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Effect of Exercise and Nutrition Intervention for Older Adults with Impaired Physical Function with Preserved Muscle Mass (Functional Sarcopenia): A Randomized Controlled Trial

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Background: Functional sarcopenia is characterized by decreased physical performance and grip strength despite preserved muscle mass. The effectiveness of a program combining exercise and nutritional support—known interventions for individuals with low muscle mass—was evaluated for its impact on older adults with functional sarcopenia.

Methods: An unblinded, parallel-group randomized controlled trial was conducted in a public medical center in a rural Korean community. Eligible older adults with functional sarcopenia were randomized into either the intervention group, receiving a 12-week program of group exercises and nutritional support, or the control group, receiving education on lifestyle management. Outcomes measured included changes in gait speed, grip strength, physical performance, and quality of life indices.

Results: The study enrolled 42 participants, with 21 allocated to each group. Compared with the control group, the intervention group showed significant improvements in the primary outcome of gait speed (mean change (m/s) 0.24 vs 0.00, $p<0.001$) and secondary outcomes, such as Short Physical Performance Battery scores, grip strength, and quality of life. No significant adverse events were reported.

Conclusion: The 12-week exercise and nutritional intervention significantly enhanced physical performance, grip strength, and quality of life among community-dwelling older adults with functional sarcopenia. This suggests that strategies commonly recommended for sarcopenia, including exercise and nutritional support, are also beneficial for individuals with functional sarcopenia, indicating the potential for broader application of such interventions.

Keywords: sarcopenia, frailty, exercise

Introduction

Sarcopenia is characterized by age-related gradual loss of skeletal mass, strength, and function,[1] increasing the risk of adverse outcomes such as mortality,[2] hospitalization,[3] and a diminished quality of life.[4] Initially classified as a muscle-specific disease[5] with an overlap with frailty—a geriatric syndrome indicating increased multi-system vulnerability—sarcopenia was considered a distinct entity.[6,7] However, as scientific research on frailty and sarcopenia has progressed, it has become clear that these two concepts are inseparable.[8,9]

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Despite extensive research in the field, defining sarcopenia based solely on muscle mass remains challenging.[10] Clinically, there are no readily available methods to directly measure muscle mass, leading most guidelines to rely on indirect assessments, such as lean muscle mass measurements.[11] However, emerging evidence suggests that physical performance may be more critical than lean mass in predicting key outcomes like falls and disability.[12] This shift highlights the growing recognition of the importance of functional measures over purely structural ones in diagnosing and managing sarcopenia.

In response, the Korean Working Group on Sarcopenia (KWGS) developed guidelines for screening and diagnosis of sarcopenia in 2023.[13] These guidelines, while incorporating global standards, also introduce several unique concepts. One such concept is functional sarcopenia, characterized by low muscle strength and physical function while maintaining muscle mass. A previous study indicated that older adults with functional sarcopenia are frailer and have a similar prognosis of mortality and institutionalization compared to non-severe sarcopenia in community-dwelling Korean older adults.[14] There is existing evidence that exercise and nutrition interventions are beneficial for individuals with sarcopenia, improving various aspects such as physical performance and quality of life.[15] However, there are currently no studies evaluating the effectiveness of sarcopenia treatment, primarily exercise and nutrition, in individuals with functional sarcopenia.

To address this gap, we hypothesized that a 12-week intervention program, comprising group exercise and nutritional support, would enhance physical performance, grip strength, muscle mass, and quality of life, as well as improve activities of daily living and reduce frailty burden among older adults with functional sarcopenia, compared to a control group.

Methods

Trial Design and Study Participants

An unblinded, parallel-group randomized controlled trial (RCT) with a 1:1 allocation was conducted at Pyeongchang County Hospital (PCH), the primary public health center in Pyeongchang County, Korea, where 32% of 40,645 residents were aged ≥ 65 years in 2023. Participants were identified through the Aging Study of Pyeongchang Rural Area (ASPRA), a prospective cohort study of older adults in Pyeongchang County. The ASPRA cohort's specific protocol is outlined in a previous study.[16] The ASPRA eligibility criteria included individuals aged ≥ 65 years, registered in the National Healthcare Service, ambulatory with or without an assistive device, living at home, and capable of providing informed consent independently or via proxies. Exclusions comprised individuals residing in nursing homes, hospitals or receiving nursing home-level care at home. ASPRA participants underwent annual Comprehensive Geriatric Assessment (CGA) with sarcopenia assessment conducted by trained nurses at regional community health posts (CHP) or PCH.

We screened 1955 older adults in the ASPRA database, categorizing 109 older adults having functional sarcopenia within 3 months as of July 2023. Exclusions were made for individuals who declined participation, were unable to walk alone for more than 5 minutes without assistance, had significant hearing impairment hindering group intervention participation, were hospitalized for ≥ 2 weeks in the past 3 months, were receiving treatment for uncontrolled congestive heart failure or metastatic cancer, or had an expected life expectancy of less than 1 year. After obtaining informed consent, we measured 49 participants following the study protocol (1^{st} measurement). Those not meeting functional sarcopenia criteria at the initial measurement (n=7) were excluded. Eligible participants were randomly assigned to the multi-component intervention group or control group. This study adhered to the Declaration of Helsinki and received approval from the Asan Medical Center Institutional Review Board (IRB number: 2023-1174). The trial protocol is registered at Clinical Research Information Service (CRIS, http://cris.nih/go.kr, registration number: KCT0008953). The trial was conducted from September 12, 2023, to March 19, 2024.

Functional Sarcopenia

According to the KWGS guidelines,[13] functional sarcopenia was defined as low grip strength and slow gait speed with preserved muscle mass. Muscle mass was measured using bioelectrical impedance analysis (BIA) with frequencies 5, 50, and 500 kHz. Appendicular muscle mass divided by height squared (ASM/h^2) was calculated by summing the lean mass

of the upper and lower extremities divided by height squared. Preserved muscle mass was defined as ASM/h^2 > 7.0 kg/m^2 in males and > 5.7 kg/m^2 in females. Grip strength was evaluated using a handgrip dynamometer (T.K.K 5401 Grip-D; Takei, Tokyo, Japan). Low grip strength was classified as less than 28 kg for males and less than 18 kg for females. The dominant hand was tested, and the highest value from two measurements was used for analysis. For gait speed, participants walked 7 m at their usual gait speed, and trained nurses measured the transit time of 4 m, excluding the acceleration and deceleration interval of 1.5 m, calculated from the time taken to walk 4 m. Slow gait speed was defined as < 1 m/s.

Interventions

Participants in the intervention group participated in a 12-week exercise and nutrition program conducted by the public healthcare center. In the exercise program, participants attended group exercise sessions led by community trainers twice weekly (24 sessions over the 12-week period). Each session lasted 60 min, beginning and ending with a 5-min warm-up and cool-down phase focusing on stretching the muscles used during the workout. The main portion of the session, lasting 50 min, was split between resistance training (30 min) and aerobic exercises (20 min). Resistance training alternated daily between upper-body exercises (targeting the chest, back, and arms) and lower-body workouts. The trainers assessed the initial strength of each participant using the one repetition maximum (1RM) method and set the starting loads at 40% of this maximum. Aerobic activity involved treadmill exercise calibrated to maintain an intensity between 50% and 70% of the participant's maximum oxygen uptake (VO2 max). VO2 max was estimated using either the Bruce Treadmill Test or maximal heart rate calculations.[17] The program was supported by two community trainers, each contributing approximately 15% of their 40-hour weekly workload. Participants also received written exercise guidelines and were encouraged to independently perform 60 min of exercise daily. Detailed program description using the Consensus on Exercise Reporting Template (CERT) guidelines is detailed in Supplementary Data 1.

For the nutrition program, a single dietitian from the public health center, contributing approximately 10% of their 40-hour weekly workload, conducted individualized nutritional education sessions at the start of the intervention. These sessions were tailored to each participant's needs and focused on practical strategies for sarcopenia management. Participants were also supplied with a protein-rich nutritional powder (DanbaegChaeum™ by Dr. WELLNESS, Seoul, Korea) for twice-daily consumption between meals. The powder, which could be mixed with water (140 mL), provided 25 g of content with 95 kcal, including 13 g of protein, 1.4 g of fat, and 8 g of carbohydrates per serving.

In contrast, participants in the control group received the standard public health center practice for sarcopenia management. This included written instructions on exercise and nutrition education, supplemented by a brief nutrition consultation with a dietitian, but without any group exercise sessions or additional nutritional supplements.

Measurements

Individuals were measured at baseline (1st measurement) and the end of the intervention (2nd measurement). Trained nurses who were not aware of the intervention status performed assessments, including demographics (such as age, sex, weight, height, years of education, or receiving medical aid due to monthly income of < 500 USD), comorbidities, and health behaviors such as physical activity or nutritional status. Twelve physician-diagnosed clinical conditions were collected: hypertension, diabetes mellitus, stroke, dyslipidemia, thyroid disease, coronary artery disease, asthma, atopy, arthritis, chronic kidney disease, liver disease, and pulmonary tuberculosis. The number of the regular ingestion of prescribed medications was recorded. Depressive symptoms were assessed using the Patient Health Questionnaire-9 (PHQ-9), with depression defined as a score > 21.[18] Cognitive function was assessed using Mini-Cog, with Cognitive dysfunction defined as a score of 2 or lower.[19] Disability was defined as impairments in one or more of the seven Activities of Daily Living (ADL) and 10 Instrumental Activities of Daily Living (IADL).[20] The SPPB, ranging from 0 to 12, was used to assess physical performance.[21] Clinical Frailty Scale (CFS) was assessed according to the Korean version of the CFS.[22]

Outcomes

The primary outcome of this study was the change in gait speed over the 12 weeks. Secondary outcomes included changes in the SPPB, grip strength, ASM/h^2, CFS, ADL, IADL, and 45-item frailty index from baseline to 12 weeks. Forty-five items are listed in Supplementary Table S1.

Sample Size Calculation

As no clinical trials regarding functional sarcopenia were available, a previous study investigating the effect size of a multicomponent exercise intervention on SPPB scores of frail older adults was utilized.[23] Based on the effect size of a 12-week intervention on SPPB score, 17 participants were required for each group with an allocation ratio of 1, an alpha error of 0.05, and a power of 0.8 (two-tailed). Considering a loss to follow-up rate of 20%, 21 participants for each group were required.

Randomization and Blinding

We employed a stratified randomization method to ensure balanced allocation across key demographic characteristics. Participants were first stratified by age (75 years and older vs younger) and gender. Within each stratum, simple randomization was performed using a computer-generated randomization list created in Excel. Participants were then allocated in a 1:1 ratio to either the control or intervention group. A study coordinator randomized participants according to the random computer-generated list of 21 control or 21 interventions. Treatment allocations were hidden in sequentially numbered, sealed envelopes, which were sequentially opened as participants were enrolled.

Due to the nature of the intervention and the public health service setting, blinding of participants and intervention providers was not feasible. However, to minimize potential bias, trained nurses who assessed participants before and after the intervention were blinded to group allocation. These measures aimed to ensure the reliability and validity of the outcome assessments.

Statistical Methods

Analysis was conducted based on the intention-to-treat method. Continuous and categorical variables of the two groups at the baseline were compared using t-tests and chi-squared tests, respectively. Mean changes for primary and secondary outcomes at 12 weeks from the baseline were compared between the two groups using linear mixed models, with time, group, and their interaction defined as fixed factors, and the subject was defined as a random factor.

Effect sizes were calculated using Cohen's d, which quantifies the difference between two means relative to the pooled standard deviation. Cohen's d was used to compare within-group changes and between-group differences, providing a standardized measure of effect size. The benchmarks for interpreting Cohen's d are as follows: small effect (d=0.2), medium effect (d=0.5), and large effect (d≥0.8).[24] Additionally, relative change was defined as the percentage change from baseline to follow-up, based on the baseline value.

We also conducted further exploratory subgroup analyses based on several criteria: age (80 years or older versus younger), sex, living arrangements (living alone versus not), and frailty index (0.2 or higher versus lower). All analyses were conducted using the R Software (version 3.6.3; R Foundation for Statistical Computing, Vienna, Austria), based on a two-tailed approach with significance set at $P<0.05$.

Results

Enrollment and Baseline Characteristics

We enrolled and randomized 42 eligible individuals (21 in the intervention group and 21 in the control group). Participants were recruited between September and November 2023. In the intervention group, the mean and standard deviation of adherence rates for the program was 89.25±10.25%. Adherence was defined as the number of attended days out of the total 24 sessions. During the study, one participant from the control group was lost to follow-up due to unsuccessful contact attempts. Adverse events were not reported throughout the study. The flow chart is shown in Figure 1.

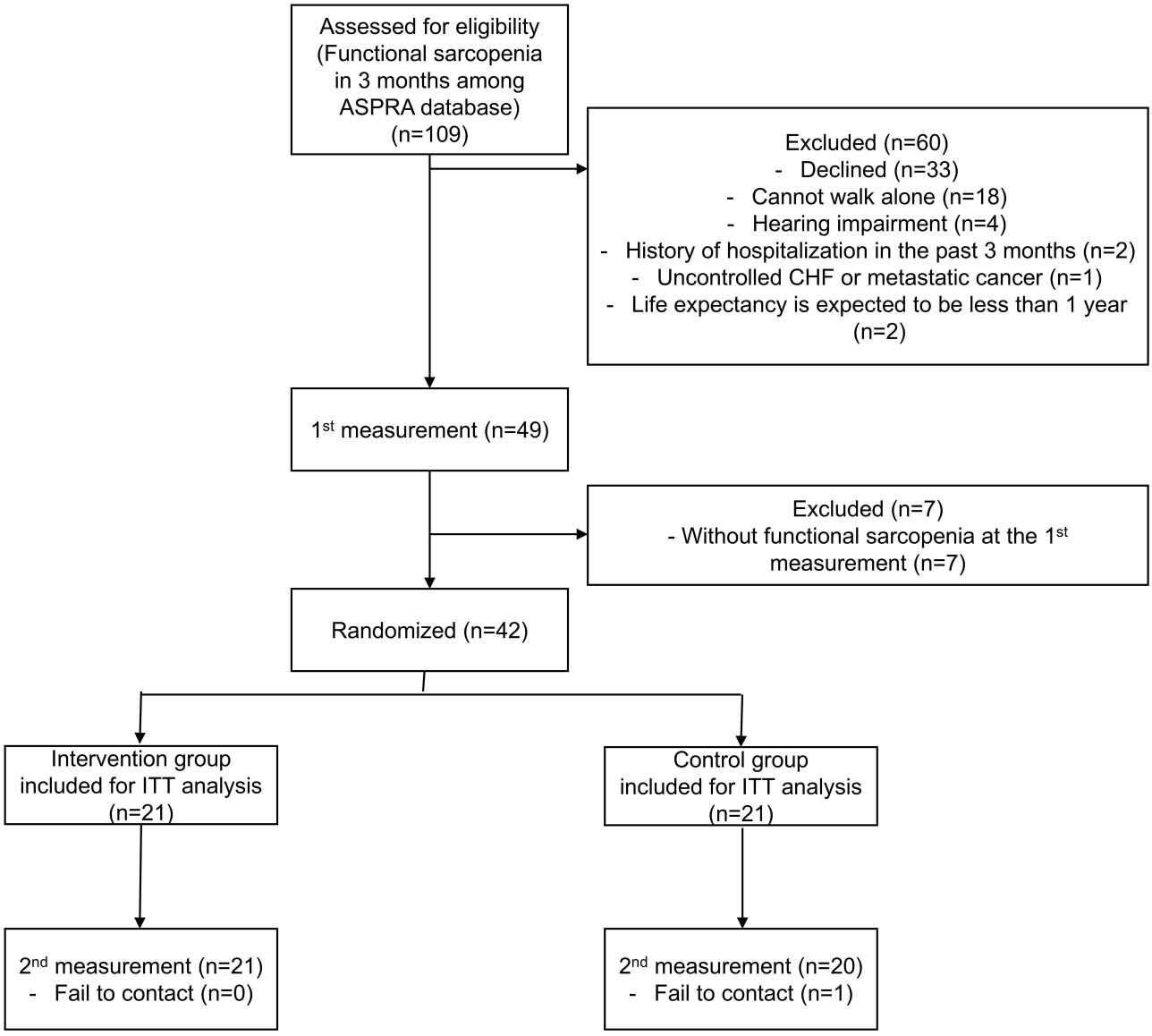

Figure 1 CONSORT (Consolidated Standards of Reporting Trials) flow diagram.
Abbreviation: ASPRA, Aging Study of Pyeongchang Rural Area.

The baseline characteristics of the two groups were similar, and no variables were statistically different (Table 1). The mean age was 77.86 ± 4.46 in the intervention group and 78.24 ± 4.47 in the control group. In both groups, 11 (52.4%) participants were female. SPPB scores were 7.81 ± 1.69 and 7.67 ± 1.20, and the frailty index was 0.20 ± 0.06 and 0.19 ± 0.06 for the intervention and control groups, respectively.

Outcomes

Regarding the primary outcome, improvement in gait speed was observed in the intervention group compared to the control group (mean change (m/s) 0.24 vs 0.00, $p<0.001$). For the secondary outcome, improvement in SPPB, grip strength, EQ-5D, and frailty index was observed in the intervention group, while SMI and CFS did not improve compared to the control group. The number of disabled ADL tasks showed no difference between the two groups. The number of disabled IADL tasks remained stable in the intervention group, whereas they worsened in the control group. The detailed results of changes in each outcome according to each group are described in Table 2.

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Table 1 Baseline Characteristics of the Study Groups

	Intervention (n=21)	Control (n=21)	*P*-value
Age	77.86 ± 4.46	78.24 ± 4.47	0.78
Female	11 (52.4)	11 (52.4)	1.00
Body mass index, kg/m^2	24.87 ± 3.47	26.59 ± 2.51	0.07
Skeletal muscle index, kg/m^2	6.77 ± 0.71	6.60 ± 0.56	0.40
Gait speed (m/s)	0.69 ± 0.07	0.70 ± 0.07	0.87
Short physical performance battery	7.81 ± 1.69	7.67 ± 1.20	0.75
Grip strength, kg	17.23 ± 4.71	17.28 ± 3.71	0.97
Mini-Cog ≤ 3	12 (57.1)	15 (71.4)	0.52
No. of chronic conditions	2.00 ± 1.41	2.48 ± 1.12	0.23
No. of medication	3.88 ± 3.38	4.00 ± 2.45	0.90
Fall in the last year	6 (28.6)	5 (23.8)	1.00
ADL disability (%)	0 (0.0)	0 (0.0)	NA
IADL disability (%)	0 (0.0)	1 (4.8)	1.00
Clinical frailty scale	3.57 ± 0.60	4.00 ± 0.77	0.05
Frailty index	0.20 ± 0.06	0.19 ± 0.06	0.73

Note: Data are presented as means (standard deviation) or numbers (%).
Abbreviations: ADL, activities of daily living; IADL, instrumental activities of daily living; NA, not applicable.

Table 2 Comparison of the Change of Gait Speed, SPPB, Grip Strength, SMI, Clinical Frailty Scale, ADL and IADL Disability, and EQ-5D Between the Intervention (n=21) and Control Group (n=21)

	Mean		Change				
	Baseline	Follow-Up	Mean Change (95% CI)	*P*-value of Interaction	Effect Size (Within-Group)	Effect Size (Between-Group)	Relative Change (Within-Group)
1) Primary outcome							
Gait speed (m/s)							
Intervention	0.69	0.93	0.24* (0.18,0.29)	<0.001	2.45	1.84	34.8%
Control	0.70	0.70	0.00 (−0.05,0.06)		0.03		0%
2) Secondary outcome							
SPPB							
Intervention	7.81	9.95	2.14* (2.94, 1.34)	<0.001	1.34	1.27	27.4%
Control	7.67	7.42	−0.24 (−1.05, 0.57)		−0.15		−3.3%
Grip strength (kg)							
Intervention	17.2	27.1	9.85* (7.34, 12.37)	<0.001	1.43	1.20	57.6%
Control	17.3	19.3	2.06 (−0.50, 4.62)		0.40		11.6%

(*Continued*)

Table 2 (Continued).

	Mean		Change				
	Baseline	**Follow-Up**	**Mean Change (95% CI)**	***P*-value of Interaction**	**Effect Size (Within-Group)**	**Effect Size (Between-Group)**	**Relative Change (Within-Group)**
SMI (kg/m^2)							
Intervention	6.77	6.82	0.05 (−0.06, 0.17)	0.74	0.07	0.06	0.7%
Control	6.60	6.63	0.02 (−0.09, 0.14)		0.04		0.5%
Clinical frailty scale							
Intervention	3.57	3.57	0.00 (−0.24, 0.24)	0.27	0.00	0.22	0%
Control	4.00	3.81	−0.19 (−0.43, 0.06)		−0.24		−4.7%
No. of disabled ADL tasks (0–7)							
Intervention	0.00	0.00	0.00 (−0.07, 0.07)	0.30	NA	−0.32	NA
Control	0.00	0.05	0.05(−0.02, 0.12)		0.32		NA
No. of disabled IADL tasks (0–10)							
Intervention	0.00	0.05	0.05* (−13, 23)	0.046	0.31	−0.60	NA
Control	0.05	0.35	0.30 (0.12, 0.48)		0.82		600%
EQ-5D							
Intervention	0.81	0.90	0.09* (0.06, 0.13)	<0.001	1.13	1.75	11.1%
Control	0.89	0.83	−0.06 (−0.09, −0.02)		−0.85		−6.7%
Frailty index							
Intervention	0.20	0.14	−0.06* (−0.08, −0.03)	<0.001	−0.88	−1.01	−6.7%
Control	0.19	0.22	0.03 (0.00, 0.05)		0.39		15.8%

Note: **P*-value <0.05, comparing the intervention group with the control group.
Abbreviations: ADL, activities of daily living; IADL, instrumental activities of daily living; NA, not applicable; SMI, skeletal muscle mass; SPPB, short physical performance battery.

We conducted exploratory subgroup analyses based on several factors: age (80 years and older versus younger), sex, frailty index (0.2 or higher versus lower), and living situation (living alone versus not). Although no significant interactions were observed in these analyses, the data suggest that individuals aged < 80 years and those not living alone tended to show a more pronounced response, as indicated in Supplementary Figure S1.

Discussion

We found that exercise and nutrition intervention significantly improved the primary outcome of gait speed in community-dwelling Korean older adults with functional sarcopenia. Additionally, we observed significant improvements in secondary outcomes such as SPPB, grip strength, EQ-5D, disabled IADL tasks, and frailty index. No statistically significant differences were noted in SMI, CFS, and disabled ADL tasks between the intervention and control groups. These findings suggest that the commonly recommended interventions for sarcopenia, such as exercise and nutrition, may also be effective for addressing functional sarcopenia, characterized by low physical performance and grip strength despite preserved muscle mass.

To our knowledge, this study represents the first evidence suggesting the efficacy of exercise and nutrition interventions in addressing functional sarcopenia. Our study builds upon existing knowledge by demonstrating that exercise and nutrition interventions can extend their benefits from addressing sarcopenia with low muscle mass to targeting functional

sarcopenia. Previous research and review papers have already indicated the effectiveness of exercise and nutritional support on sarcopenia, and these findings have been reflected in various guidelines.[25,26] For instance, a comprehensive review of previous RCTs underscored the positive impact of combining exercise with nutritional support on aspects such as quality of life, physical performance, and handgrip strength compared to usual care.[15] International Clinical Practice Guidelines for Sarcopenia strongly recommended resistance-based physical training and conditionally recommended protein support.[27] Our findings emphasize the significance of implementing interventions that combine exercise and nutritional support, particularly in individuals experiencing physical function decline despite having preserved muscle mass.

Regarding effect sizes, we observed substantial improvements in key outcomes, such as gait speed (mean change: 0.24 m/s) and the Short Physical Performance Battery (mean change: 2.14 points). These changes exceed the established minimally significant thresholds for clinical improvement in older adults (gait speed: 0.03–0.05 m/s; SPPB: 0.3–0.8 points), indicating that the observed improvements are not only statistically significant but also clinically meaningful.[28] Furthermore, these results must be interpreted in the context of the professional efforts applied. The intervention required moderate resource allocation, including two trainers contributing 15% of their weekly workload each and one dietitian contributing 10%. Despite this investment, the substantial improvements in physical function and quality of life observed suggest that the program was both efficient and impactful.

While the intervention demonstrated significant improvements in physical performance and grip strength, no significant changes were observed in SMI or CFS. The lack of change in SMI may be due to the relatively short duration of the 12-week program, as increases in muscle mass typically require longer-term interventions.[29] Additionally, participants in this study had preserved muscle mass at baseline, which may have limited the potential for detectable increases. Regarding the CFS, its broad categorical structure may not have been sensitive enough to capture subtle improvements in frailty status within this relatively healthier population.[30] However, our findings regarding the frailty index suggest that the intervention is effective in reducing the frailty burden in this population.

These results highlight the clinical importance of functional sarcopenia. In previous study, older adults with functional sarcopenia are frailer with a similar prognosis compared to those with non-severe sarcopenia.[14] Our results show individuals with functional sarcopenia are responsive to exercise and nutrition intervention. The detailed reasons for clinically noting functional sarcopenia are described in the discussion section of a previous paper.[14]

Although this is the first trial to directly compare interventions in functional sarcopenia, our results showed larger effects on gait speed, SPPB, and grip strength compared to previous sarcopenia research. An RCT conducted in China examined the effect of exercise and nutrition intervention on individuals with sarcopenia with low muscle mass and showed a smaller effect size compared to the exercise program and nutrition supplement group with the control group after 12 weeks of intervention; moreover, the effect size (Cohen's d) for gait speed and grip strength were smaller than our results (0.18 vs 1.84, 0.55 vs 1.20, respectively).[31] Our study results show a comparatively substantial than other RCT results,[15] which could be caused by preserved muscle mass or good adherence of individuals in our trial. However, further in-depth studies with various populations with functional sarcopenia are warranted.

Our findings are noteworthy as they bridge the gap in evidence regarding interventions for functional sarcopenia and physical functional decline. However, this study had some limitations. First, it was conducted in a single community in Korea, limiting its generalizability. Second, the study population had lower disability levels compared to previous functional sarcopenia research, possibly because only those capable of participating in group exercise were included.[14] Therefore, generalization should be done carefully. Second, our study only compared the results before and after the 12-week intervention, and long-term follow-up was not conducted. Therefore, investigating the long-term effect and how the impact of the intervention continued should be a focus of further study. Third, despite the relatively good adherence of the study participants, one participant from the control group was lost at follow-up; therefore, the missing values were imputed. Fourth, due to the relatively small population of our study, should be exercised when interpreting the results of the subgroup analysis.

In conclusion, the 12-week exercise and nutrition interventions led to significant improvements in physical performance, grip strength, and quality of life among community-dwelling older adults with functional sarcopenia. These findings suggest that interventions commonly recommended for sarcopenia with low muscle mass can also be effective

for individuals with functional sarcopenia, characterized by impaired physical function despite preserved muscle mass. However, given the small study population size and single center design, more clinical trials are needed that encompass a broader spectrum of the population.

Data Sharing Statement

Data sharing statement is provided in Supplementary Data 2.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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