADL) for older adults with MCI.^{13,18,19} The concepts of “near transfer” and “far transfer” describe the extent to which benefits gained from training in one activity can be applied to different tasks.^{20,21} By aligning training activities more closely with real-world tasks and situations, there is potential for individuals to transfer the skills and abilities acquired through CT into their everyday lives. Nevertheless, few CT programs for older adults are designed around real-world activities.

Virtual reality (VR) is increasingly used to enhance and sustain physical,²² cognitive,²³ psychological,²⁴ and social skills²⁵ of older adults. As described by Burdea and Coiffet (2003), VR entails a high-end user-computer interface involving real-time stimulation and interactions of an embedded subject through multiple sensorial channels (eg, visual and auditory, sometimes haptic, even smell and taste, if possible), based on a synthetic environment in which the subject feels his presence.²⁶ The concept of presence refers to the subjective experience of existing within a virtual world, where individuals perceive the artificial environment as if it were real.^{27,28} Virtual reality is classified into three types based on the level of immersion experienced by participants and their connection to the physical world: fully immersive, semi-immersive, and non-immersive. Fully immersive VR isolates participants from the physical environment and immerses them in a three-dimensional setting with multiple sensory inputs.^{25,29} Enhanced immersion can intensify the sense of presence, which improves participant engagement and training effectiveness.^{23,27} Immersive and lifelike VR environments can elicit appropriate behavioral responses, facilitating the application of skills learned in virtual settings to real-life situations.²⁹ Moreover, VR possesses several features that make it particularly advantageous for developing CT programs for older adults: (1) VR provides adaptable and safe environments for older adults,^{25,29,30} (2) VR improves the transfer of training to real-life scenarios through lifelike surroundings,^{29,31,32} (3) VR boosts motivation and engagement during training sessions,^{25,29,32} and (4) VR offers tailored training programs for older adults.^{25,29,32–34}

Current evidence supports the effectiveness of fully immersive virtual reality cognitive training (fi-VRCT) as a beneficial intervention for enhancing cognitive abilities in older adults with MCI. Many studies have demonstrated improvements in various cognitive domains, including attention, processing speed, memory, working memory, visuospatial ability, executive function, global cognition, and language.^{31,35–39} However, older adults with MCI may face challenges in transferring newly acquired skills from interventions to real-life tasks and situations.²⁰ Notably, one study reported improvements in IADL ability following fi-VRCT.³⁶ Other studies indicated that older adults generally enjoy using VR.^{40–42} Feedback from older adults with MCI suggests they often feel more relaxed, comfortable, active, and adventurous when engaging with fi-VR, experiencing reduced anxiety, tension, and worry afterward.^{40,42} Side effects or disorientation were minimal and rarely reported.^{40,41} The engaging and enjoyable nature of fi-VR greatly enhances motivation, engagement, and adherence to CT, thereby positively influencing VR training outcomes.

While research on fi-VRCT in older adults with MCI is increasing, more evidence is needed to comprehensively assess its effectiveness. Specifically, there is a gap in fi-VRCT programs focusing on daily living tasks and IADL within existing gamified interventions. Furthermore, a deeper understanding of the long-term effects of fi-VRCT on older adults

with MCI is necessary. Emotion and subjective experiences play crucial roles in learning and skill transfer,^{43,44} yet few studies have thoroughly examined the impacts of emotional responses and personal experiences during fi-VRCT. Hence, this study aims to (1) develop and assess the feasibility of a fi-VRCT program centered on IADL for older adults with MCI, (2) implement and evaluate the effectiveness of this fi-VRCT program in older adults with MCI, and (3) investigate the underlying mechanisms of the fi-VRCT program related to IADL in older adults with MCI and refine this intervention accordingly.

Methods and Analysis

We propose a comprehensive longitudinal study comprising three phases: feasibility, intervention, and extension, to achieve our objectives. The feasibility phase will focus on developing a fi-VRCT and assessing its applicability and acceptability in real-world community settings. In the intervention phase, we will implement the fi-VRCT through a cluster-randomized controlled trial involving older adults with MCI. This trial will assess the effects of this fi-VRCT on cognitive and everyday functioning. The extension phase will incorporate participant feedback to explore the mechanisms behind training outcomes and further refine the fi-VRCT. This study will utilize a mixed methods program evaluation design as described by Creswell and Clark (2017)⁴⁵ (Figure 1). We will apply an exploratory core design from the feasibility to the intervention phase, followed by an explanatory core design from the intervention to the extension phase. This integrated approach will provide valuable insights that surpass what could be obtained from purely quantitative or qualitative methods, thereby providing a solid foundation for addressing our research objectives with robust evidence.

Feasibility Phase

Development of the fi-VRCT

This intervention will be designed as a series of cognitive activities woven into a narrative centered around preparing meal for significant others. The cognitive journey starts at home, where participants select their dining companions and the meals they wish to share. They then familiarize themselves with the recipes, confirming and memorizing the

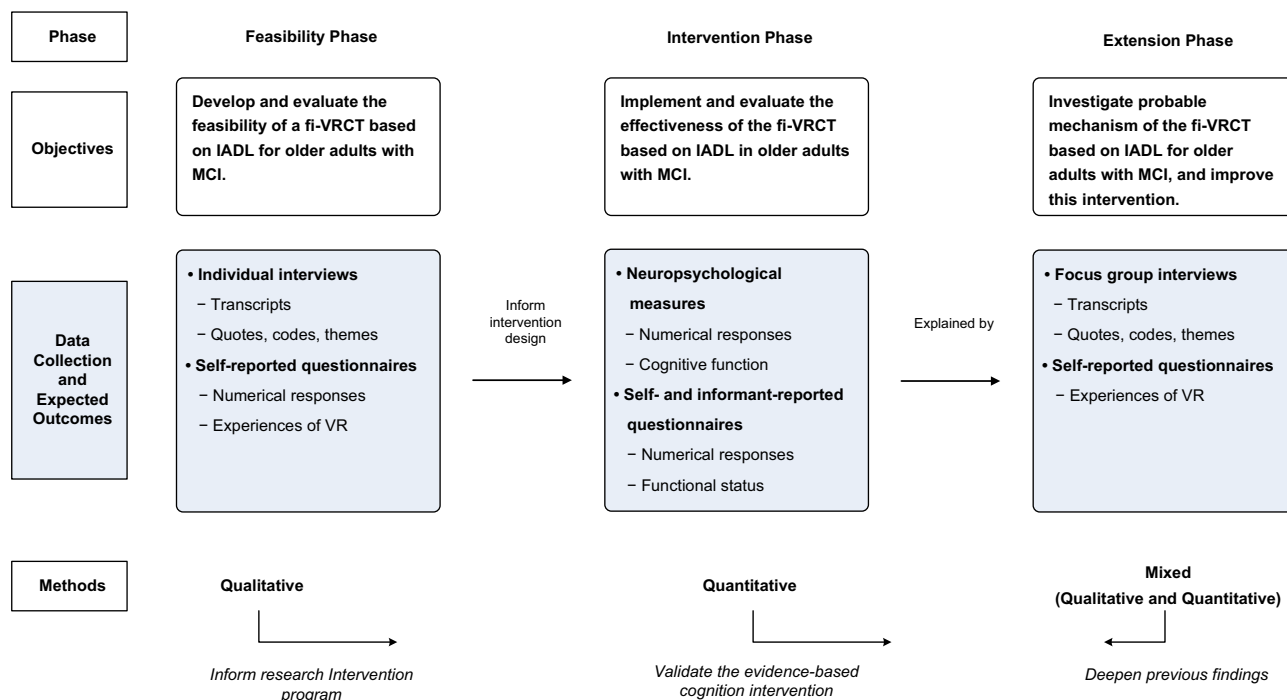


Figure 1 Flowchart of research design and the relationship among study phases.

necessary ingredients. Next, they move to a marketplace, where they have to skillfully identify and select the correct ingredients. Returning to the kitchen, participants review the recipe, memorize the cooking techniques, and determine the sequence for adding each ingredient. Following the recipe instructions, they proceed to prepare the meals step-by-step. The initial choices introduce a psychological element to enhance motivation, and as the narrative unfolds, the activities progressively increase in difficulty based on the participants’ decisions. The selection of dinner companions and dishes plays a crucial role in determining the overall challenge level of the activity.

Evaluation of the Applicability and Acceptability of the fi-VRCT

Procedure

Participants for a 70-minute fi-VRCT session will be recruited from various community settings, including community centers, senior centers, and adult daycare centers. Each session will include a 10-minute warm-up with instruction, three 15-minute training segments, two 5-minute eye massages, stretching breaks between the training segments, and a 5-minute wrap-up. Researchers will conduct interviews to gather insights into participants’ experiences and will administer questionnaires to evaluate their sense of presence, immersion levels, and potential for cybersickness. This evaluation will help assess the applicability and acceptability of the fi-VRCT for older adults with MCI.

Participants

Table 1 outlines the estimated number of participants along with the specific inclusion and exclusion criteria for recruitment. We will employ convenience and snowball sampling methods to recruit participants from various community settings, such as community centers, senior centers, and adult daycare centers, utilizing referral networks or flyer-based recruitment strategies.

Apparatus: Meta Quest 3

The Meta Quest 3 provides a fully immersive VR experience with a head-mounted display and two handheld controllers. It offers 110° horizontal and 96° vertical field of view, featuring 2064 × 2208 pixels per eye and a smooth 90 hz refresh rate. Equipped with integrated stereo speakers with 3D spatial audio, tactile feedback controllers, as well as hybrid computer vision and machine learning sensors that track users’ gestures, the device significantly enhances the immersive experience. During the intervention, participants will wear the headset and use the controllers to actively interact with the virtual environment. The VR system provides substantial benefits due to its engaging and interactive features.

Qualitative Data Collection and Analysis

The study will use in-depth, semi-structured individual interviews to collect qualitative data on participants’ experiences, emotions, and perspectives regarding the fi-VRCT. Open-ended questions will be used to encourage detailed responses, and meticulous records will be kept to ensure data accuracy and completeness, including audio recordings, verbatim transcriptions, and interview notes. Data will be analyzed using thematic analysis, following Braun and Clark’s (2012) guidelines.⁴⁶ This systematic procedure includes data familiarization, initial code generation, refinement, reorganization, and identification of overarching themes. The final report will present these themes through an analytical narrative,

Table 1 Participants Recruitment and Inclusion/Exclusion Criteria Across Three Study Phases

| Phase | Estimates (n) | Inclusion Criteria | Exclusion Criteria |
|--------------|--|--|--|
| Feasibility | 20 participants | (1) Aged 65 or above. (2) The Montreal Cognitive Assessment score between 19 and 25. (3) Capability to follow directions and do tasks. | (1) History of dementia. (2) Previous neurodegenerative illness diagnosis. (3) Severe medical or surgical problems. (4) Major psychological disorders. (5) Inability to use VR system. |
| Intervention | 52 participants (2 groups: fi-VRCT, control) | | |
| Extension | 26 participants (1 group: fi-VRCT) | | |
| | 26 caregivers | (1) Aged 18 or above. (2) Significant informative caregiver of the participant. (3) Possessing knowledge regarding the participant’s health and functional status. | (1) Inability to read and complete the questionnaire. |

supported by relevant examples and quotes. To facilitate data management and organization, Microsoft Excel and MAXQDA will be utilized for data collection and preliminary analysis. This process ensures the rigor and thoroughness of the analysis by developing a standard codebook and visualization tools.

Quantitative Data Collection and Analysis

Table 2 presents quantitative measures, including those for cognitive screening and VR experiences. Descriptive statistics will be used to summarize participants' characteristics and their responses to the questionnaire. Statistical analyses will be performed using IBM SPSS Statistics software package, version 26, for Windows (IBM Corp., Armonk, NY, USA).

Intervention Phase

Study Design and Procedure

This double-blind, cluster-randomized controlled trial is designed to assess the effectiveness of fi-VRCT on cognition and daily functioning in older adults with MCI. In this phase, we will employ convenience and snowball sampling methods to

Table 2 Quantitative Measures Used in the Three Study Phases

| Outcomes | Assessment | Measure | |
|---|--|--|------|
| Cognitive Screening (will be used in the Feasibility and Intervention Phases) | | | |
| Global cognition | Montreal Cognitive Assessment | Global cognition using 12 items with higher scores indicating better cognition. | [47] |
| Virtual Reality Experiences (will be used in the Feasibility and Extension Phases) | | | |
| Sense of presence | Presence Questionnaire, Version 2.0. | Feelings of being present in a virtual world using three categories: involved/control, natural, and interface quality. | [48] |
| Immersion levels | Immersive Tendencies Questionnaire, Version 2.0. | Capacity to completely engage in a virtual environment using three subscales: engagement, focus, and games. | [48] |
| Discomfort levels | Simulator Sickness Questionnaire | During virtual engagement, discomfort levels are measured using oculomotor, disorientation, and nausea. | [49] |
| Attitude to technology adoption | Technology Acceptance Model 3 | Confidence and attitude levels toward technology. Sub-scales will be used include Perceived Ease of Use, Perceptions of External Control, Computer Anxiety, Perceived Enjoyment, and Behavioral Intention. | [50] |
| Feeling of enjoyment | Emotional State | Emotional responses during virtual engagement with 16 items grouped into positive and negative domains. | [40] |
| Cognitive Performance (will be used in the Intervention Phase) | | | |
| Memory | Wechsler Memory Scale, Third Edition | Several memory abilities: visual, auditory, immediate, delayed, and working memory. Subtests, including Family Pictures, Spatial Span, and Word List, will be used. | [51] |
| | Wechsler Adult Intelligence Scale, Fourth Edition | Auditory working memory will be assessed by subtest Digit Span, including Digit Span Forward, Digit Span Backward, and Digit Span Sequencing. | [52] |
| Processing speed | Wechsler Adult Intelligence Scale, Fourth Edition | Subtest Coding, a digit substituted with a symbol, will be used to assess processing speed. | [52] |
| Executive function | Stroop Color-Word Test | Executive function by reading words or naming ink colors quickly within a defined time limit, including congruent and incongruent stimuli. | [53] |
| Functional Status (will be used in the Intervention Phase) | | | |
| Functional independence | Lawton Instrumental Activities of Daily Living | Participants report their current performance on eight IADLs, from complete independence to complete inability to perform it. | [54] |
| | Amsterdam Instrumental Activities of Daily Living Questionnaire, Short Version | Caregivers of participants report participants' performance on seven categories of IADL with levels of difficulty ranging from easy to impossible to do. | [55] |
| Functional mobility | Timed Up and Go | Participants perform sequential motor tasks: stand up from a chair, walk 3 meters, turn around, walk back to the chair, and sit down. | [56] |

recruit participants from community centers, senior centers, and adult daycare centers. Recruitment will involve referrals and flyers, with individuals from the same facility randomly assigned to either the fi-VRCT group or the control group. The intervention will consist of 16 sessions over eight weeks, with two sessions per week, each lasting 70 minutes. Assessments will be scheduled by evaluators at the beginning, immediately after the intervention, and during a three-month follow-up, while ensuring blindness to participants' group assignments.

Power Analysis and Sample Size Estimate

Drawing from fi-VRCT studies, effect sizes for cognitive performance vary from small to medium ($d = 0.080$ – 1.315 ; after transforming, $f = 0.040$ – 0.657),^{35–38} while effect sizes for everyday functioning are large ($d = 0.87$; after transforming, $f = 0.435$).³⁶ Using a conservative estimate of a medium effect size ($f = 0.25$), this study will implement repeated measures analysis of variance (ANOVA) with a within-between interaction design for two groups and three measurements to determine the required sample size. With a statistical power of 90% and a significance level of 0.05 for a two-sided test, a total of 36 participants (18 in each group) is needed. Accounting for a potential attrition rate of 30%, the anticipated number of participants is 52 (26 in each group).

Participants

Table 1 displays the estimated number of participants along with the specific inclusion and exclusion criteria for recruitment.

Intervention

Each group, whether intervention or control, will consist of 2 to 3 individuals in a group setting.

fi-VRCT Group

The fi-VRCT, developed during the feasibility phase, aims to enhance attention, memory, and executive function. Each session will begin with a 10-minute instruction and warm-up, followed by three 15-minute training segments, each separated by two 5-minute breaks. A 5-minute wrap-up will conclude each section. Participants in the fi-VRCT will use the Meta Quest 3 head-mounted display and handheld controllers, with the intervention being administered by an experienced research assistant.

CT Control Group

The CT control program will feature cognitive board games aiming at improving various cognitive capacities, including attention, memory, and executive function. The duration and training dosage will be equivalent to those in the fi-VRCT group. This group will be led by certified community occupational therapists.

Data Collection

Table 2 shows the training outcome measures, which include assessments for cognitive screening, cognitive performance, and functional status. Participants will complete these assessments at baseline, immediately after the intervention, and during a follow-up assessment three months later.

Data Analysis

Descriptive statistics will be used to present participants' demographics and characteristics. To identify baseline differences between the two groups, independent t -tests and chi-square tests will be conducted. Non-significant findings will suggest effective randomization allocation. A two-way repeated measures ANOVA will be performed to evaluate the effects of the intervention at three key time points: baseline, post-intervention, and during a follow-up assessment three months later. This analysis will evaluate the significant effects of group, time, and the interaction between group by time. The significance criterion for all tests will be set at a probability level of 0.05. If a significant main effect or interaction is observed, a Bonferroni post hoc test will follow. Paired t -tests will be used to assess changes within each group before and after the testing at each time point.

The effect size will be calculated to gauge the magnitude of the intervention impact on the outcomes. Cohen's d , will represent the main effect, with effect size values of 0.2, 0.5, and 0.8 indicating small, medium, and large effects, respectively. The effect size of the interaction will be presented as partial eta squared (η^2), with classifications of small ($\eta^2 = 0.01$), medium ($\eta^2 = 0.06$), and large ($\eta^2 = 0.14$).⁵⁷

We will conduct mediation analyses to clarify the relationship between an independent and a dependent variable, mediated by a third variable, known as a mediator. Two parallel mediation analyses will explore the influence of pre-intervention global cognition on post-intervention functional independence and mobility, considering mediator variables, such as age, sex, and pre-intervention processing speed. The mediation analyses will be performed using the PROCESS functions for SPSS developed by Hayes (2018).⁵⁸ Specifically, we will employ PROCESS Model 4 for the parallel mediation model. All mediation models will be thoroughly analyzed using 5,000 bootstrap samples and 95% bias-corrected confidence intervals. Statistical analyses will be conducted using IBM SPSS Statistics software package, version 26, for Windows (IBM Corp., Armonk, NY, USA).

Extension Phase

Procedure

We will use a purposeful sampling method, allowing individuals who participate in the fi-VRCT group during the intervention phase to continue into the extension phase. Both qualitative and quantitative data will be collected and synthesized to gain a comprehensive understanding of the intervention outcomes and to refine the fi-VRCT. The qualitative exploration will provide in-depth insights into participants' responses to the outcomes and their adherence to interventions, thereby elucidating the reasons behind the training results. Furthermore, qualitative feedback will help identify factors that either facilitate or hinder the success of the fi-VRCT. This information is essential for improving cognitive interventions and preparing them for broader dissemination and implementation across various community contexts. The quantitative data will complement the insights gathered through qualitative analysis, providing additional perspectives and enhancing the overall understanding of the intervention effectiveness.

Data Collection

Qualitative Strand

Following implementing the interventions, we will conduct focus group interviews to gain a comprehensive understanding of participants' experiences, feelings, perceptions, and thoughts regarding the fi-VRCT. Each focus group will comprise participants from the same intervention group who have been engaged for two months. This arrangement will facilitate the sharing of nuanced and authentic feedback among participants and promote dynamic discussions. Through the use of open-ended questions, we aim to elicit detailed descriptions of experiences, while follow-up and probing questions will help uncover previously undisclosed information. The interviews will be audio-recorded and transcribed verbatim.

Quantitative Strand

Quantitative measures related to VR experiences are outlined in [Table 2](#). Participants will be required to complete these questionnaires at several intervals, including the initial, ninth, and final intervention sessions.

Data Analysis

Qualitative and Quantitative Data Analysis

The analysis process during the extension phase will closely align with the methods utilized in the feasibility phase. The qualitative data will be analyzed through thematic analysis, while the quantitative data will be subjected to descriptive statistics and paired t -tests.

Synthesis of Qualitative and Quantitative Findings

During the mixed stage, integration will be achieved through the use of joint displays, which will organize findings from both qualitative and quantitative approaches conducted during the intervention and extension phases. The themes identified from the qualitative interview analysis will help explain the quantitative findings obtained in the intervention

phases. Joint displays will juxtapose these results, connecting and presenting the findings. This visual representation will enhance the analysis and comparison of information from various perspectives, facilitating the extraction of overarching conclusions that extend beyond either the quantitative or qualitative strand alone.⁵⁹

Ethics and Dissemination

This study will be conducted in community settings and has obtained ethical approval from the Research Ethics Committee at National Taiwan Normal University (202312EM009). Participants will be required to provide informed consent prior to enrollment. Researchers will give a clear explanation of the research content and address any questions that participants may have prior to obtaining formal consent.

Participants will be interviewed to gather their experiences, feelings, and thoughts regarding the fi-VRCT, and these interviews will be audio-recorded for subsequent analysis. Additionally, participants will complete questionnaires related to their VR experiences, cognitive function, and functional daily self-care abilities. Researchers will maintain confidentiality regarding all identifiable records and personal data, ensuring that participants' identities are protected in published research results. Participants have the autonomy to decide their involvement and can withdraw consent at any time during the study without needing to provide reasons, ensuring that their rights remain unaffected.

The aim of this research is to develop and validate an effective fi-VRCT and share the findings with the community. To achieve this, we will conduct a feasibility study and a cluster-randomized controlled trial. Initial findings will be presented at international conferences, while primary results will be published in reputable, peer-reviewed journals to reach both academic and clinical audiences. We are dedicated to communicating our findings with clarity and transparency, using formal and concise language to reflect professionalism and expertise while preserving the original intent and meaning of the text.

Discussion

This trial utilizes a mixed methods approach to evaluate both the process and effectiveness of the intervention. By comprehensively gathering data from the target population, the study aims to quantitatively measure the intervention effects while qualitatively exploring the participants' experiences. This approach will aid in developing a CT program tailored for older adults with MCI in community settings. The findings of this study will significantly contribute to the establishment of an evidence-based and practical intervention for cognitive enhancement in older adults with MCI.

While this study has numerous strengths, it also has certain limitations. One such limitation is cluster randomization, which may lead to discrepancies in key sociodemographic and other background variables among groups at baseline. However, any variations will be appropriately accounted for during statistical analyses. Additionally, participant dropout is a concern. Given that the study encompasses an eight-week program with assessments at three distinct time points, participants have the option to withdraw from the program or subsequent assessments. Anticipating a potential dropout rate of 30%, we will adjust the projected number of participants accordingly.

Conclusion

This program evaluation study is expected to yield valuable insights into the processes and outcomes of the fi-VRCT. We will share the lessons learned with program planners, implementers, and policymakers. The findings from the process evaluation can be utilized to inform future design, implementation, and enhancements aimed at benefiting older adults with cognitive impairment.

Data Sharing Statements

The study materials and the details of all analyses are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

This study received approval from the Research Ethics Committee at National Taiwan Normal University (202312EM009). Prior to enrollment, all participants will be required to provide signed informed consent, which includes

consent for the publication of anonymized responses. All procedures will be conducted in accordance with the Declaration of Helsinki.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published. ICC drafted the initial version of the manuscript, and other authors offered feedback and made revisions. All authors have reviewed and approved the final version of the manuscript for publication.

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Disclosure

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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