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Effect of the resistance-cognitive dual-task training on frailty status and cognitive function in frail community-dwelling older adults with chronic musculoskeletal pain: A pilot randomized controlled trial

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Abstract

Background: The increasing prevalence of frailty among the ageing population poses significant health challenges, including heightened vulnerability to stressors and adverse outcomes such as falls, hospitalization, and chronic musculoskeletal pain (CMP). CMP significantly contributes to functional disability. Studies indicate a strong association between pain severity and frailty, with a high prevalence of chronic pain among older adults. Cognitive decline correlates with frailty and CMP, affecting perception speed, memory, and verbal fluency.

While physical activity is effective in improving physical functions and reducing pain, hence it may improve physical frailty, its impact on cognitive improvement is limited. Current research lacks comprehensive interventions targeting cognitive frailty. Dual-task training (DTT), which integrates motor and cognitive tasks, has shown promise in enhancing physical and cognitive functions in populations with neurological conditions and cognitive impairments. This study explores the potential of DTT to improve cognitive functions and frailty status in frail individuals with CMP.

Methods: This is a pilot randomized controlled trial of around 38 community-dwelling older adults with chronic musculoskeletal pain and frailty. They will be randomly assigned to either the intervention (n=19) or control group (n=19). The intervention group will receive resistance training and cognitive tasks simultaneously, while the control group will perform flexibility exercises only. Both groups will perform exercises (twice/week) under supervision for 12 weeks.

Outcome measures and data analysis: Outcome measures of frailty status, cognitive function, pain level, and health-related quality of life will be assessed at the initial and the last sessions. To examine preliminary efficacy, within-group and between-group changes in pain and functional measures will be analysed. Acceptability of the programme will also be assessed at the end of the training programme.

Expected results: We expect participants receiving DTT will gain improvement in frailty status, physical and cognitive performances, reduction in pain, and enhancement in health-related quality of life.

Keywords: Frailty, Chronic musculoskeletal pain, Exercise, Dual-task training

Introduction

Frailty is a state shown by a regression in ageing individuals' reserves and the chief reason for the vulnerability to various stressors (Cesari et al., 2017). With the rising trend of the ageing population, the prevalence of frailty is expected to grow simultaneously. This brings about the increased risk of unfavourable outcomes like falls, hospitalization, disability, or comorbidity (Pandey et al., 2019). With deterioration in multiple physiological systems, frail individuals may suffer from negative health-related effects, and chronic musculoskeletal pain (CMP) is a major one. On the other hand, CMP may also be a leading cause of frailty since the severity of musculoskeletal pain has a direct effect on individual functions, like mobility (Blyth & Noguchi, 2017). Therefore, managing both frailty and CMP with interventions aimed at slowing down the deterioration is the key. CMP is a chief culprit for the functional disability. It has a large impact on older people's physical activity level, depression, cognitive impairment, and even frailty level (Blyth & Noguchi, 2017). Study shows that pain severity was associated with frailty, with 99% of frail individuals (n=176), classified using the FRAIL questionnaire, having moderate or severe CMP (i.e. ≥4 on the pain numeric rating scale [NRS]) (Chaplin et al., 2023). In the same study, people who transited from non-frail to frail status had greater baseline pain levels (mean NRS: 6.4) than those who remained non-frail (mean NRS: 4.7). This shows that CMP has a positive correlation to frailty. A systematic review of 23 studies showed that approximately 45% of frail community-dwelling older adults had chronic pain, and its prevalence could reach as high as 70% in prefrail or frail older people (Otones Reyes et al., 2019). Frailty could lead to the degeneration of the peripheral and central nervous system, causing nociceptive issues, pain modulation and expression (Blyth & Noguchi, 2017).

In addition to physical deterioration, the rise of cognitive problems is prevalent in frail individuals. A cross-sectional study shows that among the community-dwelling older people over 65 years old, 39% of the frail ones showed cognitive impairment compared to 22% and 16% of pre-frail and normal elderly, respectively (Macuco et al., 2012). The cognitive functions of perception speed, episodic and semantic memory, and verbal fluency showed declined performance in frail elderly (Brigola et al., 2015). Another review also found that there was a strong correlation between CMP and cognitive decline (Alcon et al., 2023). These show that cognitive impairment is a subject of concern in the older population with frailty and CMP.

Physical activity has been the main intervention in treating the frail elderly, and it has been proven effective in reducing physical frailty. Additionally, physical exercise can induce endogenous analgesia, which supports the use of exercise therapy in subjects with CMP (Daenen et al., 2015). However, a meta-analysis showed that physical activity alone had no significant effect on improving cognition (Negm et al., 2019). There are still limited studies about the effect of intervention specifically targeting cognitive frailty, and not a clear flow from the comprehensive assessment to the multimodal interventions to counter cognitive frailty (Sugimoto et al., 2021). Dual-task training (DTT), which combines motor tasks and cognitive tasks, is an intervention that has been proven effective in enhancing the physical capabilities like gait speed and postural stability (Ghai et al., 2017) of older adults in general and those with neurological diseases, like stroke or Parkinson's disease (Varela-Vásquez et al., 2020). General cognitive functions like memory and attention can also be improved by DTT in cognitively healthy populations, or patients with cognitive impairment and Alzheimer's disease (AD) (Pereira Oliva et al., 2020). Since cognitive deficits are present in older people with frailty and CMP as mentioned, DTT may be one of the feasible interventions to improve both physical and cognitive functions, targeting this group of people with physical deficits and cognitive impairment effectively. We would like to see whether a similar effect will be obtained on frail individuals with CMP. The study aims to provide insight into how we provide intervention to enhance cognitive and physical functions, which may possibly pave the way for how we treat the problems of frailty clinically.

Objectives

1. To investigate the effect of a 12-week resistance-cognitive DTT program on frailty status in community-dwelling older adults with frailty and CMP.
2. To investigate the effect of the resistance-cognitive DTT program on cognitive function, pain levels and health-related quality of life in community-dwelling older adults with frailty and CMP.
3. To assess the acceptability of the resistance-cognitive DTT program by the participants.

We hypothesize that

1. The 12-week resistance-cognitive DTT program can improve frailty status in community-dwelling older adults with frailty and CMP.
2. Resistance-cognitive DTT program can improve cognitive function, pain levels and health-related quality of life in community-dwelling older adults with frailty and CMP.
3. The resistance-cognitive DTT program is well accepted by the participants.

Research Plan and Methodology

Study design and setting

It will be a pilot randomized controlled trial on a 12-week resistance-cognitive DTT programme. 38 subjects will be recruited from the general public in Hong Kong. Potential participants will also be identified from another ongoing cross-sectional study (ChiCTR2400089069) that investigates the prevalence of frailty in community-dwelling older adults with CMP. The program will last for 12 weeks with assessments conducted at the initial and final sessions. The overall flow of the study can be found in Appendix 1. Subjects will receive assessments and training in the Hong Kong Polytechnic University under supervision.

Methods

Recruitment

To recruit subjects with frailty, recruitment posters will be posted on the notice boards of the Hong Kong Polytechnic University. Invitation posts and stories will also be posted on social media like Facebook and Instagram. Potential subjects will also be identified from another cross-sectional study (ChiCTR2400089069) with a similar target population. Eligibility criteria will be screened by online questionnaires. Eligible subjects will undergo face-to-face objective assessments after getting the written consent for participation. Participants will be randomized into the intervention and control groups after the initial assessment.

Randomization and allocation

Randomization and group assignment will be performed by an investigator not involved in recruitment or assessment. After participants' eligibility for enrolment is confirmed, a researcher will use a computer to automatically generate a random sequence using Excel software (Microsoft Corporation, Redmond, USA) to generate random integers, with odd numbers being the experimental group and even numbers being the control group. The grouping information will be stored in a separate folder. Participants will undergo the corresponding exercise program which will be supervised by the researcher.

Treatment

The entire program will be scheduled to span 12 weeks, with exercise sessions occurring twice per week on non-consecutive days. The exercise frequency will be established based on the American College of Sports Medicine's guidelines (Liguori et al. 2022), in which resistance exercise is recommended for at least two days per week. Previous research done by Salse-Batán et al. (2025) demonstrated that flexibility exercises do not influence balance. While flexibility training alone may lead to improvement in strength, Simão et al. (2011) found that the gains were significantly less than those achieved through resistance training in healthy young adults. Consequently, any enhancement in balance or strength can be attributed

to our dual-task intervention instead of the flexibility exercise or placebo effect, hence, flexibility exercise is selected for the control group.

(i) Control group:

Subjects in the control group will perform the flexibility exercises only without receiving any resistance or cognitive training. Ten-minute warm-up and cool-down sessions will precede and follow each exercise session. Flexibility exercises will include (a) overhead stretch, (b) cross-body shoulder stretch, (c) neck rotation stretch, (d) lateral neck stretch, (e) seated chest and shoulder stretch, (f) seated hamstring stretch, (g) standing quadriceps stretch and (h) standing calf stretch (Appendix 2). During the exercise, subjects should only feel tightness without any discomfort. Participants should sustain each stretched position for 15 seconds for 3 repetitions, with one minute of rest between each repetition (Izquierdo et al., 2017). Subjects will be instructed to maintain their usual physical activity level throughout the program.

(ii) Intervention group

Participants in the intervention group will engage in a DTT training program, in which resistance training will be incorporated with cognitive tasks. Ten-minute warm-up and cool-down sessions will precede and follow each exercise session. Participants will perform the resistance exercises with a very light load or no load in the warm-up phase, and cool down with the flexibility exercises similar to those performed in the control group.

- Resistance training:

Participants will be instructed to perform the following exercises with proper form: (1) squat to chair, (2) seated unilateral hip flexion, (3) seated unilateral knee extension, (4) standing unilateral knee flexion and (5) bilateral calf raise. The lower limb exercises will be followed by four upper limb exercises: (6) seated elbow flexion, (7) twisting a towel, (8) seated horizontal opening of arms and elbow, (9) seated diagonal opening of arm and elbow. The procedures of these exercises are described in Appendix 2. The modified BorgCR-10 scale will be adopted to determine the intensity of exercise (Borg, 1998). During the initial two-week familiarization period, one set of 10-15 repetitions at an intensity of 4-5 will be performed. From the third to the twelfth week, participants will perform two sets of 8-12 repetitions at an intensity of 5-6 for each exercise (Liguori et al., 2022). A two-minute rest period will be allowed between sets. Participants will be instructed to execute the concentric and eccentric phases over approximately 2.5 seconds to enhance muscle strength and power. Loads will be adjusted using ankle and wrist weights for exercises (1) to (6), and elastic bands with different resistance for exercises (8) and (9). A standard towel will be used for exercise (7), and subjects will be asked to twist and squeeze the towel with maximal force for 10 repetitions if the pain level is not increased (Izquierdo et al., 2017; Coelho-Júnior & Uchida, 2021).

In normal situations, exercising painful muscles will not change pain sensitivity either in the exercising muscle or at distant locations. However, in some patients with dysfunctional endogenous analgesia and the presence of central sensitization, there may be a risk that participants may experience an increase in pain during the initial weeks of the program (Daenen et al., 2015). If participants experience an increase in pain that surpasses their usual levels during resistance training, they will switch to alternative non-painful resistance exercises before resuming the exercise that initially causes discomfort. They will also be reminded to ensure adequate rest following the exercise session (Daenen et al., 2015). In subsequent sessions, these participants will be instructed to perform the resistance exercises at a reduced volume and intensity, with their pain levels closely monitored.

- Cognitive task:

Among different aspects of cognitive functions, verbal fluency has been chosen as a cognitive task in the training since it can serve as a predictor of cognitive decline, providing valuable insight into the potential need for early intervention (Frankenberg et al., 2021). Additionally, working memory has been selected owing to its critical role in cognitively demanding daily activities, such as problem-solving and reading comprehension (Matysiak et al., 2019).

Subjects will be asked to perform a verbal fluency task simultaneously with the resistance training exercises. The verbal fluency task will require participants, during the concentric action of the exercise, to say aloud as many words as possible within a given category for each exercise set. Each month, the task's difficulty will be increased by altering the word categories, progressing from general to specific, while semantic categories (such as animals and colours) will be varied in each exercise set. Participants will be asked to avoid repeating words and generate new ones (Castaño et al., 2022).

Apart from the verbal fluency task, subjects will also be asked to perform mental arithmetic tasks which require sufficient working memory (Nascimbeni et al., 2015). This task requires subjects to count backwards from a certain integer. Subjects will initially start by counting backwards by one beginning with two pre-determined numbers: 378 or 283. Subjects will then progress to counting backwards by four and seven **(**Winser et al., 2019). They will progress once they are managed to complete the task without making mistakes in one session. A three-digit odd number will be randomly generated by the computer as a starting number to ensure participants will not rely on the memorized sequence but actively process each number.

There will be no specific combination of cognitive tasks and resistance exercises, it will be selected randomly upon each resistance exercise. However, each participant should perform each cognitive task for a similar number of times in one session.

Inclusion and exclusion criteria

Adults, of either sex, aged 60 years or above, living in Hong Kong, being able to read and communicate verbally, screened frail using the Tilburg Frailty Indicator (TFI) (total score ≥5) with report of memory problems (question 9) (Gobbens et al., 2010), experiencing any CMP with a pain level higher or equal to 4 in the numerical pain rating scale over a consecutive 3-month period will be recruited.

Any individuals with either of the following will be excluded: absence of frailty; surgical procedure in the lower limbs or the vertebral column; wheelchair bound or inability to walk for five minutes; severe balance impairment; uncompensated cardiac or vascular condition; acute inflammatory musculoskeletal conditions; ongoing cancer; dementia; neurological diseases such as stroke, Parkinson's disease, cerebellar disease, myelopathy, and peripheral neuropathy; mental illnesses such as schizophrenia, bipolar, psychosis, borderline personality disorder; illiteracy.

Sample size consideration

As this is a pilot study, the study has been designed to generate data that will be used for setting up future larger randomised controlled trials. The sample size has been selected to evaluate the feasibility, safety and preliminary efficacy of the intervention. An exploratory sample size of 30 participants will be recruited in this study, in which 15 of them will be randomly allocated to the intervention group performing DTT, and the control group. To anticipate a 20% loss, the sample size will increase to 38. All results from the pilot study will be helpful in sample size calculations for the future large study.

Outcome measures

(i) Primary outcome

To assess the frailty status of participants, three assessment tools will be used since there is currently no gold standard in assessing frailty (Dent et al., 2017): the Tilburg Frailty Indicator (TFI) (Gobbens et al., 2010), the Fried Frailty Phenotype (FFP) (Fried et al., 2001) and the Short Physical Performance Battery (SPPB) (Ramirez-Velez et al., 2021). TFI consists of 4 parts, including physical, social and psychological components, and determinants of frailty (not scored and not subjected to change in this study), which provide us with information on the multifaceted nature of frailty other than physical deficits (Gobbens et al., 2010). Other than frailty determinants that are not scored, there are 15 items in total, with a score of 0 or 1 on each item. A total score of >5 has a validity of 0.86 to determine the frailty status of the community-dwelling older Chinese population (Dong et al., 2017). FFP consists of 5 components in assessing the severity of fraily, including weight loss, weakness, exhaustion, slowness and low physical activity (Fried et al., 2001). The frailty score is calculated and the status is categorized into robust (0), pre-frail (1-2) and frail (3-5) (Auyeung et al., 2014; Fried et al. 2001). The SPPB is an assessment tool for participants' physical function. It includes 3 components: standing balance, 4-m gait speed, and five-repetition sit-to-stand motion (Ramirez-Velez et al., 2021). Each component has a score of 0-4. It can be used to show the physical frailty of the participants. A total score of <9 is regarded as frail, with a high sensitivity (79.7-92%) and specificity (73.8-80%) (da Câmara et al., 2013; Perracini et al., 2020; Ramírez-Vélez et al., 2021).

(ii) Secondary outcome

There are four secondary outcome measures: a) cognitive function, b) pain level, c) quality of life, and d) acceptability towards the programme

- Cognitive function

To assess the cognitive status of participants, three assessment tools will be used: the Montreal Cognitive Assessment (MoCA) (Nasreddine et al., 1995), the forward digit span test (Wechsler, 2008) and the Cognitive Failures Questionnaire (CFQ) (Broadbent et al., 1982). The MoCA is a well-established 30-point test that assesses various aspects, like attention, memory and fluency. The Hong Kong version (HK-MoCA) will be used (Wong et al., 2009). A higher score indicates better cognitive function. A score of 25 or below may indicate the presence of mild cognitive impairment (Nasreddine et al., 1995). The digit span test is a measure of working memory. Participants will be presented with a random series of digits and be asked to repeat them in the order presented (Wechsler, 2008). If the participant responds correctly, the next trial presents a longer sequence. The task will terminate when participants respond incorrectly on three occasions. The participant's span will be the longest number of sequential digits that can be accurately remembered. A longer span indicates better working memory with high internal reliability (70-90%) (Conway et al., 2005). The CFQ is a self-report measure to assess individual forgetfulness, distractibility, and false triggering in everyday life (Rast et al., 2009). It has 25 items (0-4 points) scored by the client or significant other (Broadbent et al., 1982). The total score is 100 points. A higher point indicates fewer cognitive difficulties in daily life, with a high test-retest reliability of 0.71 (Bridger, 2013). A valid and reliable Chinese version of the CFQ will be used in this study (Zhou et al.,2016).

- Pain score

The average pain score will be assessed by the numerical pain rating scale (NPRS). Participants will be asked to rate the average pain level on a scale from 0 (no pain) to 10 (maximal pain). It has a high test-retest reliability of 0.95 (Ferraz et al., 1990).

- Health-related quality of life

The health-related quality of life will be assessed by the EQ-5D-5L questionnaire. It has a validated Hong Kong Chinese version (Wong et al., 2019). The questionnaire consists of 5 dimensions of health, including mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension will be rated from 1 (no problem) to 5 (extreme problems). It also has an EQ-VAS scale to self-rate the overall health perception from 0 (worst health) to 100 (best health). The questionnaire will be administered before and after the intervention programme.

- Acceptability towards the program
  The acceptability of the program will be assessed by a six-question post-program questionnaire based on the barriers to engaging in physical activity (Tiecker et al., 2024). Participants will be asked about (1) their perceived importance of physical exercise, (2) their acceptability and satisfaction of the exercises, (3) the pain or discomfort during the exercises, (4) how challenging it was to perform the exercises, (5) exercise duration, (6) whether the exercises could assist in activities of daily living. All questions will be asked to rate on a scale from 0 to 4 (Appendix 3). Participants will be asked to justify all questions to let the researchers understand their difficulties. The questionnaire will be administered at the last session of this program using a Google form.

Sociodemographic data will also be collected, including age, gender, body mass index, marital status, living status, mobility status, educational level, employment status, lifestyle variables (exercise habit, smoking, alcohol intake), number of self-reported comorbidities, and any presence of polypharmacy (i.e. concurrent use of ≥5 drugs) in the baseline assessment.

Statistical analysis
Descriptive statistics with means (SDs) or medians (IQRs) for continuous variables, and counts (percentages) for categorical variables will be reported for the demographics of the participants. Shapiro-Wilk test will be used to check data for normality. For the first and second objectives, independent t-tests for parametric statistics or Mann-Whitney U Test for non-parametric statistics will be used to compare baseline statistics between the intervention and control groups. Mixed ANOVA will be used to show the differences of change in outcome measures between both groups, and post-hoc tests will be used to check for differences in the outcomes between pre- and post-intervention in both groups. For the third objective, the Mann-Whitney U Test will be used to compare the differences in acceptability between both groups. Statistical analyses will be performed using SPSS software version 29 (IBM, New York, USA). The level of significance will be set at $p<0.05$.

Ethical considerations

The researcher will explain the risks and benefits of the study to the participants. Written informed consent will be obtained from the participants. Participants may withdraw from the project without prejudice. Data will be kept confidential in secure offices of the Department of Rehabilitation Sciences. Only group data will be published. Approval for the project will be obtained from The Hong Kong Polytechnic University Institutional Review Board. The study will adhere to the local laws, the Declaration of Helsinki, and institutional policies. This study will be registered with the Chinese Clinical Trials Registry before the first participant is recruited.

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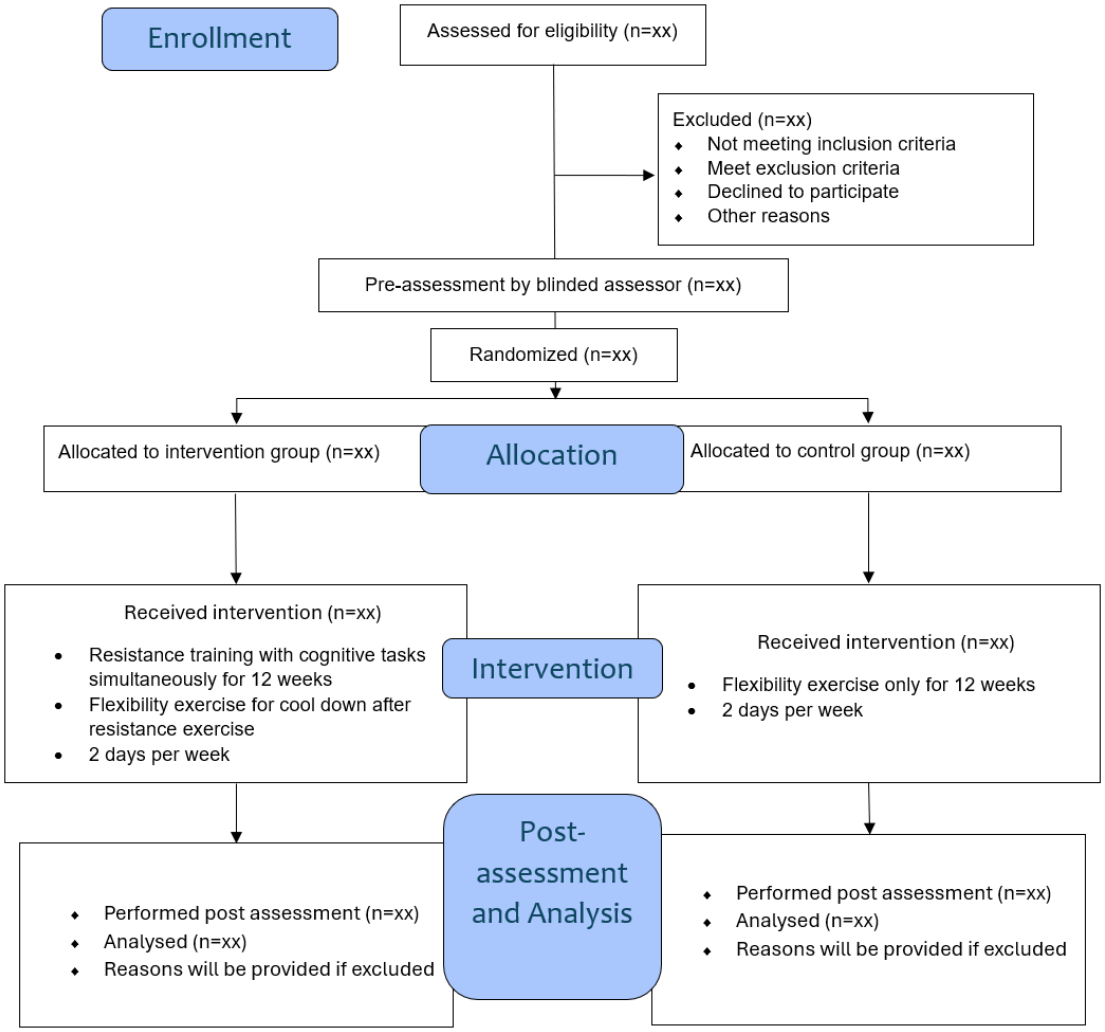
Appendix 1. CONSORT Flow Diagram



Appendix 2. Description of exercises

Flexibility exercises	
(a) Overhead stretch	Subjects stretch their arms upwards with their hands linked together as if they were to touch the ceiling.
(b) Cross-body shoulder stretch	Subjects place their hand on the opposite shoulder and keep the elbow close to the chest. Using the hand from the other arm, they push the elbow towards the opposite hand until they find a position where they feel some tension in the upper shoulder muscles.
(c) Neck rotation stretch	In sitting, subjects turn their head to the right until they feel some tension in the neck muscles.
(d) Lateral neck stretch	In sitting, subjects tip their head to the right until they feel some tension in the neck muscles.
(e) Seated chest and shoulder stretch	Subjects sit in a chair away from the back with their arms hanging on both sides of their body. They then move their arms back, trying to grab onto the back of the chair, and move their chest forward until there is a bit of tension in the arm muscles.
(f) Seated hamstring stretch	In a sitting position, subjects stretch one of their legs by supporting their heel on the ground. They place their two hands on the knee opposite the stretched leg and move their trunk forward until they feel a bit of tension in the muscles in the rear of their back and the rear of their thigh.
(g) Standing quadriceps stretch	Subjects stand up behind a firm chair or a table. They bend one leg while continuing to stretch the other, using their hand to help, and try to force bending until they feel a bit of tension in the muscles in the forethigh.
(h) Standing calf stretch	Subjects step one foot back, keeping it straight with the heel flat on the ground. The front leg is bent slightly at the knee. They keep their back straight and hips facing forward, ensuring both feet are pointing straight ahead. They lean forward slightly, bending the front knee more while keeping the back leg straight, feeling a gentle stretch in the calf of the back leg.
Resistance exercises	
(1) Squat to chair	Subjects sit in a firm chair with arms, supporting their feet well on the ground, and stand up without using the arms of the chair. In the standing position, subjects lower their body down until their buttocks touch the chair and immediately return to standing.
(2) Seated unilateral hip flexion	Subjects sit in a firm chair with arms and slowly lift one knee towards their chest as high as is comfortable with the knee bent, keeping the foot off the ground. They then lower the foot back to the floor, returning to the starting position.
(3) Seated unilateral knee extension	Subjects horizontally extend one leg, trying to keep it as straight as possible, and repeat with the other leg once they have finished the recommended sets.
(4) Standing unilateral knee flexion	Subjects stand up and, if necessary, support their arms on a firm chair or table. With their back straight, they flex the knee, keeping the foot back, and return to the initial position. They repeat with the other leg once the sets indicated have been finished.
(5) Bilateral calf raise	Subjects stand in front of a table or chair back with their feet separated and aligned with their shoulders. They get on their tiptoes until they are as high as possible, then go down gradually until their heels are on the floor. If they lose balance, they support

	themselves on the table or chair; they do not do so if they can keep their balance well.
(6) Seated elbow flexion	Subjects sit with their arms stretched across their body with a weight in each hand. They bend the elbows towards the chest, moving the weights towards the shoulders.
(7) Twisting a towel	Subjects roll up a small towel into the shape of a tube, grab the towel by the ends, and use both hands to make a movement similar to wringing out a soaking towel. They tighten gradually but as strong as they can.
(8) Seated horizontal opening of arms and elbow	Subjects hold an elastic band by the ends and roll it appropriately to prevent injury. They stretch the band at the height of their chest and separate the arms to fully extend the elbows.
(9) Seated diagonal opening of arm and elbow	Subjects hold an elastic band by the ends and roll it appropriately to prevent injury. They begin to separate the arms diagonally to extend the elbows at the height of the knees.

Appendix 3. Acceptability Questionnaire

Criteria/Score	0	1	2	3	4
Importance of engaging in the proposed exercises	None/very little				Extremely important
Acceptability and satisfaction of the exercises	None; OR Very little				Very high
Discomfort felt when performing the exercises	Extremely severe	Severe	Moderate	Mild	None/very little
Difficulty in performing the exercises	Extremely challenging	Very challenging	Moderate	Little	None; OR Very little
Duration of exercises	Very insufficient; OR Extremely too long	Insufficient; OR Too long	Indifferent	Optimal	Very optimal
Can the exercises help with activities of daily living?	Very little; OR Insignificant				Extremely important

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

INFORMATION SHEET

Title of study

Effect of the resistance-cognitive dual-task training on frailty status and cognitive function in frail community-dwelling older adults with chronic musculoskeletal pain: A pilot randomized controlled trial

Background

Frailty is a common condition among older adults. It is characterized by a gradual loss of physiological reserve and adaptability to stressful events, making frail individuals more susceptible to adverse outcomes. Frail older adults are more likely to experience chronic musculoskeletal pain, which significantly impacts their well-being. Moreover, decline in cognitive function is also associated with older individuals with frailty and chronic musculoskeletal pain.

Dual-task training has been used to improve physical and cognitive functions in the general older population and among those with neurological diseases, such as Parkinson's disease and Alzheimer's disease. However, the effect of resistance-cognitive dual-task training on community-dwelling older people with frailty and chronic musculoskeletal pain for improving frailty status and other health-related outcomes remains unclear.

Therefore, You are invited to participate in this project conducted by the undergraduate physiotherapy students: LEE Chun Hin, LEUNG Tin Yeung, LIU Hui Lok, NG Chun Wing and MA Daphne. This project is supervised by Prof. Derek YAU, Assistant Professor in the Department of Rehabilitation Sciences at The Hong Kong Polytechnic University (PolyU).

Study Purpose

The aims of this project are:

1. To investigate the effect of a 12-week dual-task training program that combines resistance and cognitive exercises on the frailty status in community-dwelling older adults who have frailty and chronic musculoskeletal pain.
2. To investigate the effect of the dual-task training program on cognitive function, pain levels and quality of life in community-dwelling older adults with frailty and chronic musculoskeletal pain.
3. To find out if the participants find the dual-task training program acceptable.

Participant Eligibility

You are eligible to take part in this study if you are an adult (≥60 years), are experiencing chronic musculoskeletal pain for at least 3 months, and are screened frail.

You are not suitable for this study if you:

- Are absent of frailty; or
- Have received surgical procedure in lower limb or vertebral column; or
- Are wheelchair bound or unable to walk for 5 minutes; or
- Have severe balance impairment; or
- Have uncontrolled cardiac or vascular conditions; or
- Have acute inflammatory musculoskeletal conditions; or

- Have ongoing cancer; or
- Have dementia; or
- Have neurological diseases such as stroke, Parkinson's disease, cerebellar disease, myelopathy, or peripheral neuropathy; or
- Have mental illness such as schizophrenia, bipolar disorder, psychosis, borderline personality disorder; or
- Are illiterate or do not understand written and verbal Chinese or English.

Study Procedure

If you agree to participate, you will be asked to complete the following after signing the consent for the study:

1. Frailty assessment
   a) Tilburg Frailty Indicator
      - A 15-item questionnaire for frailty assessment.
      - It takes about 5 minutes.
   b) Fried Frailty Phenotype
      - This is a 5-item measure assessing your frailty level consisting of:
        - Two simple questions on reporting any weight loss and exhaustion
        - Two physical function tests: hand grip strength test, 6-meter walking test
        - A questionnaire (Physical Activity Scale for the Elderly [PASE]) about your physical activity level
      - It takes about 5-10 minutes
   c) Short physical performance battery (SPPB)
      - It contains 3 subtests: chair stand test, standing balance tests, and 4-meter gait speed test.
      - It takes about 10 minutes.
2. Cognitive function
   a) Montreal Cognitive Assessment (MoCA)
      - A 30-question test for cognitive assessment.
      - It takes about 10 minutes.
   b) Forward digit span test
      - A test for working memory
      - It starts with 3 numbers and progresses with one number each time until you fail to recall all numbers correctly.
      - It takes 1-3 minutes depending on performance.
   c) Cognitive failures questionnaire
      - A 25-item questionnaire for assessing cognitive decline in daily life.
      - It takes about 10 minutes.
3. Pain level
   a) Numeric Pain Rating Scale (NPRS)
      - A 0–10-point scale for assessing your average pain level.
      - It takes less than 1 minute.
4. Health-related quality of life
   a) EQ-5D-5L (Hong Kong Chinese version)
      - A 6-item questionnaire for measuring health-related quality of life.
      - It takes about 5-10 minutes.
5. Acceptability of programme
   a) A questionnaire administered by researchers
      - It will be taken at the final session.
      - It contains 6 questions and takes about 5-10 minutes.

Assessments will be performed at the initial and final sessions of the 12-week program. Apart from the above assessments and questionnaires, your sociodemographic information and relevant medical history will also be collected by the investigators. The assessment session will take around 30-45 minutes.

There will be training sessions 2 days per week for 12 weeks consecutively. The training sessions will take place in PolyU, under the guidance and supervision from the members of our research team. You will be randomly assigned to the intervention or control group. Both groups will receive supervised exercise training programs, but the contents will not be identical. Each training session will take around an hour.

Benefits

You will receive a comprehensive assessment on your frailty status and other health-related outcomes. You will also participate in an exercise training program supervised by our research team. There will be no extra costs required for participating in this study.

Potential Risk(s) or Discomfort(s) and their minimization(s)

It is possible that you may experience pain exacerbation during the first few weeks of the program. To minimize the risk, exercise will be prescribed based on individual ability, and training intensity will be increased gradually. In addition, warm-up and cool-down phases for both groups will help reduce the risk of symptom exacerbation. You are also allowed to take regular rests during training, and the training program will be closely monitored. However, if you feel any discomfort, please inform our research team member immediately.

Confidentiality of Personal Data

The information you provide as part of the project is the research data. Any research data from which you can be identified is known as personal data. Personal data does not include data where the identity has been removed (anonymous data). We will minimize our use of personal data in the study as much as possible. The researchers and the supervisor will have access to personal data and research data for the purposes of the study. Responsible members of PolyU may be given access for monitoring and/or audit of the research.

Data Retention

All information related to you will remain confidential and will be identifiable by codes only known to the researchers. The information collected will be kept until 5 years after project completion. PolyU takes reasonable precautions to prevent the loss, misappropriation, unauthorized access or destruction of the information you provide.

Participation and Withdrawal

You understand that to participate or not in the study is voluntary. You have every right to withdraw from the study before or during the measurement without penalty of any kind.

Enquiries and Comments

The researcher has discussed with you and offered to answer your questions. You may contact Prof. Derek YAU (Principal Investigator; Tel. no.: 27665396 / Email: derek-kw.yau@polyu.edu.hk) of PolyU under the following situations:

a. if you have any further enquiries in relation to the study even after the study; or
b. if, under very rare conditions, you become injured as a result of your participation in the study; or

c. if you want to get access to/or change your personal data.

In case of you feel any discomforts during the study, please report to Prof. Derek YAU immediately as soon as possible. In case of a serious adverse event[1], the Principal Investigator will be required to report it to the PolyU IRB within 48 hours upon the receipt of your report.

In the event you have any concerns/complaints about the conduct of this research study, you may contact the Secretary of the PolyU Institutional Review Board in writing (institutional.review.board@polyu.edu.hk) or via phone at 27666379 stating clearly the responsible person and department of this study as well as the Reference Number.

Thank you for your interest in participating in this study.

[1] SAE is any adverse event that:

- Results in death
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Results in congenital anomalies or birth defects
- Is another condition which investigators judge to represent significant hazards

(Reference: NIA Adverse Event and Serious Adverse Event Guidelines.
https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf)

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CONSENT TO PARTICIPATE IN RESEARCH

Title of study

Effect of the resistance-cognitive dual task training on frailty status and cognitive function in frail community-dwelling older adults with chronic musculoskeletal pain: A pilot randomized controlled trial

I _____ hereby consent to participate in the captioned research conducted by Lee Chun Hin, Leung Tin Yeung, Liu Hui Lok, Ma Daphne and Ng Chun Wing. I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed. The procedure as set out in the attached information sheet has been fully explained. I understand the benefit(s) and risk(s) involved. My participation in the project is voluntary. I acknowledge that I have the right to question any part of the procedure and can withdraw my participation at any time without penalty of any kind.

_____	_____
Name of Participant	Name of Researcher
_____	_____
Signature of Participant	Signature of Researcher
_____	_____
Date	Date

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