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Original Research

The Effect of 2 Different Dual-Task Balance Training Methods on Balance and Gait in Older Adults: A Randomized Controlled Trial

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Abstract

Objective. The purpose of this study was to compare the effects of integrated and consecutive cognitive dual-task balance training in older adults on balance, fear of falling, and gait performance.
Methods. Fifty-eight participants (age >65 years) were randomly assigned to an integrated dual-task training group (IDTT) (n = 29) and consecutive dual-task training group (CDTT) (n = 29). Balance exercises and cognitive tasks were performed simultaneously by the IDTT group and consecutively by the CDTT group for 8 weeks. Balance was assessed using the Berg Balance Scale as a primary outcome measure and the Timed "Up & Go" Test (TUG) (standard-cognitive), fear of falling was assessed using the Tinetti Falls Efficacy Scale, and gait speed was assessed using the 10-Meter Walk Test (10MWT) (under single-task and dual-task conditions). All tests were performed before and after the training.
Results. There was no difference in group-time interaction in the Berg Balance Scale, TUG-standard, 10MWT-single task, and 10MWT-dual task tests. Group-time interaction was different in the TUG-cognitive and Tinetti Falls Efficacy Scale scores. Also, the effect of time was significantly different in all scales except for the 10MWT-single task in both groups.
Conclusion. At the end of the 8-week training period, the impact of integrated and consecutive dual-task balance training on balance and gait performance in older adults was not statistically significantly different. This study suggests that consecutive dual-task balance training can be used as an alternative method to increase balance performance and gait speed in older adults who cannot perform integrated dual-task activities.
Impact. There were no significant differences between the effects of the 2 dual-task training methods on balance and gait speed, suggesting that the consecutive dual-task balance training method can be used to improve the balance and gait of older adults. CDTT can be performed safely and considered as an alternative method for use in many rehabilitation training programs with older adults who cannot perform simultaneous activities.

Keywords: Dual-Task, Exercise, Balance, Gait, Older Adults

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Introduction

Decreases in physical and cognitive levels due to aging in older adults may result in balance and gait disorders.[1] Balance disorders and falling, which are the most important causes of mortality and morbidity for this group, are more common during dual-task activities when more than 1 task is performed simultaneously.[1–3]

There are many studies in the literature aiming to reduce balance, fall, and gait problems. Studies using dual-task training have increased in recent years, and these proved that additional cognitive tasks were effective in increasing balance and gait performance.[4–7] Dual-task training generally includes an integrated training model where tasks are performed together, and in consecutive training models, tasks are performed 1 after the other; hybrid training models include both models.[5,8,9] Training is shaped according to 2 theories. In the capacity-sharing theory, neural resources are shared between tasks and sharing capacity increases when there is an effective task integration, which increases dual-task performance (integrated dual-task training [IDTT]). In the limited resources theory, tasks compete for limited neural resources; as each task becomes automatic, competition decreases and dual-task performance increases (consecutive dual-task training [CDTT]).[10] The integrated training model has been used in most studies conducted with older adults, yet there seems to be no consensus on the consecutive training model. It is also unclear whether dual-task training should focus on task automation or integration.[11,12]

In the study of Silsupadol et al,[12] single-task (motor task) and 2 different dual-task training methods (variable – fixed priority) were performed. It was found that balance improved in all groups in single-task and dual-task conditions, and variable priority training was more effective. The results of their study also showed that task automation had effects on physical performance.

Studies showed that intense activity occurred in the prefrontal cortex, parietal cortex, and cerebellum during integrated dual-task activities.[13–15] However, during the simultaneous performance of 2 activities, cortical areas such as the lower frontal sulcus and middle frontal gyrus were suppressed.[16] It is thought that the stress that occurs in these areas, which are weakened due to aging, may negatively affect postural stability during simultaneous activity.[15–18] This situation raises the question of whether the performance losses due to aging in the neural system can be reduced through CDTT where the tasks are given separately.

In 1 study that investigated the effect of consecutive training on balance in older adults without specific balance training, there was no significant difference in balance.[19] In another study conducted in participants with Parkinson disease, it was found that integrated and consecutive training improved the gait speed of individuals at a similar level.[9] Although there are neurologic deficits in individuals with Parkinson disease, unlike older adults, this study is important to understand the integration and automatization hypotheses.

In consecutive training, tasks are performed separately but consecutively, ensuring that individuals do not experience postural instability and stress. Therefore, consecutive methods compared with integrated training are safer by nature and can be performed easily. This training model can be safely given as a home program. It can be an alternative to increasing the dual-task performance of older adults who cannot perform activities simultaneously due to cognitive-motor inadequacy in clinical practice.

We hypothesized that consecutive dual-task balance training would be as effective as IDTT on balance, gait speed, and fear of falling in older adults. Thus, we aimed to compare the effect of 2 different dual-task balance training methods (consecutive-integrated) on balance, gait speed, and fear of falling in older adults.

Methods

There were 2 intervention groups in this randomized study. The study was conducted in healthy, community-dwelling older adults in a private institution. The study was conducted in accordance with the Helsinki Declaration, and approval was obtained from the Clinical Research Ethics Committee in the Faculty of Medicine at Marmara University (protocol no.: 09.2019.181; February 1, 2019). The study protocol was registered on www.clinicaltrials.gov (Clinical Trial no. NCT03981692).

After verbal and written invitations, 64 individuals volunteered to participate in the study. The inclusion criteria were determined as follows: (1) age over 65 years, (2) Montreal Cognitive Assessment Scale score of 21 or above (the participants needed cognitive skills to understand the commands given), and (3) no balance problems caused by orthopedic or neurologic disorders.[20] The exclusion criteria were defined as follows: (1) refusal to participate for any reason; and (2) health problems preventing participants from exercising. Written consent was obtained from the participants.

Assessments were performed at baseline before randomization and after 8 weeks of intervention. Group randomization was performed by an assessor who was blinded to the evaluation of the measurements. Stratification by age (2 categories) and sex yielded 4 strata, and randomization in blocks of 7 was used to assign the participants to groups. The last 2 people were randomly assigned to groups. The randomization scheme from http://www.randomization.com was used (Fig. 1).

Sample Size

The number of participants was determined through detailed research and power analysis. Power analysis was performed using the PS 3 version 3.0.43 power and sample size software (DalePlummer, 2011, Nashville, TN, USA). We expected a similar baseline sample to the study conducted in older adult participants by Khan et al.[21] Assuming $\alpha = 5\%$, power = 80%, the difference was 4, and $\sigma = 4.5$ (σ = SD in population) in the Berg Balance Scale (BBS), the primary outcome, the number of participants required to detect a clinically significant difference between the IDTT and CDTT groups was determined. After adding 20% to allow for dropouts, it was decided that the minimum total number of participants to be reached would be 52.

Outcome Measurements

All scales were administered at the beginning and the end of the training.

Primary Outcome Measures

The BBS is used to measure balance performance in older adults and to predict fall risk in clinical studies. Fifty-six points

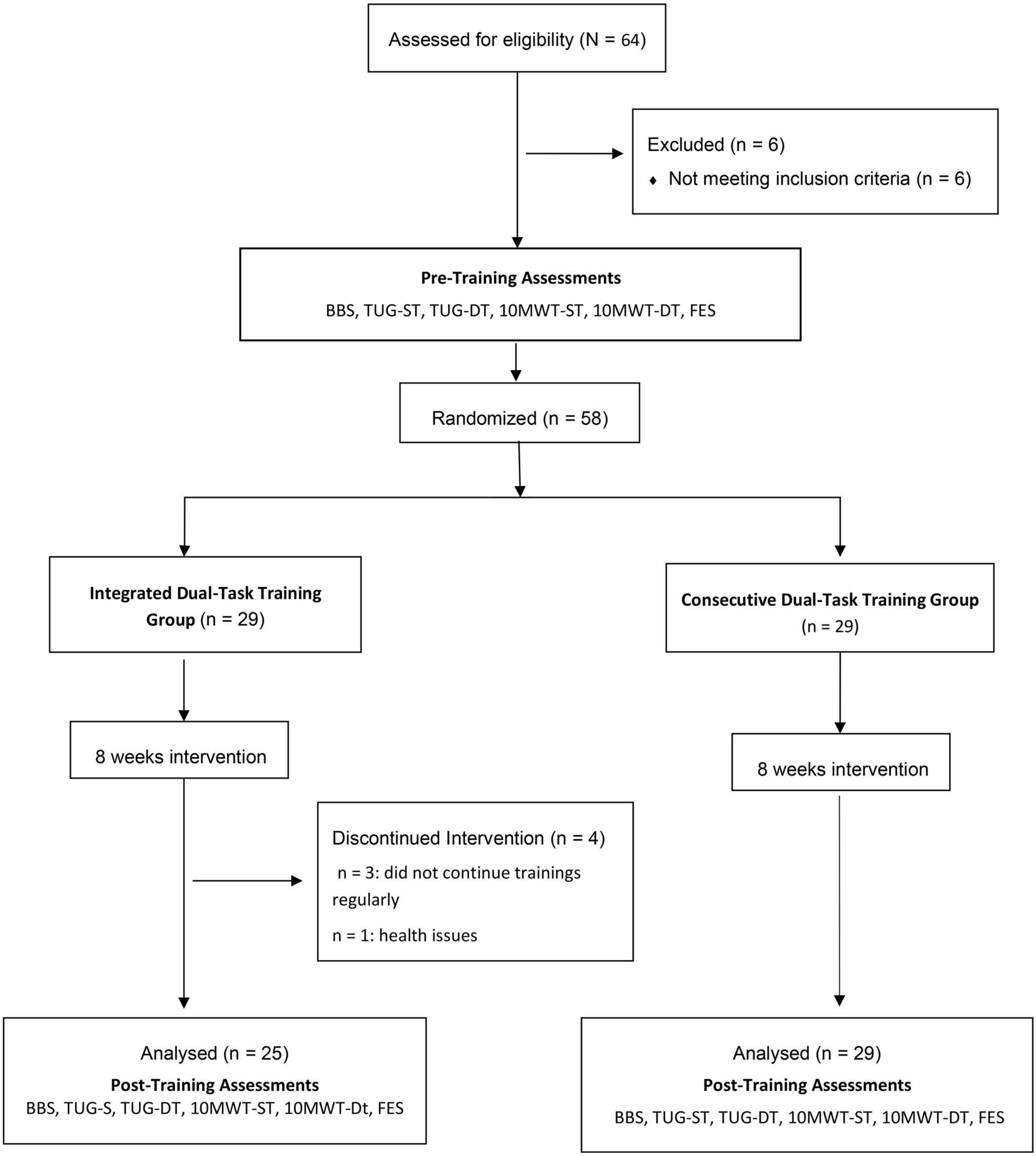

Figure 1. Flow diagram. BBS = Berg balance scale; FES = Tinetti fall efficacy scale; 10MWT-DT = 10-m walk test dual-task; 10MWT-ST = 10-m walk test single-task; TUG-Cog = Timed "Up & Go" dual-task; TUG-ST = Timed "Up & Go" standard.

is the highest score on the scale, and 45 to 46 points indicate the existence of good balance.[22]

Secondary Outcome Measures

The Timed "Up & Go" Test standard (TUG-ST) is a practical test with which dynamic balance and mobility can be assessed. During the test, participants are expected to sit on a 46-centimeter-high chair, to stand from it when asked to do so, to walk 3 m, to return without touching anything, and to sit on the chair again. The duration of the exercise is recorded.[23,24]

The TUG Cognitive Test (TUG-Cog) is the application of the TUG test with the addition of a cognitive task.[25] In this assessment, the participants are given trail making (A1-B2-C3 . . .) as a cognitive task. This task was not used during the training.

The 10-Meter Walk Test single-task (10MWT-ST) was used to assess gait speed. The participants were instructed to walk along a walkway. The first and last 2-m portions of the 14-m walkway are divided as an acceleration and deceleration part using sticking tape and are not assessed. The timing starts

Table 1. Dual-Task program[a]

IDTT Group	CDTT Group
8 wk (two sessions per wk)	
• Balance exercises were performed simultaneously with cognitive tasks	• Balance exercises and cognitive tasks were performed separately • Cognitive task was initiated immediately after each motor task (balance exercise-cognitive task-balance exercise-cognitive task) • Balance exercises were performed standing up • Cognitive tasks were performed while sitting
Balance exercises	**Progression**
a. Sit-to-stand exercise	a. Height of the place where participant was asked to sit and stand was changed
b. Standing with eyes open, feet apart	b. Standing with eyes open, feet together
c. Standing on 1 leg, eyes open	c. Standing on 1 leg, eyes closed
d. Standing on a soft surface, eyes open	d. Standing on a soft surface, eyes closed
e. Sitting on the ball, eyes open	e. Sitting on ball, eyes closed
f. Transferring of weight to the left and right on the ball, eyes open	f. Transferring weight to left and right on the ball
g. Tandem walk	g. Tandem walk, faster
h. 10-m backwards walk	h. 10-m backwards walk, faster
i. Walking in 8-shaped path between 2 chairs	i. Walking on 8-shaped path by increasing number of chairs
Cognitive tasks	**Progression**
a. Attention eg, Stand Up/Sit Down game (IDTT), find letter "Z" among mixed letters (CDTT)	Rhythm of the Stand Up/Sit Down commands were made harder or find letter "Z" among more mixed letters
b. Memory eg, Remember 5 simple words given at beginning of session	More complicated words were used
c. Arithmetic abilities eg, Simple arithmetic operations	More difficult arithmetic operations were given
d. Fluency in categories eg, What are the common features of roses and daisies?	They were asked to make more different and difficult categorizations
e. Problem solving eg, Participants were asked to create and explain scenarios suitable for questions such as "What would you do if the electricity went out in the evening?"	They were asked to find solutions to more difficult scenarios
f. Verbal fluency eg, Say the female names starting with the letter "A".	They were asked to say the initials of names of some objects and countries which are in more difficult categories
g. Information processing skills eg, "Count the days of the week, tell the date of today as month-day-year."	They were asked to tell more complicated dates (count down days of the week)
h. Abstraction skill eg, Commonly used, simple proverb interpretation.	They were asked to interpret less used and difficult proverbs

[a]Intensity for both groups: 8 weeks; 2×/week; warm-up, 10 min; dual-task balance program, 40 min; cool-down, 10 min.

between the second and the twelfth meters of the walkway measuring the participants' gait speed over 10 m. In our study, the average of 2 gait speeds was recorded as meters per second (m/s).[26,27]

In the 10MWT under dual-task conditions (10MWT-DT) assessment, the participants are asked to begin counting backwards in threes from 100.[6,28] This task was not used during the training.

In the Tinetti Falls Efficacy Scale (FES), the participants are asked how safe they feel while performing simple daily life activities (eg, bathing), rating from 1 (very confident) to 10 (not confident). When all scores are added together, a total score between 0 (low falling efficacy) and 100 (high falling efficacy) is obtained. A score of 70 and above is interpreted as the presence of a fear of falling.[29,30]

Training Protocol

As recommended in the British National Health Service Guide,[31] balance exercises for older adults should be performed at least 2 d/wk. We also used the program described in Table 1 with each participant with a physical therapist for 8 weeks as 2 individual sessions per week (Tab. 1).

The assigned cognitive tasks were planned accordingly with the cognitive functions of balance and gait of older adults.[32,33] Cognitive exercises structured for memory, executive functions, calculation, information processing speed (reaction time), and working memory were combined with motor skills (Tab.1). These exercises were determined according to the level of each participant, and they were gradually made more difficult when they were executed fluently and without errors. Balance training was personalized and conducted according to the current balance abilities of the participants. Progression was planned once participants could perform the exercise correctly for the CDTT group or without noticeable dual-task interference for the IDTT group (Tab. 1). Participants' performances were recorded by a physical therapist and their progression followed (1 = progression / 0 = same level).

Statistical Analysis

The IBM SPSS Statistics software version 25.0 software was used for statistical analysis (IBM, 2021, Armonk, NY, USA).

Descriptive statistics were used to characterize the participants by the 2 intervention groups. Repeated-measures

Table 2. Comparison of the Groups at Baseline[a]

Groups	IDTT (n = 29) Mean (SD)	CDTT (n = 29) Mean (SD)	*P*
Age, y[b]	82.9 (6.6)	85.3 (7.2)	.25
Sex, n (%)[c]			.19
Male	5 (17.2)	6 (20.7)	
Female	24 (82.8)	23 (79.3)	
Weight[b]	66.5 (7.7)	65.2 (8.9)	.72
Height[b]	159.9 (8.1)	158.6 (9.5)	.79
Body mass index, kg/m^2[b]	26.1 (2.7)	25.9 (2.6)	.93
Education, %[c]			.87
Primary school	2 (6.9)	1 (3.4)	
Secondary school	2 (6.9)	3 (10.3)	
High school	11 (37.9)	9 (31.0)	
College and university	14 (48.3)	16 (55.2)	
Berg Balance Scale[b]	43.28 (4.3)	41.48 (6.4)	.34
Timed "Up & Go" Test (standard), s[b,d]	12.72 (3.4)	12.20 (3.1)	.84
Timed "Up & Go" Test (cognitive), s[b,d]	18.20 (18.2)	17.84 (17.8)	.85
Tinetti Falls Efficacy scale[b,d]	31.20 (13.8)	29.70 (11.9)	.99
10-m walking speed single-task, m/s[b]	1.14 (0.2)	1.20 (0.2)	.43
10-m walking speed dual-task, m/s[b]	0.76 (0.2)	0.78 (0.1)	.74

[a]CDTT = consecutive dual-task training; IDTT = integrated dual-task training. [b]Independent sample *t* test. [c]Chi-square test. [d]Low scores indicate better performance.

analysis of variance was used to analyze the effect of time and group factors on the outcomes. The outcome measures were BBS, TUG-ST, TUG-Cog, FES, 10MWT-ST, and 10MWT-DT. The exposure was the IDTT or CDTT groups. Pairwise comparisons were used to ascertain differences between the groups. Multiple imputations were used to adjust to follow-up with the loss of 4 imputations.

In all statistical analyses, $P < .05$ was considered statistically significant.

Results

Six of the 64 volunteers were excluded from the study because they did not meet the inclusion criteria. The remaining 58 participants were randomly divided into 2 groups: IDTT (n = 29) and CDTT (n = 29). Three participants could not attend the sessions regularly, and 1 had health problems and dropped out from the IDTT (n = 29) group. The 8-week training was completed with 54 participants total from the IDTT (n = 25) and CDTT (n = 29) groups. There was no statistical difference between the groups in terms of age, sex, education, height, and body mass index averages ($P > .05$). At baseline, the BBS, gait speed (single- and dual-task conditions) and FES scores of the groups were similar (Tab. 2).

In the BBS and TUG-ST results, no difference was found in group–time interaction (freedom degree (df): 1, $P = .830$; freedom degree (df): 1, $P = .592$, respectively) and group effect (freedom degree (df): 1, $P = .214$; freedom degree (df): 1, $P = .661$, respectively). A difference was found in the time effect (freedom degree (df): 1, $Eta^2 = 0.565$, $P < .001$; freedom degree (df): 1, $Eta^2 = 0.448$, $P < .001$, respectively) (Tab. 3).

In the TUG-Cog and FES results, there was a difference in group–time interaction (freedom degree (df): 1; $Eta^2 = 0.2$, $P < .001$; freedom degree (df): 1, $Eta^2 = 0.266$, $P < .005$, respectively) and time effect (freedom degree (df): 1, $Eta^2 = 0.653$, $P < .001$; freedom degree (df): 1, $Eta^2 = 0.442$, $P < .001$, respectively). No difference was found in the group effect (freedom degree (df): 1, $P = .643$; freedom degree (df): 1, $P = .283$, respectively) (Tab. 3).

According to the pairwise analysis, there was a statistically significant difference between the first and second analyses of the IDTT and CDTT groups for the TUG-Cog and FES variables ($P < .001$, $P = .001$; $P < .001$, $P < .038$, respectively). The direction of the difference was $\mu_1 > \mu_2$ (Tab. 4).

In the 10MWT-ST results, there was no significant difference in group–time interaction (freedom degree (df): 1; $P = .403$), time effect (freedom degree (df): 1; $Eta^2 = 0.30$; $P = .399$) and group effect (freedom degree (df): 1; $P = .241$) (Tab. 3).

In the 10MWT-DT results, there was no significant difference in group–time interaction (freedom degree (df): 1; $P = .880$) and group effect (freedom degree (df): 1; $P = .878$). A difference was found in the time effect (freedom degree (df): 1; $Eta^2 = 0.459$; $P < .001$) (Tab. 3).

Discussion

In our study, there was no statistical difference in changes in balance (BBS, TUG-ST) and gait speed (10MWT-ST, 10MWT-DT) between the groups. The improvement in TUG-Cog and FES scores was in favor of the IDTT group. In both groups, a statistically significant improvement was found between the initial and final assessments in all parameters, except the 10MWT-ST parameter.

Studies showed that IDTT had a positive effect on the balance of older adults.[5,6,21,34–36] In our study, BBS scores showed a significant increase in the IDTT group, consistent with the literature, and the change in the CDTT group was at a similar level to the IDTT group. The balance development in the IDTT group was based on the task integration hypothesis. However, the improvement in the BBS scores of the groups may also be explained by the task automatization hypothesis, which claims that when tasks are performed as dual tasks or single tasks, automatization can improve in each task constituting the components of dual activity.[36–38] Bruce et al[19] investigated the effect of consecutive training in older adults, and they indicated no change in BBS scores, but their training program did not include any specific balance exercises. In our

Table 3. Mean and CIs for Findings on Outcome Measures and the Comparisons of Groups[a]

		Original Data		Repeated Measure		
Variables	Groups	Baseline Mean (CI)	8 Weeks After Baseline Mean (CI)	Time × Group *P*	Time *P*	Group *P*
Berg Balance Scale	IDTT	43.28 (41.70 to 44.90)	47.20 (45.30 to 49.20)	.830	< .001	.214
	CDTT	41.48 (39.10 to 43.90)	45.68 (43.60 to 47.80)			
Timed "Up & Go" standard, s[b]	IDTT	12.72 (11.60 to 13.80)	10.88 (9.79 to 11.80)	.592	< .001	.661
	CDTT	12.20 (11.10 to 13.30)	10.72 (10.10 to 11.30)			
Timed "Up & Go" cognitive, s[b]	IDTT	18.20 (16.6 to 19.80)	14.24 (13 to 15.40)	.022	< .001	.643
	CDTT	17.84 (16.10 to 19.50)	15.68 (15.60 to 15.80)			
Tinetti fall efficacy scale[b]	IDTT	31.20 (26.20 to 36.20)	18.40 (16.40 to 20.50)	.007	< .001	.283
	CDTT	29.70 (25.30 to 34.10)	25.10 (22.30 to 27.90)			
10-m walk speed single-task, m/s	IDTT	1.14 (1.05 to 1.23)	1.14 (1.06 to 1.24)	.403	.399	.241
	CDTT	1.20 (1.10 to 1.31)	1.25 (1.15 to 1.36)			
10-m walk speed dual-task, m/s	IDTT	0.76 (0.69 to 0.84)	0.91 (0.82 to 0.99)	.880	< .001	.878
	CDTT	0.78 (0.71 to 0.84)	0.91 (0.83 to 1.0)			

[a]CDTT = consecutive dual-task training; CI = confidence interval; IDTT = integrated dual task training. [b]Low scores indicate better performance.

Table 4. Mean Changes and Confidence Intervals From Baseline to After Treatment in the Groups[a]

Variables	Groups	Mean Change Mean (CI) ($\mu_1 - \mu_2$)	Pairwise Comparisons *P*
Tinetti Fall Efficacy Scale	IDTT	12.76 (7.17–18.34)	< .001
	CDTT	4.64 (0.29–8.98)	.038
Timed "Up & Go" cognitive, s	IDTT	3.96 (2.69–5.22)	< .001
	CDTT	2.16 (1.01–3.30)	.001

[a]CDTT = consecutive dual-task training; IDTT = integrated dual-task training.

study, specific balance training was performed in the CDTT group. The improvement in this group is consistent with the task automatization hypothesis.

In many studies where IDTT was given, TUG scores improved significantly in single-task and dual-task conditions.[7,39–41] In our study, after the training, although the groups were similar in terms of TUG-ST scores, the improvement in TUG-Cog scores was more significant in favor of the IDTT group, supporting the integration hypothesis as in the studies of Silsupadol et al.[5,12] Silsupadol et al[5] found that assessments in dual-task conditions changed significantly only in the groups that received dual-task training. Furthermore, they argued that their results did not conform to the task automatization hypothesis. In our study, however, the improvement in TUG-Cog scores in the CDTT group showed that task automatization affected dual-task skills. Another study showed that balance in dual-task conditions could be improved with integrated dual-task and single-task training.[12] Similar to our study, this result is consistent with the automatization theory. In our study, task automatization was provided by a CDTT model in which motor and cognitive tasks were given immediately after each other and participants were asked to move from 1 task to another as quickly as possible. Some studies state that the reaction time required for transitions between tasks is also important for maintaining dual-task performance.[11,42] In addition to the automatization in the CDTT group, the training given may be effective on dual-task performance by shortening the reaction time between task transitions. However, this view should be examined with studies that evaluate the effects of training methods in detail and observe neural changes in the background.

The fear of falling is another important problem that negatively affects balance confidence, restricting daily life activities in older adults.[43] It affects the ability of individuals to access their sources of attention appropriately, causing resources required for maintaining balance simultaneously with performing cognitive processes to be limited.[2,44] Studies are showing the positive effect of IDTT on the fear of falling.[2,44,45] Our results indicate that the significant improvement in the falling efficiency score of the groups may have resulted from the increased balance of the individuals. The improvement was more significant in favor of the IDTT group, which can be explained by the fact that integrated activities are more difficult than consecutive activities. Individuals may have transferred the confidence they gained when they felt they could do these difficult activities to other activities in daily life.

Gait speed is 1 of the parameters that affect age-related balance disorders.[46] Silsupadol et al[5,12] showed IDTT increased gait speed in single- and dual-task conditions. There are studies with similar results in the literature.[7,47] In our study, gait speed increased in dual-task conditions in both groups, but there was no increase in gait speed in single-task conditions. Considering the baseline data, this may be due to the gait speeds of our participants in single-task conditions being above the normative value.[48] The improvement in gait speed in dual-task conditions can be explained by transferring the gain obtained from task integration in the IDTT group to gait speed in dual-task conditions.[49,50] In the CDTT group, automatic balance and cognitive skills may have affected gait speed in dual-task conditions. In addition, the decrease in the fear of falling may have contributed to the increase in gait speed in dual-task conditions in both groups.

There are many studies on dual-task balance training in older adults; however, to the best of our knowledge, our study is the first to compare the results of a consecutive dual-task balance training model. In this model, balance and cognitive exercises are performed separately, following 1 after the other. This study can be used as a reference for future studies.

There are some limitations in our study showing the short-term results of the training. There was no follow-up period to show long-term results. Unfortunately, the practitioner had to collect the data. Cognitive performance during walking was not assessed. Therefore, no information was established regarding the participants' task prioritization. There was no control group. This could be useful to understand the differences between our consecutive dual-task balance method and single-task balance training. Female participants were in the majority. Studies are showing that sex differences affect postural stability.[51,52] Although women comprised the majority in our study, the distribution of sexes was similar in both groups. Therefore, we think this limitation does not affect our results. The loss of 4 participants may be the final limitation. The departure of participants was not related to our training. One person left due to a flu infection in the second week, and the other 3 people left due to family reasons in the second and third weeks.

This study is a non-inferiority trial design. The impact of integrated and consecutive dual-task balance training on balance and gait performance in older adults was not statistically significantly different. In conclusion, this study suggests that consecutive dual-task balance training can be used as a safe alternative to increase the balance and gait speed of older adults and reduce their fear of falling. Further studies are needed to investigate the long-term effects of training to determine the effectiveness of the training and their superiority over each other.

Author Contributions

Concept/idea/research design: V. Yuzlu, S. Oguz
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Data collection: V. Yuzlu
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Project management: V. Yuzlu, S. Oguz
Providing participants: V. Yuzlu, E. Aykutoglu
Providing facilities/equipment: V. Yuzlu, E. Aykutoglu
Providing institutional liaisons: V. Yuzlu, E. Aykutoglu, M.G. Polat
Clerical/secretarial support: V. Yuzlu
Consultation (including review of manuscript before submitting): S. Oguz, M.G. Polat

Ethics Approval

This study was approved by the Clinical Research Ethics Committee in the Faculty of Medicine at Marmara University (protocol no. 09.2019.181).

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Clinical Trial Registration

The study protocol was registered on www.clinicaltrials.gov (NCT03981692).

Disclosures

The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.

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