



Impact of an oral nutritional supplement on nutritional status in older adults with malnutrition: A randomized controlled trial

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Ranil Jayawardena^{1,2}, Prasani Wickramawardhane³

¹ Department of Physiology, Faculty of Medicine, University of Colombo, Colombo, Sri Lanka

² School of Exercise and Nutrition Sciences, Queensland University of Technology, Brisbane, Australia

³ Health and Wellness Unit, Faculty of Medicine, University of Colombo, Colombo, Sri Lanka

Abstract

Background: The aging population is expanding at an unprecedented rate, leading to a significant increase in the prevalence of malnutrition among older adults. Oral Nutritional Supplements (ONS) have emerged as a widely accepted strategy to address the nutritional needs of this demographic.

Objective: This study aimed to evaluate the impact of an ONS on the nutritional status of malnourished older adults.

Methods: This was an open-label, randomized-controlled, parallel-group, single-centered study. Recruitment criteria were age ≥ 60 years, and mini nutrition assessment-short form (MNA-SF) score ≤ 11 . A total of 50 participants were randomly assigned to the intervention (IG) and control (CG) groups (1:1 ratio). The IG received 200 mL of ONS as a bedtime drink for 12 weeks, while the CG received 200 mL of water. Nutrition status, biochemical analysis, and dietary assessment were performed at the beginning and end of the study.

Results: Forty-two participants (IG: $n=20$, and CG: $n=22$) completed the study. After 12 weeks, the IG showed a significant improvement in the MNA-SF score ($p<0.001$) compared to the CG ($p=0.118$). The IG experienced a substantial increment in the vitamin D level ($p=0.002$). No significant improvements were found in the serum albumin and haemoglobin levels in either group. The intervention led to significant increases in daily intake of energy ($p<0.001$), carbohydrate ($p=0.013$), protein ($p<0.001$), and fat ($p<0.001$) in comparison to the control group.

Conclusion: Supplementing with an ONS, along with a regular diet, significantly improved nutritional status, some biochemical parameters, and daily intake of energy and macronutrients in older adults with malnutrition.

Keywords: biochemical parameters, malnutrition, nutritional status, older adults, oral nutritional supplement

Corresponding author:

Ranil Jayawardena

Department of Physiology, Faculty of
Medicine, University of Colombo, Colombo,
Sri Lanka

Email: ranil@physiol.cmb.ac.lk

Introduction

Nutritional assessment is crucial for assessing nutritional status and planning necessary interventions. A comprehensive assessment of nutritional status requires several measurements including anthropometry, biochemical, clinical, and dietary details. Consequently, various nutritional screening tools have been validated for different populations. The mini nutritional assessment (MNA) has been widely recommended as a valid tool for screening malnutrition among older adults.¹

The risk of malnutrition can be accurately, specifically, and sensitively identified using the MNA. The MNA allows for the detection of cognitive and functional impairments and difficulties in eating, which is often associated with malnutrition in older adults before a severe change in weight or serum protein occurs.² Guigoz Y. et al.,³ suggested that the MNA is a reliable screening and assessment with clearly defined thresholds and it should be incorporated in the geriatric assessment and proposed in the minimum data set for nutritional interventions. Interventional studies suggest that timely intervention is associated with increases in MNA scores and prevents weight loss in malnourished older adults.³

Improving nutritional status in older adults is important for the maintenance of good health, functional independence, lower disease risk, and quality of life.⁴ A quantum of studies has used the MNA to evaluate the effectiveness of various nutritional interventions on the nutritional status of older adults. As a potential nutritional intervention, the efficacy of using an ONS has been evaluated in several studies involving malnourished older adults and has shown beneficial effects on nutritional status as measured by improvement in MNA scores.⁵⁻⁷ A recent interventional study by Na et al.,⁵ studied the impact of using an oral nutritional supplement (ONS) on nutritional status in malnourished older adults. The intervention group showed a significant increase in the MNA score from 19.7 ± 3.0 to 21.1 ± 2.6 ($p=0.004$), while the control group showed no significant change ($p=0.90$).

To date, only a limited number of studies have explored the impact of ONS on biochemical parameters in older adults, with reported findings contradicting each other. Pereira et al.,⁸ reported that ONS increases serum immunoglobulin, myoglobin, total protein, vitamin E, and magnesium in malnourished older adults. Another extensive study done by Chew et al.,⁹ observed the beneficial effect on vitamin D levels in response to 24-week oral nutritional supplementation. Conversely, a study done by Huynh et al.,¹⁰ among malnourished older adults reported no significant difference in biochemical parameters between the intervention and control group after 12-week supplementation. As a form of enteral nutrition, ONSs provide calories, high-quality protein, and micronutrients that are recommended to fulfill the basic nutritional requirements of malnourished older adults when regular diet alone is insufficient.¹¹

Previous studies have also demonstrated significant increases in the intake of energy, carbohydrate, protein, and fat.^{9, 12} In this context, the purpose of the current study was to evaluate the impact of an ONS as a bedtime drink for malnourished older adults, on MNA score, biochemical parameters, and energy and nutrient intake.

Methods

Study design

This study was an open-label, parallel-group, randomized-controlled clinical trial conducted among institutionalised Sri Lankan older adults with or at risk of malnutrition between January 2023 and May 2023. The study protocol was reviewed and approved by the ethics review committee of the Sri Lanka Medical Association (ERC/22-005). Prior to study participation, each participant voluntarily provided written informed consent. The detailed protocol regarding the methodology has been published elsewhere¹³ and a summary is given below. This clinical trial is registered at Sri Lanka Clinical Trials Registry (SLCTR/2022/021).

Participants

Participants were recruited from the Moratuwa Social Service Elderly Care Home, a long-term care facility in Western Province, Sri Lanka. Participants were screened for malnutrition using the mini nutrition assessment short form (MNA-SF) questionnaire. Older adults with malnutrition or at risk of malnutrition (MNA-SF score ≤ 11) were recruited. Inclusion criteria were age ≥ 60 years and residing in the selected elderly care institution for more than one year. Exclusion criteria were inability to consume food orally, being bedridden, intolerance to milk products, being on an end-of-life care pathway, having no capacity to consent, or any acute medical conditions.

Sample size

The main outcome was the percentage who achieved at least 5% weight gain in the intervention group (IG) compared to the control group (CG). Considering the 5% weight gain in the IG compared to the CG, 25 participants were required in each group (5% alpha, 80% power, drop-out rate 20%). The detailed sample size calculation is presented previously published study protocol¹³.

Intervention

Participants were randomly assigned to the IG or CG, to receive an ONS dissolved in 200 mL of water [Entrasol Platinum, Kalbe Pvt. Ltd., Indonesia] or 200 mL of water, respectively. The detailed nutritional composition of the ONS is summarized in Supplementary **Table 1**. Participants were instructed to consume the ONS daily before bedtime (between 9-10 pm) for 12 weeks. Both IG and CG consumed the same diet during the intervention period as all participants received the standard menu served in the institution.

Outcome measures

Nutritional status, biochemical assessment, and dietary assessment were performed at baseline (week 0), and post-intervention (week 12) visits.

- Nutritional status

The MNA-SF questionnaire was used to determine the nutritional status. The MNA score indicates three different levels of nutritional status; well-nourished (12-14 points), risk for malnutrition (8 – 11 points), and malnourished (0-7 points)¹⁴. MNA-SF score was measured on all participants in both groups, at baseline and after 12 weeks.

- Biochemical parameters

All biochemical parameters were tested at an accredited laboratory (Nawaloka Metropolis laboratory, Nawaloka Hospital PLC, Sri Lanka) following the standard procedures. A venous blood sample of 10 – 12 mL was collected for the assessment of the following biochemical parameters.

- Full blood count: Full blood count was analyzed using SYSMEX XE-2100 Haematology Automated Analyser.
- Total 25-(OH) vitamin D: The serum was separated from the venous blood sample collected and tested within 3 hours using MAGMLUMI 2000 analyzer by Competitive Chemiluminescence Immunoassay (CLIA). This test quantitatively measures the sum of both 25-(OH) vitamin D3 (cholecalciferol) and 25-(OH) vitamin D2 (Ergocalciferol) in the specimen.
- Serum albumin: The serum was separated from the venous blood sample and mixed with a bromocresol green dye reagent. The resulting colour change was measured using a spectrophotometer (Shimadzu 1800UV/Visible Scanning Spectrophotometer, Japan). The absorbance was converted into albumin concentration.
- Total serum cholesterol: Total cholesterol was determined using a Cobas c501 auto analyzer using an electrochemiluminescent immunoassay (ECLIA, Roche Diagnostics).

- High sensitivity C - reactive protein (hCRP): The Roche Cobas c501, which is an in vitro diagnostic test system, was used to quantitatively determine the C reactive protein (CRP) in human capillary whole blood and serum, EDTA K2/K3 and lithium heparin anti-coagulated whole blood and plasma by photometric measurement.

- *Dietary intake*

A 24-hour dietary recall was conducted by trained dietitians to assess the daily dietary intake of the study participants. The quantity of food was recorded using household measures (teaspoon, tablespoon, teacup, coconut spoon, etc.) with the help of caregivers. The domestic measures of the consumed solid foods were weighed in grams using a digital kitchen scale and the liquid foods were measured in millilitres. The recorded weights and volumes of the consumed food items were entered into Nutri-Survey (EBISpro), which was adjusted with Sri Lankan food composition data¹⁵ to calculate the daily intake of energy, carbohydrate, protein, and fat.

Statistical analysis

Participants who may have deviated from the study protocol or dropped out during the study were excluded and per-protocol analysis was performed. Data analysis was performed using IBM SPSS version 23 statistical software package (SPSS Inc., Chicago, IL, USA). Given the small sample size (n=50), the Shapiro-Wilk test was conducted to assess the normality, with a significance level set at a p value less than 0.05 indicating a significant deviation from normality. Baseline values were compared using independent sample t-test and expressed as the mean and standard deviation (mean±SD) for continuous variables, while categorical variables were compared using chi-square test and presented as values and percentages.

To analyze the changes in measurements between the two groups, different statistical tests were used based on the distribution of the data. The independent sample t-test was used for parametric

distributions, while for non-parametric distributions, the Mann-Whitney U test was used. When comparing the pre-and post-intervention mean values of the measurements, the paired sample t-test was applied for parametric distributions, and for non-parametric distributions, the Wilcoxon Signed Rank test was applied. A value less than 0.05 was considered statistically significant.

Results

Baseline characteristics

At the end of the 12th week, out of the total fifty participants initially enrolled, twenty in the IG and twenty-two in the CG completed the study. The CONSORT flow diagram depicting the progress through the phases of the study for the two parallel groups is shown in **Supplementary Figure 1**. The following results are based on the analysis of data from forty-two participants who completed the study. The mean age of the IG was 75.4±6.1 years, and the CG was 74.8±5.2 years (p=0.732). At the baseline, there was no significant difference in MNA-SF scores between the two groups (IG; 8.72±1.95 vs. CG; 9.56±1.45, p=0.090) (**Supplementary Table 2**).

Nutritional status

The IG showed a significant improvement in mean MNA-SF score (8.75±1.83 to 10.85±1.57; p<0.001) compared to the CG (9.27±1.24 to 8.77±1.68; p=0.118) (**Figure 1**). All the participants had a low MNA-SF (≤11) on inclusion. At the end of the 12th week, 45% of the participants in the IG had achieved normal nutritional status according to the mini nutrition assessment short form (MNA-SF score range of 12-14) (**Figure 2**). In the CG, only 5% of the participants reached normal nutritional status, while 23% were malnourished and 72% were at risk of malnutrition.

Biochemical parameters

Table 1 presents the pre- and post-interventional changes in biochemical parameters within and between the two groups.

A significant increase in vitamin D level was observed in both the IG (14.76 ± 4.70 to 23.96 ± 4.18 ng/mL; $p < 0.001$) and CG (15.36 ± 5.65 to 19.32 ± 7.20 ng/mL; $p < 0.001$), with the IG showing a significantly higher increase than the control group (IG: 9.20 ± 5.29 vs. CG: 3.96 ± 4.85 ng/mL; $p = 0.002$) **Figure 3**. Serum albumin levels decreased in both groups, but CG lost significantly more than IG (IG: -0.20 ± 0.26 vs. CG: -0.40 ± 0.19 g/dL; $p = 0.006$).

The pre- to post-intervention total serum cholesterol level was significantly reduced by -21.2 ± 16.3 mg/dL ($p < 0.001$) in the IG and by -17.4 ± 38.0 mg/dL ($p = 0.044$) in the CG. However, there was no significant difference in the changes of total serum cholesterol levels between the two groups ($p = 0.679$). An elevation in hCRP was observed in both groups (IG: 3.12 ± 7.97 vs. CG: 3.03 ± 10.04 mg/L; $p = 0.974$), but it was not significant.

Dietary intake

The changes in dietary intake after nutritional intervention are shown in **Table 2**. The levels of energy ($p < 0.001$), carbohydrate ($p = 0.013$), protein ($p < 0.001$), and fat ($p < 0.001$) were significantly increased in the IG compared to the CG.

Adverse events

The ONS was well tolerated, and no serious adverse effects were reported.

Discussion

In this study, we observed that supplementation with an ONS specifically designed for malnourished older adults improves the nutritional status, biochemical parameters, and dietary intake, of the participants in the IG compared to the CG participants.

Poor nutritional status is a common cause for concern in older adults and their caregivers, particularly those who are hospitalized or institutionalized, as it is strongly associated with elevated morbidity and mortality. The current study observed an increment of 2.1 score points in the mean MNA-SF within the IG. This aligns with previous research indicating that ONSs yield positive effects on the nutritional status of malnourished older adults. For instance, Zhang and colleagues observed a 2.1-point rise in MNA-SF score among community-dwelling older adults with malnutrition who received the supplementation.⁶ Chen et al.,¹⁶ similarly reported a significant improvement in MNA-SF score (from 9.07 ± 1.83 to 12.04 ± 1.31) in participants who received nutritional supplement drinks compared to those receiving nutritional education instead. Na et al.,⁵ used MNA long form, revealing a notable increase in nutritional status among frail older adults at risk of malnutrition with the use of oral nutritional supplementation. An observational study done in 38 nursing homes in Spain, reported that malnourished older adults increased their MNA-SF score by 4 points in response to energy and protein-rich ONS for 3 months.¹⁷ It is important to note that variations in MNA score changes across studies may arise from differences in ONS nutritional composition, study duration, sample size, and participants' health status. Nevertheless, the collective evidence supports the crucial role of ONS in enhancing the nutritional status of older adults with malnutrition.

In turn, the impact of the ONS on biochemical parameters showed a substantial improvement in the vitamin D level in the IG. At the baseline, the study sample was deficient in vitamin D (Supplementary Table 2). Within the relatively short study period, the mean vitamin D level increased by 9.20 ng/mL in the IG, and this increment is significantly high when compared to the CG. One serving of the intervention product provides 2.8 mcg (112 IU) of vitamin D (Supplementary Table 1). Although there is an improvement in vitamin D levels, still many participants remain deficient in vitamin D.

Table 1. Changes in biochemical parameters over 12-weeks

Serum Biomarker	Intervention group (n=20)		p value ^(a)	Control group (n=22)		p value ^(a)	p value ^(b)
	Pre-value	Post-value		Pre-value	Post-value		
WBC (Per Cu mm)	7638±2104	6772±1655	0.013	7450±1940	6265±1547	<0.001	
WBC change (Per Cu mm)	-866±1422			-1185±1126			0.422
Haemoglobin (g/dl)	11.22±1.11	11.34±1.04	0.378	11.67±1.16	11.66±1.02	0.940	
Haemoglobin change (g/dl)	0.12±0.59			-0.01±0.56			0.473
RBC (10 ⁶ /UL)	3.93±0.48	3.76±0.45	0.004	4.05±0.48	3.89±0.44	0.004	
RBC change (10 ⁶ /UL)	-0.17±0.23			-0.16±0.23			0.930
Platelet count (Per Cu mm)	300000±94780	287000±87647	0.184	293000±58899	290000±112669	0.832	
Platelet count change (Per Cu mm)	-13000±42541			-3273±71261			0.595
Vitamin D (ng/mL)	14.76±4.70	23.96±4.18	<0.001	15.36±5.65	19.32±7.20	0.001	
Vitamin D change (ng/mL)	9.20±5.29			3.96±4.85			0.002*
Serum albumin (g/dl)	4.28±0.23	4.08±0.24	0.003	4.38±0.35	3.98±0.43	<0.001	
Serum albumin change (g/dl)	-0.20±0.26			-0.40±0.19			0.006*
Total serum cholesterol (mg/dl)	166.2±44.2	145.0±45.0	<0.001	208.4±53.1	191.0±51.84	0.044	
Total serum cholesterol change (mg/dl)	-21.2±16.3			-17.4±38.0			0.679
Hs-CRP (mg/L)	1.28±1.46	4.40±8.57	0.105	1.49±1.52	4.52±10.12	0.182	
Hs-CRP change (mg/L)	3.12±7.97			3.03±10.04			0.974

Values are mean ± standard deviation, *, p value statistically significant. ^a, Paired sample t-test or Wilcoxon signed rank test. ^b, Independent sample t-test or Mann-Whitney U test. WBC; white blood cell, RBC; red blood cell, Hs-CRP; high sensitivity C reactive protein.

Table 2. Comparison of the impact of ONS on daily dietary intake between the two groups

Energy and macronutrient	Intervention group (n=20)		p value ^(a)	Control group (n=22)		p value ^(a)	p value ^(b)
	Pre-value	Post-value		Pre-value	Post-value		
Energy (kcal)	1346.20±157.33	1651.60±162.54	<0.001	1381.10±143.58	1379.10±160.56	0.901	
Difference in energy intake (kcal)	305.40±68.03			-1.99±74.22			<0.001*
Carbohydrate (g)	212.58±34.64	250.85±42.47	<0.001	219.43±36.68	225.63±42.15	0.522	
Difference in carbohydrate intake (g)	38.27±34.20			6.19±44.64			0.013*
Fat (g)	39.12±6.89	57.79±10.16	<0.001	40.06±7.55	34.81±15.20	0.089	
Difference in fat intake (g)	18.66±10.41			-5.24±13.80			<0.001*
Protein (g)	33.84±6.04	48.46±7.91	<0.001	35.48±6.41	38.05±5.63	0.171	
Difference in protein intake (g)	14.62±8.82			2.57±8.51			<0.001*

Values are mean ± standard deviation, *, p value statistically significant. ^a, Paired sample t-test or Wilcoxon signed rank test. ^b, Independent sample t-test or Mann-Whitney U test.

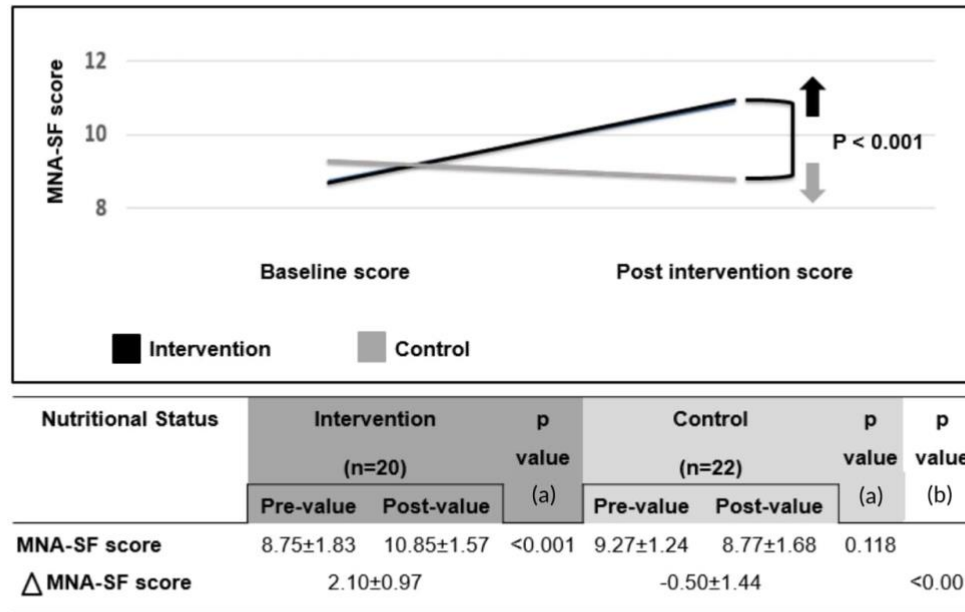


Figure 1: Change in the MNA-SF score between the intervention and control group. MNA-SF; mini nutrition assessment short form. a, Paired sample t-test. b, Independent sample t-test.

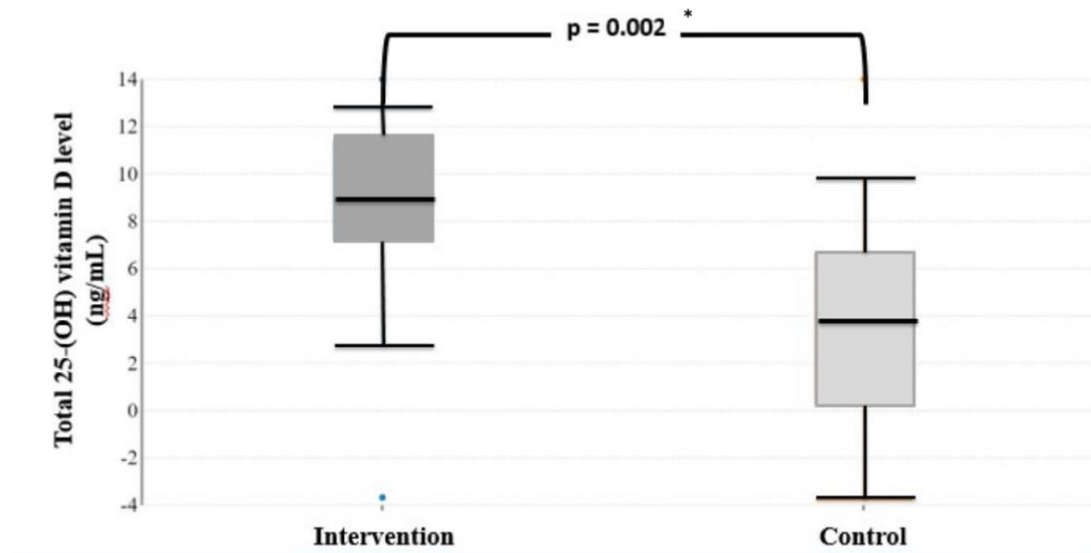


Figure 3: Change in total 25-(OH) vitamin D level between the intervention and control group. *, p value statistically significant. Independent sample t-test was used to analyze the difference in changes in vitamin D levels between the two groups.

Supplementary Table 1. Nutritional composition (serving size: 4scoops (57g) of the ONS

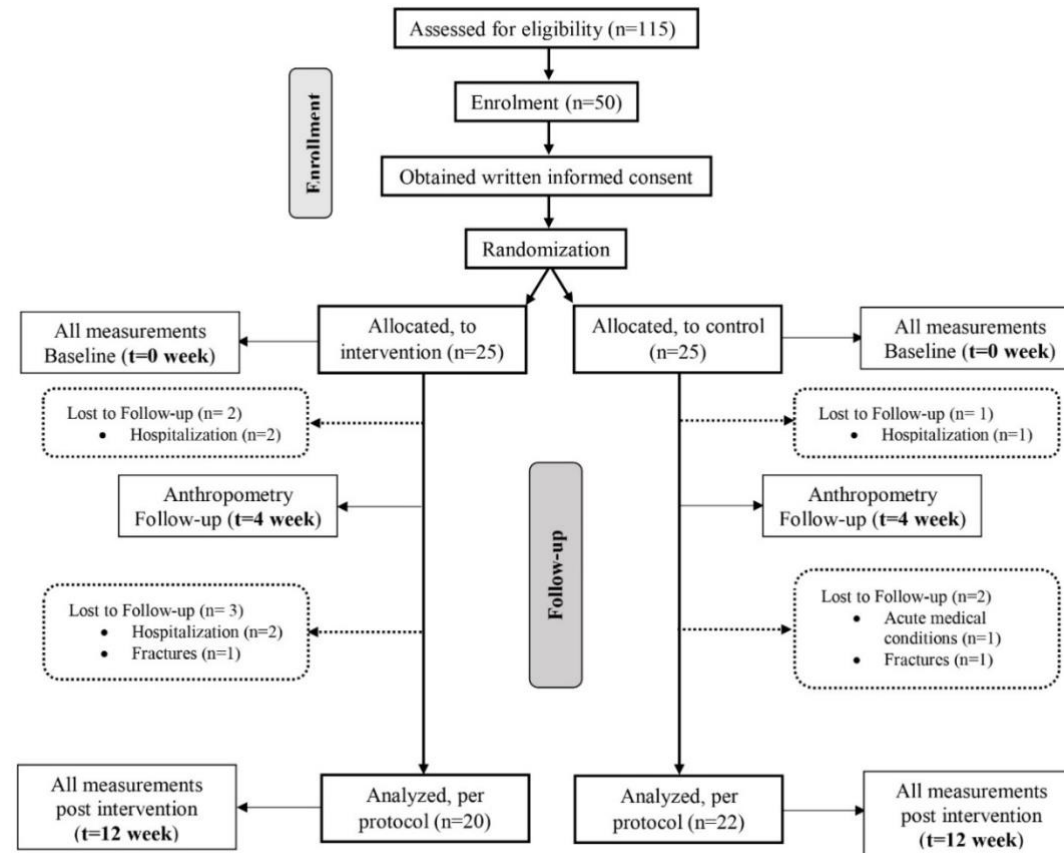
		% DV	Per serving	Per 100 g
Total Calories	kcal		247	434
Total fat	g	12	8	14
<i>SFA</i>	g	23	4.5	8
<i>MUFA</i>	g		2	3
<i>PUFA</i>	g		1	2
<i>Trans Fatty Acids</i>	g		< 0.5	< 0.5
<i>Cholesterol</i>	mg		< 0.5	< 0.5
Protein	g	20	12	21
Total Carbohydrate	g	10	32	55
<i>Dietary fiber</i>	g	17	5	9
<i>Sucrose</i>	g		7	12.5
<i>Sodium</i>	mg	10	153	268
<i>Potassium</i>	mg	2.5	126	221
<i>Vitamin A</i>	mcg	30	184	323
<i>Vitamin B₁</i>	mg	25	0.3	0.55
<i>Vitamin B₂</i>	mg	25	0.4	0.71
<i>Vitamin B₃</i>	mg	30	4.7	8.2
<i>Vitamin B₅</i>	mg	40	2.1	3.6
<i>Vitamin B₆</i>	mg	35	0.4	0.75
<i>Vitamin B₇/Biotin</i>	mg	60	17.6	30.7
<i>Folic acid</i>	mcg	30	125	220
<i>Vitamin B₁₂</i>	mcg	30	0.7	1.3
<i>Vitamin C</i>	mg	40	26.8	64.5
<i>Vitamin D₃</i>	mcg	20	2.8	4.9
<i>Vitamin E</i>	mg	30	4.6	8.1
<i>Calcium</i>	mg	20	219	384
<i>Magnesium</i>	mg	8	26.6	46.6
<i>Phosphorus</i>	mg	15	88.7	156
<i>Iron</i>	mg	9	2.1	2.7
<i>Iodine</i>	mcg	30	46.2	81
<i>Zinc</i>	mg	30	3.9	6.8
<i>Chromium</i>	mcg	15	3.3	5.8
<i>Selenium</i>	mcg	15	4.1	7.2

SFA - Saturated Fatty Acids, *MUFA* - Monounsaturated Fatty Acids, *PUFA* - Polyunsaturated Fatty Acids

Supplementary Table 2. Demographic and baseline clinical characteristics of biochemical parameters, and daily dietary intake

Variable	Intervention group (n=20)	Control group (n=22)	p value ^(a)
Age (Years)	75.4±6.1	74.8±5.2	0.732
Gender n (%)			0.588
Male	7 (35%)	6 (27%)	
Female	13 (65%)	16 (73%)	
Duration of staying at the elderly care residence (Years)	5.20±5.23	4.49±4.22	0.599
MNA-SF score	8.72±1.95	9.56±1.45	0.118
Blood parameters			
WBC (Per Cu mm)	7638±2104	7450±1940	0.765
Hemoglobin (g/dl)	11.22±1.11	11.67±1.16	0.209
RBC (10⁶ /UL)	3.93±0.48	4.05±0.48	0.404
Platelet count (Per Cu mm)	300000±94780	293000±58899	0.776
Serum albumin (g/dl)	4.28±0.23	4.38±0.35	0.275
Total serum cholesterol (mg/dl)	166.2±44.2	208.4±53.1	0.008*
hCRP (mg/L)	1.28±1.46	1.49±1.52	0.659
Vitamin D level (ng/mL)	14.76±4.70	15.36±5.65	0.710
Dietary intake per day			
Energy intake (kcal)	1346.20±157.33	1381.10±143.58	0.457
Carbohydrate intake (g)	212.58±34.64	219.43±36.68	0.538
Fat intake (g)	39.12±6.89	40.06±7.55	0.677
Protein intake (g)	33.84±6.04	35.48±6.41	0.400

Values are mean ± standard deviation for continuous variables and n (%) for categorical variables. *, p value statistically significant. ^a, Independent sample t-test or chi-square test. MNA-SF; mini nutrition assessment short form, BMI; body mass index, WBC; white blood cell, RBC; red blood cell, Hs-CRP; high sensitivity C reactive protein.



Supplementary Figure 1: CONSORT flow diagram

To address this, ONS may need to incorporate higher amounts of vitamin D to more effectively meet the needs of individuals and mitigate deficiencies. A recent study done by Chew et al.,⁹ showed significant improvements in the vitamin D deficiency and insufficiency status in the IG, in contrast to a worsening vitamin D status in the placebo group. Nevertheless, it is worth noting that the previous study utilized an ONS containing 15.5 mcg (620 IU) of vitamin D over a relatively longer supplementation period of 24 weeks.

Albumin, the most abundant protein in human serum, has been used as an indicator of malnutrition.¹⁸ In the current study, a decline in serum albumin levels was observed in both IG and CG, with the CG experiencing a significant decrease. However, serum albumin levels were still within a normal range in both the IG and CG. These findings are consistent with those of Chen and Lee (2023), who reported a decrease of -0.09 g/dL in participants who received a nutritional supplement and -0.02 g/dL in those who received nutritional education only.¹⁶ Nevertheless, serum albumin is no longer regarded as a precise indicator of nutritional status due to its lack of specificity and long half-life.¹⁹ Furthermore, serum albumin concentration is not solely indicative of poor nutritional status, as it can also be influenced by factors such as inflammation, hepatic insufficiency, and renal losses in nephrotic syndrome.²⁰ Aging is another factor contributing to the decrease in serum albumin levels, with levels decreasing by approximately 0.1 g/L per year.²¹ In light of these findings, the current study suggests investigating the impact of ONS on valid prognostic indicators such as serum pre-albumin and transferrin level as well rather than relying only on serum albumin level.

Haemoglobin is another good marker of nutritional status in older adults. The study's findings of relatively unchanged Haemoglobin levels in both groups suggest that the impact of the ONS may not have been immediately discernible within the short study duration.

The majority of the study participants were taking statin medication to manage their altered cholesterol levels. Consequently, we observed a significant difference in total serum cholesterol

levels between the two groups at the study's outset. Therefore, we did not anticipate any significant impact on their total cholesterol levels.

ONSs are specifically designed to provide calories, high-quality protein, and micronutrients that are recommended to fulfil the basic nutritional requirements of individuals when a regular diet alone is insufficient. The given ONS contributed to the observed significant increase in carbohydrate, fat, and protein intake in the IG. Following the present results, previous studies have also demonstrated a significant increase in energy, carbohydrate, fat, and protein intake in the treatment group compared to the control group.⁹

The main strength of this study is the high follow-up rate with 100% compliance, which can be attributed to the extensive support provided by caregivers who routinely monitored the ONS consumption. A higher follow-up rate is crucial for minimizing potential bias and ensuring the accuracy of the study findings. Additionally, the controlled environment in which the study was conducted helped to minimize confounding factors, particularly dietary intake, further strengthening the study's validity.

However, the study is subject to certain limitations. Conducting the study in a single elderly care institution limits the generalizability of the findings. Despite this, the institution accommodated nearly 200 older adults at the time of the intervention, a significantly high number compared to other institutions in Sri Lanka. The institution is representative of various demographics, including urban, rural, and suburban areas, and encompasses major ethnic groups in Sri Lanka (Sinhala, Tamil, and Muslim). Therefore, we believe the findings are applicable to other elderly care and community settings. Additionally, the older adults in this institution exhibit a wide range of medical conditions and comorbidities, suggesting that the findings may also be relevant to other healthcare settings. Another limitation is the inability to assess vitamin D intake from food sources and measure sun exposure among subjects. Furthermore, the short duration of ONS administration in our study limits our ability to assess the sustainable effects of ONS.

Conclusion

In conclusion, ONSs show promising improvements in nutritional status, beneficial effects on some biochemical parameters, and a significant increase in nutrient intake among malnourished older adults. Future studies should include multiple elderly care institutions and community settings to enhance the generalizability of the findings. Extending the duration of ONS administration will help assess the long-term sustainability and effectiveness of ONS. Incorporating measures to assess vitamin D intake from food sources and sun exposure will provide a more comprehensive nutritional evaluation. Additionally, evaluating more biomarkers related to inflammation and other health conditions will offer a detailed understanding of the effects of nutritional interventions. These improvements will provide deeper insights into the impact of ONS and help develop tailored, effective strategies to combat malnutrition in older adults.

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Author contributions

R.Jayawardena was involved in conceptualization of the study, supervision, data interpretation and review of the manuscript. P.Wickramawardhane was involved in data curation, data analysis and writing the manuscript.

Conflict of interest

The authors declare there is no conflict of interest regarding this article.

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