Appendix I: AF01-34.1 Informed Consent Form [Clinical Trial]

Institutional Review Board of Dali Jen-Ai Hospital, Jen-Ai Medical Foundation

Informed Consent Form

We invite you to participate in this clinical trial. This informed consent form provides information about the study. The principal investigator or research staff will explain the details and answer any questions you may have.

IRB Protocol Number: 114-86 Project Number: Not Assigned Study Title: The Effects of Augmented Reality Treadmill Walking on Cognitive Function, Body Composition, Physiological Responses, and Acceptability in Older Adults: A Randomized Controlled Trial
Executing Institution: National Taiwan College of Performing Arts Contact Number: (02) 2936-7231 Principal Investigator: Cheng-En Wu Affiliation: National Taiwan College of Performing Arts Department/Title: Division of Physical Education / Assistant Professor Telephone: 0982-204905 Mobile: 0921-001460 Co-Principal Investigator: Wei-Yang Huang Affiliation: National Taiwan College of Performing Arts Department/Title: Division of Physical Education / Associate Professor Telephone: (02) 2936-7231 Mobile: (02) 2936-7231 24-Hour Emergency Contact: Cheng-En Wu Telephone/Mobile: 0982-204905
Participant's Name: Gender: Age: Mailing Address: Contact Number:
Study Period: Approximately from December 2024 to December 2025

1. Introduction and Background of the Study

With the global trend of population aging becoming increasingly severe, enhancing the physical and mental well-being of older adults has emerged as a critical concern for both society and academia. Research has shown that appropriate exercise not only improves physical functions in older individuals but also helps maintain cognitive function and psychological health. In recent years, Augmented Reality (AR) technology, characterized by immersive experiences and high interactivity, has been recognized as an innovative tool to enhance exercise engagement and effectiveness, particularly for elderly populations. AR integrates visual stimulation, real-world simulation, and real-time feedback, which may contribute to improved gait performance, increased exercise motivation and tolerance, and greater acceptance of technology. However, current research on the overall health effects of AR treadmill training in older adults remains limited. Therefore, this study aims to address this empirical gap.

2. Study Objectives

This study aims to investigate the effects of augmented reality (AR) treadmill walking training on four major dimensions in older adults:

- Cognitive function (including stride length, walking speed, and balance)
- Body composition (BMI, skeletal muscle mass, fat mass, and body fat percentage)
- Physiological responses (heart rate, calorie consumption, exercise duration, and distance)
- Technology acceptance (perceived usefulness, perceived ease of use, and behavioral intention)

The study further analyzes whether body composition and physiological responses are associated with AR technology acceptance. The research hypothesizes that AR-based training will significantly improve the above indicators and foster a positive attitude toward the intervention among older adults.

3. Participant Eligibility Criteria

Inclusion Criteria:

Community-dwelling older adults aged 65 years or above with general health status, capable of performing basic activities of daily living and possessing normal cognitive function.

Able to walk independently and participate in treadmill walking training.

No chronic conditions that significantly impair exercise capacity (e.g., mild hypertension, well-ontrolled diabetes).

No regular use of AR-related devices for exercise in the past three months.

Exclusion Criteria:

Severe visual or auditory impairments that may interfere with the AR experience.

Major cardiovascular disorders or joint-related conditions that prevent completion of exercise training.

Inability to consistently participate in the training or adhere to study protocols during the research period.

4. Study Methods, Procedures, and Related Assessments

Participants

This study utilizes a randomized controlled trial (RCT) design. After conducting normality and homogeneity tests based on participants' demographic data, eligible individuals will be randomly assigned to either the experimental group (EG) or the control group (CG). Participants in the EG will undergo augmented reality (AR) treadmill walking training, while those in the CG will engage in conventional treadmill training. The intervention period spans eight weeks, with sessions scheduled three times per week, each lasting 60 minutes and comprising a warm-up (10 minutes), treadmill walking (40 minutes), and cool-down stretching (10 minutes).

The study procedure consists of four phases:

- Recruitment of healthy older adults aged 65 and above through posters and online platforms, followed by preliminary screening and signing of the informed consent form.
- Group allocation and pre-test assessments, including baseline measurements of cognitive function, body composition, and physiological indicators.
- Implementation of the eight-week training intervention.
- Post-test assessments and data analysis, including repeated measurements of all variables and retrieval of the AR technology acceptance questionnaire, aimed at evaluating overall effectiveness and conducting statistical analysis.

5. Potential Adverse Effects, Incidence Rates, and Management Procedures

This study involves a moderate-to-low intensity walking exercise intervention designed for healthy older adults, and the overall risk is considered low. However, in view of participants' age and physiological conditions, the following adverse effects and discomforts may occur:

5.1 Potential Adverse Effects

- Exercise-related discomforts: such as muscle soreness, mild joint pain, fatigue, dizziness, or shortness of breath.
- Impaired balance or fall risk: particularly during initial exposure to the AR treadmill, participants may experience dizziness or temporary instability due to visual stimulation or slope changes.
- Acute exercise injuries: including contusions, ligament sprains, muscle or tendon strains.
- Psychological stress or operational anxiety: some participants may experience anxiety or mental discomfort related to learning and using the AR system.

5.2 Estimated Incidence Rates

According to the literature (e.g., Blomqvist et al., 2021; Korn et al., 2019) and the exercise intensity used in this study, the estimated incidence of exercise-related injuries is below

2%, primarily consisting of mild discomforts or reversible symptoms.

5.3 Management Procedures and Safety Mechanisms

If acute exercise injuries occur during the intervention—such as contusions, sprains, or strains—initial management will follow the R.I.C.E. principle (Rest, Icing, Compression, Elevation):

- Immediate rest: terminate the exercise to prevent further injury.
- Icing the affected area: apply ice packs intermittently for 20 minutes.
- Compression with elastic bandages: to control swelling and bleeding.
- Elevation of the injured limb: to promote circulation and reduce swelling.

In addition, research staff on site will promptly notify the institution's school nurse and physician for further assessment. If necessary, the visiting physician will be contacted for medical evaluation. Mild cases will be monitored and treated with continued icing; in the case of serious injuries, the participant will be sent for medical treatment immediately. That individual will discontinue further participation in the intervention to ensure their health and safety.

6. Alternative Therapies and Explanations

- None

7. Anticipated Benefits of the Trial

This study utilizes an augmented reality (AR) treadmill walking intervention and is expected to yield the following tangible benefits for older adults in terms of physical and mental health, as well as technology acceptance behaviors:

7.1 Direct Benefits to Participants

- Enhancement of cognitive function: Indicators such as stride length, walking speed, and balance are critical for cognitive health. Training is expected to improve attention, reaction speed, and executive function in older adults, thereby reducing the risk of cognitive decline.
- Improvement in body composition: The intervention is expected to increase skeletal muscle mass and decrease body fat percentage, helping to prevent or delay sarcopenia and enhance the ability to perform daily activities.
- Improved exercise tolerance and cardiopulmonary function: Regular training may increase exercise duration and walking distance, strengthening cardiopulmonary endurance and metabolic efficiency.
- Increased exercise motivation and technology acceptance: The interactive nature of AR may enhance enjoyment during exercise, thereby promoting long-term adherence to physical activity.

7.2 Indirect Benefits for Academic and Practical Applications

- Provision of evidence-based foundations for technology interventions in aging: By evaluating the effects of AR technology on cognitive and physical health, this study may

support future research and promotion within elderly care and smart health domains.
- Facilitation of personalized exercise prescription development: Study outcomes may serve as a basis for designing individualized, high-engagement exercise programs that strengthen self-health management among older adults.
- Establishment of health promotion models: If AR training proves effective, it may be implemented in long-term care facilities, community centers, and similar settings, thereby expanding innovative approaches to health promotion in aging populations.

8. Participant Restrictions, Prohibitions, and Compliance During the Trial

- You will be required to follow the instructions provided by the research staff throughout the course of the study.

9. Confidentiality

To safeguard participants' personal data and privacy rights, this study will strictly comply with the Personal Data Protection Act and research ethics regulations to ensure the confidentiality of all information. The following measures will be implemented:

Data Coding and Anonymization

Each participant will be assigned a coded identifier (e.g., S001, S002). The research process will not involve names, national ID numbers, or any personally identifiable information, thereby preventing any form of identity disclosure.

Data Storage and Access Restrictions

All paper-based questionnaires and measurement records will be stored in locked filing cabinets. Electronic data will be saved on password-protected computers and cloud drives, accessible only to the principal investigator and approved research personnel.

Data Processing and Analysis

Only coded data will be used during the analysis phase. No identifiable participant information will be disclosed in study publications or conference presentations. All data will be used solely for statistical analysis.

Data Retention Period

Following the conclusion of the study, all data will be retained for five years as an audit reference. Upon expiration, documents will be destroyed in accordance with regulations (paper documents will be shredded; electronic files will be permanently deleted).

Disclosure During Informed Consent Procedure

Prior to signing the informed consent form, all participants will be clearly informed of the scope of data usage and confidentiality measures. Participants will retain the right to withdraw from the study at any time. Upon withdrawal, their data will be excluded from analysis and destroyed accordingly.

This study will be conducted in full accordance with the principles of the Declaration of Helsinki, rigorously protecting the privacy and confidentiality of participant information to uphold research integrity and ethical compliance.

10. Compensation, Costs, Liability, and Insurance

10.1 By signing this consent form, you will not waive any of your legal rights.

11. Participant Rights

11.1 Any significant findings related to your health or medical condition that may affect your willingness to continue participating in this clinical trial will be promptly disclosed to you during the course of the study.

11.2 To ensure proper execution of the trial procedures, you will receive care from the Director and Head Nurse of the Chiayi County Cibo Elderly Care Center. If you experience any issues or concerns now or during the trial period, please do not hesitate to contact the Director of the Chiayi County Cibo Elderly Care Center (24-hour contact number: 05-253-7112).

11.3 If you have questions about the nature of the trial, concerns about your rights, or suspect that you have been injured as a result of participating in the study, you may contact the Institutional Review Board (IRB) of Jen-Ai Foundation Dali Jen-Ai Hospital. Office hours: Monday to Friday, 9:00–12:00 and 13:30–16:30 Contact number: 04-24821771

12. Withdrawal and Termination from the Study

12.1 You are free to decide whether or not to participate in this study. During the course of the study, you may withdraw your consent and discontinue participation at any time without providing any reason. Doing so will not cause any negative consequences or affect the medical care you receive at the Chiayi County Cibo Elderly Care Center. If necessary, the principal investigator may also suspend or terminate the study. In such cases, you will be notified immediately and provided with appropriate treatment and follow-up care.

12.2 Handling of specimens and data upon early withdrawal from the study:

☐ I agree to the continued use of collected and analyzed specimens and data.

☐ I do not agree to the use of collected specimens and data, but I agree that already analyzed specimens and data may continue to be used.

☐ I do not agree to the continued use of either collected or analyzed specimens and data (excluding data that cannot be linked to personal information or that have already been publicly published).

13. Signature

13.1 Person Providing Consent Explanation

(Serving in this study as: ☐ Principal Investigator ☐ Co-Principal Investigator ☐ Research Staff)

I have thoroughly explained the nature and purpose of the study procedures described above, as well as the potential risks and benefits, and have answered the participant's questions.

Signature of Person Providing Explanation:

Date of Signature: ____ / ____ / _____

13.2 Participant

Following the explanation, I fully understand the study procedures and the potential risks and benefits. All questions I had about this study have been clearly addressed. I agree and voluntarily consent to participate in this study and will retain a copy of the consent form.

Participant's Signature:

Date of Signature: ____ / ____ / _____

Principal Investigator's Signature:

Date of Signature: ____ / ____ / _____