STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN AND INFORMED CONSENT FORM

OFFICIAL STUDY TITLE: THE EFFICACY OF A TECHNOLOGY-ASSISTED BLOCK TRAINING PROGRAM ON COGNITIVE FUNCTION, HAND DEXTERITY, AND GRIP STRENGTH IN COMMUNITY-DWELLING OLDER ADULTS: A MIXED-METHODS RESEARCH

IRB PROTOCOL NUMBER: FJU-IRB NO: C113099

Document Date: April 23, 2025.

Statement of Translation:

This document includes the English translation of the Study Protocol, Statistical Analysis Plan, and Informed Consent Form. The content is identical to the original Chinese version approved by the Human Research Ethics Committee of Fu Jen Catholic University on April 23, 2025.

1. Background

Aging significantly impacts the physical and cognitive functions of older adults, often leading to the loss of muscle strength, balance, and flexibility, as well as a decline in cognitive functions such as attention, memory, executive function, language, and visuospatial abilities.

2. Objective

This study aims to develop a technology-assisted cognitive training tool using building blocks, leveraging their potential to enhance creativity and visuospatial thinking. The goal is to assist older adults in improving their cognitive functions, hand strength, flexibility, and overall quality of life.

3. Methods and Design

This study adopts a single-group pretest-posttest design, recruiting community-dwelling older adults aged 65 and above through convenience sampling.

Participants will undergo a technology-assisted cognitive training intervention once a week for two hours per session, for a total of three sessions.

The study will be conducted in three phases:

Initial phase: Collect knowledge on aging-related cognitive and hand functions, and establish the foundational content for the building block tool and lesson plans.

Mid-phase: Complete the design of the building block lesson plans and the development of the training tool.

Final phase: Validate the effectiveness of the intervention in community settings while evaluating the usability of the technology-assisted cognitive training program and participants' engagement in the activities.

4. Outcome Measures

Cognitive function and quality of life: Assessed using questionnaires before and after the intervention.

Physical function: Hand grip strength, finger strength, and hand flexibility will be measured.

5. Statistical Analysis Plan (SAP)

The effectiveness of the intervention will be analyzed using **paired-sample t-tests** to compare pretest and posttest scores on cognitive function, hand strength, and quality of life measures. Data will be analyzed using statistical software suitable for quantitative analysis.

Fu Jen Catholic University Human Research Ethics Committee Participant Information and Consent Form

Project Name: The Efficacy of a Technology-Assisted Block Training Program on Cognitive Function, Hand Dexterity, and Grip Strength in Community-Dwelling Older Adults: A Mixed-Methods Research

Principal Investigator: Chia-Jung Hsieh (Professor of Nursing)

Co-Principal Investigator: Yu-Ling Chen

Protocol Number: FJU-IRB NO: C113099

Date: April 23,2025.

Introduction

We invite you to participate in this study. This consent form provides you with information related to this study. The study principal investigator or researcher will explain in detail and answer any questions you may have. Please consider carefully before signing. You must sign this consent form to participate in this study.

Research Background

The global population is rapidly aging, and Taiwan is about to enter a "super-aged society." Aging poses multiple challenges to the physical and mental health of older adults, with common issues including declines in muscle strength, balance, and flexibility. In addition, age-related changes in brain structure and neurological function can affect cognitive abilities such as attention, memory, and language. This study aims to explore how technology-assisted educational tools can improve cognitive function and hand dexterity among community-dwelling older adults. We will use building blocks as training aids, as they stimulate creativity and promote visuospatial thinking, thereby helping enhance overall functioning. This one-year study will be conducted in a community in Yilan to comprehensively evaluate the program's effectiveness for older adults.

Research Purpose

This project aims to help community-dwelling older adults improve cognitive function and hand dexterity. We will use building blocks as technology-assisted tools, which not only enhance the quality of life of older adults but also support the promotion of healthy aging. Through this study, we hope to promote the use of such assistive tools in the community and further enhance overall well-being and health. We invite you to participate in this research to help us collect data and evaluate the effectiveness of these tools.

Participant Eligibility

Participants in this study are older adults residing in communities in northeastern Taiwan.

Inclusion criteria: (1) age 65 or above, (2) clear consciousness and able to communicate and interact, and (3) willingness to participate in the block-based intervention activities.

Exclusion criteria: (1) a diagnosed dementia condition, (2) significant hearing impairment or inability to communicate, and (3) hand fractures or physical disabilities that prevent participation in the activities.

This study uses a single-group design and will conduct pretest and posttest without group assignment.

Research Methods and Procedures

This study uses a mixed-methods design, including quantitative assessments and a brief qualitative interview.

For the quantitative part, you will complete pretest and posttest consisting of:

(1) a demographic questionnaire (12 items, about 2 minutes);

(2) a cognitive function assessment (10 items, 5–10 minutes);

(3) a quality-of-life scale (5 items, about 2 minutes);

(4) health function measurements conducted by the research staff, including a basic physical check-up, hand grip strength, and hand dexterity tests. Before the grip test, we will ask about any hand pain to ensure safety.

There are no right or wrong answers. Please answer based on your condition over the past week. Questionnaires will be completed on site and collected immediately after. For the qualitative part, some participants will be invited to a short interview after the intervention to share their experiences and feelings about the program. All procedures are non-invasive, and your comfort and safety will be prioritized throughout the study.

Possible Inconveniences and Risks

Scheduling inconvenience: You will need to complete the questionnaires and measurements at the designated times (approx. 20-30 mins per session).

Physical discomfort: Some measurements, such as the grip strength test, may cause brief discomfort but will not result in any long-term health effects.

Psychological stress: Some questionnaire items related to personal health may cause mild emotional stress.

Privacy risks: Although strict data protection measures are in place, there remains a minimal risk of data breaches.

Expected Benefits

Building blocks promote creativity and visuospatial thinking. Block activities can improve neural plasticity, supporting cognitive function. This study aims to use early cognitive screening to better understand the condition of older adults. For healthy older adults, the program may enhance cognitive function, hand function, and dexterity, improving overall quality of life.

Confidentiality and Data Storage

The original data you provide will only be used for this research. Your data will be processed and stored by National Taipei University of Nursing and Health Sciences and saved on the researcher's computer with encryption. Paper documents will be kept in a locked cabinet. Three years after the completion or publication of the study, the data will be destroyed.

Rights and Withdrawal

Participation is voluntary. You are free to withdraw your consent and exit the research at any time during the study without providing any reason and without any adverse consequences.

Contact Information

If you have any questions or experience discomfort, please contact:

Principal Investigator: Chia-Jung Hsieh (02-28227101 ext. 3109)

Co-Investigator: Yu-Ling Chen (0958-270011)

IRB Contact: Fu Jen Catholic University Research Ethics Committee (02-2905-6277)

Signature Section

I have explained in detail the content of this research project, as well as the risks and benefits.

Signature of Explainer: _____ Date: _____

I understand the content of the research project and voluntarily participate.

Participant's Signature: _____ Date: _____