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Self-administered dual-task training reduces balance deficits and falls among community-dwelling older adults: a multicentre parallel-group randomised controlled trial with economic evaluation protocol

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ABSTRACT

Background Falls are common causes of disability, reduced disability-adjusted life years and death in older adults. Balance deficits and cognitive impairment are common causes of falls. Dual-task training is a new strategy that can potentially improve balance and cognitive function, leading to decreased falls. The effectiveness and cost-effectiveness of self-administered dual-task (sDT) training to improve balance and prevent falls is not known. We developed sDT training combining physical and cognitive tasks to improve balance and reduce falls. The proposed randomised controlled trial (RCT) with economic evaluation is to test the effectiveness and cost-effectiveness of the sDT compared with self-administered single-task training (sST) in this population.

Methods and analysis In this RCT, we will recruit 190 community-dwelling older adults with a history of at least one fall over the last 6 months from 11 elderly centres. The older adults will be randomly assigned to the sDT (n=95) and sST groups (n=95). Each group will be offered in six training workshops to teach the participants either sDT or sST depending on the group allocation. Each workshop will last an hour and will be held once every 2 weeks for 3 months. Besides, the participants will be instructed to repeat the exercises at home two times weekly for 3 months. Following the intervention phase, the participants will continue unsupervised home-based exercises for 6 months. Assessments will be performed before, after and 6 months after completing the intervention. A fall calendar and cost diary will be provided to each older adult to record the number of falls and fall-related costs during and after the intervention to assess fall incidence and cost-effectiveness. Effectiveness will be assessed using a negative binomial regression model following the intention-to-treat principle for falls and a linear mixed model for the additional measure and cost-effectiveness using a Markov model.

Ethics and dissemination This study has ethical approval from the PolyU Institutional Review Board for conducting research on human subjects (Ref: HSEARS20210322005). The results will be disseminated through seminars for individuals and health practitioners, international conferences and published in peer-reviewed journals.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study has rigorous methodology, including randomisation, assessor-blinding and multicentres, to assess the effectiveness and cost-effectiveness of self-administered dual-task (sDT) training in preventing falls among community-dwelling older adults in Hong Kong.
⇒ The derived cost from fall-related injury will be used to determine whether the sDT intervention is a cost-saving treatment option for fall prevention. The findings of this analysis will inform policymakers on cost-saving options for preventing falls among the target group.
⇒ Our multicentre randomised controlled trial will recruit participants from different elderly centres across three districts in Hong Kong to ensure the generalisability of our study findings for all healthy older adults.
⇒ The findings of this study will inform clinicians and researchers about the dosage of the sDT intervention to improve balance and prevent falls among older adults.
⇒ Since we will not consider older adults with pathological conditions, the findings of our study cannot be generalised to those older adults with limited mobility and comorbidity. Our future research will explore the benefits of sDT among such populations with limited mobility.

Trial registration number NCT05533333.

INTRODUCTION

Globally, the prevalence of falls among adults over 65 years is 28%–35%, rising to 32%–42% for those over 70 years.[1] More than 40 million older adults annually experience a fall in China, and 36 million falls are reported in the USA.[2 3] Falls are the leading cause of

injury deaths in Australia (42%), New Zealand (48%) and China (39%).[4–6] Falls add to the economic burden of high-income countries, including the USA.[7] Annually, US$50 billion is spent on fall-related injuries and US$754 million on fall-related deaths in the USA.[8] In China, the annual estimated cost of fall-related injuries among older adults is US$9–11.8 billion.[9] In Hong Kong, fall-related costs for community-living older adults are reported to be over US$70 million every year.[10] Therefore, there is a pressing need for effective and cost-effective fall prevention programmes for this population.

Studies have demonstrated that single-task training, such as endurance, strength, adapted physical activity, Wii Fit training, multisensory, whole-body vibration and aerobic and cognitive training, has positive short- and long-term effects on balance in older adults.[11] Single-task training refers to cognitive and physical exercises performed in isolation sequentially.[12] Previous studies have explored combinations of different single-task training, including flexibility and resistance training, aerobic and resistance training, to improve balance and reduce fall incidence.[13] These interventions have been associated with a 21% reduction in fall rates among older adults.[14]

Dual-task training refers to integrating cognitive and physical exercises performed simultaneously to enhance balance.[15] It is a promising strategy to minimise the number of falls among older adults who are at high risk of falling.[15] Older adults benefit from dual-task training compared with single-task training, improving motor function and cognitive performance.[16 17] This dual-task training intervention is feasible to deliver without any associated risk.[16]

Previous studies used dual-task training, combining unstable strength exercises with cognitive training, resulting in functional performance improvements in older adults.[18] A study integrating the simultaneous performance of resistance training with cognitive exercises yielded improvements in balance and working memory.[13] A recent study has reported improvement in static and dynamic balance and short-term memory using concurrent agility ladder training paired with cognitive tasks.[19] In a study involving older women, simultaneous gait and balance exercises with cognitive components led to improvements in gait, balance, muscle strength and cognition.[20] Despite these positive outcomes, there remains a lack of exploration of the 'self-administered' mode and the long-term effects of dual-task interventions on balance improvement and fall prevention.

Self-administered exercise is beneficial for enhancing the balance and quality of life among older adults.[21] It involves performing activities independently after receiving training from practitioners. In addition, older adults complete the task on their own initiative, outside of a research or healthcare setting, with little to no interaction with researchers or study staff. A practitioner or researcher trains and advises the participant to engage in exercise. Exercising in their home without direct supervision from a physiotherapist can alleviate the burden for both older adults and the healthcare system.[21]

Therefore, our team designed a dual-task programme for improving balance and reducing falls that can be self-administered by older adults.[15] We hypothesise that our newly designed self-administered dual-task (sDT) training will improve balance and reduce falls among older adults. A recently published meta-analysis reported that exercise reduced 30% of falls.[22] Thus, we hypothesise that older adults participating in the sDT compared with the self-administered single-task (sST) training programme will report a 30% reduction in falls. Previously published studies had a 1:1 participant-to-physiotherapist ratio and did not consider group training, which may not necessarily be cost-effective.[23 24] It is crucial to ascertain the cost-effectiveness of group interventions using sDT training. We hypothesise that the healthcare costs associated with falls and fall-related injuries will be reduced by 10% following sDT conducted in groups.

In this study, we aim to perform a multicentre randomised controlled trial (RCT) to (1) compare the effects of the sDT training with the sST training on improving balance and reducing the number of falls experienced by older adults and (2) conduct an economic evaluation to establish the cost-effectiveness of the sDT training. This paper reports the study protocol of our RCT that tests the effectiveness and cost-effectiveness of our newly designed sDT training for a group of community-dwelling older adults in Hong Kong in improving balance and reducing falls. This study's findings will help policymakers integrate new fall prevention strategies into state policy for this population.

METHODS AND ANALYSIS

Study registration and guideline

This multicentre RCT has been registered in the ClinicalTrials.gov database (NCT05533333).[25] This study follows the Standard Protocol Items: Recommendations for Interventional Trials guidelines for reporting.

Study design

This is a 9-month, assessor-blinded, multicentre parallel-group RCT with an economic evaluation comparing the sDT and the sST groups for preventing falls. Older adults will be randomly assigned to each treatment arm, either in the trial experimental group receiving the sDT training programme or the control group receiving the sST training programme.

Randomisation, blinding and concealment

Using permuted block randomisation, older adults will be allocated randomly to blocks with a block size of 10. Permuted block randomisation is the process of dividing older adults into blocks of a certain size, followed by allocating interventions within each block. A statistician will prepare a random number list, and a research assistant not involved in the study will use it to randomise

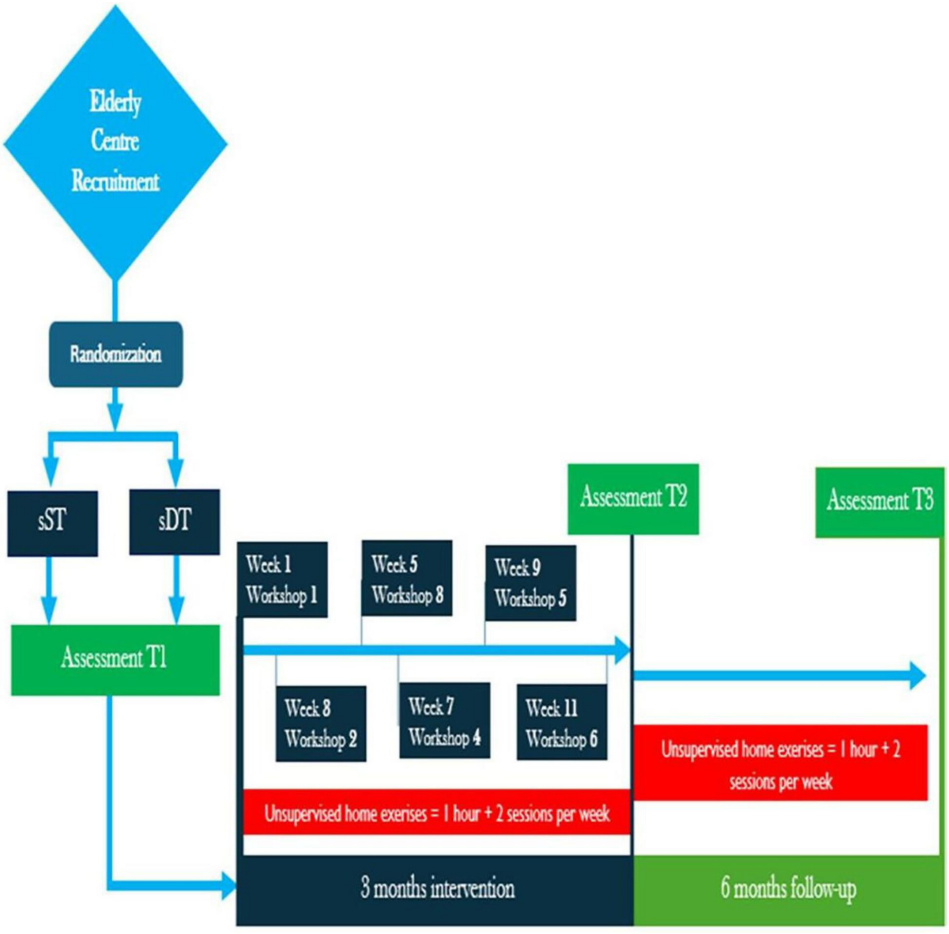

Figure 1 Intervention plan of the study. sST, self-administered single task, sDT, self-administered dual task; T1, assessment time point 1 implies the baseline assessment right before the intervention; T2, assessment time point 2 represents the postintervention assessment after 3 months; T3, assessment time point 3 indicates the follow-up assessment after 6 months.

the centres before the baseline assessment. One Hong Kong-registered physiotherapist will conduct workshops and teach exercise interventions to all older adults. Physiotherapists will be notified about the study group and allocation via text or email to maintain concealment. A research postgraduate student will handle all other project-related methodological procedures. A postgraduate student who is blind to treatment conditions will conduct the assessments. A statistician will perform an economic evaluation using healthcare utility estimation. After completing the analysis, the treatment allocation will be revealed to the statistician to ensure the analysis is blinded. Randomisation and the blinding procedure are shown in figure 1.

Assessment procedure, time points and venue

Assessments will be conducted at three time points in accordance with the repeated measures design. The eligibility of older adults will be determined using a questionnaire. The eligible older adults will then undergo the baseline assessment (T1) following 12 weeks of intervention, participants will undergo a postintervention assessment (T2) and after 6 months, a follow-up assessment (T3) will be conducted as shown in figure 1. All assessments and interventions will take place in the community centres for the older adults of Hong Kong. Assessment of groups on different days may cause performance bias.[26] Therefore, all older adults in the same treatment group will undergo evaluations on the same day to eliminate potential performance differences.

Study settings, centre recruitment and source of participants

Potential older adults will be recruited from various elderly care centres across three districts of Hong Kong located on Hong Kong Island, Kowloon and the new territories.

Eligibility criteria for participation

We will include older adults, both males and females, who meet the following criteria: (1) aged 65 years or older; (2) resides in the community; (3) ambulant for at least 5 min with or without the use of an assistive device; (4) experienced at least one fall within the past 6 months and (5) obtained a score of ≥24 in the mini-mental state examination, which indicated that they did not have cognitive impairment. Older adults will be excluded if they have (1) dementia or Alzheimer's disease; (2) a history of psychiatric illness; (3) can only walk with hand-held support or

(4) a significant visual impairment that limits participation in exercise.

Sample size calculation

The power analysis and sample size software determined the sample size. The sample size is determined based on the primary outcome—the number of falls. Following our feasibility study and other supporting studies,[27 28] the sample size was estimated assuming a power level of 90%, a type I error of 5%, a moderate effect size of 0.5, a dropout rate of 20% and an intraclass correlation coefficient of 0.1. The estimated number of older adults required for each treatment arm was 95. Hence, the study will recruit a total of 190 older adults.

Intervention

The older adults recruited will participate in 1-hour workshops once every 2 weeks for 3 months and practice the exercises taught twice a week at home for an hour over the 3 months. In addition, the exercises taught in the workshop will be practised unsupervised, two times a week at home for 6 months during the follow-up phase,[29] as outlined in table 1. Each older adult will be trained in general stretching and strengthening exercises and fall prevention strategies.

sDT training

The older adults in the sDT training group will perform a 10-min warm-up, 40 min of dual-task training and 10 min of cool-down exercises, as outlined in table 1. All exercises for warm-up and cool-down will be performed in a sitting position, while march walking in a standing position. In a 10-min warm-up, older adults will participate in stretching and strengthening exercises that focus on the lower limbs. Older adults begin by stretching the back muscles while seated in a chair, extending one leg and reaching for toes without bending the knee. This is followed by calf muscle stretching, which involves straightening the knee with dorsiflexion of the ankle. Hip strengthening exercises include forward and backward cycling, during which older adults lift the knees to the chest. Additionally, they perform exercises that involve lifting the knee and turning the leg outward and inward. The session concludes with march walking, where older adults alternate lifting each leg to a 90-degree hip flexion.

The sDT training programme incorporates motor exercises into various cognitive exercises. The motor exercises will include walking, sit-to-stand movement, heel and toe raising, stepping, tandem standing and walking and multidirectional reaching tasks. In the sit-to-stand exercise, older adults perform the action of standing up and sitting down from a chair with their arms crossed. During the one-leg standing exercise, participants will be instructed to stand on one leg with their eyes open and then bend the knee of the opposite limb while opening their eyes. The toe-standing exercise will involve standing on both toes by lifting the ankles while maintaining an upright position. In the side lunges exercise, older adults will stand with their feet spread wide apart, toes pointing forward and bend the hip and knee of one leg while keeping the other leg straight, alternating between the right and left sides. During forward lunges, older adults will stand tall with one foot placed forward at hip-width, bending the front leg and foot simultaneously to shift their weight forward. Heel standing exercise requires standing on both ankles while lifting the toes and maintaining a standing position. During the 10-m backward walk, older adults practice walking in a backward direction. In figure-of-eight walking, two objects will be placed opposite each other at three feet, and participants will walk in a figure-eight pattern between them. Multidirectional reaching exercises will involve participants standing on one leg, bending the knee of the other leg, and reaching out with their hands in various directions—sideways, right, left and overhead—while maintaining balance. Tandem stepping will involve standing with one foot in front of the other and continuing to walk in this position. Lastly, tandem standing requires standing with one foot in front of the other while maintaining an upright posture.

The cognitive exercises will include the following tasks. Older adults will perform a heel raise while hearing the letter H to improve attention and auditory discrimination with the assistance of a helper. During the recall memory task, participants will be required to memorise a list of five simple words: ‘red’, ‘lion’, ‘bus’, ‘bottle’ and ‘phone’, and subsequently recall them at the session’s conclusion. The mental tracking task involves performing basic arithmetic operations, such as counting backwards from 100 by subtracting 2 (eg, 100, 98, 96 and 94). For fluency in the categories task, participants will be asked to describe and list the common features of roses. In the problem-solving task, older adults will generate and explain scenarios in response to questions like, ‘What would you do if the electricity went out in the evening?’. In addition, short storytelling will be used to enhance verbal fluency. The verbal fluency task will involve naming five individuals with the surname ‘Lee’, such as ‘Bruce Lee’. During the information processing skills task, participants will be required to either count the days of the week or state the current date in the month-day-year format. Lastly, the working memory task will involve naming items within specific categories, such as ‘apple’, ‘orange’ and ‘banana’ for fruits; ‘broccoli’ and ‘tomato’ for vegetables; or ‘tiger’ and ‘crocodile’ for animals. These exercises align with previous research on dual-task training for older adults with mild cognitive impairment.[30] Older adults can mix and match the physical and cognitive tasks to increase the level of challenge.

sST training

The sST training schedule will include 10 min of warm-up exercises, followed by 20 min of motor tasks and 20 min of cognitive tasks and then 10 min of cool-down exercises. Older adults will receive instructions to perform the exercises at the same dosage as the sDT group. After a

Table 1 Exercise regime for the study

Warm-up phase (10 min)	**Stretching exercise**	**Strengthening exercise**
	Back, hamstring and calf stretching	Weight shifting of hip, hip flexion, extension and flexion to right and left, march walking.
Exercises phase (40 min training)	**Motor type exercise**	**Cognitive type exercise**
	1. Sit-to-stand exercise 2. Standing one leg, eyes open 3. Forward lunges 4. Side lunges 5. Toe standing 6. Heel standing 7. 10 m backwards walk. 8. Walking in an eight-shaped path between two chairs 9. Multidirectional reaching exercises (half-setting, one leg) 10. Tandem stepping and standing	1. Attention and auditory discrimination Accent a word that letter starts with 'Z'. 2. Recall memory Remember five simple words given at beginning of session. 3. Mental tracking Simple arithmetic operations, counting backwards, subtraction and deviation. 4. Fluency in categories What are the common features of roses? 5. Problem solving Participants will be asked to create and explain scenarios suitable for questions such as 'What would you do if the electricity went out in the evening?' 6. Verbal fluency Say the female names starting with the letter 'A'. 7. Information processing skills 'Count the days of the week, tell the date of today as month-day-year'. 8. Abstraction skill Commonly used, simple proverb interpretation. 9. Working memory Naming fruits, vegetables or animals.
Cool-down phase (10 min)	**Stretching exercise**	**Strengthening exercise**
	Back, hamstring and calf stretching	Weight shifting of hip, hip flexion, extension and flexion to right and left, march walking.

Dose: 1 hour per session, one set (10 repetitions) each exercise, two times a week. Participants can cross-match the exercises.

follow-up period of 6 months, the sST group will receive two free sessions of dual-task training.

Training progression

The training will be tailored to older adults' adaptability and performance levels. The level of the motor and cognitive exercises of the training programme will be systematically modified to increase intensity and challenge.

Intensity will be increased by adding new and cross-matching motor and cognitive exercises every 2 weeks. In the first workshop, older adults will practice sit-to-stand, standing on one leg with attention, auditory discrimination and recall memory tasks. The second workshop will add side and forward lunges, mental tracking exercises and fluency in categories exercises. The third workshop will include toe standing, heel standing, problem-solving and verbal fluency exercises. In the fourth workshop, participants will perform a 10-m backward walk, figure-eight walking, information processing and abstraction exercises. The fifth workshop will feature multidirectional reaching exercises, tandem stepping, standing exercises and working memory tasks. In the sixth workshop, participants will practice all exercises. The older adults will practice one set, equivalent to 10 repetitions of each exercise.

The challenge of motor exercises will be increased by limiting the base of support and reducing hand support. The challenge of cognitive tasks will be increased by limiting the time spent on each cognitive task and providing complex activities.[31] In the initial workshop, older adults will engage in exercises while maintaining a limited base of support by reducing the distance between their feet. The second workshop will further challenge participants by eliminating hand support, instructing them to perform tasks without the aid of sticks or a chair. The third workshop will focus on constraining the response rate for cognitive tasks. During the fourth workshop, participants will execute exercises with both a limited base of support and a restricted response time. The fifth workshop will combine the reduction of hand support with a limited response time for cognitive tasks. Finally, in the sixth workshop, participants will practice exercises incorporating a limited base of support, reduced hand support and a constrained response time for cognitive tasks.

Strategies to promote adherence

We will adopt several strategies to improve adherence rates. First, we will provide an information sheet with clear and concise information detailing the study's purpose, procedures and expectations. Second, we will distribute exercises paired with figures and comprehensive instructions after each workshop. Third, we will inform caregivers and older adults about the potential benefits and risks of the study, emphasising their significant role in encouraging adherence. Fourth, social workers of the participating study centres will contact caregivers and older adults through phone calls, texts, or emails, helping them keep track of appointments and exercises. Fifth, we will offer incentives, including a financial compensation of 100 Hong Kong dollars (HKD) to cover transportation expenses. Finally, we will maintain flexibility in scheduling workshops for older adults.

Safety of the intervention

Interaction between motor and cognitive activities increases the risk of falling when older adults engage in challenging tasks. To ensure the safety of older adults, it is essential to calibrate the difficulty level of the cognitive task carefully. During face-to-face training sessions, the cognitive and physical tasks will be adjusted based on the older adults' tolerance levels, and instructions will be provided to ensure that they have a caregiver or assistant present throughout the session. Caregivers will be informed of the importance of contacting the study team if they notice any warning signs, such as increased instability or discomfort during the exercises. Electronic diaries will be used to track adherence to the intervention protocol and minimise the number of missing data points and recall errors. We will purchase insurance for each participant to cover any trial-related injuries during the entire study period.

Outcome measures

Primary outcome

Number of falls

We define 'fall' as a situation in which an older adult loses balance due to unintentional movement or activity and ends up resting on the floor or other lower surfaces after stumbling or experiencing a similar occurrence.

A digital fall calendar and cost diary will be used to collect falls data once every week. Those without internet access or those unwilling to use an online fall calendar will be provided with a printed fall calendar and cost diary. During the first 3 months of the project, the fall calendar and cost diary will be collected once every 2 weeks from older adults during workshop days. During the 6-month follow-up period, the social worker will collect the calendar and cost diary at the facility once every month.

Secondary outcomes

We will assess dual-tasking ability using the dual-task TUG (dTUG),[32] dynamic balance using the standard-TUG (sTUG),[33] static balance using the Berg Balance Scale,[34] fear of falling using the Falls Efficacy Scale-International,[35] general health outcomes using the Short Form of the Health Survey,[36] global cognition using the Montreal Cognitive Assessment[37] and health-related quality of life using the five-level version of the EuroQol five dimension five level (EQ-5D-5L).[38] The scoring, interpretation, assessment timeline and psychometric properties are reported in table 2.

Healthcare cost estimation

The older adults in this study will use digital diaries to record healthcare service consumption costs. The digital diary will summarise completed items for all included participants. Non-responders will be followed up by

Table 2 Primary and secondary outcome measures

Outcome measures	Assessed domains and result interpretation	Assessment			
		T0	T1	T2	T3
Primary					
Falls	Definition: The operational term 'fall' refers to a situation in which an older adult loses balance due to unintentional movement or activity and ends up resting on the floor or other lower surfaces after stumbling or experiencing a similar occurrence. Number of falls: Obtains using digital diary.	√	√	√	√
Secondary					
sTUG	Definition: The individual stands up, walks 3 m, turns 180 degrees and sits down. Lower the time expresses better balance and walk. The sTUG test is considered a valid assessment tool for measuring dynamic balance and walking for older adults. Domain: Motor activity Item: 1 Interpretation: The shorter the time to accomplish the sTUG, the better the balance and the lower the risk of falling. Psychometric properties: High inter-rater reliability (ICC=0.97; 95% CI 0.66 to 0.82) and acceptable concurrent validity (r=−0.88; p<0.001) for assessing dynamic balance among older adults.[50 51]		√	√	√
dTUG	Definition: Individuals perform either motor or cognitive tasks during the dTUG test. A shorter duration implies better performance. The dTUG test is a valid measure of the dynamic balance and gait of older adults. Domain: Activity Item: 1 Interpretation: A shorter duration of completing the dTUG indicates improved balance and a lower risk of falling. Psychometric property: Excellent test–retest reliability (r_{T1-T2}=0.98) and concurrent validity (r=−0.66; p<0.001) for assessing dynamic balance and risk of falls in older adults.[32]		√	√	√
DT cost of balance	The estimation of the DT cost of balancing performance will be determined by using the formula[25]: (dTUG–sTUG)/sTUG)×100. This estimation will be based on the scores obtained from the sTUG test and the dTUG test.		√	√	√
DT cost of cognitive	The DT cost of cognition performance will be evaluated by using the following formula[25]: (dTUG–sTUG)×100. This estimation will be based on the scores obtained from sTUG test, the dTUG test and the standard counting backwards.		√	√	√
BBS	BBS is a reliable and valid measure of static balance in older adults. Scores range from 0 to 56 with higher scores indicating better balance. Domain: Functional balance Item: 14 Score (minimum–maximum): 0–56 Interpretation: A higher score indicates better improvement in balance. Psychometric property: The inter-rater reliability (ICC=0.99; 95% CI 0.988 to 0.996) and concurrent validity (r=0.84; p<0.001) are excellent for assessing static balance in older adults.[34 50]		√	√	√
FES-I	The FES-I scale reliably measures older adults' fear of falling. Scores range from 16 to 64, with 16 representing 'no concern' and 64 representing 'extremely concerned with falling'. Domain: Fear of falling Item: 16 Score (minimum–maximum): 16–64 Interpretation: Higher scores indicate a greater fear of the risk of falling. Scores of 16–19 indicate low, 20–27 indicate moderate, and 28–64 indicate significant concern about falls.[35] Psychometric property: The test–retest reliability (ICC=0.96; 95% CI 0.79 to 0.95) is excellent, and convergent validity (r=0.67; p<0.001) is acceptable assessing fear of falling among community-living adults.[52 53]		√	√	√

Continued

Table 2 Continued

Outcome measures	Assessed domains and result interpretation	Assessment			
		T0	T1	T2	T3
SF-12	The SF-12 health-related quality of life measure summarises residents' physical and mental health. Domain: Physical and mental health Item: 12 Interpretation: Higher scores on the SF-12 scales and summary measures imply better health. Psychometric property: The reliability of the SF-12 is high (Cronbach's α=0.91), and the convergent and divergent validity is acceptable (r>0.60; p<0.005) for assessing physical and mental health among older adults.[36]		√	√	√
MoCA	The MoCA screens global cognition. The overall score ranges from 0 to 30 points. Scores above 23 suggest individuals are cognitively sound.[54] Domain: Global cognition Item: 1 Score (minimum–maximum): 0–30 Interpretation: Higher scores indicate better cognitive health. Psychometric property: The inter-rater reliability (ICC=0.81; 95% CI 0.75 to 0.87) is excellent, and the concurrent validity (r=0.79; p<0.001) is high for assessing global cognition in community-living older adults.[37 55]		√	√	√
EQ-5D-5L	The EQ-5D-5L scale, a standardised tool for assessing health status, will be used for economic evaluation. Domain: Quality of life Item: 5 Interpretation: Lower scores imply better health. A higher score on EQ-VAS indicates better health (EQ-VAS). Psychometric property: The test–retest reliability (ICC=0.84; 95% CI 0.81 to 0.87) is high and discriminant validity (r=0.6–0.7; effect size=0.5) is acceptable for assessing health-related quality of life in the community-dwelling adults.[38 56]		√	√	√
QALY	EQ-5D-5L will be weighted ranges from 0.2 (unable to perform activity) to 1 (no health issue). After eliciting weights, the scores from the EQ-5D will be translated into an index score using those weights.[57]		√	√	√

T0=assessment time point 1 for the past 6 months of study enrolment; T1=assessment time point 1 implies the baseline assessment right before the intervention; T2=assessment time point 2 represents the post-intervention assessment after 3 months and T3=assessment time point 3 indicates the follow-up assessment after 6 months.
BBS, Berg Balance Scale; DT, dual-task; EQ-5D-5L, EuroQol five dimension five level survey; FES-I, Falls Efficacy Scale-International; ICC, intraclass correlation coefficient; MoCA, Montreal Cognitive Assessment; QALY, quality-adjusted life year; SF-12, 12-item Short Form of the Health Survey; sTUG, standard time up and go test; VAS, Visual Analogue Scale.

telephone once a week. Older adults without frequent internet access will receive a paper version of the cost and fall diary. Postage-paid envelopes will be included with every printed cost diary to achieve a higher response rate. The direct medical charges incurred are listed in table 3. The contents of the table are consistent with the derived cost items based on earlier work on cost estimation for adults with cerebellar ataxia in Hong Kong. These costs correspond to prospective healthcare costs in HKD.[39 40]

Statistical analysis

Analyses will be performed based on the intention-to-treat model. Missing data are common in RCTs, causing bias in the results.[41] Therefore, the US National Research Council Panel on Handling Missing Data for Initial Analysis in Clinical Trials recommends missing data at random assumptions.[42] The term missing data at random refers to the fact that the outcomes that are missing may not be caused by random chance.[43] However, a valid method to accommodate missing data under missing at random is the multiple imputation method.[42] Thus, the missing data in our study will be replaced using the multiple imputation method if the missing rate accounts for more than 20%. In addition, to avoid errors in data input, the dataset will be checked and rechecked. The normality and homogeneity of the data will be examined.

Demographic and baseline data will be reported using means, SD and 95% CIs for continuous variables; medians and IQRs for non-normal continuous or ordinal data and percentages for categorical data.

A negative binomial regression model will be used to estimate fall incidence rates 6 months after intervention. For group comparisons, a negative binomial regression model will be used to report the fall rate and incident rate ratio (IRR), with 95% CI (CI).

Linear mixed models will be used to evaluate the secondary outcome measures. Missing data will be managed with a linear mixed model without imputations.[44] The immediate treatment effects will be assessed by comparing T1 and T2, and the retention of treatment effects will be evaluated by comparing T1 and T3.

Table 3 Fall-related direct medical unsubsidised charges of older adults based on Hospital Authority, Hong Kong, 2019

List of cost items	Assessment				Charges (Hong Kong dollars)
	T0	T1	T2	T3	
Medical related					
1. Consultation with a doctor			√	√	2210/visit
2. Geriatric day hospital			√	√	1760/day
3. Specialist outpatient clinics, including allied health clinics			√	√	1190/visit
4. Consultation with traditional chinese medicine			√	√	120/visit
5. Accidents and emergency hospital admissions and hospitalisation			√	√	6650/day
6. Admission to the intensive care unit			√	√	15350/day
7. Surgery due to falls, medicine, dressing or injection			√	√	72 050*/surgery
8. Private nursing service or community nursing service			√	√	730/day
9. Community allied health services			√	√	1730/day
10. Auxiliary equipment and apparatus			√	√	N/A
Intervention related					
1. Research assistant			√	√	141.31/hour
2. Physiotherapist			√	√	600/hour
3. Staff			√	√	167/hour
4. Phone and internet			√	√	0.21/min
5. Venue			√	√	650/hour

Medical care costs require continuous evaluation right from the commencement of intervention. T0=assessment time point 1 for the past 6 months of study enrolment; T1=assessment time point 1 implies the baseline assessment right before the intervention; T2=assessment time point 2 represents the post-intervention assessment after 3 months and T3=assessment time point 3 indicates the follow-up assessment after 6 months. N/A: prices are according to the average costs of five rehabilitation shops in Hong Kong.
*Surgery due to a fall is considered major III surgery.
N/A, not applicable.

An econometric model is often necessary to estimate healthcare use and costs based on the distribution of the data, as healthcare use and expenditures are often skewed. We will employ two-part models with bootstrapping to analyse the correlation between treatments and medical expenses, considering cost fields with zero values. We will also include older adults' baseline demographic and health information in the models to account for any imbalances in characteristics across groups and improve estimation accuracy.

EQ-5D-5L responses will be transformed into utility ratings to assess the quality-adjusted life year (QALY) gain or loss over the follow-up period. Each group's 6-month mean QALY gain, or loss, will be calculated, as shown in table 2. In addition, the mean incremental QALY gain will be calculated for the intervention groups. The incremental cost-effectiveness ratio (ICER) will be calculated by substituting mean incremental cost and effect using the formula:

$ICER = \varnothing C/\varnothing E$, where E is QALY gain, and C is cost.

The Markov model will be used for the cost-effectiveness analysis. The cost-effectiveness of the tested intervention will be illustrated in a geographical context using the cost-effectiveness plane. The cost-effectiveness threshold (λ) will be calculated based on the willingness to pay for one unit of effect (QALY).

In addition, we will evaluate the cost-effectiveness of the intervention using two thresholds: (1) the gross domestic product per capita in terms of purchasing power parity, which is the threshold recommended by the WHO Commission for Macroeconomics and Health for an intervention to be considered 'very cost-effective' and (2) country-specific thresholds published by Woods *et al* based on extrapolating healthcare spending opportunity costs in the UK.[45] After determining the threshold value, we will create a cost-effectiveness acceptability curve (CEAC). We will use the CEAC to make predictions based on different threshold levels to determine the most cost-effective treatment option.

Furthermore, we will perform a one-way sensitivity analysis to investigate how uncertainty in the parameters affects the model results. Both deterministic and probabilistic sensitivity studies will be conducted to account for parameter uncertainty. We will estimate costs, illness outcomes and ICERs for each bootstrap sample to create a CI with a 95% level of certainty using the percentile approach.

Data management plan

A research postgraduate student will collect quantitative data, including demographic information, baseline measurements, intervention outcomes and follow-up data,

using electronic data capture systems and paper forms. Data will be securely stored on a computer. Access to the data will be restricted to authorised personnel, managed by the research postgraduate student and shared with collaborators under confidentiality agreements.

Data monitoring and harms

Serious adverse effects for older adults participating in this trial are not anticipated; therefore, a formal data monitoring committee and predefined stopping rules will not be established. A research postgraduate student will complete the interim analysis. However, if any adverse effects are observed during the trial, the research postgraduate student will document these incidents, report them to the supervisor and address them in any subsequent publications or reports. Additionally, during the fall calendar collection, the research team will contact social workers and caregivers to assess any potential harm caused by the intervention.

Patient and public involvement

Following the trial completion, we will offer one free hands-on workshop targeting 500 community-dwelling older adults. During this 1-hour talk with hands-on training, we will summarise our study findings, demonstrate sDT exercises and provide informative flyers to the public. The flyer will contain the instructions and dosage of each exercise.

ETHICS AND DISSEMINATION

Ethical approval was obtained from the PolyU Institutional Review Board for conducting research on human subjects (Ref: HSEARS20210322005). Written informed consent will be obtained from the older adults before they are assigned to training groups (online supplemental file 1).

The results will be disseminated through international conferences and published in peer-reviewed scientific journals. The findings will be shared with all participants once the study is completed.

Time horizon

The recruitment of participants began in December 2022, and the trial was completed in December 2024.

DISCUSSION

Our proposed sDT training is an innovative strategy requiring minimal resources, self-administered in nature, potentially cost-saving and easy to use. This training offers a valuable exercise programme for older adults, particularly those who face barriers to accessing professional support or specialised equipment. The long-term viability of exercise programmes depends on affordability and ease of access. We designed the sDT training to be inclusive, allowing a wide range of older adults, including those in resource-limited settings, to participate in the exercises without the need for expensive facilities or equipment. Moreover, older adults can perform sDT training in the comfort of their own homes. This autonomy eliminates the need for continuous supervision or instruction, thereby reducing costs and improving the programme's accessibility, which in turn supports its sustainability. Given the low resource, self-administered nature and user-friendly protocol of the sDT training, the findings of our future RCT testing its effectiveness are essential.

Our study has the following strengths: (1) the adoption of rigorous randomisation, (2) blinding of assessors and (3) multicentre RCT across Hong Kong. The rigorous randomisation process will enable us to identify any outcome variations between the groups that can be attributed to the intervention. The multicentre design will yield more generalisable findings for the study. Adopting a blinding assessor will reduce assessment bias, increase the credibility and reliability of the data and make the results more comparable by minimising bias.[46 47] The sDT intervention will be compared with the active control group to ensure that the improvement in any outcomes in the sDT group is not due to a placebo effect.[48] The study includes a 6-month follow-up period, which will assess the long-term effects of the interventions.

This study has some limitations. (1) This study will not include older adults with pathological conditions. This limits our ability to apply our findings to all older adults. (2) Since we will not follow the randomisation of the man-woman ratio 1:1, women participants will be likely higher than men as women are more prone to fall compared with men, which might reduce statistical power in detecting gender-specific effects of the intervention.[49]

This innovative research would benefit healthcare providers, researchers, policymakers and older adults if our hypothesis is supported. For healthcare providers, policymakers and older adults, the findings of this research will provide cost-effective treatment options for preventing falls and improving balance. For the researchers, this study's findings will help answer whether sDT can be a choice of treatment delivery for preventing falls among older adults.

A decline in cognitive and physical function among older adults challenges dual-tasking. Poor dual-tasking capacity among this population increases the risk of falls. Therefore, interventions targeting dual-tasking help reduce falls. Our newly designed sDT enables easy use and flexibility in performing exercises at the user's convenience. The findings of this series of research will add to the body of literature on efficient and cost-effective treatment options for preventing falls and improving balance among older adults.

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