

## Original Article



# Evaluation of Oral Nutritional Supplementation in the Management of Frailty among the Elderly at Facilities of Community Care for the Elderly

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## ABSTRACT

Adequate nutritional intake in elderly individuals improves frailty. Elderly individuals may exhibit improvements in frailty with the use of community care facilities. Therefore, this study evaluated the effects of nutritional intervention in elderly subjects at community care facilities receiving oral nutritional supplements (ONSs) and determined their nutritional status. Sixty-two elderly individuals using community care facilities were divided into the experimental group (EG) (before [n = 31]/after [n = 28]) and control group (CG) (before [n = 31]/after [n = 25]). Subjects in both groups were treated with ONSs (200 mL/200 kcal) for 90 days. However, those in the EG received the product with increased protein; vitamins A, C, D, and E; phosphorus; calcium; and zinc. The data collected included anthropometric data, dietary assessment findings, frailty status (Korean version of the Fatigue, Resistance, Ambulation, Illnesses, and Loss of weight questionnaire), and nutritional status (Mini Nutritional Assessment, MNA). The changes in the two groups were analyzed using the Mann-Whitney U Wilcoxon signed-rank test. Nutritional intervention increased the weight, body mass index, and lean body mass in the EG ( $p < 0.05$ ). Protein, calcium, and iron levels increased only in the EG ( $p < 0.05$ ). The MNA score increased and sum of frailty indicators improved in the EG, and the increase in the MNA score in the EG was greater than that in the CG. This study verified the improved anthropometric data and dietary intake in the EG. Thus, the higher number of pre-frailty elderly individuals at facilities of community care indicates the need for adequate nutritional supplementation for frailty management.

**Keywords:** Nutritional support; Frailty; Nutritional status; Randomized controlled trial

## INTRODUCTION

Elderly individuals aged 65 years or older accounted for 14.9% of the population in Korea in 2019 [1], which is continuously increasing, reflecting the trend worldwide. As this trend can lead to social challenges such as increased medical expenses and dependent population, various investigation and management for the welfare of the elderly are needed at the national level. Thus, the government is implementing a long-term elder care system to address the social problems, and facilitate the health care management of the elderly

**Conflict of Interest**

The authors declare that they have no competing interests.

population [2]. The facilities ensure the activities of daily life for the elderly who require relatively lower levels of care. The objectives of the facilities of community care for the elderly are to delay the decrease in physical function, and to enhance the physical recovery by providing meals and leisure/rehabilitation programs.

The decreased physical function in the elderly is attributed to aging, while the functional challenges are due to frailty [3]. It is not a simple aging phenomenon, but the loss of functional homeostasis to cope adequately with external stimuli [4]. Frailty increases the duration of hospitalization in patients sustaining falls and contributes to mortality of the elderly [5,6]. Severe frailty requires increased levels of long-term care and management due to decreased physical activities and slow recovery. Thus, decreasing the risk factors underlying frailty in the elderly is very important to enhance their quality of life and health expectancy, and to reduce medical expenses.

Several factors such as age, number of chronic diseases, falls, depression, activities of daily living, and nutritional status affect the progress of frailty [7-9]. Nutritional status is related to subjective health status, chronic diseases, type of living (living alone or together with family), social support, and dietary intake [10-13]. In particular, dietary intake has the greatest effect on the status of frailty [14,15]. Previous studies reported that the intake of total energy, protein, vitamin D, and calcium determined frailty, hospitalization rate, and mortality [16-20]. The elderly population consuming enough protein and vitamin D showed improved physical function and increased muscle mass [21,22]. An analysis of health conditions based on the intake of calcium, vitamin D, magnesium, and phosphorus, which is associated with musculoskeletal health, showed that the body function scores were significantly low in the group with low intakes of these nutrients [23]. Zinc and iron are known to be associated with reduced oxidative stress and are likely to be important in preventing muscle loss [24].

Epidemiological studies and clinical trials have focused on improving the nutritional status of the elderly mainly via single nutrient supplementation. Therefore, studies are needed to elucidate the effects of multiple nutrient supplementations on elderly to improve their nutritional status.

Thus, following the administration of oral nutritional supplement (ONS) including multinutrients to the elderly at the facilities of community care for the elderly, the effects of ONS on the management of frailty were evaluated according to the nutritional status and relevant frailty indicators.

## MATERIALS AND METHODS

### Subjects and exclusion criteria

A case-controlled, double-blind, and randomized controlled trial was conducted to evaluate the effects of a multinutrient-ONS. The number of study subjects was determined using the G-power 3.0. A paired t-test at a significance level of 5% and a power of 0.8 based on a 95% confidence interval were used. The total number of subjects was 52 including 26 per group, and the final number of subjects was set at 62 based on a 20% dropout rate. The present study was approved by the Clinical Test Deliberation Commission of Institutional Review Board (IRB), Wonkwang University (WKIRB-201907-HR-057). Subjects were selected based on a 2-week preliminary study starting from August 2019, targeting the elderly at 2 facilities of

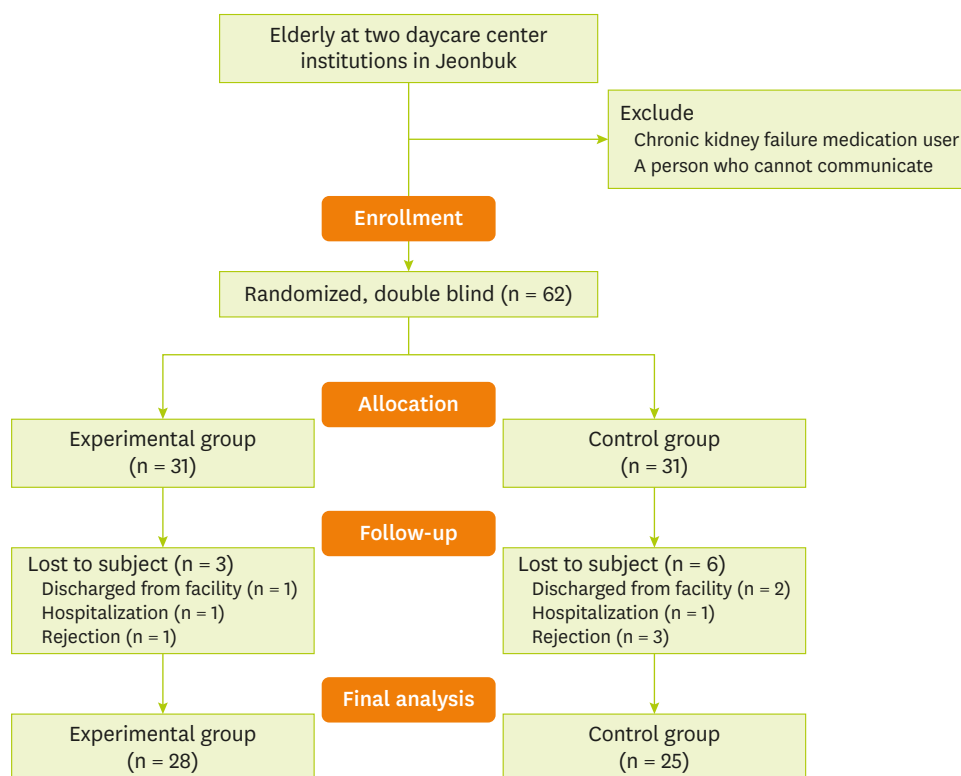


Figure 1. Flow diagram of subject selection.

community care in Jeollabuk-do following informed consent. Anthropometric measurements were conducted. In addition, hand grip, health behavior, and dietary intake were measured. We excluded patients who were treated with medications for chronic renal failure or could not communicate. Finally, the study randomized the 62 elderly subjects to 2 groups of 31 each based on sex and frailty status via stratified cluster random sampling. The number of research participants until the termination of this study included 28 subjects in the experimental group (EG) and 25 subjects in the control group (CG) (Figure 1).

### Nutritional intervention

#### Composition of ONS and placebo

An ONS (200 mL, 200 kcal per day per dose) was provided as a drink made by the manufacturing approved company. Each dose of the ONS administered to the EG contained 15 g of protein, 23 g of carbohydrate, and 6 g of fat. In addition, the ONS contained calcium (daily intake/intake ratio compared with daily recommended calories; 350 mg, 50%), phosphorous (298 mg, 42.5%), zinc (8.5 mg, 94.4%), vitamin A (333 µg RAE, 60.5%), vitamin C (60 mg, 60%), vitamin D (13 µg, 86.7%), and vitamin E (7 mg, 58.3%). Placebo contained the same calorie levels as the ONS. It contained protein 1 g, carbohydrate 33 g, fat 8 g, calcium (140 mg, 20.0%), phosphorus (140 mg, 20.0%), zinc (1.5 mg, 16.7%), vitamin A (70 µg RAE, 12.7%), vitamin C (10 mg, 10%), vitamin D (1 µg, 0.7%), and vitamin E (2 mg, 16.6%). The nutritional supplement was administered for 90 days to each group (Figure 2).

In this study, ONS was supplied for 90 days. We asked the participating agencies to ensure the same level of meals served during that period. ONS was also served once daily during the morning snack time. In the case of weekends or when participants were off, the center

Nutrition Facts			1 Serving size 200 ml/200 kcal		
Amount/serving	% daily value		Amount/serving	% daily value	
Sodium	210 mg	11 %	Zinc	8.5 mg	100 %
Carbohydrate	23 g	7 %	Vitamin A	333 µg RE	48 %
-Sugars	8 g	8 %	Vitamin B1	0.2 mg	20 %
-Dietary fiber	3 g	12 %	Vitamin B2	0.3 mg	20 %
Fat	6 g	11 %	Vitamin B6	0.3 mg	20 %
-Trans	0 g		Vitamin B12	0.2 µg	10 %
-Saturated fatty acid	1.6 g	11 %	Vitamin C	60 mg	60 %
Cholesterol	5 mg	2 %	Vitamin D	13 µg	130 %
Protein	15 g	27 %	Vitamin E	7 mgα-TE	64 %
Calcium	350 mg	50 %	Folic acid	80 µg	20 %
Phosphorus	298 mg	43 %	Naicin	3 mg NE	20 %
Potassium	370 mg	11 %	Pantoteic acid	1 mg	20 %
Magnesium	80 mg	25 %	Biotin	6 µg	20 %
Iron	2.4 mg	20 %	BCAA	2,000 mg	

[Supplementation in experimental group]

Nutrition Facts			1 Serving size 200 ml/200 kcal		
Amount/serving	% daily value		Amount/serving	% daily value	
Sodium	210 mg	11 %	*Zinc	1.5 mg	18 %
*Carbohydrate	33 g	10 %	*Vitamin A	70 µg RE	10 %
-Sugars	8 g	8 %	Vitamin B1	0.2 mg	20 %
-Dietary fiber	3 g	12 %	Vitamin B2	0.3 mg	20 %
*Fat	8 g	11 %	Vitamin B6	0.3 mg	20 %
-Trans	0 g		Vitamin B12	0.2 µg	10 %
-Saturated fatty acid	1.6 g	11 %	*Vitamin C	10 mg	10 %
Cholesterol	5 mg	2 %	*Vitamin D	1 µg	10 %
*Protein	1 g	2 %	*Vitamin E	2 mgα-TE	18 %
*Calcium	140 mg	20 %	Folic acid	80 µg	20 %
*Phosphorus	140 mg	20 %	Naicin	3 mg NE	20 %
Potassium	370 mg	11 %	Pantoteic acid	1 mg	20 %
Magnesium	80 mg	25 %	Biotin	6 µg	20 %
Iron	2.4 mg	20 %			

[Supplementation in control group]

**Figure 2.** Nutrient composition of the supplementation.

\*Indicated value means nutrients of different amount content in the 2 products.

officials provided the ONS in advance. The effect of nutritional supplementation was evaluated as described in “Analysis of Effects” part.

### Analysis of effects

#### Dietary intake

We investigated the dietary intakes using dietary records before and after nutritional intervention. The meal type, mealtime and food quantity were determined. Also, in case of elderly subjects who returned home early, we called their guardians to investigate the meal and food intake at home. The nutrient intake from meal and food was analyzed using CAN-Pro 5.0 (web version).

### *Anthropometry*

All anthropometric measurements were performed in subjects wearing light clothing without shoes and after visiting the toilet. Body weight was measured to the nearest 0.1 kg using a calibrated weighing scale. BMI was calculated as weight (kg) divided by the estimated height in meters squared (m<sup>2</sup>). The circumference of calf and arm was measured to the nearest 0.1 cm on the left side of the body using a measuring tape. Body composition was measured via bioelectrical impedance analysis (BIA) with Inbody S10 (Inbody, Seoul, Korea).

### *Physical function*

Physical function was measured in terms of handgrip strength using a Hand Dynamometer GRIP-SYS, model DW-781/780 (Deawoo Sports Industry, Seoul, Korea). We measured both hands, each twice, and used the average value. All values were expressed in kg.

### *Health status*

To evaluate the effects of the multi nutrient containing ONS, we evaluated the frailty, health and dietary status of the subjects. The frailty status was determined using the Korean version of the fatigue, resistance, ambulation, illnesses, and loss of weight scale (K-FRAIL) [25]. The evaluation was based on a total of 5 items such as fatigue, resistance, ambulation, illness and loss of weight. A score of zero meant normal status, 1–2 points suggested pre-frail, and 3–5 points indicated frail. In case of illness, chronic disease was indicated by the presence of 5 or more diseases, including hypertension, diabetes, cancer, chronic lung disease, myocardial infarction, heart failure, angina, asthma, arthritis, cerebral infarction, and kidney disease.

The nutritional status was evaluated using the Mini Nutritional Assessment (MNA). The MNA score was based on a total of 18 items such as anthropometry, overall physical/psychological assessment, dietary status, and self-perception of health and nutrition [26]. Based on the total score of 30, malnutrition was indicated by a score less than 17. The risk of malnutrition was indicated by a score of 17–23.5, whereas scores 24 or higher suggested adequate nourishment. The health status was evaluated using the Korean Activities of Daily Living (K-ADL) instrument [27] and Korean version of Mini-Mental State Examination (MMSE-K) [28]. The evaluation of the K-ADL was based on seven items such as getting dressed, washing face, taking a bath, having a meal, moving, using the bathroom, and controlling the bowel and bladder function, and based on the cumulative score complete independence, partial and complete dependence was established. The total score was 21, and a higher score indicated higher dependence. The MMSE-K included a 27 items, including time orientation, place orientation, memory registration, attention/concentration & calculation, memory recall, and composition of language & time-space. The scores were based on sex, age, and level of education according to the user guidelines. The MMSE-K depends on the total score of 30, with a score of 0–19 indicating definite dementia, 20–23 suggesting suspected dementia, and 24–30 considered normal. The appetite assessment questionnaire was evaluated using the Simplified Nutritional Appetite Questionnaire [29], and the evaluation included 4 items such as appetite, satiety, taste, and the number of meals taken each day. In the total score of 20, a score of 0–14 suggested loss of appetite and a score of 15–20 was considered normal.

### **Statistical analysis**

The t-test and  $\chi^2$  test was performed to compare before intervention. And the Wilcoxon signed rank test was performed to validate the changes in both groups after nutritional intervention. In case of non-normal distribution, the Mann-Whitney U test was conducted for comparative analysis. In order to analyze the distribution of frailty diagnosis in the

experimental and CGs, the cross-tabulation analysis was conducted. The statistical analysis was conducted using the SPSS version 24.0. The significance level was set at a  $p < 0.05$ .

## RESULTS

### General baseline characteristics

The general characteristics, anthropometry, frailty status, and MNA of the 62 subjects recruited initially are listed in **Table 1**. The 62 subjects were divided into an EG ( $n = 31$ ) and a CG ( $n = 31$ ). The study included 11 male (17.7%). The average age was  $80.8 \pm 7.0$  years. A normal status was found in ten (16.1%) subjects, whereas pre-frailty was observed in 45 (72.6%) subjects, and frailty was detected in seven (11.3%) subjects. The MNA score was  $19.8 \pm 3.1$ , suggesting no significant differences between the 2 groups. Data that analyzed only the final subjects before the experiment are presented in **Supplementary Table 1**.

### Changes in anthropometry and health status after nutritional intervention

The changes in anthropometry and health status after each nutritional intervention are listed in **Table 2**. The final analysis targeted 28 subjects in the EG and 25 subjects in the CG. In the EG, the weight was significantly increased from  $56.0 \pm 10.3$  kg to  $57.7 \pm 10.1$  kg ( $p = 0.004$ ), while the BMI was also significantly increased from  $23.4 \pm 3.6$  kg/m<sup>2</sup> to  $24.1 \pm 3.4$  kg/m<sup>2</sup> ( $p = 0.004$ ). The anthropometric values of EG were increased along with a significant increase in the arm and calf circumference, and lean mass. In the CG, the MMSE-K was significantly decreased from  $16.1 \pm 4.8$  to  $14.8 \pm 5.2$  ( $p = 0.040$ ). Even though no changes were detected in the EG, the cognitive function was diminished in the CG.

**Table 1.** General characteristics at baseline

Variables	Total (n = 62)	Experimental group (n = 31)	Control group (n = 31)	p value
Sex (male)	11 (17.7)	5 (16.1)	6 (19.4)	0.740*
Age (yr)	$80.8 \pm 7.0$	$79.5 \pm 7.0$	$82.1 \pm 6.9$	0.143*
No. of medicine	$4.0 \pm 5.1$	$4.5 \pm 7.0$	$3.5 \pm 1.6$	0.446*
Living alone	16 (25.8)	9 (29.0)	7 (22.6)	0.562 <sup>†</sup>
Regular exercise				0.858 <sup>†</sup>
None	4 (6.5)	2 (6.7)	2 (6.3)	
1–3 times/wk	5 (8.1)	3 (10.0)	2 (6.3)	
Over 4 times/wk	53 (85.5)	25 (83.3)	28 (87.5)	
BMI (kg/m <sup>2</sup> )	$22.8 \pm 3.4$	$23.1 \pm 3.7$	$22.4 \pm 3.0$	0.391
Height (cm)	$153.1 \pm 8.6$	$154.0 \pm 9.1$	$152.4 \pm 8.1$	0.480
Weight (kg)	$53.5 \pm 9.8$	$55.0 \pm 10.7$	$52.1 \pm 8.7$	0.247
SBP (mmHg)	$125.1 \pm 18.7$	$123.4 \pm 19.4$	$126.7 \pm 18.1$	0.488
DBP (mmHg)	$70.7 \pm 10.2$	$70.0 \pm 10.6$	$71.6 \pm 9.9$	0.588
Arm circumference (cm)	$27.0 \pm 3.2$	$27.2 \pm 3.4$	$26.7 \pm 3.1$	0.525
Calf circumference (cm)	$31.4 \pm 3.4$	$32.0 \pm 3.5$	$30.9 \pm 3.2$	0.202
Hand grip (kg)	$12.6 \pm 5.8$	$12.7 \pm 5.1$	$12.4 \pm 6.3$	0.871
Frail status				0.778 <sup>†</sup>
Normal	10 (16.1)	6 (18.8)	4 (13.3)	
Pre-frail	45 (72.6)	23 (71.9)	22 (73.3)	
Frail	7 (11.3)	3 (9.4)	4 (13.3)	
MNA	$19.8 \pm 3.1$	$19.8 \pm 3.1$	$19.7 \pm 3.2$	0.953

Data are shown as mean  $\pm$  standard deviation or number (%).

BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; MNA, mini nutritional assessment.

\*Comparing the values between groups using t-test before intervention; <sup>†</sup>Comparing the values between groups using  $\chi^2$  test before intervention.



**Table 2.** Changes in anthropometry and health status after nutritional intervention

Variables	Experimental group (n = 28)				Control group (n = 25)				p value <sup>‡</sup>
	Before	After	p value <sup>*</sup>	Mean change from baseline	Before	After	p value <sup>†</sup>	Mean change from baseline	
Weight (kg)	56.0 ± 10.3	57.7 ± 10.1	0.004	1.7	51.8 ± 8.6	51.8 ± 8.6	0.230	0.6	0.501
BMI (kg/m <sup>2</sup> )	23.4 ± 3.6	24.1 ± 3.4	0.004	0.7	22.2 ± 3.1	22.7 ± 3.2	0.152	0.5	0.580
Arm circumference (cm)	27.5 ± 3.3	28.2 ± 2.9	0.028	0.7	26.5 ± 3.1	27.3 ± 2.5	0.174	0.7	0.907
Calf circumference (cm)	32.4 ± 3.3	33.7 ± 3.4	0.010	1.4	30.8 ± 3.3	31.6 ± 3.2	0.093	0.7	0.337
Body fat (%)	35.0 ± 7.0	35.2 ± 7.5	0.858	0.2	34.4 ± 7.1	35.0 ± 7.1	0.564	0.6	0.809
Lean mass (kg)	36.2 ± 7.1	37.3 ± 7.8	0.011	1.1	32.9 ± 4.8	31.7 ± 5.2	0.051	0.8	0.603
Hand grip (kg)	12.9 ± 5.2	13.1 ± 5.5	0.790	0.2	11.9 ± 5.5	11.9 ± 4.8	0.954	0.1	0.914
ASM (kg)	14.7 ± 4.0	14.9 ± 4.1	0.183	0.2	12.6 ± 3.0	12.5 ± 2.9	0.403	-0.1	0.122
ASM/height (kg/m <sup>2</sup> )	6.0 ± 1.1	6.1 ± 1.1	0.154	0.1	5.4 ± 0.9	5.3 ± 0.8	0.464	-0.0	0.127
ADL	9.6 ± 2.9	9.3 ± 2.4	0.450	-0.3	10.0 ± 3.3	9.3 ± 1.9	0.311	-0.7	0.059
SNAQ	14.0 ± 1.7	14.6 ± 1.6	0.165	0.6	14.6 ± 1.8	14.0 ± 1.8	0.203	-0.6	0.258
MMSE	15.9 ± 6.1	15.7 ± 6.2	0.710	-0.2	16.1 ± 4.8	14.8 ± 5.2	0.040	-1.3	0.148

Data are shown as mean ± standard deviation.

BMI, body mass index; ASM, appendicular skeletal muscle mass; ADL, Korean activities of daily living; SNAQ, simplified nutritional appetite questionnaire; MMSE, Korean version of mini-mental state examination.

\*Comparing the values between before and after intervention in experimental group using Wilcoxon single rank test; †Comparing the values between before and after intervention in control group using Wilcoxon single rank test; ‡Comparing the values of change between groups using Mann-Whitney U test.

### Changes in frailty diagnosis and nutritional indicators after intervention

The changes in frailty diagnosis and indicators are listed in **Table 3** and **Figure 3**. None of the subjects in the experimental or the CG showed significant differences in frail status. The MNA was changed significantly from 19.7 to 21.1 in the EG (p = 0.004). But MNA was showed no significant differences in the CG (p = 0.900). Based on the sum of frailty indicator (range, 0–5)

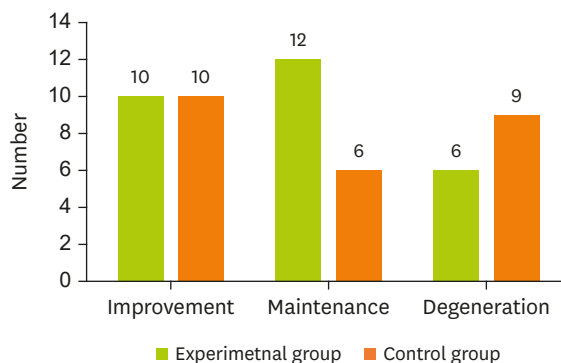
**Table 3.** Changes in frailty status and nutritional status after nutritional intervention

Variables	Experimental group (n = 28)			Control group (n = 25)		
	Before	After	p value	Before	After	p value
Frail status			0.549			0.841
Normal	7 (25.0)	10 (35.7)		4 (16.0)	5 (20.0)	
Pre-frail	19 (64.9)	15 (53.6)		17 (68.0)	15 (60.0)	
Frail	2 (7.1)	3 (10.7)		4 (16.0)	5 (50.0)	
Frail score (total 5)	1.4 ± 1.0	1.2 ± 1.1	0.312*	1.7 ± 0.9	1.6 ± 1.1	0.641†
MNA total score	19.7 ± 3.0	21.1 ± 2.6	0.004*	19.8 ± 3.2	19.7 ± 4.3	0.900†

Data are shown as mean ± standard deviation.

MNA, mini nutritional assessment.

\*Comparing the values between before and after intervention in experimental group using Wilcoxon single rank test; †Comparing the values between before and after in control group using Wilcoxon single rank test.



**Figure 3.** Comparison of improvement levels through frail parameter after nutrition intervention. The bars and digits indicate that the level of sum of frail parameter score. Changes of improvement levels through sum of frail parameter before and after the nutrition intervention were compared between control group and experimental group.

**Table 4.** Changes in dietary intake after nutritional intervention

Variables	Experimental group (n = 28)				Control group (n = 25)				p value <sup>‡</sup>
	Before	After	p value <sup>*</sup>	Mean change from baseline	Before	After	p value <sup>†</sup>	Mean change from baseline	
Energy (kcal)	1,311.6 ± 192.9	1,479.6 ± 339.2	0.031	168.0	1,259.0 ± 226.0	1,402.1 ± 280.2	0.002	143.1	0.769
Carbohydrate (g)	207.9 ± 29.3	235.3 ± 40.0	0.006	27.4	202.9 ± 28.3	228.3 ± 36.3	0.001	25.3	0.849
Fat (g)	33.0 ± 6.7	30.7 ± 13.3	0.390	-2.3	30.7 ± 10.0	33.3 ± 12.7	0.233	2.6	0.157
Protein (g)	43.7 ± 8.6	62.1 ± 19.4	0.000	18.4	41.4 ± 10.9	44.0 ± 15.0	0.315	2.6	0.003
Protein (g/kg) <sup>§</sup>	0.8 ± 0.2	1.1 ± 0.3	0.000	0.30	0.9 ± 0.3	0.9 ± 0.4	0.449	0.04	0.004
Fiber (g)	15.5 ± 3.5	20.7 ± 7.0	0.001	5.3	16.0 ± 4.6	19.5 ± 5.9	0.002	3.5	0.325
Vitamin A (ug RAE)	415.2 ± 168.0	1,169.7 ± 387.7	0.000	754.4	392.7 ± 191.9	806.6 ± 304.3	0.000	413.9	0.004
Vitamin D (ug)	0.8 ± 0.8	13.5 ± 0.5	0.000	12.7	1.0 ± 1.1	1.4 ± 0.5	0.131	0.4	0.000
Vitamin E (mg)	16.1 ± 3.5	17.6 ± 7.5	0.390	1.5	14.5 ± 5.4	13.5 ± 6.3	0.568	-1.0	0.308
Vitamin K (ug)	77.3 ± 84.4	245.7 ± 148.5	0.001	168.3	75.1 ± 69.2	228.0 ± 100.4	0.000	152.9	0.766
Vitamin C (mg)	29.4 ± 12.5	103.5 ± 15.2	0.000	74.1	27.1 ± 13.6	49.2 ± 16.5	0.000	22.1	0.000
Thiamin (mg)	1.0 ± 0.2	1.3 ± 0.4	0.004	0.3	0.9 ± 0.3	1.2 ± 0.4	0.000	0.3	0.892
Riboflavin (mg)	0.8 ± 0.2	0.9 ± 0.3	0.017	0.2	0.8 ± 0.3	1.0 ± 0.2	0.000	0.2	0.490
Niacin (mg)	7.7 ± 1.8	7.8 ± 2.3	0.880	0.1	7.5 ± 1.9	7.3 ± 2.2	0.761	-0.1	0.753
Vitamin B6 (mg)	0.8 ± 0.2	1.2 ± 0.3	0.000	0.4	0.7 ± 0.2	1.1 ± 0.3	0.000	0.4	0.901
Folate (ug)	242.1 ± 88.3	218.7 ± 60.0	0.280	-23.5	241.4 ± 88.6	201.6 ± 64.8	0.024	-39.8	0.547
Vitamin B12 (ug)	2.9 ± 2.7	4.6 ± 3.0	0.003	1.8	3.3 ± 2.4	4.4 ± 2.7	0.184	1.1	0.516
Calcium (mg)	409.6 ± 175.7	671.3 ± 73.4	0.000	261.7	401.7 ± 195.4	439.8 ± 85.9	0.405	38.1	0.001
Sodium (mg)	3,207.8 ± 897.2	3,650.7 ± 1,097.9	0.051	442.9	2,939.2 ± 676.7	3,197.6 ± 904.7	0.214	258.4	0.533
Phosphorus (mg)	540.9 ± 202.4	949.5 ± 234.5	0.000	408.6	540.4 ± 226.4	663.4 ± 185.9	0.005	112.9	0.001
Zinc (mg)	4.4 ± 1.4	14.2 ± 2.1	0.000	9.7	4.3 ± 1.6	5.5 ± 1.6	0.000	1.2	0.005
Iron (mg)	11.6 ± 3.2	13.8 ± 3.9	0.012	2.2	11.5 ± 3.6	12.6 ± 2.9	0.127	1.1	0.290

Data are shown as mean ± standard deviation.

\*Comparing the values between before and after in experimental group using Wilcoxon single rank test; †Comparing the values between before and after in control group using Wilcoxon single rank test; ‡Comparing the values of change between groups using Mann-Whitney U test; §This data was analyzed protein intakes (g) divided by weight (kg).

after nutritional intervention, 10 persons showed improvement in both groups. The subject who remains in the pre-experimental state, were 12 persons in the EG and 6 persons in the CG. The sum of frailty indicators deteriorated in 6 persons in the EG and 9 persons in the CG.

### Changes in dietary intake after nutritional intervention

The changes in dietary intake after nutritional intervention are shown in **Table 4**. Even though no changes were detected in the CG, the nutrient levels were slightly increased in the EG. In case of dietary intake, the levels of energy, carbohydrate, dietary fiber, vitamin A, vitamin K, vitamin C, thiamine, riboflavin, and vitamin B6 were significantly increased in both groups. However, the levels of protein, calcium, and iron intakes were increased only in the EG.

## DISCUSSION

In order to evaluate the effects of ONS on the management of frailty in the elderly using facilities of community care for the elderly, nutritional intervention was performed for 90 days and resulted in a significant improvement in anthropometric parameters and dietary intake in the EG.

The MNA score was 19.8 in the elderly subjects at facilities of community care. According to the national survey of the elderly with dementia, the MNA was 17.9, which suggested a relatively higher nutritional status of study subjects. Also, compared with the normal group comprising 16.1% frail subjects, pre-frail was detected in 72.6% and frail in 11.3% (average age, 80.8), suggesting that most of the subjects were diagnosed with pre-frailty. In a study of community-based frailty cohort (Aging Study of Pyeongchang Rural Area), however,



normal (29.3%), pre-frail (43.2%), and frail (27.5%) subjects were found (average age, 74.4 years) [30], suggesting that the distribution based on frailty status of other study differed slightly from this study. The study subjects showed a relatively low distribution in the normal and frail groups, probably because of fewer subjects in the normal category as their age was higher than in other studies. Also, this study only targeted the elderly in facilities of community care as their health status was relatively good without the need for transfer to nursing hospitals. Thus, based on the comparison of the current and the previous studies, the differences in health status of the elderly depended on their residence. Therefore, the elderly who exhibited potential for improvement were densely distributed in the facilities of community care, which delayed the changes in their health status, suggesting the need for concrete nutritional management.

The comparison of dietary intake and nutritional status of experimental and CGs after ONS intervention showed that the intake of protein, vitamin A, vitamin D, vitamin C, and calcium was significantly increased in the EG. In the meta-analysis by Milne et al. [31], the complications and mortality among malnourished elderly subjects were reduced by treatment with ONS. In this study, the intake per weight was increased from 0.7 to 1.1 g in the EG. In the study by Campbell et al. [32], the intake of 0.8 g per weight increased the excretion of urinary nitrogen. Due to the catabolism of muscle protein, it is essential to ensure adequate protein intake in the elderly. Thus, the intake of protein supplement in this study is regarded as appropriate for the study subjects. In the analysis of before and after nutritional status, the supplementary protein intake was increased from 19.7 to 21.1 g in the EG, while it was decreased from 19.8 to 19.7 g in the CG. In the study by Pedro, 91 elderly persons were exposed to nutritional supplementation and exercise for 12 weeks, and their nutritional status was evaluated [33]. The nutritional status was improved after the intervention. Jukkola et al. [34] conducted a case-control study by providing beverages and food as nutritional supplements to hospitalized patients, which resulted in no significant differences between the 2 groups. Thus, the differences in the results of each study might be attributed to differences based on community, facilities of community care, and hospitalization in the elderly. The number of subjects varied as well, which may have resulted in differences in the improvement of nutritional status between groups.

The results of this study showed that weight, BMI, arm circumference, calf circumference, and lean body mass were significantly increased in the EG, but not in the CG. Payette et al. [35] reported that treatment of the elderly in the community with protein-energy supplement and nutrient intake through food, resulted in weight increase in the EG and, the observation was similar to this study.

The effects of ONS treatment in the elderly yielded significant results based on physical function, such as Short Physical Performance Battery, Timed Up-and-Go test and handgrip [33,36]. However, no significant differences between the 2 groups were detected in the case of handgrip test evaluating physical function index in this study.

In summary, there are several implications based on research subjects and study design. First, this study evaluated nutritional intervention by administering the ONS only for 90 days. Even though this intervention simply changed the anthropometric parameters such as weight or muscle mass in the elderly, the effects on improvement of physical function are insignificant. Previous studies showed improvement in physical function because nutrition was combined with exercise intervention. Therefore, nutritional management programs for delaying frailty would need to include an exercise component.

In the analysis of cognitive function, activities of daily living, and appetite, the changes in physical function and health status were analyzed via nutritional intervention, even though the study subjects were elderly with diminished cognitive function. The MMSE decreased by about 0.2 point in the EG during the nutritional intervention but decreased by 1.3 points in the CG. Even though no significant differences occurred between the 2 groups, considering the elderly with continuous and progressive aging, it is necessary to conduct a follow-up evaluation of the effects on cognitive function via long-term intake.

However, this study has several limitations. In case of dietary intake measurements conducted before and after the study, the estimated data were adjusted for actual intake by the elderly subjects at DC centers. Even though the study is significant in reflecting the actual intake, it may differ from the usual dietary intake. The subjects were recruited via convenient sampling in selected areas, and therefore it is difficult to generalize the findings for all elderly subjects using the facilities of community care for the elderly.

Nevertheless, this study is valuable as a randomized controlled trial which investigated the elderly using facilities of community care in improving their nutritional status and management of frailty. This study evaluated the effects of nutritional intervention using ONS, although the data have not been validated at the community level in Korea. It showed improvement in anthropometric parameters (physical status) and dietary intake. The study targeted individuals in need of relatively low level of care due to their activities of daily living, and low risk of illness. Therefore, given the increasing elderly population in Korea, it will be necessary to conduct a specialized nutritional management program at facilities of community care in the future.

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## SUPPLEMENTARY MATERIAL

### Supplementary Table 1

General characteristics of final subjects who conducted nutrition intervention

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