

# Study protocol: cluster randomized controlled trial on physical-cognitive training for fall prevention in institutionalized older adults with cognitive impairment

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## Abstract

Falls are common among institutionalized older adults, especially those with cognitive impairment. These events lead to significant injuries and decrease the quality of life. The effectiveness of fall prevention strategies, including multifactorial and multi-component interventions, remains unclear for this population. This protocol aims to comprehensively describe the study design, methodology, and procedures for implementing combined Physical-Cognitive Training (PCT) to prevent falls among residents with cognitive impairment. A double-blind, cluster-randomized controlled trial will be conducted with participants aged 60

and above. At least sixty-eight residents from two institutions will be recruited, with one group receiving combined PCT and the control group receiving only physical training. The intervention consists of 30 minutes of physical training (range of motion, strengthening, balance, and deep breathing) and 20 minutes of cognitive stimulation therapy, performed twice weekly over 12 weeks. Trained instructors will deliver the intervention using a structured module, with the principal investigator overseeing adherence to the protocol. Measurements, including balance (Timed Up and Go Test), muscle strength (30' Chair Stand Test, fear of fall (Fall Efficacy Scale-16), and number of falls, will be collected by assessors at baseline, post-intervention, and 12-week follow-up. This protocol provides a detailed framework for implementing combined interventions to prevent falls among residents with cognitive impairment. The protocol ensures replicability and contributes to evidence-based practices in long-term care settings for older adults.

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## Introduction

The prevalence of falls in older adults residing in healthcare institutions exceeds that in other settings.<sup>1,2</sup> Previous studies have highlighted a higher incidence of falls among residents compared to those living in the community.<sup>3</sup> Annually, approximately 50% of Nursing Home (NH) residents experience falls, with 10%-30% sustaining major injuries such as hip fractures, head injuries, and lacerations requiring hospitalizations.<sup>4,5</sup> However, residents in NHs face significant health challenges, with a decline in the ability to do daily activities, malnutrition, pressure sores, urine incontinence, pain, constipation, depression, and polypharmacy that may affect fall incidents.<sup>6</sup> The significant factors that increase the incidence and risk of falls make it a major concern in older adults' residential care institutions.

Health problems and changes among older adults affect all bodily systems, including cognitive and affective functions. Physiological changes in the musculoskeletal system, neurosensory system, and cognitive function contribute to increased fall risks among older adults.<sup>7</sup> Meanwhile, cognitive impairment has also been identified as a risk factor for falls in older adults.<sup>8</sup> In clinical settings, residents with severe cognitive impairment might become bedridden, while those with mild cognitive impairment are at a higher risk of unsafe walking patterns and wandering.<sup>9</sup> Unsafe walking patterns and wandering make them especially prone to an advanced fall prevention program.

The urgency of addressing fall prevention in NHs is emphasized by the high prevalence of falls among residents. It is also preferable to proceed by implementing interventions for those identified as high-risk older adults.<sup>10</sup> Nurses are critical in imple-

menting fall prevention programs in NHs, contributing to direct care, assessment, planning, education, and research.<sup>11,12</sup> They are responsible for leading multidisciplinary fall prevention teams as they hold the most detailed information on fall incidents within the ward.<sup>11</sup> Educating nurses on assessing and assigning fall risk is inadequate for fall prevention.

Research has identified various fall prevention activities, including physical exercise, cognitive training, artificial intelligence-based equipment training, pharmacological treatments, and educational programs aimed at preventing falls.<sup>13-16</sup> Additionally, advancements have been made in fall prevention through multifactorial and multiple-component interventions.<sup>2,14,17</sup> However, the effectiveness of these strategies remains uncertain, particularly among nursing home residents, due to the variability of trial settings and the limited number of participants in these trials.

### Physical training

The most prevalent single intervention for fall prevention is physical exercise, although the type, frequency, and duration vary significantly. Previous studies have demonstrated that exercises focusing on muscle strength and balance training effectively enhance fall-related outcomes and reduce the number of falls.<sup>18,19</sup> These exercises aim to improve and maintain residents' gait and body balance. Other practical physical exercises include tai chi, yoga, walking, and aerobic exercise.<sup>19-22</sup>

Lower limb strength training can increase muscle mass, which improves the ability and endurance of the legs while walking among older adults. This is complemented by balance exercises, which help them maintain better stability both when walking and standing. As leg strength and balance improve through training, so does their confidence. Older adults with cognitive impairment often experience gait disturbances, such as taking small steps and walking on their tiptoes. Strength and balance training can help them improve their walking patterns. However, symptoms like wandering and agitation among older adults with cognitive impairment increase the risk of falls, which cannot be fully addressed through physical exercise alone.

### Cognitive training

Another intervention to prevent falls among older adults is cognitive training. A systematic review concluded that cognitive-motoric intervention appears to have similar effectiveness in ameliorating falls compared to traditional programs.<sup>23</sup> As outlined in the CST leader's guidebook, this therapy typically lasts for 14 weeks, with 45-minute sessions conducted twice a week by two facilitators for groups of 8-12 participants. The CST includes engaging in group activities and discussions designed to improve cognitive and social functioning in older adults.<sup>24</sup>

Cognitive stimulation therapy has been proven to enhance orientation and memory in older adults with cognitive impairment. This group-based therapy is particularly well-suited for nursing home residents. Improved orientation increases their awareness of their surroundings, leading to greater caution. Enhanced memory not only helps older adults with cognitive impairment recall information but also aids in recognizing and planning necessary activities, thereby reducing purposeless wandering.<sup>25</sup>

### Combined physical cognitive training

A group therapy combining physical and cognitive interventions emerges as a rational and sustainable approach, addressing both physical and cognitive factors that contribute to increased fall risk. A combination of muscle strengthening, balance, and cognitive training has a significant impact on balance in older adults, as

measured by the Timed Up and Go Test (TUG).<sup>26-28</sup> The effectiveness of combined physical and cognitive training in reducing fall incidents and fall-related outcomes in older adults has been demonstrated in a systematic review article by the author. The meta-analysis from this article reveals a moderate effect of the combined intervention; however, the total sample size remains small, and variations in the study methodology limit the generalizability of the findings and the feasibility of conducting a meta-analysis.<sup>29</sup>

The combined intervention was therefore developed to address the high incidence of falls among residents by considering the main significant fall risk factors: gait and balance disorders, as well as cognitive impairment. This study protocol aims to provide a comprehensive framework for evaluating the effectiveness of a combined physical-cognitive training intervention for fall prevention in institutionalized older adults with cognitive impairment. In addition to detailing the intervention procedures, this protocol outlines the overall study methodology, including participant recruitment, randomization, intervention delivery, and outcome assessments. By providing a structured and replicable research design, this study seeks to contribute to evidence-based fall prevention strategies and support the integration of structured physical and cognitive training into long-term care settings.

## Materials and Methods

### Study design

This study employs a double-blinded Cluster Randomized Controlled Trial (CRCT) design, comparing a Combined Physical Cognitive Training (PCT) group with a Single Physical Training (PT) group. The PCT group undergoes simultaneous physical exercise and cognitive stimulation therapy, while the PT group receives physical exercise alone. Measurements occur at baseline, 12 weeks post-intervention, and 12 weeks after follow-up.

The study will take place at two Panti Sosial Tresna Werdha (PSTW) facilities, owned by the Jakarta provincial government in Indonesia. Both institutions share similar characteristics, with most residents being neglected older adults. Participants were randomly selected to represent each residential unit within the institutions, following inclusion and exclusion criteria determined by the principal investigator and local nurses. All selected participants were gathered to receive a detailed explanation of the study, and then individually signed informed consent forms (Figure 1).

This research protocol was registered on 23 September 2024, on the Australian New Zealand Clinical Trials Registry with registration number ACTRN12624001154594p. It also received ethical approval from the Health Ethics Committee of the Faculty of Nursing, Universitas Indonesia (KET-206/UN2.F12.D1.2.1/PPM.00.02/2024). Participation in the study was entirely voluntary, with no coercion involved. The researcher will assume full responsibility for any negative effects proven to be caused by the study's interventions, ensuring the trial is safe and feasible for all participants.

The study population includes PSTW residents with cognitive impairments. The sampling method combines purposive sampling for selecting the location and stratified random sampling for selecting participants, a technique known as multistage or cluster sampling.<sup>30</sup> Sample size calculation was conducted using G-Power software (version 3.1.9.4) with an alpha level of 0.05, a power level of 90%, and a medium effect size (0.2) across two groups and

three measurement points. To account for an anticipated attrition rate of 20%, the required sample size was calculated to be 68 participants, who will be evenly divided into two groups of 34 residents each.

The inclusion criteria for the study were as follows: participants aged 60 years or older, able to walk with or without assistive devices, a Mini-Mental State Exam (MMSE) score between 13 and 24 (indicating mild to moderate cognitive impairment), and the ability to speak the Indonesian language. Residents who were involved in other trials during the same period were excluded. Additionally, individuals with a history of lower limb orthopedic surgery or comorbidities such as cancer, neurological or psychiatric disorders, and significant visual or auditory impairments were also excluded from the study.<sup>22,31</sup>

### Study intervention

The combined Physical Exercise and Cognitive Stimulation Therapy (PCT) will be administered simultaneously for 50 minutes twice a week over twelve weeks. The PCT session initiation assessment includes a vital sign assessment, which involves checking Blood Pressure (BP), temperature, and pulse. Participants who report any health complaints before the session will be assessed the eligibility to continue the session.

Group intervention involves eight to ten participants with one randomly assigned group instructor and facilitator. The instructor, a nurse with therapist responsibilities, undergoes training on intervention delivery. The therapist holds at least a bachelor's in nurse-level education, completes eight hours of training, and undergoes randomization. The facilitator supports the instructor, assists participants in understanding instructions, and ensures proper intervention execution. The facilitators in this intervention were nurses from each institution.

Following training, an intervention guidebook is distributed to instructors and facilitators, providing step-by-step instructions for physical exercise and CST. The intervention manuals were developed separately for each institution, consisting of a PCT and PT intervention manual. The guidebook includes images of each movement, tools, and how to perform used in both combined and single groups. Instructors and facilitators record baseline, post-

intervention, and follow-up measurements in a participant record book. The record book records participant names, session attendance, and initial session assessment results, all signed by the instructor.

The 30-minute physical exercise includes a range of motion, balance, muscle strength, and deep breathing exercises (Table 1). These exercises target limb and body muscles, addressing stiffness and reduced range of motion in older adults. Emphasizing lower limb exercises, known for their role in fall prevention, these exercises balance and strengthen muscles, with additional time allocat-

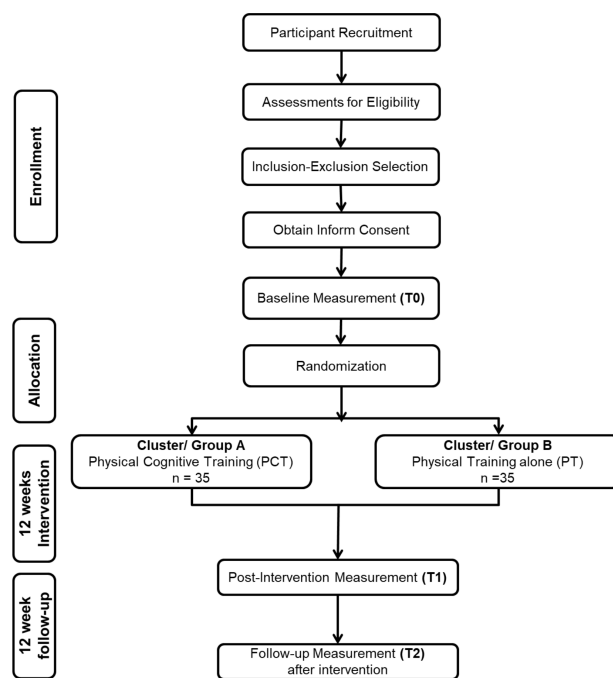


Figure 1. Flow diagram of study participants.

Table 1. Physical and cognitive training.

Physical Training		
Exercise	Detail movement	Time and tools
Range of motion	Head, shoulder, arm, back, waist, feet	7 minutes, backrest chair
Balance exercise	Standing, balancing, walking	10 minutes, backrest chair, bloc
Muscle strength exercise	Upper-lower arm, upper thigh-lower feet	10 minutes, step board, backrest chair
Deep breathing	Purse-lip breathing	3 minutes, backrest chair
Cognitive training		
Part	Detail activities	Duration
Opening	Memorizing and orientation (introducing self, date-day of today, number of participants, today's topic)	3 minutes
Primary	Activities included throwing and catching a ball, listening to sounds, storytelling, tasting food, ABC 5 Basics word game, discussing current news, identifying famous faces and places, completing missing words, crafting with plasticine, mapping hometowns, estimating prices, playing snakes and ladders, solving crossword puzzles, engaging in origami, playing paired card games, recognizing songs, and assembling puzzles.	15 minutes
Closing	Wrap-up, checklist intervention book, next meeting	2 minutes

ed for optimal results. Using the pursed-lip technique, deep breathing helps relax muscles after exercise, preparing participants for subsequent cognitive training.

The Cognitive Stimulation Therapy (CST) implementation follows physical training without interruption, lasting twenty minutes, and comprising three integral components: the opening stage, primary activity, and closing stage (Table 1).<sup>32</sup> The opening phase focuses on memory and orientation training, incorporating questions about the current day and date. The primary activity centers on thematic exploration, involving twelve predetermined topics discussed cyclically to ensure comprehensive cognitive engagement. The closing stage integrates and documents the session, emphasizing reflection of the session. This structured yet adaptable approach aims to enhance cognitive resilience and contribute to the overall well-being of nursing home residents, aligning with the study's comprehensive objectives for fall prevention.

Various tools are essential for delivering the intervention and will be arranged by the researcher. Instructors and facilitators responsible for tool arrangement ensure their in proper condition before use. Physical exercise requires tools such as backrest chairs, blocks, and step stools. Each set should be ready and arranged for participants before starting the session. The chair must be sturdy and equipped with a backrest for exercise support. Each group will share ten wooden blocks measuring 20 cm × 10 cm × 8 cm. Additionally, step boards can be made of wood with dimensions of 50 cm × 10 cm × 30 cm and must be stable and capable of supporting body weight safely. For Cognitive Stimulation Therapy (CST), tables and chairs are used to accommodate participants, the instructor, and facilitators. Refreshments are provided during discussions, along with additional materials such as a speaker, pictures, plasticine, maps, origami paper, whiteboards, newspapers, picture cards, and puzzles, which are used based on specific topics and alternated between groups at each institution. In the single group as control, participants receive only physical exercise, following the same training stages as the combined intervention group, concluding within 30 minutes, and utilizing similar tools as in the combined intervention group.

### Outcome measurement

This study will conduct three measurements, all of which will be performed by a trained assessor. The time frame between the baseline measurement (T0) and post-intervention measurement (T1) is twelve weeks, with a twelve-week follow-up marking the final measurement (T2). The outcome measures adhere to established reliability and validity standards recommended by the CONSORT group.<sup>33</sup> The measurements prioritize participant safety to

prevent physical and mental harm and enhance measurement quality. Screening includes the Mini-Mental State Exam (MMSE), with a score between 13 and 24 indicating mild to moderate cognitive impairment, which guides participant inclusion. Sociodemographic characteristics are captured using a questionnaire, including age, gender, fall history, comorbidities, impaired vision, medications, Body Mass Index (BMI), and institutional service satisfaction.

### The timed-up and go test

The study focuses on four main dependent variables: balance status, muscle strength, fear of falling, and the number of falls. A trained assessor with a bachelor's in nursing conducts measurements three times using established protocols. Balance status is evaluated through the Timed-Up and Go Test (TUG), a widely used technique due to its simplicity and speed.<sup>34</sup> Participants start by sitting, then stand, walk three meters, turn around, walk back, and sit down again.<sup>35</sup> The assessor records the time using a reliable stopwatch. Measurements are taken twice, and the shortest time is used. The principal researcher conducted TUG testing with two assessors to assess measurement consistency. Inter-rater reliability analysis (two-way random) showed excellent agreement (Intraclass correlation/ ICC 0.926, 95% CI 0.869–0.961).

### The 30-second chair-stand test

Muscle strength measurements employ the 30-second Chair and Stand Test (30sCST), focusing on the functional lower limb strength.<sup>36</sup> Participants performed sit-stand movements with their hands on their chest for 30 seconds using a sturdy chair and a stopwatch. The assessor carefully counted the number of completed sit-stand cycles while ensuring safety.<sup>37</sup> Inter-rater reliability analyses (two-way random) conducted by the principal researcher and two assessors showed excellent agreement (ICC 0.947, 95% CI 0.906–0.973).

### The fall efficacy scale international

Fall efficacy, which indicates the fear of falling, is measured by the Falls Efficacy Scale-International (FES-I), a validated instrument with high reliability, consisting of seven items.<sup>38</sup> A systematic review of 58 articles shows that the short FES-I has good to excellent internal consistency values (Cronbach's alpha 0.96, ICC 0.96).<sup>39</sup>

### Number of falls

The number of falls will be recorded based on the participants' frequency of fall history in the last year during the baseline assess-

**Table 2.** Guidelines for physical and cognitive training.

Recommendations	
<b>Physical training</b>	
Intensity	Adjust to participants' physical conditions. Assist post-stroke elderly with walking difficulties and do not force perfect movements.
Speed of movement	Perform movements slowly so all participants, regardless of physical ability, can follow comfortably.
Set	Gradually increase intensity
Repetition	Perform exercises in order without repetition.
<b>Cognitive training</b>	
Interest	Instructors should be engaging, friendly, and supportive.
Ability	Assign more active roles to capable participants while assisting those who need extra support.
Language	Use simple and informal language. Communicate clearly and include light humor to keep participants engaged and cheerful.
Appreciate	Encourage confidence through verbal praise, gestures, and gentle physical affirmation.

ment and monitored throughout the intervention and follow-up periods for the following measurements.<sup>28,40</sup> Recording the number of falls will start at the beginning of the intervention using a book provided to each participant. The number of falls is assessed by monitoring unintentional incidents in which a resident descends to a lower level, regardless of whether a witness is present.<sup>41</sup> The total number of falls will be counted from the start to the end of the intervention and reported in the second measurement (post-intervention). During the follow-up period, the book will be handed to the facilitator, who will record any falls among participants. The recording during this period will include the date of the fall, the cause, any resulting injuries, and the facilitator's initials. If needed, recorded falls will be verified with the institution's facilitator and a local nurse.

### Sample size estimation and statistical analysis

The sample size calculation will be conducted using G-Power software (G\*Power 3.1.9.4). The statistical test was chosen as the parameter of ANOVA with a repeated measures within-between interaction, with an alpha level of 0.05, a power level of 90%, and a medium effect size of 0.2, using two groups and three time measurements. The effect size for the sample calculation is based on recommendations from a previous systematic review of older adults with cognitive impairment who received combined aerobic and cognitive training interventions to assess their executive function.<sup>42</sup> The sample size calculation yielded 56 participants, with an additional 20% attrition rate, resulting in an estimated 68 residents to be included as participants in this study. The participants will be divided into two groups, with each cluster consisting of an equal number of participants, namely 34 residents per group. The data analysis of this study will be divided into univariate, bivariate, and multivariate analyses using the Statistical Package for the Social Sciences (SPSS) for Windows, version 25. Data processing of measurement results on participants will use the Intention-to-Treat (ITT) method. This is done because researchers want to uphold the integrity of the randomization carried out, provide conservative estimates of the intervention effect, and reflect compliance and dropout in clinical practice.<sup>43</sup> Univariate analysis will describe each variable in detail, with numeric data (e.g., age and dependent variables) presented as central tendencies, standard deviations, minimum-maximum values, and 95% Confidence Intervals (CI), while categorical data (e.g., gender, education, comorbidities, BMI, and medications) will be shown as frequency distributions and percentages.<sup>44</sup> Bivariate analysis will assess the intervention's effect on the dependent variables using the Friedman test, as the data will be converted into binary form. Homogeneity between groups will be tested using Levene's test, with  $p > 0.05$  indicating equal variance.<sup>44</sup> Multivariate analysis will compare the effectiveness of the two interventions while controlling for demographic and participant characteristics. Given the repeated measurements within the same group, the Generalized Estimating Equation (GEE), an extension of the General Linear Model (GLM), will be applied, using the binomial distribution and logit link to account for main effects, interactions, demographic data, and participant characteristics. This approach provides a robust understanding of how independent variables and covariates influence study outcomes.<sup>44,45</sup>

### Discussion

This study aims to evaluate the effect of concurrent physical and cognitive training on balance, muscle strength, fear of falling,

and fall-related psychosocial factors among nursing home residents, comparing it with a group receiving solely physical exercise. Conducted in group therapy with 8-10 participants, the intervention aims to empower nurses facing burnout challenges.<sup>46</sup> Effective, scalable interventions are crucial for sustainable post-research implementation. Involving local nurses, provided with training and equipment, can significantly reduce falls through nursing care in homes.<sup>2,12</sup>

Aligned with systematic reviews and meta-analyses, this research highlights the importance of balance training in physical exercise and cognitive training focused on orientation.<sup>34</sup> A minimum 12-week intervention, meeting recommended session and duration criteria, is based on these findings.<sup>26,36,47</sup> Participant group size adheres to established parameters in older adult group therapy research.

Instrument choices are grounded in prior studies; Timed-Up and Go (TUG) for balance assessments, highlighting its convenience and reliability.<sup>27,48</sup> Muscle strength, a crucial aspect in fall prevention, is addressed through targeted lower extremity exercises. Fear of falling, assessed with FES-I, relies on participants' self-reporting abilities. Primary outcomes focus on fall occurrences, necessitating close collaboration with local healthcare providers, considering individual perceptions and fall incident reports for accurate data.

### Conclusion

In conclusion, this study protocol provides a comprehensive framework for evaluating the feasibility and potential benefits of combined physical-cognitive training for fall prevention in institutionalized older adults with cognitive impairment. By detailing the intervention design, methodology, and implementation process, the protocol aims to ensure clarity and replicability in future research. The findings from this trial are anticipated to inform the integration of structured group-based physical and cognitive training programs into routine nursing care for residents in institutional settings.

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