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Distinctive Effects of Combined Physical Cognitive Training and Physical Training on Fall and Fall-Related Outcomes in Institutionalized Older Adults with Mild Cognitive Impairment

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TABLE OF CONTENT

FIGURE & TABLE

Figure

Table

ABSTRACT

Background

Institutionalized older adults face significant fall risks due to the aging physiological changes among the bodily systems, including cognitive function and vulnerable factors. Falls lead to injuries and decrease the resident quality of life. The effectiveness of fall prevention strategies, including multifactorial and multiple-component interventions among cognitively impaired residents, remains unclear.

Purpose

This study examines the effectiveness of a combined intervention (physical and cognitive training) and physical training alone in fall incidence and fall-related outcomes among institutionalized older adults with mild cognitive impairment. The fall-related outcomes include balance, muscle strength, and fear of falling.

Method

Employing a blinded Cluster Randomized Controlled Trial (CRCT) design, two older adult care institutions in Jakarta Province, Indonesia, will be randomly assigned to either the combined intervention or a single intervention group. Measurements will be taken at baseline, 12 weeks post-intervention, and another12 weeks follow-up. The study will include 68 participants, divided equally between the two groups. Various validated instruments, including the Timed-Up and Go Test (TUG), 30-second Chair Stand Test (30-s CST), and Fall Efficacy Scale-International (FES-I). Assessors, leaders, and facilitators will receive appropriate training before randomization. Intention-to-treat (ITT) analysis will be applied to the study. Univariate, bivariate, and multivariate analysis will utilize descriptive statistics,

Friedman test, and multilevel modeling analysis Generalized Estimating Equation (GEE) with binomial distribution and logit link, respectively. Ethical principles will be strictly followed to ensure participant safety and rights.

Expected Outcomes

The entire study is expected to become a solution for fall prevention among institutionalized older adults with mild cognitive impairment. The combined intervention is expected to reduce fall incidence and enhance fall-related outcomes compared to physical training alone.

Keywords

Combined intervention, fall prevention, fall-related outcomes, physical cognitive training, PSTW, resident.

CHAPTER I. INTRODUCTION

Background

Institutionalized older adults, commonly known as residents, represent a distinct population with unique care needs. Globally, the population of nursing home residents ranges from 1% to 5% of the total older adult population, which is influenced by the country's income level and available healthcare services (WHO, 2015). In the United States (US), there are approximately 1.4 million residents (2.41%), while Japan and Taiwan respectively resettled 586,000 (1.62%) and 180,000 (4.2%) nursing home residents of the total older adult population (Fudosan, 2023; MoHW, 2020; NCHS, 2023). However, residents in nursing homes face significant health challenges, with a decline in the ability to do daily activities, undernutrition, pressure sores, urine incontinence, pain, constipation, depression, and polypharmacy (Bakerjian, 2022). Chronic conditions such as renal disease, mental health issues, cardiac arrhythmia, diabetes, and cancer are prevalent among nursing home residents (Manis et al., 2023). The physical and psychological vulnerability of residents underscores the complexity of managing their healthcare needs.

Older individuals are considered at risk due to various biological, lifestyle, and environmental factors predisposing them to health issues (Stanhope & Lancaster, 2012). Given their unique characteristics, this risk is further worsened among older adults residing in nursing homes. The term "vulnerable population" aptly describes residents in nursing homes, as they face multiple challenges in accessing healthcare services and are at higher risk of health problems due to a combination of social, economic, cultural, and health-related factors (Havrilla, 2017; Sanchini et al., 2022). Extensive research in this area underscores the importance of

community-based interventions tailored to the needs of vulnerable groups, including nursing home residents. Healthcare services for vulnerable older adults vary widely in each country and are adjusted based on the country's income level.

Indonesia is a developing country in Asia, home to a significant aging population, with approximately 27 million older individuals accounting for 10% of the total population (Kemenkes, 2020). Tresna Werdha Social Home (PSTW) is a residential and long-term care facility for older adults in Indonesia, overseen by the regional government and the Ministry of Social Affairs. However, a majority of PSTW residents are older adults who have been neglected and lack familial support (Susilowati et al., 2022). It is estimated that around 18 thousand (0.06%) elderly individuals reside in PSTW, where care services focus primarily on social support (Rahayu et al., 2018). Health issues in residents, not solely attributed to aging, pose significant challenges that necessitate advanced treatment.

Changes among older adults occur physically and psychologically in all bodily systems, including cognitive and affective functions. Physiological changes in the musculoskeletal system, neuro-sensory system, and cognitive function are responsible for increasing fall risks among older adults (Chantanachai et al., 2021). Meanwhile, cognitive impairment has also been identified as a risk factor for falls in the elderly (Leroy et al., 2023). In more detail, it is known that only mild cognitive impairment has a positive relationship with the risk of falls (Seijo-Martinez et al., 2016). 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. Unsafe walking patterns and wandering make them especially need measures to prevent falls.

Previous studies have highlighted a higher incidence of fall among residents compared to those living in the community (Cameron et al., 2018). Annually, approximately 50% of nursing home residents experience falls, with 10%-30% sustaining major injuries such as hip fractures, head injuries, and lacerations requiring hospitalizations (CDC, 2020; Luebbert et al., 2022). The urgency of addressing fall prevention in NHs is emphasized by the high prevalence of falls among residents by the nursing. Nurses are critical in implementing fall prevention programs in NHs, contributing to direct care, assessment, planning, education, and research (Morse, 2009; Ojo & Thiamwong, 2022). Educating nurses on assessing and assigning fall risk is inadequate for fall prevention. It is preferable to proceed by implementing interventions for those identified as high-risk older adults (Huang et al., 2021). Nurses are responsible for leading multidisciplinary fall prevention teams as they hold the most detailed information on fall incidents within the ward (Morse, 2009).

Research has identified various fall prevention activities, such as physical exercise, cognitive training, training using artificial intelligence-based equipment, pharmacologic treatments, and educational programs on fall prevention (Albasha et al., 2023; Delbroek et al., 2017; Montero-Odasso et al., 2022; Xing et al., 2023). Additionally, advancements have been made in fall prevention through multifactorial and multiple-component interventions (Montero-Odasso et al., 2022; Sanchez-Sanchez et al., 2022; Vlaeyen et al., 2015). However, the effectiveness of these strategies is still uncertain, particularly among nursing home residents, due to the variability of trial settings and lack of trial participant numbers. While these interventions may reduce fall rates among fallers and recurrent fallers, their impact on fall-related outcomes is less clear, given the lack of systematic reviews in this area (Hopewell et al., 2018; Vlaeyen et al., 2015). Additionally, findings from a systematic review article on combined interventions suggest a moderate effect. However, the overall sample size is small

(<150 older adults) and utilized a group strategy (Wati et al., 2024). Effective fall intervention strategies simultaneously address multiple fall risk factors while considering whether they are individually tailored or group intervention. .

Ensuring effective fall interventions for residents by combining physical and cognitive training interventions in a group emerges as a rational and sustainable approach, identified as precise interventions based on evidence-based practice (Wati et al., 2024). A group intervention that delivers massively among participants without particular assessment initially is part of multiple-component fall prevention (Hopewell et al., 2018). The combined intervention addresses the high fall incidence among residents by considering various significant fall risk factors, as explained above. The current study will contribute to institutionalized older adult care, which is fall prevention, by implementing a combination of physical and cognitive training interventions. The effectiveness of combined intervention on fall incidence, balance, fear of falls, and muscle strength will be investigated in this study among nursing home residents with mild cognitive impairment as well as comparing the effects with the single exercise intervention

Significances of The Study

The study carries significant implications for addressing challenges among institutionalized older adults, especially those in nursing homes. Firstly, falls are prevalent among nursing home residents, with approximately 50% experiencing falls annually, causing severe health risks compared to older adults living in the community (Cameron et al., 2018; CDC, 2020). Secondly, given that about half of nursing home residents have varying levels of cognitive impairment, they face an increased risk of falls due to behaviors like agitation and wandering (Seijo-Martinez et al., 2016; Steven Marshall, 2023). The second condition categorizes

nursing home residents as vulnerable (Havrilla, 2017; Sanchini et al., 2022). The risk of various comorbidities, limited access to healthcare services, environmental risks, and cultural factors further increase vulnerable conditions. There is an essential need for fall prevention programs that can address multiple significant fall risk factors for residents. The combination of physical and cognitive training is a solution based on evidence pointing to preventing falls among nursing home residents. This combined approach covers multiple risk factors and is expected to be sustainable and feasible for staff to implement continuously, reducing their workload (Wati et al., 2024). By adopting comprehensive outcome measurements and following existing recommendations from previous studies, this research seeks to provide nuanced insights into the effectiveness of interventions.

Nurses are crucial in executing fall prevention programs in nursing homes, from assessment and diagnosis to planning interventions and providing care (Ojo & Thiamwong, 2022). Nurse-led initiatives have shown promise in addressing fall prevention, emphasizing the importance of this upcoming research in addressing the pressing concern among older adults. The combination of physical and cognitive training interventions represents a direct intervention, likely generating more effective results in reducing fall rates than providing education alone to nurses (Huang et al., 2021).

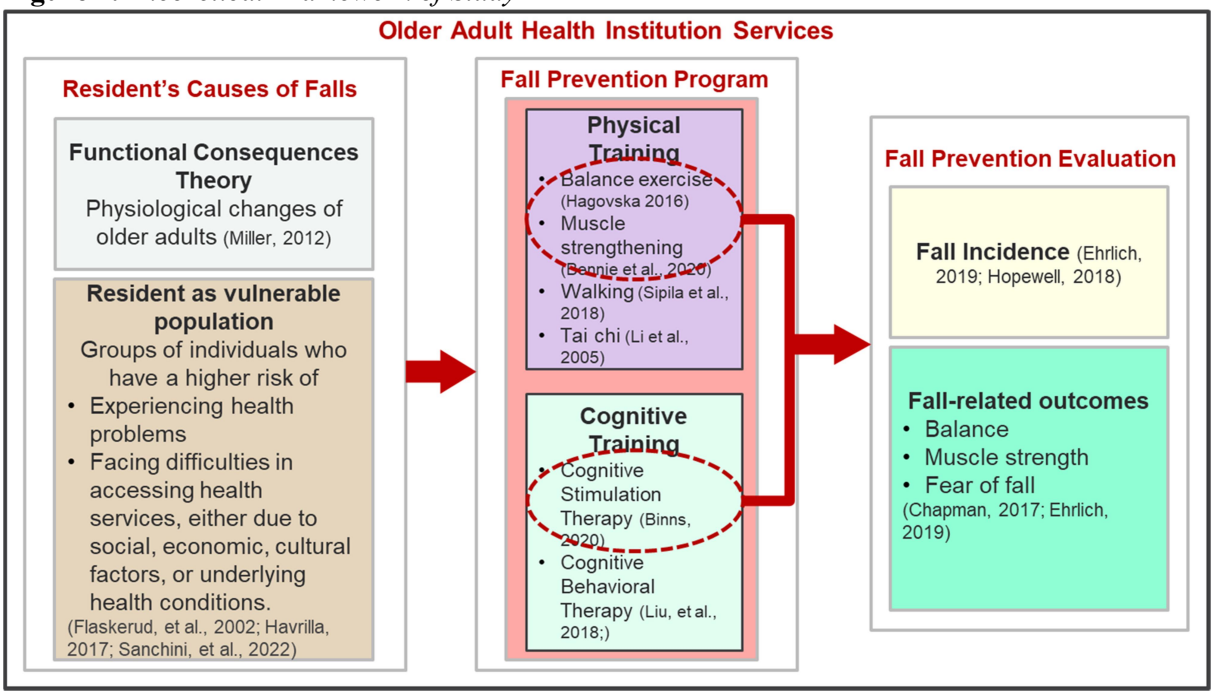
Long-term care services for the elderly in Indonesia are currently developing slowly, despite the population of elderly individuals nearly doubling in the past five years (Ref...). This slow development is evident in both the number of institutions and the quality of services provided. Fall prevention programs for the elderly in institutions such as residential care homes face various challenges due to inadequate facilities and staff knowledge. This study

aims to provide an effective and efficient solution for fall prevention among residents in these care homes, particularly those with mild cognitive impairment.

The proposed interventions have broader implications for enhancing the care of institutionalized older adults, particularly in nursing homes. This study addresses gaps in fall prevention. It aims to significantly decrease fall incidence and enhance fall-related outcomes for institutionalized older adults.

Theoretical Framework of The Study

Figure 1. *Theoretical Framework of Study*



The above figure becomes this study's theoretical conceptual framework, incorporating one theory and concept widely utilized in nursing research. The framework describes how the theory and concept are employed to identify issues and guide intervention determination and evaluation as an integrated unit within older adult institutions.

The setting utilized in this study is older adult care institutions, where residents live together in a facility characterized by homogenous individual characteristics and environment. The theory of functional consequences of aging processes by Carol A. Miller (2012) explains physiological changes across all bodily systems and functions in older adults. These changes in the neuro-sensory system, musculoskeletal system, and cognitive functions require implications for residents' lives in nursing homes, rendering them susceptible to falls (Chantanachai et al., 2021; Frontera, 2017; Grimmer et al., 2019). While the step-by-step physiological changes enable adaptation in older adults, various factors complicate efforts to ensure residents' safety from fall incidents.

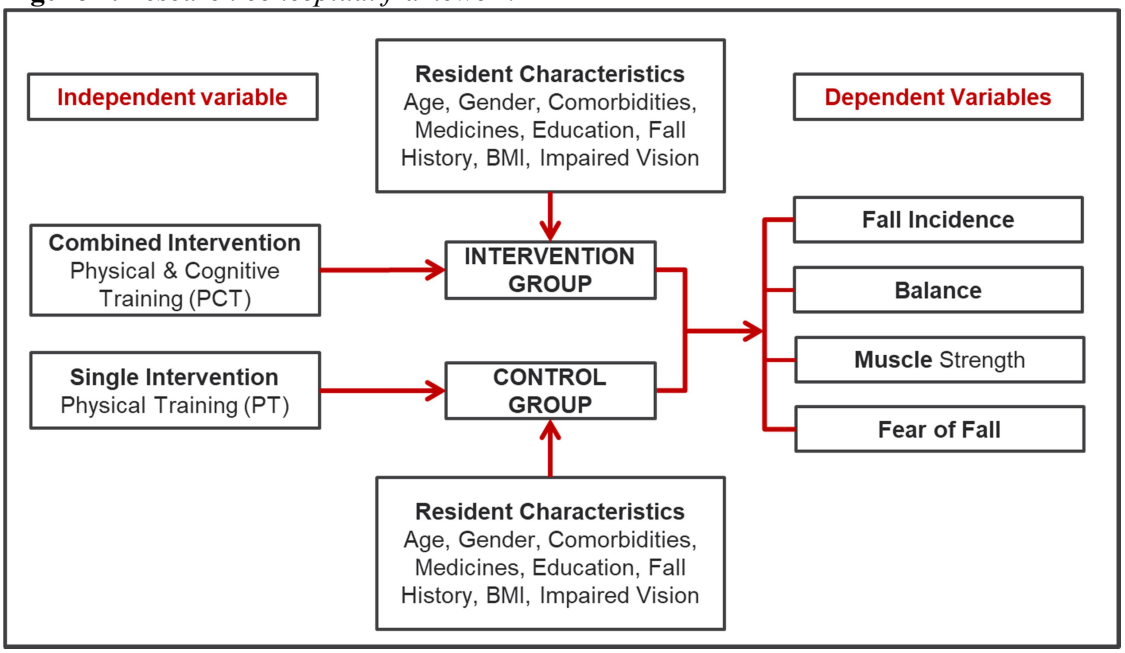
The concept of vulnerable populations is widely employed by community health nurses to describe groups or individuals with an increased risk of health problems and difficulties accessing healthcare services due to social, economic, cultural, or other issues (Flaskerud et al., 2002; Havrilla, 2017; Sanchini et al., 2022). Residents in nursing homes exhibit higher levels of dependence and health issues such as undernutrition, pressure sores, urine incontinence, pain, constipation, and depression compared to older adults living with families in the community (Bakerjian, 2022; Cameron et al., 2018). These conditions significantly impact balance, gait, muscle strength, and vision, including cognitive impairments, as additional predisposing factors for residents to experience fall incidents. The physiological aging changes and vulnerability of a population at risk underscore the urgency of implementing fall prevention programs in elderly care institutions, referencing both factors based on the explained theory and concept.

Fall prevention programs for nursing home residents are mandatory and should be led by nurses. Previous studies have explicitly emphasized the importance of physical exercise in

enhancing muscle strength, balance, and gait, which are critical elements in fall prevention (Bennie et al., 2020; Hagovska et al., 2016; Li et al., 2005; Sipilä et al., 2018). Over time, research advancements have also demonstrated the association between fall incidents and cognitive impairments, warranting cognitive exercises to reduce fall incidence in older adults (Binns et al., 2020; Liu et al., 2018). This study merges exercises most frequently identified to decrease fall incidents and enhance falls-related outcomes into a combined exercise regimen. This combination exercise comprises balance and muscle strength exercises alongside cognitive stimulation simultaneously to address multifactorial fall risks in residents.

The efficacy of the implemented combined exercise program will be evident following evaluation. The evaluation recommended in this study encompasses utilizing multiple instruments simultaneously to confirm results across different areas (Martins et al., 2018). Indeed, fall incident rates constitute a crucial outcome requiring measurement, although often not directly observed by staff. To validate intervention outcomes, various outcomes combined into a fall-related outcomes framework are expected to enhance fall incident reduction efforts among older adult residents in nursing homes.

Figure 2. *Research conceptual framework*



This study encompasses various variables, including dependent and independent variables, and factors influencing subject variables, each serving distinct roles in examining the research focus, which will be explained in a chart below (Figure 3). The dependent variable, or the outcome variable, is the main focus of the investigation, representing the phenomena under scrutiny (Faizi & Alvi, 2023; Pagano & Gauvreau, 2018). In this context, the dependent variables include fall incidence and fall-related outcomes such as muscle strength, fear of falls, and balance. Emphasis is placed on addressing fall prevention among nursing home residents with mild cognitive impairment, with primary outcomes revolving around fall incidence, balance, muscle strength, and fear of fall. Conversely, cognitive status is a secondary outcome due to its peripheral relevance to the primary research objectives (Cresswell, 2018). The interventions, categorized as Group A with PCT intervention and Group B with PT intervention, serve as the independent variables in the study. Conversely, factors influencing subject variables are instrumental in forecasting or elucidating variations in the dependent variable, owing to their inherent influence or association with the phenomenon of interest (Cresswell, 2018). Past research suggests that age, gender, education,

comorbidities, Body Mass Index (BMI), fall history, impaired vision, and medications are among the factors influencing subject variables pertinent to the study's dependent variable (Binns et al., 2020; Hagovská & Olekszyová, 2016; Lipardo & Tsang, 2020).

Research Purposes

The study aims to examine and compare the different effect of the combined intervention involving physical and cognitive training and physical training alone on fall and fall-related outcomes among institutionalized older adults with mild cognitive impairment.

Specific Aims

1.1 To examine the effects of the combined and single intervention on fall and fall-related outcomes (balance, muscle strength, and fear of falls), in institutionalized older adults with mild cognitive impairment, respectively.

1.2 To compare the effects of the combined and single intervention on fall incidence and fall-related outcomes (balance, muscle strength, and fear of falls), in institutionalized older adults with mild cognitive impairment, respectively..

Hypotheses

1.1 The combined (physical cognitive training) intervention would decrease fall incidence and enhance fall-related outcomes in institutionalized older adults with mild cognitive impairment.

1.2 The single (physical training) intervention would decrease fall incidence and enhance fall-related outcomes in institutionalized older adults with mild cognitive impairment.

1.3 The combined intervention has a better effect on decreasing fall incidence and enhancing fall-related outcomes than the single intervention for institutionalized older adults with mild cognitive impairment.

Definition of The Terms

Balance

Balance, the intricate coordination of the musculoskeletal, central nervous, and sensory systems, enables the body to maintain stability and control its position, whether stationary or in motion, encompassing both static posture against gravity and dynamic stability during weight shifts (Xing et al., 2023; Dunsky et al., 2017).

Operational Definition: The present study assesses balance using the Timed-Up and Go Test (TUG), a standardized procedure involving the measurement of the time taken for individuals to perform specified movements: rising from a seated position, walking a predetermined distance of three meters, executing a turn, and returning to the initial seated position. The test administration entails an observer timing the participant's performance with a stopwatch, conducting the assessment twice, and recording the shortest duration achieved (Dunsky et al., 2017). Required materials for conducting the TUG test include a chair equipped with armrests and a backrest, a stopwatch for precise timing, and a designated marker denoting the three-meter distance (feasibly demarcated using adhesive tape or a physical marker). Notably, a completion time exceeding 12 seconds indicates compromised functional balance among older adults, as established by previous research (Susilowati et al., 2022).

Muscle strength

Muscle strength is an individual's ability to perform daily tasks effectively, assessed by measuring their functional capacity in specific instructed movements (Bennie, 2020). This differs from muscle mass, which is more accurately measured at the cellular level by quantifying the amount of muscle tissue in the body.

Operational Definition: The muscle strength assessment in this study utilizes the 30-second Chair-Stand Test (30-s CST), where older adults perform alternate sitting and standing movements for 30 seconds using a chair with back and hand support against a secure wall.

Repetitions completed within the timeframe are counted, with an additional repetition recorded if the individual is in the process of sitting when the time expires. A cutoff point of 12 sit-to-stand movements within 30 seconds indicates leg muscle weakness, based on previous research recommendations in Indonesia with a similar population (Figueiredo et al., 2021; Susilowati et al., 2022).

Fall efficacy

Fall efficacy is widely utilized as a psychosocial measure associated with falls, reflecting individuals' feelings or concerns about experiencing a fall. Fall efficacy interchangeability with the term "fear of fall" underscores their similar conceptualization. Fear of falling is typically measured through a self-reported questionnaire to obtain a comprehensive overview of concerns about falling during daily activities (Delbaere et al., 2010).

Operational definition: The instrument chosen for measuring fear of falling in this study is the Fall Efficacy Scale-International (FES-I), comprising seven questions. These questions cover daily tasks such as dressing or undressing, bathing, transitioning in or out of a chair, and participating in social events outside the residence (Delbaere et al., 2010). Each question on the FES-I is rated on a four-point scale, ranging from "not at all concerned" to "very concerned." The total score is calculated by summing individual scores for each question, with scoring categories guiding interpreting results and reflecting different levels of concern from regular to high.

Fall Incidence

Fall incidence is defined by previous research as an unintentional event where an older adult finds themselves in a lower position or on the floor, regardless of whether injury occurs or witnesses are present (Kobayashi et al., 2009). All fall incidents are counted based on staff reports or resident accounts and verified for accuracy due to potential cognitive impairments that may affect the reliability of information.

Operational Definition: Measurement of fall incidents involves recording each event reported by staff and tallying the occurrences for each resident, which are then reported to the researchers. Baseline measurements are based on the frequency of falls in the past month. The second measurement counts falls from the start to the end of the intervention. The third measurement record falls from the end of the intervention to the final assessment.

CHAPTER II. LITERATURE REVIEW

Institutionalized Older Adult with Cognitive Impairment

Older Adult Care Institution

Older adult care institutions offer long-term care that provide vital services to assist older adults in daily activities, foster independence, conduct rehabilitation services, provide recreational opportunities, and deliver essential healthcare support (NIA, 2023). Distinct from acute care settings such as hospitals, these institutions encompass nursing homes, senior residential, and dementia care facilities (Miller, 2012). Particularly in developed nations facing significant demographic shifts, the prevalence of elderly care institutions is rapidly increasing. The demand for long-term care services among older adults is rising due to several factors, including the need for more extensive assistance as they age, the prevalence of complex health conditions, and the challenges associated with dementia-related behaviors (Abbasian M., 2019). Insurance coverage in several developed countries (Manis et al., 2023), such as Japan and the United States, facilitates access to such facilities, enhancing accessibility for older adults.

Institutionalized older adults present unique characteristics and health challenges necessitating tailored service approaches. Nursing home residents have extended stays, most living out the end of their lives here. In contrast to older adults living independently, nursing home residents typically exhibit diminished levels of independence, lower educational attainment, heightened susceptibility to falls, reduced physical activity, poorer overall health, and advanced age (de Medeiros et al., 2020). Common health problems among residents include diabetes, hypertension, stroke, heart disease, depression, cognitive impairment, sleep problems, and immobility (Boatswain, 2016). The rising number of older adults, along with

their more complex health issues, drives the need for more advanced healthcare services for this group. In developed countries, the government meticulously ensures high-quality services in nursing homes. It contrasts with the situation in developing countries, where the services for older adults often lack scope and quality.

Cognitive Impairment among Institutionalized Older Adults

The prevalence of residents displaying symptoms resembling dementia is markedly high, although the categorization of the precise type of cognitive impairment may vary significantly. More than half of nursing home residents generally have Alzheimer's disease or other dementia-related disorders (Richard Fleming, 2020), with 45.6% in the US (CDC, 2016) and around 46.6% in Australia, despite a decreasing trend (Harrison et al., 2020). Neuropsychiatric and behavioral symptoms are pervasive among nearly all older adults affected by dementia, encompassing manifestations such as agitation, wandering, hallucinations, depression, and sleep disturbances (Marshall, 2023; Jones, 2021; van der Mussele, 2015). Specifically, research indicates that symptoms of agitation and wandering are prevalent in approximately 60% of older adults diagnosed with MCI (van der Mussele, 2015).

Elderly Care Institution in Indonesia

Indonesia, situated in Asia, ranks fourth globally in terms of its older adult population, trailing behind China, India, and the United States (Udan Suheli, 2015). With approximately 27 million older adults, constituting nearly 10% of the population, Indonesia is undergoing a significant demographic shift towards aging (Kemenkes, 2020). Indonesia's national health development policy focuses on strengthening primary health care, targeting maternal, child, and reproductive health (DirjenNaKes, 2022). Currently, older adult health is not a priority in

health development in developing countries like Indonesia. While efforts have been made to address the needs of older adults, they often need to be more robust.

In Indonesia, services for older adults are still limited, offering few options. The Tresna Werdha Social Home (PSTW) is a long-term care facility run by the Ministry of Social Affairs or local governments. It mainly serves older adults who are often neglected and have social challenges, including many who are homeless and brought in by authorities (Susilowati et al., 2022). However, PSTWs mainly provide basic needs like food, shelter, and social activities, with healthcare being a smaller part of their services.

Presently, 277 PSTWs accommodate more than 18 thousand residents around the archipelago. Among them are three PSTWs managed by the central government, 71 managed by regional governments, and the rest developed by the private sector (ADB, 2021). Jakarta, a magnet for urbanization, particularly from neglected older adults, boasts a higher concentration of PSTWs than other regions. Nine PSTWs are operated by the Jakarta Special Capital Region (DKI) government (DinsosDKIJakarta, 2024). The healthcare workforce at PSTWs primarily comprises nurses, with infrequent visits from doctors. In contrast, private institutions offering long-term elderly care services tend to cater to individuals from middle to upper economic strata due to the associated costs (Susilowati et al., 2022).

Activities at PSTWs primarily revolve around assisting residents with daily tasks, engaging in religious and recreational activities, and participating in group exercises (Rahayu et al., 2018). The resident demographic at PSTWs typically exhibits characteristics such as low educational attainment, inadequate self-care abilities, cognitive impairment, malnutrition, and gait and balance disorders (Nurbasari & Gondodiputro, 2019; Wati et al., 2018). Common

health diseases prevalent among PSTW's residents include hypertension, stroke, arthritis, diabetes, and psychosis (Rahayu et al., 2018). Researchers observed that at several PSTWs in the Jakarta area, once a week, there is a physical exercise in the form of morning exercises attended by all residents and staff. The exercise, led by one instructor, involved fast-paced aerobic routines without facilitators to assist residents with mobility or cognitive problems or those using walking aids and wheelchairs. As a result, many residents could not fully participate because the exercises were not explicitly designed for their needs.

Nursing staff predominantly possess diploma qualifications, maintaining a nurse-to-resident ratio of approximately one to 40. Non-healthcare-trained caregivers, typically holding high school diplomas, supplement the care team with a ratio of roughly one caregiver to 10 residents. Nursing students from Universitas Indonesia and other nursing education institutions have been in clinical practice as part of academic learning courses in the PSTWs. The researchers have also been involved in the facilities' student supervision and practical training. Information regarding the PSTWs comes from the researchers' experience and interviews with nursing and PSTW office staff.

Fall Risk Factor among Institutionalized Older Adults with Mild cognitive impairment

Study indicates that residents experiencing cognitive decline face a twofold increased risk of falling annually (Livingston et al., 2020). Cognitive impairment is a significant risk factor for falls in nursing home residents due to the three reasons explained below. Firstly, studies have shown that symptoms of agitation and wandering are widespread, affecting roughly 60% of older adults diagnosed with MCI (Van der Mussele et al., 2015). Notably, agitation and wandering behaviors have been recognized as significant contributors to the heightened risk of falls among older adults (Lanctôt et al., 2017; Steven Marshall, 2023). Secondly, older

adults with cognitive impairment commonly present with gait and balance disturbances characterized by short steps, slow walking, and diminished movement coordination, often accompanied by neurological complications (DeMaagd & Philip, 2015). Lastly, the risk of falls escalates with the utilization of psychotropic medications, such as sedatives and antidepressants, frequently prescribed to older adults exhibiting symptoms of dementia (Richard Fleming, 2020). Given the urgency of this problem, it is imperative to conduct routine assessments to obtain accurate insights into the mild cognitive impairment experienced by residents, thereby facilitating effective fall prevention strategies.

Fall Prevention Programs

Fall Prevention Scope

The fall prevention program is widely recognized and implemented in many older adult care institutions, following established protocols from reputable organizations such as the World Health Organization (WHO), the American Geriatric Society (AGS), and the British Geriatric Society (BGS). The WHO, AGS, and BGS provide fall prevention guidelines for older adults in institutions firstly by emphasizing comprehensive risk assessments; implementing regular physical exercise,s including balance, strength, and flexibility training; educating residents and staff; modifying the environment by removing hazards; conducting medication reviews, especially for medicines that affect balance and cognition; and lastly, performing post-fall assessments to evaluate the effectiveness of a fall prevention program in the institution (Leung et al., 2024; Montero-Odasso et al., 2022). Despite various research efforts to develop effective fall prevention interventions for older adults, outcomes have varied. However, a consensus is that preventing falls is crucial for reducing injury and mortality risks (Montero-Odasso et al., 2022). The programs should be meticulously planned and evidence-based, adaptable to different settings. A significant challenge remains in intervention strategies and

outcomes standardizing to evaluate the effectiveness of these programs accurately. Comprehensive and rigorous fall prevention strategies must be formulated, especially for older adults in institutions, to ensure the program can achieve the expected outcomes.

The researchers conducted an investigation on all studies that implemented combined interventions through a systematic review. The manuscript explores the effectiveness of combining physical exercise and cognitive training in preventing falls among cognitively impaired older adults. Through a systematic review and meta-analysis of randomized controlled trials (RCTs) conducted in Europe, New Zealand, and the Philippines, the study found that this combined intervention significantly improves balance. The meta-analysis revealed a moderate effect size (ES = 2.29, SMD = 0.41, $p < 0.05$) with no heterogeneity ($I2 = 0\%$). The intervention included activities like balance exercises and cognitive training focused on memory and orientation, which were administered over more than 14 sessions, each lasting at least 60 minutes. The study emphasizes the critical role of balance and cognitive function in fall prevention for older adults, particularly those with cognitive impairment. The findings suggest that the combined intervention of physical and cognitive training effectively addresses the primary risk factors for falls, offering a promising approach to improving balance and reducing fall risk. However, the study also highlights the need for further research with standardized protocols and larger sample sizes to strengthen the evidence and refine fall prevention strategies for this vulnerable population

Fall Prevention Strategies for Institutionalized Older Adults

Evidence from previous research informs strategies for fall prevention programs in institutional evidence that older adults' research strategies differ from those used by older individuals living in community settings with their families (Montero-Odasso et al., 2022). Commonly employed strategies in institutions include single, dual, multifactorial, and

multiple-component interventions. Each approach has distinct characteristics that require further investigation to determine their effectiveness in improving fall-related outcomes (Fairhall et al., 2014). Research indicates that multifactorial and multiple-component interventions exist low-quality evidence for reducing fall risk and may have minimal impact on fall prevention (Hopewell et al., 2018). In older adult care institutions, it is crucial to consider not only the characteristics of the residents but also the availability of facilities and the capacity of staff to implement interventions correctly and sustainably (Lin et al., 2022).

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 fall incidence (Papalia et al., 2020; Thomas et al., 2019). These exercises aim to improve and maintain residents' gait and body balance. Other practical physical exercises include tai chi, yoga, walking, and aerobic exercise (Di Lorito et al., 2021; Nick et al., 2016; Sipilä et al., 2018; Thomas et al., 2019). Another intervention to prevent falls among older adults is Cognitive Stimulation Therapy (CST), which positively decreases fall incidence. The therapy, outlined in a guidebook for CST leaders, typically spans over 14 weeks, with a time duration of 45 minutes, with two sessions per week conducted by two assessors for groups of 8-12 older adults (Spector et al., 2006). CST involves engaging in group activities and discussions to enhance cognitive and social function in older adults (Aguirre et al., 2014). While physical exercise and CST individually in institutions address fall-related issues, more specific and effective interventions are needed to cover multiple fall risk factors comprehensively.

Combined interventions, also known as dual interventions, have been explored in previous studies but have yet to demonstrate conclusive efficacy in influencing fall-related outcomes due to limitations in participant numbers (Mai Ba & Kim, 2022)Wati et al., 2024). The combination proposed in this study entails integrating two types of training: physical exercise and cognitive training. Both exercises, when implemented individually, have shown significant promise in reducing the risk of falls and are recommended components of fall prevention programs (Binns et al., 2020; Liu et al., 2018; Papalia et al., 2020; Sipilä et al., 2018; Thomas et al., 2019). Drawing from this evidence, the amalgamation of these two exercise modalities is anticipated to yield enhanced effectiveness in mitigating fall risks among elderly residents (Binns et al., 2020; Donnezan Combourieu et al., 2018; Hagovska et al., 2016; Lipardo & Tsang, 2020; Turunen et al., 2022). These exercises have individually demonstrated the capacity to improve muscle strength, balance, gait, and cognitive function in the elderly, all of which are dominant risk factors for falls (Beck Jepsen et al., 2022; Davis et al., 2015; Liu-Ambrose et al., 2019; Porto et al., 2021). Consequently, combination interventions hold considerable promise as a viable approach to fall prevention among elderly residents, particularly those residing in institutional settings.

Elderly care institutions require fall prevention interventions that efficiently reduce the risk of falls among residents with particular characteristics that are susceptible to falls. Given the constraints of limited staffing and high workload, coupled with a significant portion of residents being at high risk of falling, it is imperative to implement intervention strategies that can adapt to these conditions (Gouveia et al., 2016; Morse et al., 1989; Mutch, 2022). Group-based fall prevention interventions, facilitated by two staff members for groups of eight to nine residents, offer a pragmatic solution as they streamline time and staff requirements compared to individual interventions. This combined approach also addresses

multiple goals concurrently, targeting both physical and cognitive function issues, rendering it an optimal intervention choice. However, staff necessitates specialized training to ensure competency aligned with intervention guidelines.

Fall prevention programs for older adults in institutions are generally not specified only for cognitively impaired residents. This is partly because the number of residents who experience falls is more significant in residents with cognitive impairment (43%) than in residents without cognitive impairment (34%) (Seijo-Martinez et al., 2016). So, fall prevention programs have generally targeted residents with cognitive impairment. However, recommendations from the dementia elderly community provide direction in the form of balance and muscle strength exercises that can be key to reducing the risk of falls. Still, only one type of exercise is not an effective strategy. So, mixed strategies are the leading choice in preventing falls in residents in nursing homes who experience cognitive impairment (Parachute, 2018).

Fall-Related Outcomes from Fall Intervention

Fall-related outcomes are crucial metrics in previous research, providing a structured framework for identifying various factors associated with falls. Multiple measurement instruments are recommended for studies on falls among older adults, as highlighted by prior literature. An umbrella review of 31 systematic review articles on fall risk in older adults revealed that no single instrument could comprehensively capture fall incidents in this population. The study recommends using multiple instruments simultaneously for a complete assessment in fall-related research on older adults. Among the recommended instruments are the Timed-Up and Go Test (TUG), Berg Balance Scale (BBS), gait speed, dual-task assessments, single leg stance, Functional Reach (FR) Test, tandem gait and stance, and CST

(Beck Jepsen et al., 2022). The use of diverse instruments is essential to determine the effectiveness of an intervention because each instrument can complement the others, thus providing broader insight into how an intervention has an impact. (Martins et al., 2018). Commonly included variables in fall-related research outcomes encompass measurements of balance, fear of falling, risk of falling, and muscle strength, which are complemented by psychosocial outcomes (Binns et al., 2020; Chapman et al., 2017; Combourieu Donnezan et al., 2018; Ehrlich et al., 2019; Hagovska et al., 2016; Schoenfelder & Rubenstein, 2004). These instruments are favored in research endeavors due to their established high levels of validity and reliability.

Research on fall-related outcomes typically includes measuring fall incidence, assessing balance and muscle strength, and evaluating psychosocial factors such as fear of falling. The term fall-related outcome has been used in several previous studies, and fall-related injury and fall-related fracture are also widely used choices (Mielenz et al., 2016; Tsou et al., 2022). One article states that the term fall-related outcome or injury impacts services that use an interprofessional approach (Eckstrom et al., 2016). Because the term includes the focus of services from several professionals so that by using this term, professionals can work together to solve problems. This term is the right choice for research that prioritizes sustainability in services.

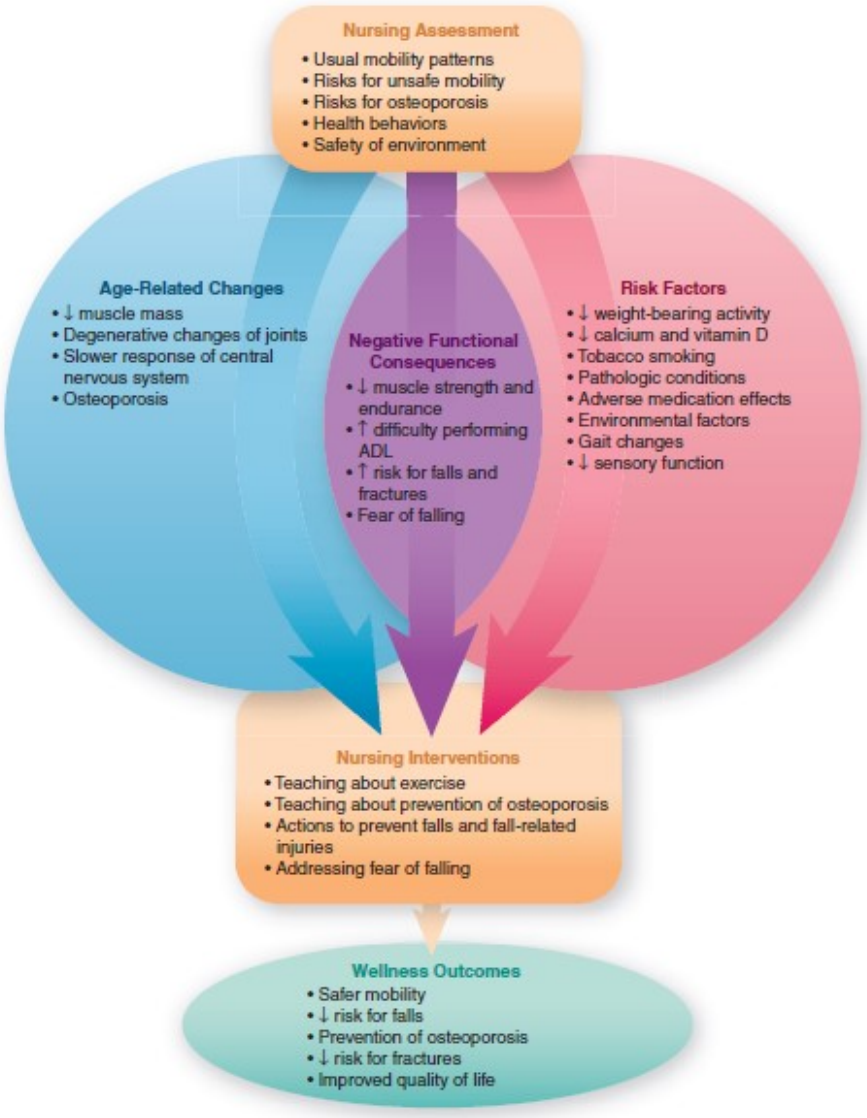
Functional Consequences Theory

The Functional Consequences Theory developed by Carol A. Miller is a nursing theory that provides a detailed explanation of health promotion and wellness for older adults. This theory explains how various factors influence the functional abilities of older adults, aiming to enhance quality of life and promote successful aging (Miller, 2012). There are five key

components of the functional consequences theory: functional consequences, age-related changes, risk factors, nursing interventions, and outcomes (Miller, 2012; Touhy, 2020). Essentially, functional consequences can have positive effects that enhance bodily functions or negative effects that decrease quality of life. Various changes in bodily and cognitive systems include the musculoskeletal, sensory, and nervous systems. Several risk factors can increase vulnerability in older adults, such as unhealthy lifestyle choices like smoking, sedentary behavior, or the presence of comorbidities. Nurses play a critical role in providing interventions that reduce risk factors, optimize bodily and cognitive functions, and evaluate the success of interventions by establishing clearly measurable outcomes.

The following is an application of the Functional Consequences Theory to the musculoskeletal system changes due to aging (Figure 3). It is explained in detail using the key concepts of the theory, resulting in several outcomes. Musculoskeletal changes in older adults, such as decreased muscle mass, reduced bone density, and joint stiffness, significantly increase the risk of falls. These age-related changes are compounded by sensory impairments (e.g., vision and proprioception) and slower reaction times, affecting balance and coordination. Intrinsic factors like chronic conditions (e.g., arthritis, osteoporosis) and extrinsic factors like environmental hazards (e.g., poor lighting, slippery floors) further elevate fall risk. To mitigate these risks, interventions such as strength and balance exercises, home safety modifications, and education on fall prevention are essential for enhancing mobility and reducing fall incidents, thereby improving overall quality of life.

Figure 3. *Functional Consequences Theory on Musculoskeletal System*



CHAPTER III. METHODS

Research Design

This study employs a blinded Cluster Randomized Controlled Trial (CRCT) design. In this study, the researchers will assess the effectiveness of the intervention provided to two groups within two older adult care institutions called Tresna Werdha Social Home (PSTW). A CRCT design is employed because randomizing individual participants is impractical; instead, randomization occurs at the institutional level, making the study more practical and efficient. This design is believed to have advantages in reducing between-group contamination and resource utilization efficiency (Hayes & Moulton, 2017). The combined intervention undergoes simultaneous physical exercise and cognitive training (PCT), while the single intervention receives physical training (PT) alone. Measurements occur at baseline, 12 weeks post-intervention, and another 12 weeks after follow-up.

Sample and Setting

This study will be conducted in two residential care facilities for older adults in Jakarta's capital regions. An interview with the PSTW's staff office said these facilities collectively accommodate approximately 250-300 individuals aged 60 years and above. Despite being geographically separated by around 2 kilometers, both establishments share similar architectural designs, institutional protocols, funding sources, and daily routines tailored for their residents. This shared framework suggests a degree of uniformity in their operational characteristics. Each PSTW comprises eight residential rooms, three designated for male and five for female residents.

The population of this study comprises PSTW residents with mild cognitive impairment. The sampling techniques used involve a combination of purposive sampling for location selection

and stratified random sampling for participant selection. These techniques, termed multistage or clustering sampling, involve identifying clusters or groups and selecting participants from each cluster (Cresswell, 2018). The selection of PSTW was purposively based on their similar environment and suitability for the study's participant characteristics, considering factors such as resident population, staffing, room activities, and resident characteristics. The second technique, stratified random sampling, involves randomly selecting residents in equal numbers from each room to ensure fair representation (Hayes & Moulton, 2017)

The sample size calculation was conducted using G-Power software (G*Power 3.1.9.4). The statistical test was chosen as the parameter of ANOVA with repeated measures within-between interaction, with an alpha level of 0.05, a power level of 90%, and a medium effect size of 0.20, with two groups and three-time measurements. The effect size for sample calculation is based on recommendations from a previous systematic review on older adults with cognitive impairment receiving combined aerobic and cognitive training interventions to assess their executive function (Combourieu, 2018). The sample size calculation obtained 56 participants, with an additional 20% attrition rate, resulting in an estimated 68 participants to be included in this study. The participants will be divided into two clusters or groups, with each cluster consisting of an equal number of participants, namely 34 residents per cluster, meaning five to six residents will be selected from each residential room.

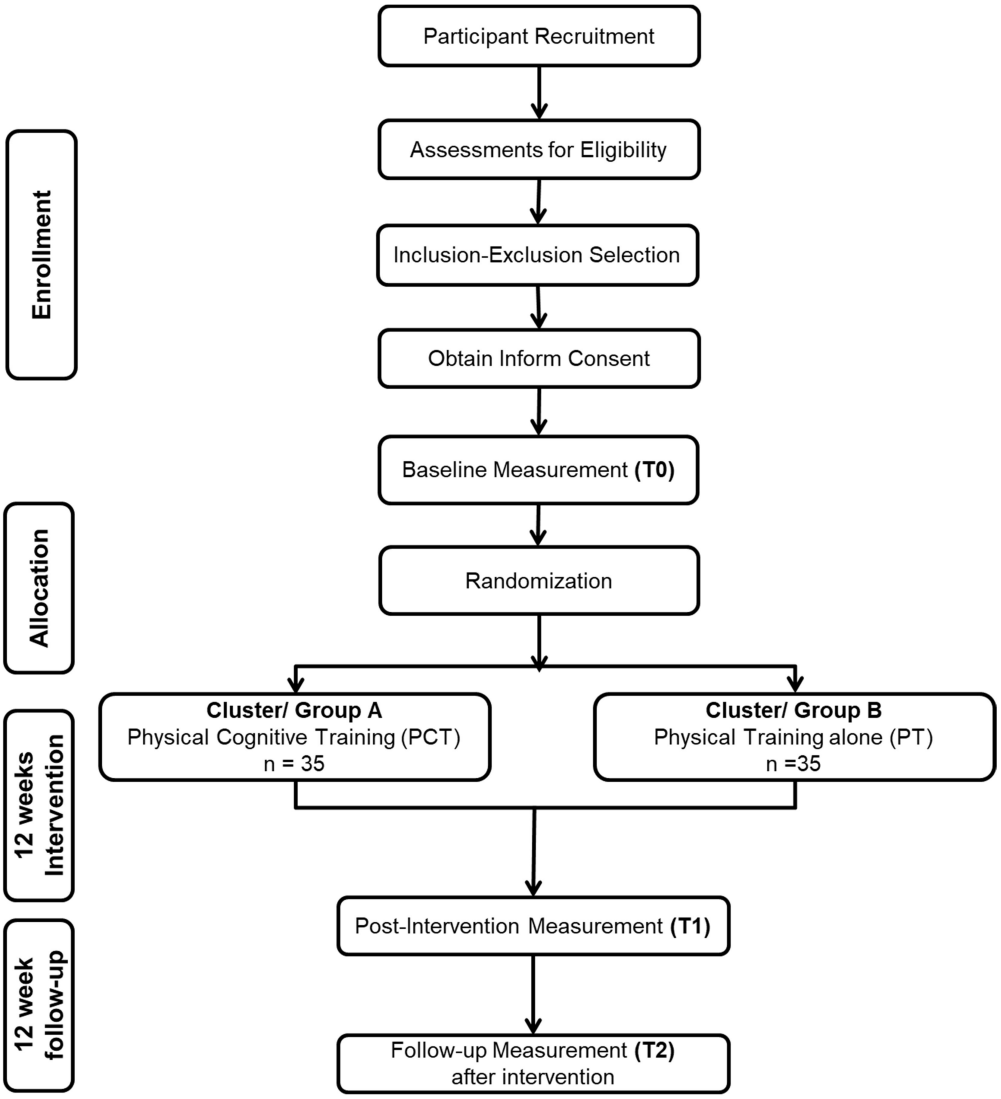
Inclusion and Exclusion Criteria

Inclusion criteria consist of age of 60 years old or above, ability to walk with or without an assistive device, score Mini-Mental State Exam (MMSE) 13≥ score ≤ 24 (indicating moderate-mild cognitive impairment), and proficiency in Bahasa Indonesia. A score of 13 on the MMSE was used as the lowest cutoff point for inclusion criteria considering the

educational background (Fagundes et al., 2021). Exclusion criteria include participation in another trial, lower limb orthopedic surgery, and comorbidities such as cancer, neurological or physiatric disorders, and significant visual or auditory impairments (Liu-Ambrose et al., 2019; Sipilä et al., 2018).

Participants from each residential room, selected randomly and meeting the inclusion and exclusion criteria, will complete informed consent and baseline measurements. The first six resident individuals with odd serial list numbers will be randomly selected from the list of residents in each room. This is part of the stratified random sampling applied to the selection of participants in this study (Hayes & Moulton, 2017). The facilitator will screen these individuals according to the inclusion and exclusion criteria. If selected individuals do not qualify, the following odd-numbered residents will be selected until six qualified participants are obtained from each room.

Figure 4. *Flow Diagram of Study Participants*



Randomization and Blinding

Randomization carried along enrollment, allocation, intervention, and follow-up. Institutions are randomly assigned to combined or single intervention groups, with participants allocated in a 1:1 ratio within each group. The participant flow chart in Figure 3 illustrates this process. Participants are aware of receiving the same intervention within their institution/cluster but are prevented from accessing information about other institutions'/ cluster interventions.

This research will implement blinding in the data collection process, intervention, and follow-up to prevent bias and increase the study's validity (Beauchamp & Childress, 2019). The data collection team includes assessors, leaders, and facilitators, each with specific roles. Assessors are responsible for conducting three measurements. We have recruited two assessors who will be trained to use the instruments but must be informed about the type of intervention given to the two groups. Assessors will be randomly assigned to each time measurement. Leaders, two per cluster, are recruited to deliver the interventions. They will receive separate training on delivering interventions without disclosing details to other clusters or knowing if they provide the primary intervention. Leaders will have a guidance book containing only the intervention protocol they administer. Additionally, a team of local nurses will act as peer facilitators. Facilitators will assist with the technical aspects of preparing and implementing the intervention and communicate between leaders and participants. Blinding will be applied to assessors, leaders, facilitators, and participants, ensuring that none of them know the complete details of the intervention or whether it is the primary focus of the study.

Ethical Consideration

Ethical clearance and research permit will be carried out before data collection begins. Ethical clearance will be sought from the Faculty of Nursing Ethics Committee, Universitas of Indonesia (FoN UI) in Depok, Indonesia. Additionally, research permits for the two PSTW locations in East Jakarta, DKI Jakarta Province, will be requested from the DKI Jakarta Government through the One-Stop Integrated Service (PTSP). Obtaining the Institutional Review Board (IRB) and permit documents requires several administrative letters and typically takes two to three weeks.

Various principles of research ethics applied to the study, including autonomy, beneficence, maleficence, and justice (Beauchamp & Childress, 2019). Autonomy and beneficence principles will be shown in participants' enrollment and allocation. Selected residents will gather in the PSTW halls separately, and the principal researcher will explain the research objectives and activities. Despite being informed only about the specific interventions their cluster will experience, this is part of the blinding process. Residents will be allowed to ask questions and express their opinions. Once all questions are addressed, residents will sign an informed consent form indicating their willingness to participate in the study assisted by the assessor. If any resident declines to participate, they will not be persuaded, and additional participants will be recruited once each cluster has at least 35 residents.

In carrying out interventions and measuring participant data, the research team will rigorously apply the principle of non-maleficence. Non-maleficence is a core principle of research ethics that addresses researchers to prevent any interventions or measurements that could harm participants (Beauchamp & Childress, 2019; Jecker, 2024). Training sessions for assessors, leaders, and facilitators will emphasize protecting participants from potential harm or coercion. They must ensure that participants do not report severe complaints before and after each exercise or measurement. If complaints arise, the principal researcher will monitor the participant's condition and offer further examination if necessary. The principal researcher will take full responsibility if any unpleasant conditions experienced by participants are related to the research intervention.

Concerning the intervention duration, which may potentially lead to participant exhaustion, this aspect has been carefully considered based on previous research involving similar activities and participant characteristics, which reported no complaints associated with the

intervention (Binns et al., 2020; Combourieu Donnezan et al., 2018). Similarly, any cases of violence or coercion will be promptly addressed directly. Older adult participants often have vulnerable conditions, so researchers must pay detailed attention to participant responses to ensure that no activities endanger participants (Jecker, 2024). Participants are encouraged to raise objections or withdraw from the intervention if they feel uncomfortable due to force or harm. Ensuring that no harm is done to participants is a primary commitment of this research.

Data Collection Procedure

The data collection process in this study will include three measurements: baseline (T0), post-intervention (T1), and follow-up (T2). Baseline measurement will be arranged after the participant is willing to participate in the research. Initially, the assessor will introduce themselves, explain the measurement's purposes, and inquire if the participant has any complaints that could affect the measurement process and the result. Assessors are prohibited from asking about the specific intervention the participants have performed. Measurements will be organized individually, ensuring data is accurately noted for each participant before moving on to the next. Participants will give their intervention books to the assessor during the measurement. The assessor will measure all participants in the same cluster/ group, with each measurement estimated to take fifteen to twenty minutes per participant. The facilitator will assist by bringing participants in turn for their measurements.

The assessor will prepare the necessary instruments for all participants within a cluster. They also will fill out the forms using a clipboard to avoid unclear handwriting. Assuming each participant requires 20 minutes. Assessors can mark demographic data and participant characteristics as needed and clarify responses with PSTW officers. In addition, baseline fall

history is based on falls in the past year, while subsequent measurements will be taken from the notes in the book.

Fall-related outcomes will be measured using the TUG, 30-sCST, and FES-I forms. The TUG test will be conducted twice, with the best result (shortest time) noted to indicate balance. After completing the TUG test, participants will rest briefly before the 30-s CST test, performed only once. The following three instruments involve asking questions by reading questionnaires and then making a checklist sign on the form for participant responses. Measurements of fear of falling will be conducted face-to-face to facilitate clear communication. The assessor will technically explain the question types and how to respond, allowing participants to seek clarification. The assessor will read the list of questions in the FES-I format to avoid bias. In the T1 measurement, participants will be asked to provide an assessment of their satisfaction with the intervention they received. They will be asked to rate their satisfaction on a scale from 1 to 100, with a score of 100 indicating perfect satisfaction with the intervention.

Finally, the assessor will answer all questions before returning the participant to their residential room. If questions still need to be completed, the assessor will follow up until the instrument is fully completed. Assessors are encouraged to communicate assertively, avoid rushing, and ensure data accuracy.

Instruments

In this study, seven instruments will be divided into two sections. The first part focuses on assessing participant demographics and characteristics. Conversely, the second part encompasses all dependent variables, including fall incidence and fall-related outcomes such

as balance, muscle strength, and fear of fall. The entire instrument is written in Bahasa Indonesia.

Participant Characteristics

This questionnaire collects demographic data and participant characteristics, covering (1) age, (2) gender, (3) fall history, (4) comorbidities, (5) impaired vision, (6) medicines, (7) Height and weight (BMI), and (8) education level. Previous research has identified these variables as influential factors on the study's population and variables, namely fall prevalence and fall-related outcomes.

The assessment will be conducted by an assessor who will directly query residents, accompanied by caregivers, to ensure data accuracy. The "Resident Age" item will inquire about residents' known age in years (excluding months). Gender will be identified, allowing participants to select either male or female. Regarding diseases, residents will select from options such as cardiovascular disease (hypertension, stroke, heart disease), diabetes mellitus, depression, and mental disorders (Chantanachai et al., 2021; Manis et al., 2023), with the option to select multiple conditions.

Participants will be asked about their fall frequency history within the last year to determine if they have a history of falls (Hagovská & Olekszyová, 2016; Lipardo & Tsang, 2020). Fall history in this section will only include a yes or no history of falling without writing the frequency. The frequency will be written in the fall incidence question section in the baseline measurement. Questions related to visual complaints will ascertain the presence of self-reported impaired vision based on the participants' difficulty in recognizing individuals across the street or reading, even with corrective lenses (Ehrlich et al., 2019), with answer choices of yes or no. Medicines known to have a significant relationship with falls will be listed,

including anti-hypertensive drugs, antidepressants, anti-hypnotics, diuretics, anti-psychotics, and benzodiazepines (Imaginário et al., 2021; Montero-Odasso et al., 2022). Participants can choose more than one drug option. Several previous studies have identified residents at PSTW as having a low educational background ((Susilowati et al., 2022; Wati et al., 2018), so this level of education will be divided into no school, primary school (elementary and junior high school), and advanced school (high school above). Body mass index (BMI), calculated as the ratio of body weight to height, will be assessed and interpreted based on the standards established by the Ministry of Health of the Republic of Indonesia for older adults (DirjenKesMasKemenkes, 2019). The results will be categorized into underweight, average weight, and overweight.

Fall Incidence

The second part of the instrument, which involves the dependent variables, begins with questions about fall incidence. The fall incidence will be recorded based on the participants' frequency of fall history in the last year during the baseline assessment and monitored throughout the intervention and follow-up periods for the following measurements (Ehrlich et al., 2019; Lipardo & Tsang, 2020). Recording the number of falls will start at the beginning of the intervention using a book provided to each participant. Each participant will bring the book to every intervention session to hand over and fill out by the leader. The entries in the notebook will include the training date, any complaints at that time, blood pressure, pulse, and whether any falls occurred since the last session, along with the leader's initials. 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 fall date, 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.

The instruments used for fall-related outcomes will be administered by trained assessors who have been instructed on intervention implementation and accurate data collection. Fall-related outcomes include six instruments, including balance assessment using the Timed-Up and Go Test (TUG), muscle strength evaluation using the 30-second Chair-Stand Test (30-sCST), and assessment of fear of falling using the Fall Efficacy Scale International (FES-I) 7-item questionnaire.

The Timed-Up and Go test

The Timed-Up and Go (TUG) test evaluates balance by measuring the time in seconds taken for an individual to perform sequential tasks starting with sitting, standing, walking three meters, turning towards a chair, and sitting again into one cycle (Dunsky et al., 2017). Stopwatch timing starts when the participant initiates the standing motion and ends when they resume sitting, with two trials conducted to determine the fastest duration (Dunsky et al., 2017). TUG test durations are categorized as normal or abnormal, with a cutoff score of 12 seconds indicating compromised functional balance in older adults (Susilowati et al., 2022). The TUG inter-rater reliability test shows satisfactory results with ICC values ranging from 0.69 to 0.99 (good to moderate) (Mollinedo & Ma Cancela, 2020).

The 30-second Chair-Stand Test

Muscle strength assessment in this study focuses on the functional evaluation of lower extremity muscles, which are essential for mobility, using the 30-second Chair-Stand Test (30-s CST). Participants are instructed to repetitively sit and stand on a chair with armrests for 30 seconds, with each complete cycle calculated as one movement (Barrios-Fernández et

al., 2020). Using a stopwatch, the assessor records the number of cycles completed within the allotted time. A cutoff point of 12 sit-to-stand movements within 30 seconds indicates lower limb muscle weakness, based on previous research recommendations in Indonesia with a similar population (Susilowati et al., 2022). The relative reliability of the 30-CST among type 2 diabetes mellitus respondents showed excellent results ICC > 0.9 (Barrios-Fernández et al., 2020). Meanwhile, research on patients on hemodialysis in Brazil found that this instrument also had high test-retest reliability (ICC= 0.93), and the exact value of 12 repetitions was the cutoff point for stratification of individuals with low exercise capacity (Figueiredo et al., 2021).

The Fall Efficacy Scale International

Fear of falling is counted using the Fall Efficacy Scale International (FES-I), consisting of seven items (Delbaere et al., 2010). Items are rated on a four-point scale, ranging from one (not concerned) to four (very concerned). Total scores range from seven to 28, with higher scores indicating more significant concern. Categorization of FES-I total scores includes normal concern levels (scores < 7), low concern (scores 7-8), moderate concern (scores 9-13), and high concern (scores 14-28) (Norouzi et al., 2023). Meanwhile, the results of a systematic review of 58 articles show that the short FES-I has good to excellent internal consistency values (Cronbach's alpha range 0.63-0.98), as shown by the test-retest results, its reliability is between good to excellent (ICC range 0.77 - 0.99) (McGarrigle et al., 2023). Thus, there is no doubt about the reliability of this instrument when used.

The mentioned instruments are widely recognized as standard tools utilized in research across various countries and settings, particularly among elderly populations, including Indonesia. Consequently, translations into Indonesian are considered unnecessary, as existing translations from prior studies in Indonesia will be employed. To assess the instruments'

validity and reliability, the principal researcher and assessors will conduct a preliminary trial involving 30 residents from other PSTWs who share similar characteristics with those intended for the study. This trial evaluates the instrument's reliability with the research participants before its implementation. Subsequent adaptation of the instrument will be considered, if necessary. The table below presents the validity and reliability values of the instruments based on previous research.

Table 1. *Psychometric Properties of Previous Studies Instrument*

Reference	Population & Setting	Instrument	Psychometric Properties
Susilowati, I. H., et al., 2022 (Indonesia)	326 older adults (≥60 years old) in long-term care facilities and community dwellings	TUG	NA
		30-sCST	NA
Abasmay, F. et al., 2020 (Indonesia)	39 elderly at the Outpatient Medical Rehabilitation Clinic	TUG	NA
		FES-I	NA
Mollinedo, I. & Cancel, J. M., 2020 (Systematic Review: 24 articles, from 2011-2018)	939 older adults (≥60 years old)	TUG	IIC values range from 0.69 to 0.99 (good to moderate)
Figueiredo, P.H.S., et al., 2021 (Brazil)	63 hemodialysis patients (age mean 48.3 years old)	30-sCST	ICC=0.93 (high reliability).
McGarrigle et al., 2023 (Systematic review: 58 articles)	NA (mean age between 39.6 – 77.2)	FES-I (7 items)	the test-retest results are between good to excellent (ICC range 0.77 - 0.99)

Not Available (NA), Timed-Up & Go Test (TUG), 30-second Chair & Stand Test (30-sCST), Fall Efficacy Scale-International (FES-I).

Intervention

The PCT and PT interventions will be administered by trained leaders under the direct supervision of the principal researcher and with the assistance of facilitators who are nurses at PSTW. The priority of having professional leaders who can effectively deliver interventions is crucial for achieving better outcomes (Di Lorito et al., 2021). These interventions will be meticulously executed according to established procedures, including specific stages,

movements, and durations detailed in the guideline book. Leaders will undergo 4 hours of training on intervention materials and practice, while facilitators will receive 2 hours of training. To maintain blinding, the training material provided to both leaders and facilitators will include only the specifics of the intervention they will administer without disclosing the entire research protocol.

The combination intervention is designed based on a systematic review of the literature. Table 2 provides a comparison of four references that implemented combination interventions for fall prevention in older adults. The table clearly lists the authors, year, country, study setting, type of intervention, number of participants per group, duration, instruments used, and the outcomes of the interventions. The most frequently provided physical exercises are balance and muscle strength training (Binns et al., 2020; Hagovska et al., 2016; Lipardo & Tsang, 2020), which include movements such as walking over obstacles and walking up and down stairs (Hagovska et al., 2016; Wati et al., 2018). Meanwhile, cognitive training varies widely but includes cognitive stimulation, reminiscing, socializing, memorizing, gaming, attention, and orientation (Binns et al., 2020; Combourieu Donnezan et al., 2018; Hagovska et al., 2016; Lipardo & Tsang, 2020). All activities are encompassed within cognitive stimulation therapy (CST) (Aguirre et al., 2014).

Table 2. *Previous Studies Combined Intervention*

Author, Year Country Setting	Participants	Intervention Duration	Outcomes of interest	Study Result
Binns, 2020 New Zealand Resident Aged Care	IG (n=13) Age±SD= 87.5±81-95 Female= 9/13 MoCA±SD= 16.0±4.2 Balance±SD= 2.4±1.6 CG (n=10) Age= 83.6±71-95 Female= 8/10 MoCA±SD= 18.0±5.6 Balance±SD= 2.4±1.4	IG: CogEx (aerobic exercise, strengthening, balance exercise) plus CST CG: CST (reality orientation, reminiscing, socialising, and actively stimulating) 1h twice a week for 7 weeks (14 sessions)	1. Cognition: MoCA, ADAS-Cog11 2. Balance: Brief BESTest 3. Functional mobility: SPPB	No difference between groups at baseline or after seven weeks

Author, Year Country Setting	Participants	Intervention Duration	Outcomes of interest	Study Result
Donnezan, 2018 France Specialist Clinic	G1 (n=14) Age±SD= 77.1±1.44 MMSE±SD=28.2±1.46 TUG±SD=9.96±1.75 G2 (n=14) Age±SD= 76.3±1.5 MMSE±SD= 27.3±0.42 TUG±SD=10.24±2.68 G3 (n=20) Age±SD= 75.2±1.3 MMSE±SD= 28.1±1.36 TUG±SD= 12.79±2.17 G4 (n=14) Age±SD= 79.2±4 MMSE±SD= 27.3±0.5 TUG±SD= 11.65±2.04	G1. *Physical Training (PT):* Aerobic training on bike G2. *Cognitive Training (CT)*: working memory, mental flexibility, inhibition, reasoning and updating using commercialized gaming software. G3. *Combined Simultaneous Physical and CognitiveTraining (PCT)*: Combination of CT and PT G4. *Control Group (CG)*: Usual lifestyle 1-h session per week over 12 weeks.	*Executive Measures* 1. The flexiblity part of 3. the Stroop Color Word Test 2. DSF 3. DSB *Motor Measures* 1. TUG test Single-task walking (normal environment & electronic walkway) 2. WSC 3. Dual task walking condition	- PT group improved in two measures (cognitive and motor). - CT group improved only in one cognitive measure. - PCT group improved in eight measures, included both cognitive and motor.
Hagovska, 2016 Slovak Republic Outpatient Psychiatric Clinic	IG (n=40) Age±SD=68±4.4 Female=18/40 MMSE±SD=25.97 ±2.57 TUG±SD=10.02±2.82 FES±SD=18.67±15.6 CG (n=38) Age±SD=65.9±6.2 Female= 21/38 MMSE±SD=26.02±1.47 TUG±SD= 9.09±2.12 FES±SD=15.40±8.63	IG: Combined Cognitive training battery (attention, working memory, long-term memory, executive functions, visiomotor coordination, spatial processing) and Balance Training (walk over obstacles, walk with direction, walk with load, walk up and down the stairs). CG: Balance exercise only 30min, 10 weeks (20 training total)	*Assessment of the fear of falling , balance and mobility*: 1. FES 2. Tinneti performance oriented mobility assessment 3. TUG 4. Multi-Directional Reach test	All measures improved significantly when compared within groups.
Lipardo, 2020 Philiphine Community Dwelling Older Person	PACT (n=23) Age=67 (median) Female= 16/23 MoCA±SD= 17.5±4.7 TUG±SD=10.7±2.8 PT (n=23) Age=73 (median) Female=22/23 MoCA±SD= 17.0±4.1 TUG±SD= 10.6±3.0 CT(n=23) Age=68 (median) Female=18/23 MoCA±SD=20.4±4.9	PT (balance, strenght, endurance and flexibility) CT (paper-based cognitive exercise on executive function, memory, attention and orientation training) PACT: Combination of physical and cognitive training WG: Usual activities Three times per week over 12 weeks with 60-90	1. Fall incidence 2. PPA-short form 3. TUG 4. The 10-meter walk test 5. The 30-second chair stand test	- No significant difference in fall incidence among the groups at 12 week (p=0.152) and at 36 weeks (P=0.954) - The combine physical and cognitive training group had a statistically significant reduction in overall fall risk from baseline to 12 weeks (P=0,009)and from baseline to 36 weeks (p=0.001)

Author, Year Country Setting	Participants	Intervention Duration	Outcomes of interest	Study Result
	TUG±SD= 9.1±3.0 WG (n=23) Age=68 (median) Female=17/23 MoCA±SD=18.3±4.1 TUG±SD=10.6±4.0	minutes per session.		

Abbreviations: ADAS-Cofl1, Alzheimer's Disease Assessment Scale-Cognitive; Brief BESTest, Brief Balance Evaluation Systems Test; CogEx, Cognitive Exercise; CST, Cognitive Stimulation Therapy; CG, Control Group; CT, Cognitive Training; DSB, Digit SpanBackward test; DSF, Digit Span Forward test; IG, Intervention Group; MoCA, Montreal Cognitive Assessment; PACT, Physical And Cognitive Training; PT,Physical Training; RAC, Residential Aged Care; SD, Stadard Deviation; SPPB, Short Physical Perfomenace Battery; QOL-AD, Quality of Life-Alzheimer's Disease; TUG, The time Up and Go test; WG, Waitlist Group.

The combined interventions are the primary focus of this study, integrating physical and cognitive training simultaneously in a small group. Participants from one cluster will engage in the entire PCT intervention, starting with 30 minutes of physical exercise followed immediately by 20 minutes of cognitive training. The other cluster will provide PT only. The interventions will be held in a small peer group (eight to nine participants) as recommend by previous studies (Di Lorito et al., 2021; Spector, 2007), in the indoor hall, with participants seated in a circle and provided with movable chairs and tables as needed. The initiation of an intervention session includes a thorough assessment of vital signs, including blood pressure (BP) and pulse. Participants will report any health complaints, and the leader will assess eligibility to continue the intervention. Vital signs and current complaints will be noted in the participant's book and handed over to the leader before the training session starts.

All necessary tools will be prepared for each peer group, ensuring adequate supplies for all participants. Muscle strength training for older adults does not require expensive and complicated equipment; simple equipment or other modified equipment can function well (Bennie et al., 2020). Participants are asked to arrive five minutes before the session starts and wear comfortable clothing suitable for exercise, such as loose trousers and a t-shirt, with

or without footwear. Beyond executing the intervention procedures, leaders and facilitators are encouraged to motivate participants to engage in the activities actively.

The 30-minute physical exercise includes a range of motion (ROM), balance, muscle strength, and deep breathing exercises (Table 1). These exercises target limb and body muscles, addressing stiffness and slowness in older adults' range of motion (Bennie et al., 2020; Wati et al., 2018). Emphasizing lower limb exercises, known for fall prevention, balances and strengthens muscles, with additional time allocated for optimal results. The physical activity program is composed of four main components. The ROM exercise is one of the components, which involves exercises that flex the head, shoulders, arms, back, waist, and feet. The exercises are done while sitting in a chair and take five minutes. Balance exercises form the second component, which involves standing, balancing, and walking. The exercises use a chair and a block to support and take 10 minutes. The third component of the program is muscle-strength exercises that aim at the upper and lower arms, upper thighs, and lower feet. This is performed while using a chair and stepboard. This also takes 10 minutes. The fourth exercise is deep breathing exercises, which involve stretching exercises while pursed-lip breathing is applied. It stretches for 5 minutes and is done while sitting in a chair. Deep breathing relaxes muscles post-exercise, preparing participants for subsequent cognitive training.

Table 3. *Physical Training Activities*

Types of Exercise Duration	Movements	Equipment
	Warm-up Exercise	
Range of motion (5 minutes)	**Head**: Look left and right, tilt left and right, turn 180^{o} **Shoulder**: shoulder and arm rotation **Arm**: Straighten your arms up, bend backward, and hold momentarily. **Back**: Sit in the middle of a chair, open your legs, and lower your body down until you are holding your calves. **Waist**: Waist rolls **Leg**: Bend your knees forward and hold	A chair with a backrest
	Core Exercise	

Types of Exercise Duration	Movements	Equipment
Muscle- Strength Exercise (10-minutes)	**Leg lift**: In a sitting position, lift one leg to thigh height **Squat**: Place a chair in front of you to hold on to, adjust the distance between your body and the chair, half squat, hold on, and stand up **Heel raises**: Stand straight, legs slightly apart; you can hold on to a chair, stand on your tiptoes for a moment, and stand straight again **Step-up**: Letakkan stepboard didepan, langkahkan kaki naik kiri kanan bergantian **Marching**: Walk in place, raise your legs high, do it slowly, maybe while holding on to a chair **Leg stretching**: Straighten your legs forward and to the side, let them relax	- A chair with a backrest - A step board
Balance Exercise (10-minutes)	**Standing one foot**: Lift one leg by holding onto a chair or open arms for balance, and hold for a few moments **Moving leg lift**: Swing your legs forward, sideways, and back slowly while holding on **Mini lunges**: One leg forward, bend the knee, hold for a moment, and straighten it again. **Sit to stand**: Sit in the middle of a chair, raise your arms straight before you, stand up, then sit back down**.** **Walking from heel to toes**: Walk 3 meters, step with the tip of your big toe meeting the heel of your other foot, arms open to the side **Walking sideways and over the blocks**: Arrange ten blocks forward 0.5 meters apart, walk through the blocks without touching, turn 90^{o} walking sideways past the blocks	- A chair with a backrest - Block size 20cmx10cmx5cm
Cool-down Exercise		
Deep breathing (5 minutes)	**Up-down arms**: Inhale through your nose and exhale from your mouth by slowly raising and lowering your arms **Open-close arms**: Inhale through your nose and out through your mouth by slowly opening and closing your arms to your chest **Shoulder rolls**: Slowly roll your shoulders forward and back while doing purse lip breathing	A chair with a backrest

The cognitive training utilized in this research is cognitive stimulation therapy (CST), pioneered by Spector and colleagues in 2000 and designed for older adult populations in nursing homes with mild to moderate dementia. The CST has demonstrated efficacy in improving mental status, cognitive assessment, and overall quality of life (Spector et al., 2001; Spector et al., 2003). The CST session is structured into three parts: opening, primary,

and closing. The duration of the CST will be shortened considering that longer intervention times can cause participant fatigue. Therefore, CST will be conducted for 20 minutes, with the total duration including physical training (PT) being 50 minutes. The Opening phase, lasting 5 minutes, involves memorizing and orientation activities, including self-introduction, stating the date and day, noting the number of participants, and introducing the day's topic. The Primary section, which lasts 15 minutes, features a variety of activities such as physical games, sounds, childhood, food, current affairs, faces/ scenes, word association, being creative, categorizing objects, orientation, using money, word games, and team quizzes. The session concludes with a five minute Closing phase, including a wrap-up, updating the checklist intervention book, and a discussion of the next meeting. All CST steps in this exercise follow a manual explicitly created for CST's group leaders for older adults with cognitive impairment (Spector, 2007).

Table 4. *Cognitive Stimulation Therapy Activities*

Stages	Session Topic	Equipment
Introduction (5 minutes)	- Welcoming all members individually to the group - Group naming* - Select theme song*, sing together - Time orientation - Hot news discussion - Offer Refreshemet * First session only	
Main Activity (15 minutes)	**1st Session: Games** A. Throw a softball around, asking them to say something about themselves B. Throw the ball into the basket **2nd Session: Sounds** A. Indoor sounds, outdoor sounds, animal sounds B. Sounds part of the song. **3rd Session: Childhood** A. Fill out a printed sheet (their name, other family members name) B. Discuss food, hobbies, or other childhood experience	- Whiteboard and pens - Soft ball - Tape-recorder - Songbooks - Old-fashioned toys - Grocery replicas - Photograph of local scenes - Country map - Photographs of famous faces - playing cards - Quiz book

Stages	Session Topic	Equipment
	4th Session: Food A. Groceries shopping using case B. food taste to trigger memories and discuss **5th Session: News** A. Discuss hot news, asking their opinion B. Discuss their opinion about the different roles of men and women; who in the world do you admire most? Where is your favorite place? **6th Session: Famous faces and scene** A. Guess and discuss a famous photograph B. Guess and discuss the scene photograph **7th Session: Words** A. Ask the group to supply the missing word B. Ask to sing a song lyrics given **8th Session: Creativity** A. Clay modeling B. Make simple drinks **9th Session: ABC** A. Count the alphabet, and mention fruits or cities or animal name B. Make a group from the picture given. **10th Session: Map** A. Show the city place in Indonesia B. Discuss the city where they are coming from **11th Session: Price** A. Guess things prices B. Discus current price and before **12th session: playing cards** A. Playing number card B. Playing snake and ladders **13th Session: Words** A. Guess the missing alphabet from the word B. Playing crossword puzzle "Sessions 14 to 23 will repeat topics from	

Stages	Session Topic	Equipment
	sessions 1 to 10: **24th Session: Farewell** A. Play a quiz B. Special group tea with cakes	
Final Activity (5 minutes)	- Session Summarize - Feed back - Theme song - Next meeting - Closing	

Statistical Analysis

The data analysis of this study will be divided into univariate, bivariate, and multivariate Analysis using the Statistical Package for the Social Science (IBM 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 (Piantadosi, 2017). Before the data is entered into SPSS, all data will be cleaned, and a data set will be created using Excel. This data set will not be changed to be used as a reference if there is a discrepancy in the SPSS data. Confidentiality, data accuracy, and storage of research data are entirely the responsibility of the researcher (Polit & Beck, 2018). Researchers will keep all participant notebooks, assessor notes, and leaders for five years before being destroyed to be rechecked if necessary.

Before proceeding to the final analysis, an Intraclass Correlation Coefficient (ICC) analysis will be conducted on the baseline data to determine the internal cluster variability and the variability between clusters. This step is crucial to ensure that there are no significant differences between clusters. Ensuring homogeneity between clusters is important so that cluster effects do not need to be a concern in the final analysis.

Univariate data analysis aims to describe in detail the characteristics of each variable. This Analysis will be presented as central tendencies, standard deviations, minimum-maximum values, and 95% control intervals (CI) for numeric data and percentages for categoric data (Field, 2013). The current study will describe demographic data, participant characteristics, fall incidence, and fall-related outcomes in univariate ways. The numeric data as age and all the dependent variables will present in central tendencies, standard deviations, minimum-maximum values, and 95% control intervals (CI). Meanwhile, categorical data will be presented in frequency distribution and percentages such as gender, education, comorbidities, BMI, and medicines.

The next stage will be carried out as a bivariate analysis, which aims to determine the effect of the intervention given on the dependent variable in both groups. Dependent data will be converted into binary data so that non-parametric statistics will be used, namely the Friedman test. The requirements that must be met are the homogeneity of the two groups to ensure equality between the two regardless of normality. Levene test will be used for homogeneity testing with a p-value> 0.05, and the assumption of homogeneity of variance is met(Field, 2013).

Multivariate statistical tests in this study will be carried out to compare the effectiveness of the two interventions on the dependent variables (outcomes) after being controlled by demographic variables and participant characteristics. Studies that conduct repeated measurements on the same group (not independent) to compare the effectiveness of the two interventions can use an extension of the General Linear Model (GLM), namely the Generalized Estimating Equation (GEE), which is more robust (Dobson, 2018). All

dependent variables in the data will be converted into a binary categorical scale for this Analysis. The binomial distribution and logit link are the appropriate GEE model for binary data. This is done because it considers the main effects, interactions, demographic data, and participant characteristics. This GGE model is expected to understand better how the relationship between independent variables and covariates affects the study's dependent variable (outcome) (Field, 2013).

Table 5. *Statistical Analysis for Independent and Dependent Variable*

Aims	Components	Measurement Scale	Statistical Analysis
Univariate To describe the characteristics of the participants in both groups	***Demographic and participant characteristics***		
	Age	Continuous/ interval	Central tendency (Mean, median, modus), Standard Deviation (SD), 95% Control Interval (CI), and Range Min-Max.
	Gender	Categorical/ nominal	n (%)
	Education background	Categorical/ ordinal	
	Comorbidities		
	Body Mass Index (BMI)		
	Fall history		
	Impaired vision		
	Medication		
	Dependent Variable (Outcomes)		
	Fall incidence	Continuous/ ratio	Central tendency (Mean, median, modus), Standard Deviation (SD), 95% Control Interval (CI), and Range Min-Max.
	Balance	Continuous/ ratio	
	Muscle strength	Continuous/ ratio	
	Fear of fall	Continuous/ interval	
Bivariate To examine the effects of the combined and single intervention on fall prevalence and fall-related outcomes, respectively.	**Variable Dependent (Outcomes)**		Friedman Test
	Fall incidence	Categorical/ Binner	
	Balance		
	Muscle strength		
	Fear of fall		
	Variable Independent (Intervention)		
	Intervention Group: PCT	Categorical/ ordinal	
	Control Group: PT	Categorical/ ordinal	

Aims	Components	Measurement Scale	Statistical Analysis
Multivariate To compare the effects of combined and single intervention on fall incidence and fall-related outcomes.	**Demography and Characteristics Participants**		Multilevel modeling analysis: Generalized Estimating Equation (GEE) with binomial distribution and logit link
	Age	Continuous/ interval	
	Gender,	Categorical/ nominal	
	Education,	Categorical/ ordinal	
	Comorbidities		
	BMI		
	Fall history,		
	Impaired vision,		
	Medication		
	Variable Dependent (Outcomes)		
	Fall incidence	Categorical/ Binner	
	Balance		
	Muscle strength		
	Fear of fall		
	Variable Independent (Intervention)		
	Intervention Group: PCT	Categorical/ ordinal	
	Control Group: PT	Categorical/ ordinal	

CHAPTER IV. EXPECTED OUTCOMES

This study focuses on fall prevention programs for cognitively impaired institutionalized older adults. It aims to demonstrate the effectiveness of a combined physical and cognitive training intervention in reducing fall incidents and improving fall-related outcomes in institutionalized older adults with mild cognitive impairment, compared to physical training alone. The expected outcomes of this research are:

1. To offer an evidence-based fall prevention solution for a critical issue in the care of institutionalized older adults.
2. To enable researchers to adequately deliver the interventions and distinguish between the impacts of combined and single interventions on fall prevention in study's population.
3. To show that combined interventions more effectively reduce fall incidents and enhance fall-related outcomes among the population.
4. To establish a trial intervention that local nurses and staff in residential care settings can adopt and continue.

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