The Effect of SMART±STEP Cognitive-Motor Training in Community-Dwelling Older People with Mild Cognitive Impairment: A Single-Blind Randomized Controlled Trial

Version Number: 1

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SYNOPSIS

Protocol title: The Effect of SMART±STEP Cognitive-Motor Training in Community-Dwelling Older People with Mild Cognitive Impairment: A Single-Blind Randomized Controlled Trial

Protocol version: 1.0

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RESEARCH SITES

Faculty of Physical Therapy, Mahidol University

FUNDING BACKGROUND

Strategic Research Fund (Starter), Mahidol University
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SUMMARY

Study title: The Effect of SMART±STEP Cognitive-Motor Training in Community-Dwelling Older People with Mild Cognitive Impairment: A Single-Blind Randomized Controlled Trial

Protocol version: 1

Research Objectives
Primary aim

1. Assess the feasibility of Smart±step cognitive-motor training for older people with MCI
2. Evaluate the program's impact on falls risk factors
3. Examine neurophysiological outcomes

Secondary aims

1. Compare fall risk, program enjoyment, adherence, and adverse events at 3 months
2. Assess 3-month effects on cognitive, physical, and psychological performance
3. Evaluate 6-month impacts on fall risk factors and neurophysiological outcomes

Study design: Single blind randomised control trial (RCT)
Planned sample size: 70 participants, with 35 participants per group each phase.
Selection criteria: The study will include Thai-speaking community-dwelling adults aged 60+ with mild cognitive impairment (MCI), who can walk 10m independently. Participants will be excluded if they have dementia, recent stroke, neurodegenerative disorders, residential care residence, uncorrectable sensory impairments, illiteracy, or medical conditions that could compromise study safety, including severe musculoskeletal pain, recent surgeries, unstable cardiovascular or metabolic conditions, and uncontrolled mental health disorders.
Study procedure: All participants will undergo a comprehensive test battery including physical, cognitive, neurophysiological functional, and QOL assessments at baseline, at three months, at six months and at 12 months. The baseline and follow-up assessments will be completed at Faculty of Physical Therapy, Mahidol University Concealed randomisation will be performed by a person independent of the study after baseline assessment. The intervention group will endeavour to undertake conitive-motor training at home. The intervention involves three training sessions per week for 30 minutes per session. There are 2 phase of the intervention (phase 1: 3 months intervention and phase 2: 6 months intervention with differnce group of the participants). The control group will receive usual care and healthy living information.
Sample size calculation: The sample size calculation was based on the Stroop Stepping Test, using an effect size of 0.15 and accounting for covariates like age, gender, education, and intervention. With 80% statistical power and a 5% Type I error rate, the study requires 55 participants to detect a 15% change in cognitive and motor skills. Anticipating a 20% dropout rate, the total sample size was increased to 70 participants, with 35 participants per group.
Analysis plan: An intention-to-treat analysis will be used for all analyses. General linear models will be used to assess the effect of group allocation on the continuously scored outcome measures. Modified Poisson regression models will be used to compare groups on dichotomous outcome measures. Predictors of adoption and adherence will be analysed using multivariate modelling techniques such as general linear models, multiple linear and logistic regression. Negative binomial regression will be used to compare the number of falls in the intervention and control group.

Study duration: 12 months

The Effect of SMART±STEP Cognitive-Motor Training in Community-Dwelling Older People with Mild Cognitive Impairment: A Single-Blind Randomized Controlled Trial

OVERVIEW

As the global population ages, mild cognitive impairment (MCI) presents a significant challenge, with prevalence ranging from 5% to 40% among older adults. Individuals with MCI face a substantially higher fall risk—five times greater than their cognitively intact peers—due to cognitive and physical impairments. Current research suggests that combined cognitive-motor interventions offer the most promising approach to fall prevention. The Smart±step exergaming program represents an innovative solution, integrating interactive computer gaming with targeted cognitive and physical challenges. This study aims to evaluate the Smart±step program's feasibility and effectiveness in reducing fall risks among community-dwelling older people with MCI, potentially offering a groundbreaking strategy for enhancing senior health and independence.

BACKGROUND

As the world population ages, the number of older individuals with physical frailty and cognitive impairments will increase.[1-2] The prevalence of mild cognitive impairment (MCI) in older adults ranges from 5 and 40 %,[3-4] varying due to inconsistent diagnostic criteria and sampling differences.[5-9] MCI is an intermediate state between normal cognitive ageing and dementia, significantly raises the risk of developing Alzheimer's disease (10% to 47% per year) compared to those without MCI (1% to 2% per year).[9-12] Previous, but limited, literature has demonstrated that older people with MCI are at an increased risk of falls.[13-14] Reduced cognitive function has been associated with gait disturbances and balance deficits in older people with MCI [15-19], which may contribute to this increased fall risk.[17-18] Research has shown the odds of falling in cognitively impaired older people is 5 times greater than their cognitively intact peers, with the literature reporting fall prevalence of more than 60% in this population.[20-24] Older people with MCI, by definition, have preserved ability in activities of daily living (ADLs), this suggests that falls could be at least in part related with cognitive dysfunction. When compared to cognitively intact older people, physical impairments have also been demonstrated in older people with MCI,

but potentially these are below the threshold required to affect ADL performance or are mitigated by compensation strategies.[25-27] However, these physical impairments are still important in relation to fall risk.[20,24,28-29] Therefore, specifically targeted fall prevention interventions should address both cognitive and physical issues in this population.

Cognitive training including computer-based training and training by therapists has been demonstrated to improve cognitive outcomes such as executive functioning, memory performance and attention and global cognitive function in older people with MCI.[30-33] Some of these cognitive functions (e.g. executive function and attention) have also been associated with falls in this population.[15,34-35] Physical exercise, specifically exercise that involves moderate to high challenge balance training, prevents falls in community-dwelling cognitively healthy older people.[36] In older people with MCI, a recent systematic review reported physical exercise can improve fall-related risk factors like walking speed and global cognitive function, while cognitive training alone did not improve cognitive fall-related outcomes in this population.[37] Combined interventions, involving both physical (motor) and cognitive training, have shown promise in relation to fall prevention in older people with MCI.[38-39] These studies have demonstrated that cognitive-motor interventions can improve balance, dual-task ability and cognitive outcomes.[37,39-40] However, there is limited evidence that this approach can reduce fall risk factors in community-dwelling older people with MCI.[37-39] Rigorous and robust evaluation of the fall prevention efficacy of cognitive-motor interventions in people with MCI is needed.

The *Smart±step exergaming* program, is an interactive computer gaming system that targets both cognitive and motor training.[41] *Smart±step* involves targeted stepping tasks combined with a variety of cognitive tasks using a step mat to engage with computerized video games. A recent large randomised controlled trial with three arms (cognitive-motor, seated cognitive, control) assessing *Smart±step's* fall prevention efficacy showed that *Smart±step's* cognitive-motor program significantly reduces the rate of falls compared to the control group in cognitively healthy populations.[42] However, such cognitive-motor exercise programs like *Smart±step* have not been tested in older people with MCI. Improving physical and cognitive function using novel combined approaches may offer additional value for preventing falls and improving function in this population.

STUDY OBJECTIVES

Hypothesis

Cognitive-motor training will maintain or improve cognitive performance, physical and functional performance, neurophysiological outcomes, and qality of life in community-dwelling older people with mild cognitive impairment, and prevent falls

Primary aims:

1. To evaluate the feasibility of *Smart±step* cognitive-motor training program in community-dwelling older people with MCI
2. To evaluate the effect of *Smart±step* cognitive-motor training on falls risk factors in community-dwelling older people with MCI
3. To evaluate the effect of *Smart±step* cognitive-motor training on neurophysiological outcomes in community-dwelling older people with MCI

Secondary aims:

1. To compare the fall risk score, the enjoyment score of the program, the percentage of adherence and the percentage of adverse events before and at 3 months of *Smart±step* cognitive-motor training in community-dwelling older people with MCI.
2. To evaluate the effect of 3 months of *Smart±step* cognitive-motor training on cognitive, physical and psychological performance (falls risk factors) in community-dwelling older people with MCI.
3. To evaluate the effect of 6 months of *Smart±step* cognitive-motor training on falls risk factors and neurophysiological outcomes in community-dwelling older people with MCI.

RESEARCH PLAN, METHODS AND TECHNIQUES

Study Design

A 12 month single-blind (assessor) randomised controlled trial (RCT) examining the effectiveness of *Smart±step* cognitive-motor training carried out at home for six months compared with no training will be undertaken in 70 community-dwelling older people with mild cognitive impairment. The intervention will exercise using *Smart±step* system at least 120 minutes per week for 12 weeks (phase 1) and 24 weeks (phase 2). The *Smart±step* will target both physical and cognitive training e.g. executive function, processing speed and attention. The control group will receive usual care and healthy living information. All participants will undergo a comprehensive

test battery including physical, cognitive, functional, psychological, neurophysiological, quality of life assessments at baseline, at three months, at six months (at completion of *Smart±step* cognitive-motor training for intervention group) and at 12 months (i.e. six months after completion of *Smart±step* cognitive-motor training. The baseline and follow-up assessments will be completed in the participants' home (or at the Faculty of Physical therapy, Mahidol university if the participant prefers). Trial reporting will be guided by the CONSORT guidelines.

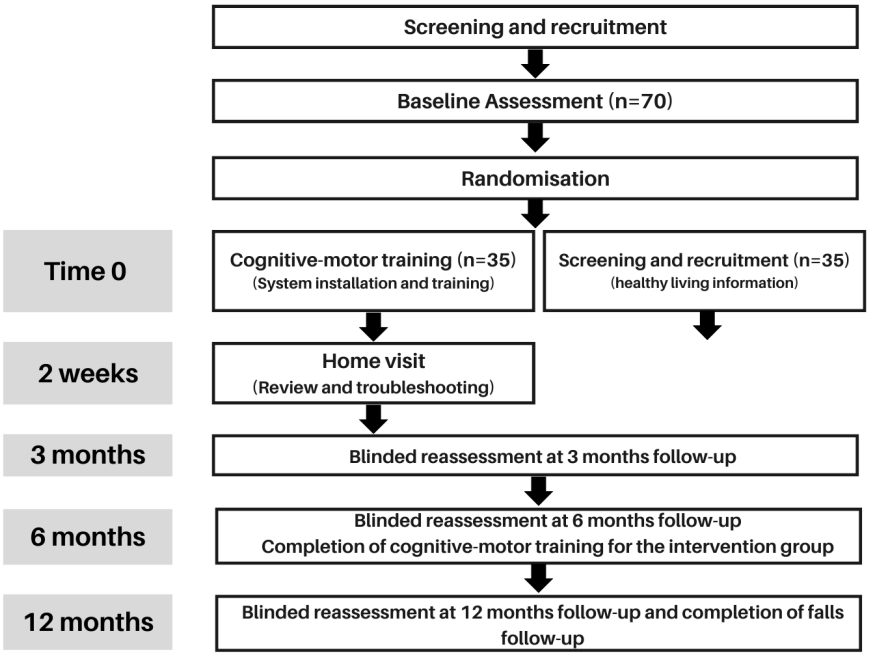


Figure 1. Study flow diagram

Participant selection

Seventy volunteers with MCI based on the core criteria outlined by the diagnostic scheme of MCI by Petersen[6] and the National Institute on Aging-Alzheimer's Association [43] and as follows:

1) Subjective cognitive complaints (SCCs) will be assessed by using the four most frequently endorsed questions from participant's subjective complaints questions by the Slavin et al. study.[44] There are three memory questions ("Have you noticed difficulties with your memory?", "Compared to 5 years ago, do you now find that you lose track of what you are doing?", and "In general how would you describe your memory as compared to 10 years ago") and one

nonmemory question ("Compared to 5 years ago, do you have more difficulty finding the right words?"). Each question will give a score of 1 (the complaint is endorsed) or 0 (the complaint is not endorsed), which will ask participants to rate the score by themselves. The score ≥ 3 will be considered to have subjective cognitive complaints.

2) Objective cognitive impairment will be assessed by using the Montreal Cognitive Assessment Thai version (MoCA). The MoCA consists of 16 items and 11 categories covering multiple cognitive domains (e.g. visuospatial, executive functions, naming, memory, attention, language, abstraction, and orientation). The MoCA has been shown to be a sensitive tool for neurocognitive disorder detection. A cut-off score of <26 out of a possible 30 has been reported to discriminate normal cognitive function and MCI with high sensitivity (90%) and specificity (87%) for detecting MCI. A MoCA score under 21 points (after adding 1 point for people with ≤12 years of education) is sensitive (88%) and specific (95%) in discriminating mild Alzheimer's disease (AD) from MCI. Therefore, this study will use the MoCA to determine objective cognitive impairment; a score of 20-25/30 for participants with ≤12 years of education and a score of 21-25/30 for participants with more than 12 years of education will be considered inclusion criteria.[45-48]

3) Normal or minimally impaired in functional abilities will be assessed by using the Bayer Activities of Daily Living Scale (B-ADL). The B-ADL will be administered by trained study staff. The B-ADL consists of 25 items that is to be answered by the caregiver. Each B-ADL item is rated from 1 to 10, where 1 indicates 'never' and 10 indicates 'always' have difficulty. The total score the B-ADL range between values 1.00 and 10.00. The participates who obtain the score of <3 on the B-ADL will be considered as no functional impairment.[49-50]

4) Participants will not have dementia as determined by the MoCA. Participants scoring < 20 with ≤12 years of education and those scoring <21 with more than 12 years of education will excluded as this cut-off has a high sensitivity and specificity for dementia.[45-48]

Inclusion criteria

- MCI defined using the above criteria.
- Aged 60 years or more.
- Living in the community or retirement village.
- Thai-speaking language.

- Able to walk 10m independently (without a walking aid).

Exclusion criteria

- Diagnosis of dementia or Alzheimer's disease at baseline by a specialist clinician (e.g. Geriatrician) or using the MoCA cut-point <20-21 (depending on education level).
- Having had a stroke in the last 2 years.
- Having a progressive neurodegenerative disorder e.g. Parkinson's disease, Multiple sclerosis, amyotrophic lateral sclerosis (ALS).
- Living in a residential aged care facility.
- Having visual/hearing impairment that cannot be corrected with eyeglasses or hearing aids.
- Unable to read or write.
- A medical condition that would interfere with the safety and conduct of the training and testing protocol or interpretation of the results, such as:
    - Musculoskeletal conditions e.g. severe pain of lower extremities (pain score > 4/10), recent TKR/THR (*less than* or equal to *12 months after operation*) and recent fracture (12-months).
    - Cardiopulmonary conditions e.g. unstable angina, uncontrolled hypertension.
    - Metabolic conditions e.g. severe or poorly controlled diabetes.
    - Mental health conditions e.g. severe or poorly controlled depression or psychiatric condition.

Recruitment

Participants will be recruited from the Sawang Kanives Retirement Village in Bang Pu, as well as from Baan Ua-Athorn Buddhamonthon Sai 5 in Sam Phran, Maha Sawat Tambon, Salaya Tambon, and Khong Yong Tambon, all located in Phutthamonthon, Nakhon Pathom. Additionally, participants may include individuals who are users of the geriatric clinic at Luangphopern Hospital and Golden Jubilee Medical Center. Both Thanwarat (Principal Investigator) and Jenjira (Co-Investigator) have extensive clinical volunteer experience within these communities. Their strong track record in successfully recruiting participants for clinical trials will significantly contribute to maximizing recruitment for this study.

Baseline, reassessment and follow-up assessment

Baseline, reassessment and follow-up assessments will be conducted in the participants' homes by trained assessors. The baseline assessment will involve a structured interview with the participant to obtain demographic, health, physical activity and lifestyle information. Reassessment will be undertaken at three months, six months and an additional follow-up assessment at 12 months. Reassessment and follow-up assessors will be blinded to group allocation. Table 1 outlines the assessments to be completed.

Table 1 List of assessments to be completed at Baseline (B), 3-month reassessment (3-mo), 6-month postintervention (6-mo), and follow-up (12-mo) indicating primary (P) and secondary (S) outcomes (O)

Assessment/Outcome variable	B	3-mo	6-mo	12-mo	O
Socio-demographics Age, gender, marital status, education, type of residence, number of co-inhabitants, previous technology use	/	X	X	X	-
General health and function Medical conditions, medication use, mobility, ADLs, history of falls	/	X	X	X	-
Physical Assessment					
Stroop stepping test (SST)	/	/	/	/	P
Physiological profile assessment (PPA)	/	/	/	/	P
Timed Up and Go Test (TUG) (single and dual task)	/	/	/	/	S
Short Physical Performance Battery (SPPB)	/	/	/	/	S
30s-Chair-Stand Test (CST)	/	/	/	/	S
Cognitive assessment					
Trail-Making Test (TMT) Part A and B	/	/	/	/	P
The Controlled Oral Word Association test (COWAT)	/	/	/	/	S
The modified switching verbal fluency test (mSVF)	/	/	/	/	S
The digit symbol substitution	/	/	/	/	S
The Digit Span test (DST)	/	/	/	/	S
Psychological function					

Short Falls Efficacy Scale international: Short FES-I	/	/	/	/	S
Thai Geriatric Depression Scale: TGDS	/	/	/	/	S
Thai Geriatric Anxiety Scale: Thai GAS-10	/	/	/	/	S
Neurophysiological assessment					
EEG	/	/	/	/	S
ERP	/	/	/	/	S
Physical activity					
Physical Activity Scale for Elderly Thai version (PASE-TH)	/	/	/	/	S
Quality of life					
WHOQOL–BREF–THAI	/	/	/	/	S
Prospective falling record					
Falls rate (monthly diaries and telephone calls)	X	/	/	/	S
Usability					
System Usability Scale	X	/	/	X	S
Enjoyment					
Physical Activity Enjoyment Scale (PACES) Thai version	X	/	/	X	S
Adherence					
Sessions and time recorded by training system and logbook record	X	/	/	X	S

Primary outcome measures

Stroop stepping test (SST) will be used to measure the ability to perform accurate stepping with response inhibition using the Choice Stepping Reaction Time Test. [51] This equipment consists of a custom-made dance pad (150×90cm) which is connected to a computer and display screen (1280 × 768 pixels; 60 Hz; 58 cm). The test will start when an arrow shows in the centre of the monitor pointing in one of four directions (up, down, left and right) that matched the four possible step directions (forward, backward, left and right). A word indicating a different direction will be written inside the arrow. Participants will be instructed to 'Step by the word' and will have to inhibit the response indicated by the arrow's orientation. Four practice trials are not included in the score and 20 trials will be administered randomly by the directions of word and orientation. The average time (ms) and number of errors will be recorded.[51]

Fall risk assessment will be assessed using the Physiological Profile Assessment (PPA). The PPA consists of five assessments including edge contrast sensitivity, lower limb proprioception, lower limb strength, simple hand reaction time, and postural sway. Briefly, edge contrast sensitivity will be assessed using the Melbourne Edge Test, which presents 20 circular patterns containing edges with reducing contrast. Correct identification of the orientation of the edge on the patches provides a measure of contrast sensitivity in decibel units. Lower lime proprioception will be assessed by instructing seated participants with eyes closed to align their lower limbs on either side of a vertical clear acrylic sheet inscribed with a protractor and placed between their legs. Any difference in matching the great toes on either side of the acrylic sheet will be measured in degrees. Lower limb strength will be measured using a spring gauge. Participants will be asked to extend their leg against the spring gauge while seated with the hip and knee joint angles positioned at 90°. Maximal force will be recorded in kilograms. Simple hand reaction time will be measured using the modified computer mouse connected with light stimulation system. Participants will be asked to press the mouse with their finger as quickly as possible in response to a light stimulus. The response data will be recorded in milliseconds. Postural sway will be measured using a swaymeter that measures displacements of the body. Participants will be instructed to stand as still as possible with the eyes open and closed on a firm surface and on a piece of medium-density foam rubber while wearing the sway meter at waist level. The sway area in the 30 second period in each condition will be recorded in square millimeters.[52]

Secondary outcome measures

- ***Physical function***

Mobility will be measured using the Timed Up and Go Test (TUG). Participants will be instructed to rise from a standard chair with arms, walk a distance of three metres at usual pace, turn around, walk back to towards the chair, and sit down again. The time in seconds will be recorded beginning at the instruction “go” and stopping when the participant is seated. One practice trial is not included in the score and therefore the mean of 2 trials will be calculated and used for statistical analysis.[53]

Dual task test will be assessed using TUG test combined with a verbal fluency task by naming animals. Participants will be instructed to rise from a standard chair with arms, walk a distance of three metres, turn around, walk back to towards the chair, and sit down again. In the

meantime, participants will have to name as many animals as they can. The time to complete the TUG will be recorded in seconds. The mean of 2 trials will be calculated and used for statistical analysis.[54-55]

Lower extremity functioning will be assessed using the Short Physical Performance Battery (SPPB). The scores range from 0 to 12 (higher score indicating better performance) and are based on performance on three tasks including gait speed, chair stand, and static standing balance with different three standing positions.[56]

- ***Cognitive function***

Executive function will be assessed using Trail-Making Test (TMT) Part B and the Controlled Oral Word Association test (COWAT). For TMT Part B, participants will be instructed to draw a line to connect consecutive numbers in numerical order and letters in alphabetical order in an alternating sequence (e.g., 1–A–2–B–3) as quickly and correctly as possible.[57] For the COWAT, participants will have to generate as many words as possible in a 60s timeframe starting with F, then A, then S. The score will be calculated by the number of words correctly iterated.[58]

Attention and processing speed will be assessed using Trail-Making Test (TMT) Part A and the digit symbol Substitution. For TMT Part A, participants will be instructed to draw a line to connect consecutive numbers in numerical order as quickly and correctly as possible (e.g., 1–2–3).[57] For the digit symbol substitution, participants will be instructed to match symbols to numbers according to a key located on the top of the paper test. Participants will have to copy the symbol into spaces below a row of numbers. The score will be calculated by the total number of correct symbols within the allowed time, usually 90 to 120 seconds.[59]

Short-term auditory memory and working memory will be measured using the two parts of the Digit Span test: Digits Forward and Digits Backward. These will be administered separately. The digits will be presented at a rate of one per second. In Digits Forward (DSF), the patient is required to repeat the digits in the same order as presented. In Digits Backward (DSB), the patient is required to repeat the digits in reverse order. Participants will listen to a series of numbers presented at 1 number per second and repeat them either in the same order (DSF) or in reverse (DSB). For example, after hearing "6, 9, 4, 7," participants will repeat "6, 9, 4, 7" (DSF) or "7, 4, 9, 6" (DSB). Numeric sets will range from 2 to 10 digits. Each set will be tested three times. If participants correctly recall the sequence at least twice, they will pass that set. Failure to do so will result in stopping the test.[60]

Semantic fluency will be assessed using the animals naming test. Participants will be asked to generate as many animals as they can within 60 second. The total score will be calculated from the maximum number of animals listed.[61]

The modified switching verbal fluency test (mSVF) will be a cognitive flexibility test. In this test, participants will be required to alternately present words from two categories, fruits and animals, as many as possible within a 1-minute period. The researcher will record the correct word count for each category.[62]

- ***Psychological function***

Anxiety symptoms will be assessed using Goldberg Anxiety Scale (GAS). The GAS consists of 9-item for self-rating of anxiety experienced in the past month which includes affective and somatic symptoms of anxiety. The score will be rated as yes (1) or no (0) answers with a total score ranging from 0 to 9 which higher scores substantially increase the probability of a significant anxiety disorder.[63]

Symptoms of depression will be assessed using Thai Geriatric Depression Scale (TGDS). The short form of TGDS is a 15-item self-report questionnaire that inquiries about depressive emotion in daily situations experienced in the past week. Participants will rate each item as yes or no, scores range from 0 to 15, with higher scores indicating greater symptom severity.[64-66]

Fear of falling will be assessed using short Falls Efficacy Scale international (Short FES-I). The Short FES-I version which is an interview-based questionnaire contains 7 activities of daily living. The level of concern about falling through a combination of pictures and matching short phrases is scored on a 4-point scale (1 = not at all concerned to 4 = very concerned). The total score ranges from 7 to 28.[67]

- ***Neurophysiological assessment***

Participants will perform two tasks: 1) electroencephalogram (EEG) recordings during resting-state, and 2) event-related potentials (ERPs) recordings during Go/No-go task in response to visual stimuli. In the resting-state, each participant will seat in a comfortable chair in a relaxed position during the EEG measurement, which consists of 5-minute session for eyes opened and eyes closed conditions. The EEG signals will be recorded during resting state using an eegoTMmylab ANT Neuro (32-electrodes EEG cap) as showed in Figure 3. The EEG recording will use a sampling rate of 512 Hz and a notch filter of 50 Hz. A software filter will set to bandpass

with a low pass of 0.3 Hz and a high pass of 100 Hz. The impedance of the electrode-skin interface will keep below 20kΩ, as recommended in prior scholarship.[68] The EEG instrument consisted of 32 channels (Figure 4) at the recording of position includes Fp_1, Fp_z, Fp_2, F_7, F_3, F_z, F_4, F_8, FC_5, FC_1, FC_2, FC_6, T_7, T_8, C_3, C_z, C_4, CP_5, CP_1, CP_2, CP_6, P_3, P_7, P_z, P_4, P_8, PO_z, O_1, O_z, O_2, M_1, M_2, CP_z (reference electrode), and AF_z (ground electrode).

Figure 2. The EEG system using an eegoTMmylab ANT Neuro

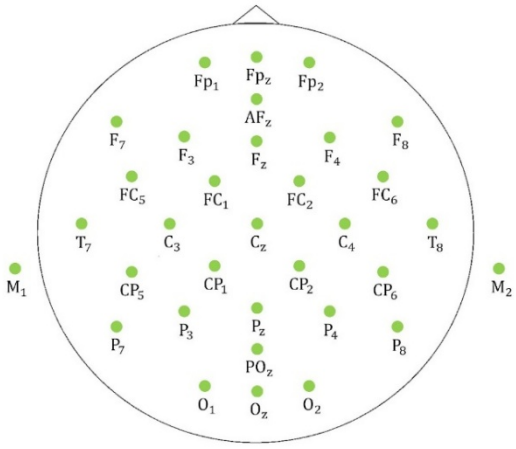


Figure 3. Montage of the EEG system in the experiment, 32 electrodes

- Participants will perform the event-related potentials (ERPs) recordings during Go/No-go task (using 4 images) in response to visual stimuli. Participants will have the brain activity measured with an electroencephalography (EEG) cap while performing an image-viewing task. The cap will record the brain signals as participants view images and respond by pressing a pedal with their's dominant foot. Participants will complete practice pedal presses to become familiar with the response before the actual test. When

participants see image “(1)” or “(3)” they should press the pedal; when they see image “(2)” or “(4)” they should not press the pedal. The picture stimuli will present in random order during each trial, and each trial lasted 2-minutes. Participants will give a 5-minute rest between trials, and the duration of the two experiments was 40 minutes.

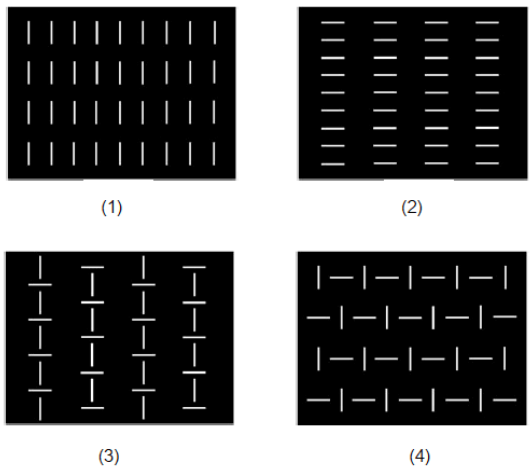


Figure 4. The two insets show the stimuli used in the experiment for image 1 and 3 (O) and No-go for image 2 and 4 (X)

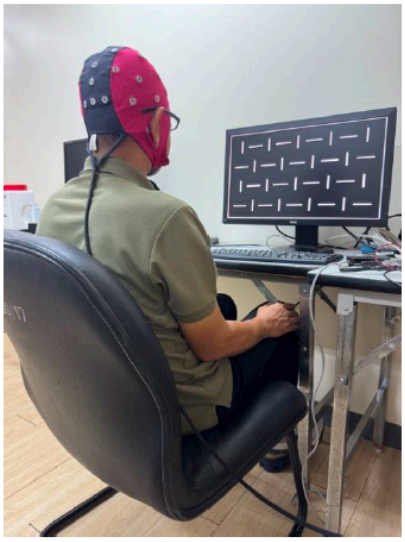


Figure 5. ERPs recording by using foot switch during Go/No/go task

EEG data analysis

In resting-state, the absolute power spectrum of the respective frequency bands derived by Fast Fourier Transformation (FFT) will express as follows: delta (0.5-4 Hz), theta (4.5-8 Hz), alpha (8.5-13 Hz), and beta (13.5-30 Hz) wave ranges. The EEG data will separate in six brain areas with corresponding electrodes which demonstrated both the functional and anatomical aspects of the brain's organization. There are the pre-frontal, frontal, central temporal parietal, and occipital areas. The ERPs recordings, and peak amplitudes and latencies of the N2 and P3 waves will measure over the midline occipital (O_z), parieto-occipital (PO_z), midline parietal (P_z), midline central (C_z), and midline frontal (F_z) electrode sites. The peak amplitudes (measured with respect to 100 millisecond pre-stimulus baseline) and latencies of major ERPs component will calculate for each participant in the following time window: N2 within 200–300 ms[(69)], and P3 within 250–500 ms.[(70)] The peak amplitude (μV) will define as the voltage difference between the baseline and the negative- and positive-going peak of the ERPs waveform after stimulus presentation. The peak latency (ms) will define as the time from stimulus onset to the point of the maximum negative and positive amplitude of the N2 and P3 waves respectively.

Statistical analysis for neurophysiological assessment

All statistical tests will be performed in Jamovi, and data visualization within the R statistical framework (version 4.0, R Foundation for Statistical Computing) and ASA software. Three metrics will of interest in this study; EEG during resting-state, ERPs during Go/No-go tasks, and physical response when participants push down with their leg during Go/No-go tasks. To assess the normality of the data, Shapiro-Wilk tests will initially apply to the data. Therefore, a generalized linear mixed modelling (GLMM) will be used to report the linear predictor between EEG during resting-state in brain areas (random), and pre-post recording (fixed) effects. One-way ANOVA will be used to compare pre-post recording with respect to peak amplitude and latency of N2 and P3 of the ERPs recording, response time, and the number of correct responses. The significance level will be set at $\rho<0.05$.

- ***Physical activity***

The Physical Activity Scale for the Elderly (PASE) Thai-version evaluates physical activity through 10 questions covering walking, exercise, household chores, and work. Participants will report activity type, frequency, and duration over the past week. Scores are calculated by multiplying activity frequency and duration by assigned weights. Activities like chores and work are scored based on average daily hours, adjusted by weights; sedentary tasks score 0. The total score, ranging from 0 to 400, excludes sitting activities.[71]

- ***Quality of life measure***

The participants' QOL will also be evaluated by using the WHOQOL-BREF-Thai questionnaire that can be assessed by self-report. In situations that the participants cannot read, the assessor will read for them, and they will have to choose the answer by themselves. The WHOQOL-BREF questionnaire has two types of questions: perceived objective and self-report subjective, and it includes four components of well-being: physical, psychological, social, and environmental. Each item is scored from 1-5. This Thai version has a good internal consistency with Cronbach's alpha 0.84.[72] The higher score indicates better QOL.

- ***Number of fall events***

Each participant will be given weekly fall diaries to mark any falls during the study period. A fall is defined as "an unexpected event in which the person comes to rest on the ground, floor, or lower level". If fall data is not received, telephone calls will be used to obtain fall data.

- ***System usability (intervention group only)***

At the completion of the *Smart±step* training (3 months and 6-months), participants will rate the usability of the *Smart±step* training using the System Usability Scale (SUS): SUS scores of 50–70 are acceptable, 71–85 are good to excellent, >85 are excellent usability, and <50 are considered unacceptable.[73-74]

- ***Adherence and Adverse Events***

All participants will be instructed to complete a logbook immediately after each exercise session to ensure data accuracy. Adherence to the intervention will be calculated as the percentage of *Smart±Step* sessions attended, using the formula: ((n/24 sessions) x 100). Any adverse events occurring during the study, such as injuries, falls, fatigue, or other exercise-related issues, will be documented. Furthermore, participants will be asked about their training experiences and any health issues at every follow-up point throughout the study. They will also be encouraged to contact the research team at any time with questions or concerns.

- ***Enjoyment***

Enjoyment during engaging in the Smart±Step training exercise will assess using Physical Activity Enjoyment Scale (PACES) Enjoyment Scale (PACES). The PACES is an 8-item scale questionnaire that measures the level of enjoyment using a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). The scores for enjoyment were obtained through the sum of PACES scores. A higher score indicates a greater level of enjoyment.

Randomisation and concealment

Randomisation will occur after baseline assessment (Figure 1) and will be stratified by site. Concealed randomisation will be performed by a person independent of the study using established randomisation software at Faculty of Physical Therapy.

Cognitive-motor training Intervention

Participants allocated to the intervention group will be provided with the *Smart±step* system and recommended to exercise at least 120 minutes per week for 24 weeks, which is a best practice recommendation for fall prevention exercise program.[75] The *Smart±step* system uses a floor step mat and small computer installed in the participant's home. The program is performed in standing and participants need to step onto targets using the wireless electronic floor step mat. The *Smart±step* cognitive-motor training has built-in motivating features and provides instant feedback on performance. To ensure a variety of games are played, participants will be required

to play a core game on each training day, this will unlock their other games. The exergame can be tailored to individual by offering five different levels of challenge. Medals are awarded based on the number of minutes played each week (bronze for >80min, silver for >100min, gold for >120min) to encourage adherence. To facilitate motivation and progression, participants will receive feedback after each game; that is, the score for the game just completed and their highest score for that game to date.

Within 2 weeks of randomisation, intervention participants will receive an initial home visit from a physiotherapist who will install the equipment in an appropriate location in the home and provide training. The training equipment will consist of the *smart±step* system and step mat to interface with their television screen (or provided a monitor). The participants will be asked to play the games while standing and taking quick and appropriate steps on the mat. The physiotherapist will discuss goal setting and barriers to training with participants to facilitate adherence and exercise progression. Participants game level will be prescribed depending on their performance and will be encouraged to progress every two weeks to provide a more challenging program. Participants will be provided with all equipment at no cost during the 3-month exercise period as well as an instruction manual containing safety precautions.

Figure 6. Smart±step motor-cognitive training

Monitoring

The adherence of individual's program will be transferred from participants' *smart±step* computers to a secure server at Faculty of Physical therapy, Mahidol University. Participants adherence will be monitored by study staff, they will be contacted individually by telephone to encourage adherence if the number of minutes played each week < 80 minutes. The phone call will aim to review goals and address barriers to training. A second home visit will be provided at

4 weeks to monitor safety, progress and address any issues. Telephone support and additional home visits will be provided upon request and a final home visit will occur on completion of the 3 month program to collect equipment and assess for outcome measures.

Control group

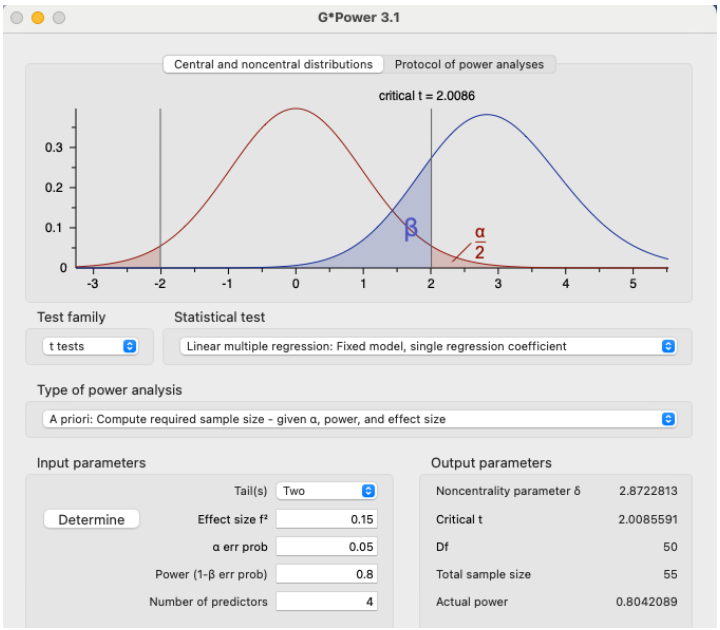
The control group will receive usual care and existing healthy living information (Blue book) https://eh.anamai.moph.go.th/web-upload/10x2f8665bc5c6742a30312c81435ca284e/202201/m_news/33518/207917/file_download/7dc90c0368663c51b2fdfeabc3a88a7d.pdf

Safety

We are not expecting any safety concerns directly related to the intervention. The hardware will be installed in a safe place within the home by a trained research assistant. However, there is a small risk of injury during physical assessment. However, this is unlikely as the assessments will be undertaken by trained research staff and all of the assessments are commonly used in research and clinical practice.

Sample size calculation

The sample size calculation for this study was based on the Stroop Stepping Test (SST) from previous research, with an effect size (f^2) of 0.15.[51] The calculation used a two-tailed t-test (Linear multiple regression: fixed model, single regression coefficient) and included four covariates: age, gender, education, and intervention. The statistical power was set at 80%, and the Type I error rate was set at 5%. The resulting sample size required for this study is 55 participants, which would allow for the detection of a 15% change in cognitive and motor skills test outcomes. Additionally, to account for potential dropouts (estimated at 20% of participants), the total sample size was increased to 70 participants, with 35 participants per group. The sample size calculation was performed using the G*Power 3.1 software.



Statistical analysis

Demographic variables will be analysed for between-group differences using independent samples t-tests for continuous variables and chi-square tests for nominal variables. Mann Whitney U test will allow to use for a nonparametric test. Generalised linear models were used to compare between-group differences in the outcome measures at 3-, 6- and 12-months while adjusting for baseline scores. Per-protocol and intention-to-treat (ITT) analyses will be completed. Missing data will be imputed using the following methods: participants who are physically unable to complete a physical test and cognitively unable to complete a cognitive test will be given a score of 3SD above or below the baseline mean (whichever indicates poorer performance) as these data are not missing at random. For the remaining missing data Little's Missing Completely at Random test will be used to determine if the data is missing at random, if it is estimated marginal means single imputation will be used as long as the values are missing for no more than 10% of the cases. If the missing completely at random test is not satisfied multiple imputation will be used. Significance will be two sided and will set at $P < .05$. All statistical analyses will conduct using SPSS.

Project timeline

Table 2 Project timeline

	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)

	1	2	3	4	1	2	3	4	1	2	3	4
Staff recruitment & training												
Ethical approval												
System refinement												
Recruitment and assessment												
Intervention												
Three month reassessments												
Six month reassessments												
Twelve months follow-up completed												
Data entry & analysis												
Manuscript preparation and submission												

Outcomes and significance

This work aims to develop interventions to specifically address physical, cognitive and psychological contributions to falls in people with MCI. More than 60% of community-dwelling older people with cognitive impairment fall each year. Yet, the evidence for effective fall prevention interventions is currently lacking in people with cognitive impairment, particularly in older people with MCI. Falls in people with cognitive impairment have more serious consequences when compared to their cognitively healthy peers, for example, they are more likely to result in injuries (hip fractures and head injury), loss of function, placement in residential care and death. This work aims to develop successful and cost-effective fall risk preventative strategies with the ultimate objective of improving the quality of life and health and wellbeing of this growing population. Combining cognitive and physical training will not only prevent falls but also help to improve functional ability and reduce the proportion of individuals transitioning to dementia.

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For MU-CIRB Staff

Protocol No.: MU-CIRB 2025/080.1402 COA(T) No. MU-CIRB 2025/147.0205

Informed Consent Form

☐ Original ☐ Revise No. ..... Revise Date ...../...../.....

Date..... /...../.....

My name is....., aged.....years old, address ..... road/street.....sub-district/tambon..... district/amphur..... province..... postal code…….....tel. .....

I hereby express my consent to participate as a subject in the research project entitled "Cognitive–Motor training in Community-Dwelling Older People with Mild Cognitive Impairment"

In so doing, I am informed of the research project's origin and purposes; its procedural details to carry out or to be carried out; its expected benefits and risks that may occur to the subjects, including methods to prevent and handle harmful consequences; and remuneration, and expense. I thoroughly read the detailed statements in the information sheet given to research subjects. I was also given explanations and my questions were answered by the head of the research project.

I therefore consent to participate as a subject in this research project.

On the condition that I have any questions about the research procedures, or on the condition that I suffer from an undesirable side effect from this research, I can contact Lect. Dr. Thanwarat Chantanachai via phone number +66 815235692 (available 24 hours)

On the condition that I am not treated as indicated in the information sheet distributed to subjects, I can contact the Chair of Mahidol University Central Institutional Review Board, (MU-CIRB) at the office of the President, Mahidol University, Tel 66-2-8496224-5, Fax 66-2-849-6224.

For MU-CIRB Staff

Protocol No.: MU-CIRB 2025/080.1402 COA(T) No. MU-CIRB 2025/147.0205

I am aware of my right to further information concerning benefits and risks from the participation in the research project and my right to withdraw or refrain from the participation anytime without any consequence on the service or health care I am to receive in the future. I consent to the researchers' use of my private information obtained in this research, but do not consent to an individual disclosure of private information. The information must be presented as part of the research results as a whole.

I thoroughly understand the statements in the information sheet for the research subjects and in this consent form. I thereby give my signature.

Signature..... Participants/ Proxy/ Date...../...../.....

(.....)

Signature..... Principal Investigator/ Representative

(.....)/ Date...../...../.....

In case that the participant is illiterate, the one who read this document for the participant is (Mr./Mrs./Ms…

…….), who gives his/her signature as a witness.

Signature.....Impartial Witness/ Date...../...../.....

(.....)